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, 2024

OR

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

Commission File Number 001-39661

ATEA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its Charter)

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

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

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

Indicate by check mark whether the registrant 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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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 28, 2024, 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 $253.0 million.

The number of shares of Registrant's Common Stock outstanding as of March 4, 2025 was 85,525,179.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2025 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, 2024, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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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 development timelines and results and other future conditions. The words “aim,” “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “goal,” “intend,” “may,” "objective," "on track," “plan,” “possible,” “potential,” “predict,” “project,” “seek,” “should,” “target,” “will,” “would” or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

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

- our expectations relating to clinical trials for our hepatitis C virus (“HCV”) product candidate and other potential product candidates, including projected costs, study designs and the timing for initiation, recruitment, completion, and reporting interim, top-line and final data;
- the potential therapeutic benefit of our HCV product candidate and market opportunities therefor;
- the safety profile and related adverse events of our HCV product candidate;
- our plans to research, develop and commercialize our current and future product candidates;
- the potential benefits of any future collaboration we may enter into;
- the timing of and our ability to apply for, and if successful, obtain and maintain regulatory approvals for our product candidates;
- the rate and degree of market acceptance and clinical utility of any products for which we may receive marketing approval;
- our manufacturing and commercialization capabilities and strategy;
- our estimates regarding future revenue, expenses and results of operations;
- the progress of, timing of and amount of expenses associated with our research, development and commercialization activities;
- our future financial position, capital requirements, cash runway, needs for additional financing and the availability of such financing;
- our business strategy;
- developments relating to our industry and our competitors, including competing HCV treatments;
- our expectations regarding federal, state and foreign laws and regulations; and
- our ability to attract, motivate, and retain key personnel.

These forward-looking statements are based on management’s current expectations, estimates, forecasts and projections about our business and the industry in which we operate. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Factors that may cause actual results to differ materially from current expectations include the initiation, execution and completion of clinical trials, uncertainties surrounding the timing of availability of 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”* in this Annual Report on Form 10-K. You should read these risk factors and the other cautionary statements made in this report as being applicable

to all related forward-looking statements wherever they appear in this report. The risk factors are not exhaustive and other sections of this report may include additional factors which could adversely impact our business and financial performance.

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

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

As used in this Annual Report on Form 10-K, unless otherwise specified or the context otherwise requires, the terms “we,” “our,” “us,” and the “Company” refer to Atea Pharmaceuticals, Inc. and its subsidiary. All brand names or trademarks appearing in this 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:

- 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 not again achieve or maintain profitability.
- We may require substantial additional financing, which may not be available on acceptable terms, or at all. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.
- We may engage in strategic collaborations or other transactions that could disrupt our business, cause dilution to our stockholders, reduce our financial resources, and subject us to other risks.
- Our ability to use our net operating loss carryforwards and other tax attributes to offset taxable income may be subject to certain limitations.
- Our business is highly dependent on the success of our product candidate, the regimen of bemnifosbuvir and ruzasvir for the treatment of HCV infection. If we fail to successfully develop this product candidate or we are unable to obtain regulatory approval or successfully commercialize this or any other product candidates, or are significantly delayed in doing so, our business will be harmed.
- The regulatory approval processes of the U.S. Food and Drug Administration ("FDA") and comparable foreign regulatory authorities are lengthy, expensive, time-consuming and inherently unpredictable.
- Clinical development, including enrollment of patients in clinical trials, is an expensive, lengthy and uncertain process. We may encounter substantial delays and costs in our clinical trials, or may not be able to conduct or complete our clinical trials on the timelines we expect, if at all.
- We intend to develop certain of our product candidates in combination with other product candidates that we discover or acquire, which exposes us to additional risks.
- Our product candidates may be associated with serious adverse events, undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.
- We currently conduct and may in the future conduct clinical trials of our product candidates in sites outside the United States ("US"). The FDA may not accept data from trials conducted in foreign locations.
- Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- We may not be successful in our efforts to identify and successfully develop additional product candidates.
- Risks related to healthcare laws and other legal compliance matters may materially and adversely affect our business and financial results.
- Risks related to commercialization may materially and adversely affect our business and financial results.

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

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PART I

Item 1. Business.

Overview

We are a clinical-stage biopharmaceutical company leveraging our deep understanding of antiviral drug development, medicinal chemistry, biology, biochemistry and virology to discover and develop novel orally administered product candidates to treat serious viral diseases. Our lead product candidate is a regimen consisting of bemnifosbuvir and ruzasvir which we are developing for the treatment of chronic hepatitis C virus (“HCV”) infection. Currently, we expect to commence enrollment of patients in an HCV Phase 3 program evaluating the regimen in April 2025.

HCV

HCV is a blood-borne, positive-sense, single-stranded ribonucleic acid ("RNA") virus that primarily infects liver cells. HCV is a leading cause of chronic liver disease, liver transplants and liver cancer in the US, Europe and Japan.

Despite the availability of direct-acting antiviral (“DAA”) oral combination treatment regimens and eradication efforts by the World Health Organization ("WHO") and others, HCV continues to be a serious viral disease. An estimated 50 million people globally live with chronic HCV infection, with approximately 1 million new infections occurring each year. In 2022, HCV led to an estimated 242,000 deaths. These deaths are primarily attributable to cirrhosis and hepatocellular cancer, each of which are serious long-term consequences resulting from prolonged exposure, generally up to 20 years of HCV infection.

In the US, it is estimated that there are between 2.4 and 4.0 million persons with untreated HCV infection. Further it is reported that on an annual basis in the US, there are greater than 160,000 newly reported HCV infections. This incidence of newly reported infections substantially outpaces the stagnant rates of treatment.

In the US and elsewhere, HCV is increasingly affecting younger people, with high case rates among those between 20 to 49 years of age. Since recently infected and younger patient populations are less likely to have developed cirrhosis given the relatively shorter cumulative exposure to the virus, there has been a trend in the US of a decreasing incidence of cirrhosis among individuals with HCV infection. It is estimated that less than 10% of the HCV-infected population in the US has cirrhosis.

In 2024, global net sales of branded HCV therapeutics known in the US as Epclusa® and Mavyret® together with the authorized generic copies of Epclusa exceeded $2.9 billion with the US contributing approximately 50% of these sales. Given the large number of patients currently infected with HCV and high rates of annual incidence, it is expected that a substantial global market will exist for the foreseeable future.

Our Goal

The objective of our HCV development program is to improve upon the current standard of care ("SOC") by offering the regimen of bemnifosbuvir and ruzasvir, as a differentiated pan-genotypic protease inhibitor-free therapeutic for HCV-infected patients, if successfully developed and approved. We believe that a novel treatment that can be easily prescribed for and administered to today’s population of HCV-infected patients (e.g. young, newly infected, non-cirrhotic) would be a significant improvement to the current SOC.

Presently, there are no short-course (i.e., 8 week) nucleoside inhibitor-based, pan-genotypic HCV treatment regimens. Results from the clinical and nonclinical studies we have conducted to date, including a global Phase 2 clinical trial which enrolled 275 HCV infected patients, have shown that the regimen of bemnifosbuvir and ruzasvir offers high potency, a low risk for drug-drug interactions, good

tolerability and convenience in that it can be taken with or without food. This is a profile that we believe would offer a significant improvement to the current SOC, if approved.

Based upon the encouraging clinical and nonclinical results to date, we are advancing the regimen of bemnifosbuvir and ruzasvir to Phase 3 clinical development. In the Phase 3 clinical trials, we will evaluate an 8-week treatment duration for patients without cirrhosis and a 12-week treatment duration for patients with compensated cirrhosis. We believe that the regimen of bemnifosbuvir and ruzasvir, if approved, will rapidly become a therapy preferred by both HCV prescribers and patients.

Results of Phase 2 Study Evaluating the Regimen of Bemnifosbuvir and Ruzasvir for the Treatment of Chronic HCV - Primary Endpoints Met and End-of-Phase 2 Meeting with FDA Completed

The global Phase 2 study evaluating the regimen of bemnifosbuvir and ruzasvir enrolled 275 HCV treatment-naïve patients, both with and without compensated cirrhosis. The study was designed to evaluate the safety and efficacy of 8 weeks of treatment with the regimen consisting of once-daily bemnifosbuvir 550 mg and ruzasvir 180 mg. The primary endpoints were safety and sustained virologic response (“SVR”) at 12 weeks post treatment (“SVR12”) in the per-protocol treatment adherent population. Secondary and other endpoints included SVR12 in the efficacy evaluable population (a broader analysis population which included treatment non-adherent patients), SVR at 24 weeks post treatment (“SVR24”), virologic failure and resistance.

In December 2024, we announced that this Phase 2 study met its primary endpoints of safety and SVR12. The regimen was generally well-tolerated with no drug-related serious adverse events (“SAEs”) or treatment discontinuations. Primary efficacy endpoint results showed a 98% (208/213) SVR12 rate in the per-protocol treatment adherent patient population after 8 weeks of treatment with the regimen of bemnifosbuvir and ruzasvir. The efficacy evaluable patient population, which included 17% treatment non-adherent patients, achieved a 95% (242/256) SVR12 rate.

Additional results from the Phase 2 study showed in treatment-adherent patients who were non-cirrhotic and infected with HCV genotypes ("GT") -1, -2, -3 and -4, that an SVR12 rate of 99% (178/179) was achieved, demonstrating pan-genotypic potency. Treatment adherent patients with compensated cirrhosis achieved an 88% (30/34) SVR12 rate. Although viral kinetics were slower in cirrhotic patients, all cirrhotic patients (100%; 34/34) achieved an end of treatment response at Week 8. Based on these Phase 2 results, we have designed the Phase 3 clinical trials to evaluate 8 weeks of treatment for patients without cirrhosis and 12 weeks of treatment for patients with compensated cirrhosis.

The results from the Phase 2 study were further evaluated in a multiscale viral kinetics model of HCV infection and treatment to assess the efficacy of the regimen of bemnifosbuvir and ruzasvir. In this model, the population estimate for the time to achieve HCV RNA less than the lower limit of quantification (“<LLOQ”) in blood plasma was approximately 12 to 16 days while the corresponding time to achieve cure was approximately 7 to 8 weeks. We believe these modeling data provide further support for evaluating the regimen of bemnifosbuvir and ruzasvir in the Phase 3 clinical program with treatment durations of 8 weeks in patients without cirrhosis and 12 weeks in patients with compensated cirrhosis.

In January 2025, we met with the U.S. Food and Drug Administration (“FDA”) at an End-of-Phase 2 meeting to seek feedback on the design of the Phase 3 clinical trials. The End-of-Phase 2 feedback from the FDA supported our decision to advance the program to Phase 3 clinical development.

Global Phase 3 Program

The global HCV Phase 3 program we are currently initiating includes two randomized, open label Phase 3 trials comparing the regimen of bemnifosbuvir and ruzasvir to the regimen of sofosbuvir and velpatasvir in patients with chronic HCV infection. The overall clinical trial design is similar for each trial. Currently, we are planning for one trial to be conducted in the US and Canada and one trial to be conducted outside of North America. This global geographic footprint is intended to assist us in enrolling patients with varied HCV genotypes.

Each trial is expected to enroll approximately 800 treatment-naïve patients, both with and without compensated cirrhosis. Patients will be stratified by genotype and cirrhosis status, and patients with

controlled human immunodeficiency virus ("HIV") co-infection will be allowed to enroll in the trials. For patients without cirrhosis, 8 weeks of the regimen of bemnifosbuvir and ruzasvir will be compared to 12 weeks of the regimen of sofosbuvir and velpatasvir. For patients with compensated cirrhosis, 12 weeks of the regimen of bemnifosbuvir and ruzasvir will be compared to 12 weeks of the regimen of sofosbuvir and velpatasvir.

Each trial in the Phase 3 program will be an open label study. While blinding the clinical trial sites and the patients to the treatment assignment is not possible due to the varying lengths of treatment and the necessity to provide the active comparator in its commercially available packaging, we, at Atea, will remain blinded throughout the study, including during any internal cumulative data reviews, to the individual patient treatment assignment.

The primary efficacy endpoint in each Phase 3 trial is HCV RNA < LLOQ at 24 weeks from the start of treatment. Measurement of sustained response at the Week 24 study visit is selected to ensure the primary endpoint occurs at the same relative timepoint from start of treatment in all patients. As the treatment duration is 8 weeks for patients without cirrhosis in the bemnifosbuvir and ruzasvir study arm and 12 weeks for all other study arms, the primary endpoint encompasses the period at least through the SVR12 timepoint for each treatment arm.

Potential Strategic Partnerships

To maximize the value of our HCV product candidate, the regimen of bemnifosbuvir and ruzasvir, we are selectively seeking advantageous collaborations to strengthen our commercialization capabilities in the US and enhance our global commercialization reach. In December 2024, we announced that we had engaged Evercore LLC, an independent global investment bank, to assist us in identifying and exploring such potential strategic partnerships.

Our HCV Product Candidate –The Fixed Dose Combination of Bemnifosbuvir and Ruzasvir

Our product candidate for the treatment of HCV is a regimen consisting of the combination of two investigational DAAs, bemnifosbuvir and ruzasvir.

Bemnifosbuvir is an investigational, novel, orally administered guanosine nucleotide double prodrug which targets the HCV non-structural protein 5B (“NS5B”) RNA-dependent RNA polymerase and inhibits HCV replication. In *in vitro* studies, AT-511, the free base of bemnifosbuvir, was 6- to 11-fold more potent than sofosbuvir. We believe that utilizing this double prodrug moiety approach allows us to improve formation of the active triphosphate metabolite potentially resulting in an oral antiviral product candidate that is selective for and highly effective at preventing replication and transcription of HCV and other single stranded RNA (“ssRNA”) viruses while avoiding toxicity to host cells.

Ruzasvir is an investigational, potent, small molecule inhibitor of HCV non-structural protein 5A (“NS5A”), an essential protein for HCV replication. In *in vitro* studies, ruzasvir has demonstrated picomolar activity against all HCV genotypes. The combination of bemnifosbuvir and ruzasvir has demonstrated potent synergistic HCV antiviral activity *in vitro.*

We have exclusively licensed ruzasvir from MSD International GmbH, an affiliate of Merck & Co, Inc. ("Merck"), for all human indications on a worldwide basis.

Our Team and our Pipeline

We have assembled and are utilizing the expertise and experience of a team with a demonstrated track record of efficiently and successfully discovering, developing, obtaining global regulatory approvals and commercializing innovative oral DAAs**.** Our team has very specific expertise in the identification of unmet patient needs, virology, medicinal chemistry, particularly nucleos(t)ide chemistry and optimization, drug discovery, preclinical and clinical development, regulatory affairs and commercialization. We are deploying this expertise and experience to discover and develop novel or differentiated DAAs that we believe have the potential to meet unmet medical needs or improve the current standard of care.

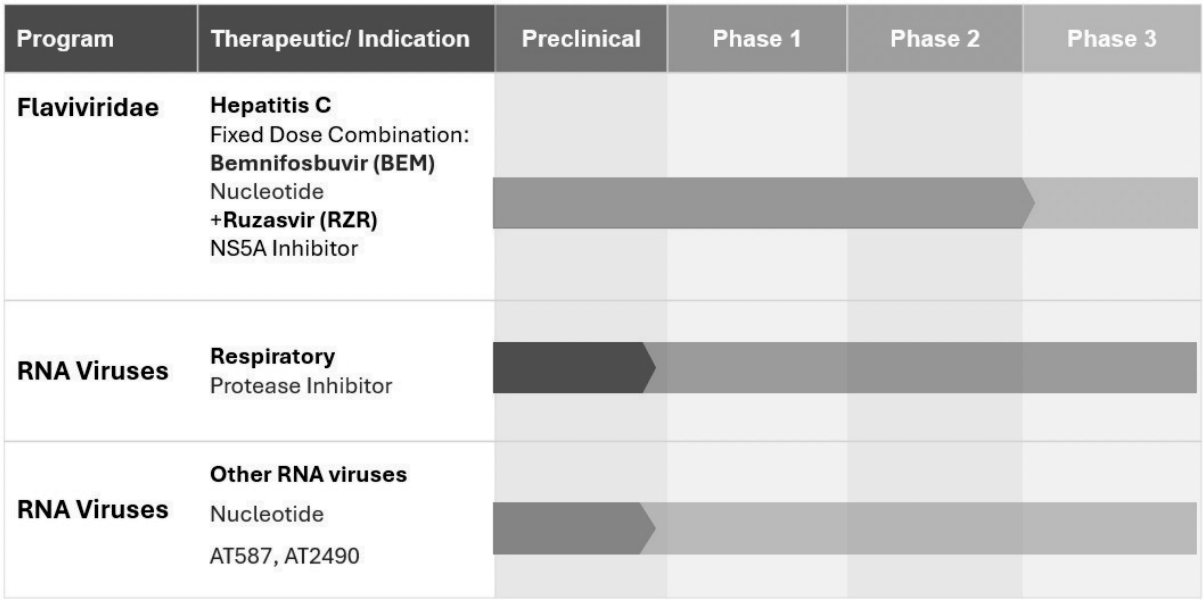
We have relied on that expertise to:

- discover bemnifosbuvir, the investigational, novel, double prodrug nucleotide analog, which we are developing for the treatment of HCV; and
- identify and in-license ruzasvir, the investigational NS5A inhibitor, that we are evaluating in combination with bemnifosbuvir for the treatment of HCV.

We are also relying on this expertise to discover and advance additional oral DAA product candidates. Currently, we are engaging in efforts to:

- design an optimized second-generation protease inhibitor for the treatment of respiratory virus infections; and
- discover potential treatments for other RNA viral infections where there are unmet medical needs.

Our current pipeline is set forth below.



Our Development Program

The regimen of Bemnifosbuvir and Ruzasvir for the Treatment of HCV

HCV – Disease Overview and Current Standard of Care

HCV is a blood-borne, positive sense, ssRNA virus, that primarily infects liver cells. HCV is a leading cause of chronic liver disease, liver transplants and liver cancer. It is most commonly transmitted through the reuse or inadequate sterilization of medical equipment (especially syringes and needles in healthcare settings), the transfusion of unscreened blood and blood products, and injection drug use through sharing of contaminated syringes and needles. Diagnosis of HCV is made through blood tests, utilizing either serology tests that measure HCV antibody or molecular tests that allow for the detection, quantification and analysis of viral genomes and the classification of an infection into GTs. Hepatitis C infection becomes chronic in 75% to 85% of acute cases, with an incubation period lasting from two to 26 weeks.

HCV is classified into seven GTs (GT-1 through GT-7) and 67 subtypes, with HCV GT-1 being responsible for more than 70% of HCV cases in the US. Patients with HCV are also classified by liver function status: compensated cirrhosis (liver scarring) denotes those patients that do not yet have clinically significant impaired liver function, while decompensated cirrhosis describes patients with moderate to severe liver function impairment.

According to the WHO, an estimated 50 million people globally live with chronic HCV infection, with approximately 1 million new infections occurring each year. The WHO estimated that approximately 242,000 people died in 2022 from HCV related liver diseases. Most HCV-related deaths are due to liver scarring (cirrhosis) and liver cancer (hepatocellular carcinoma).

However, there is a wide gap between the number of reported cases versus estimated cases. Most individuals who become infected with HCV remain unaware that they are infected because HCV can go undetected until the condition progresses to symptomatic disease or until specific clinical tests are performed to confirm diagnosis. Consequently, cases are unreported, skewing actual disease prevalence rates. The burden of underreporting is realized when high medical expenditures (comorbid treatment costs, liver transplants) and mortality rates from advanced chronic liver disease do not proportionally align with reported prevalence rates.

Antivirals for the treatment of HCV

While no vaccine exists for the prevention of HCV, several sequentially improved oral antiviral therapeutics have been introduced beginning in 2014. Currently, the leading HCV products are combination therapies comprised 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 GT, cirrhotic status, concomitant medications and any prior treatment determine the appropriate antiviral to be used in treatment. In the US, currently the two leading therapeutics for treatment of chronic HCV are:

- Epclusa® (sofosbuvir and velpatasvir): an orally administered, fixed dose combination regimen consisting of sofosbuvir, an HCV nucleotide analog NS5B polymerase inhibitor, and velpatasvir, an HCV NS5A inhibitor, was first approved by the FDA in 2016. It is indicated for the treatment of adults and pediatric patients ≥3 years with chronic HCV GT-1, -2, -3, -4, -5 or -6 infection, without cirrhosis or with compensated cirrhosis. For patients with decompensated cirrhosis, Epclusa is approved for use in combination with ribavirin, a guanosine analog used to stop RNA synthesis and viral RNA capping. Patients on Epclusa require 12 weeks of treatment.
- Mavyret® (glecaprevir and pibrentasvir): an orally administered, fixed dose combination regimen consisting of glecaprevir, an HCV NS3/4A protease inhibitor, and pibrentasvir, an HCV NS5A inhibitor, that was first approved by the FDA in 2017. It is indicated for the treatment of adults and pediatric patients ≥3 years with chronic HCV GT-1, -2, -3, -4, -5 or -6 infection, without cirrhosis or with compensated cirrhosis. Mavyret was the first and remains the only 8-week treatment approved for HCV GT-1, -2, -3, -4, -5 or -6 in adult patients without cirrhosis and with compensated cirrhosis who have not been previously treated. Longer treatment durations (up to 16 weeks) are indicated for some treatment-experienced populations. It is recommended that Mavyret be taken with food. Mavyret is not approved for use in patients with decompensated cirrhosis.

Our HCV Product Candidate Development

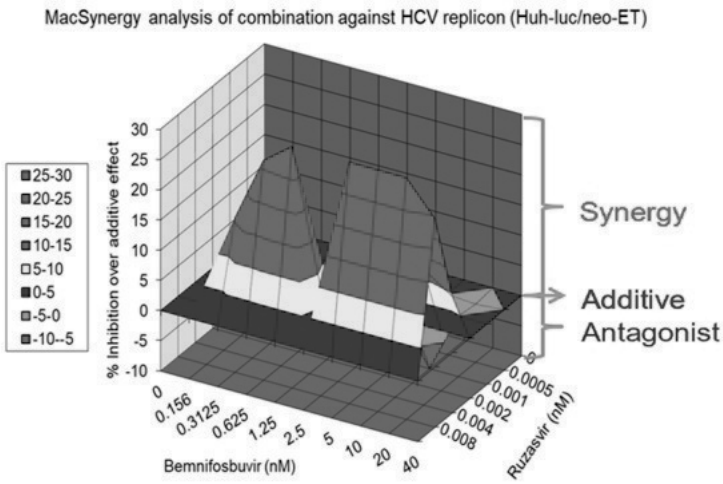
We are developing the regimen of bemnifosbuvir and ruzasvir for the treatment of HCV. Based on our preclinical and clinical data to date, we believe that this regimen, if approved, could offer the following potential benefits:

- convenient (no food effect) protease inhibitor-free treatment with an 8-week duration in HCV-infected patients without cirrhosis and a 12-week duration for those HCV-infected patients with compensated cirrhosis;
- well-tolerated regimen, with low potential for drug-drug interactions; and
- high efficacy across all genotypes, regardless of cirrhosis status.

Non-clinical data supporting the clinical development of the regimen of bemnifosbuvir and ruzasvir for the treatment of HCV

To support our clinical development of the regimen of bemnifosbuvir and ruzasvir, we conducted *in vitro* synergy experiments in HCV GT-1b replicon assays. As shown in the figure below, these experiments demonstrated that the combination resulted in substantially greater inhibition of HCV replication than with either agent alone, suggesting a synergistic antiviral effect between the two inhibitors.

***In vitro* Synergy: Assay performed in HCV GT1b replicon**



Viral resistance has emerged as an important consideration since it may impact the effectiveness of antiviral treatments for HCV infection. We profiled the antiviral activity of AT-511, the free base of bemnifosbuvir, and ruzasvir against major HCV NS5A and NS5B Resistance-Associated Substitutions ("RASs ") selected *in vitro* or identified in HCV patients with hard-to-treat sub-genotypes who have failed treatment with currently available DAAs.

In these *in vitro* studies, AT-511 was approximately 10-fold more active than sofosbuvir against a panel of laboratory strains and clinical isolates of HCV GTs tested (GT-1, -2, -3, -4, -5) and bemnifosbuvir was not resistant to known sofosbuvir RASs such as S282T and L159F/S282T. AT-511 also retained antiviral activity against most HCV GT-1a and HCV GT-3a NS5A single RASs tested. In GT-1a, ruzasvir was 10 times more active than velpatasvir, and retained single-digit picomolar potency against a panel of RASs selected by previous NS5A inhibitors and was 10 times more potent than velpatasvir against selected double mutants. In HCV GT-3a, one of the most difficult to treat HCV GTs, ruzasvir was six times more active than velpatasvir and retained sub-nanomolar potency against select NS5A RASs which were treatment-emergent in HCV GT-3 patients failing currently available DAAs.

Ruzasvir and a panel of other NS5A inhibitors were profiled for antiviral activity against seven difficult-to-treat HCV sub-genotypes using the HCV GT-1b replicon backbone. Both ruzasvir and velpatasvir maintained picomolar potency over the majority of these difficult-to-treat sub-genotypes such as HCV GT-1l, -4r, and -6v. All tested NS5A inhibitors exhibited 100- to 1000-fold EC_{50} shifts for HCV GT-3b and GT-3g.

In a 13-week combination toxicity study in rats, bemnifosbuvir and ruzasvir were well tolerated when administered orally at 500 mg/kg/day alone or in combination. No test article-related adverse effects were noted for any of the three dose groups. Systemic exposures of bemnifosbuvir, its metabolites, and ruzasvir were similar when dosed alone or in combination, suggesting no significant drug-drug interactions between the two drugs.

Clinical Development

Summary

We believe the results from clinical studies conducted to date support the Phase 3 evaluation of the regimen of bemnifosbuvir and ruzasvir for the treatment of chronic HCV infection.

The principal clinical study supporting the advancement to Phase 3 development was a global Phase 2, single-arm, open-label trial in 275 treatment-naïve patients with chronic HCV infection (both with and without compensated cirrhosis) who received bemnifosbuvir (550 mg) and ruzasvir (180 mg) once daily for 8 weeks. Patients with GT -1, -2, -3 and -4 enrolled in the trial.

In the study's primary analysis population, which was the per-protocol treatment adherent population (n=213), the overall SVR12 rate was 98%. The efficacy evaluable patient population (n=256), which included 17% treatment non-adherent patients, achieved a 95% SVR12 rate. High SVR12 rates (99%) were observed in patients without cirrhosis (n=179) with the 8-week regimen. Treatment adherent patients with cirrhosis (n=34) achieved an 88% SVR12 rate. Although viral kinetics were slower in cirrhotic patients, all patients with cirrhosis (100%; 34/34) achieved an end of treatment response at Week 8. Based on these Phase 2 results, we have designed the Phase 3 clinical trials to evaluate the regimen of bemnifosbuvir and ruzasvir for 8 weeks of treatment for patients without cirrhosis and for 12 weeks of treatment for patients with compensated cirrhosis. We believe that the longer treatment duration we will study in the Phase 3 clinical trials will improve SVR12 rates for patients with compensated cirrhosis.

In addition to the Phase 2 study described above, other clinical studies we have conducted with bemnifosbuvir as monotherapy or in combination with daclatasvir, a first generation NS5A inhibitor and ruzasvir as monotherapy or in combination with other DAAs each contributed supporting data for the respective development of bemnifosbuvir and ruzasvir in combination and progression to Phase 3. Dose-related HCV RNA reductions in HCV-infected subjects were observed in a bemnifosbuvir monotherapy study, with the once daily bemnifosbuvir doses of ~550 mg showing the highest HCV RNA reductions. Bemnifosbuvir exhibited equally potent antiviral activity regardless of GT (including GT-3 infected subjects) or cirrhosis status, with HCV RNA reductions of 4.4 - 4.6 $\log_{10}$ IU/mL with 7-day dosing. In the first treatment study of bemnifosbuvir with a first-generation NS5A inhibitor (daclatasvir), a Phase 2 study that enrolled GT-1 -infected subjects, similar potent viral kinetics were observed with 8 of 9 subjects achieving SVR12 after 8 weeks of treatment. For ruzasvir, results from a Phase 1b proof-of-concept ("POC") study in HCV-infected subjects conducted by Merck showed viral load reductions greater than 3 $\log_{10}$ in HCV GT-1, -2 and -3-infected subjects. High SVR12 rates were subsequently observed in Phase 2 studies conducted by Merck evaluating 180 mg ruzasvir as part of a prior combination not including bemnifosbuvir.

Additional Phase 1 clinical pharmacology studies conducted in healthy subjects also support the advancement of the regimen of bemnifosbuvir and ruzasvir to Phase 3 clinical development. The pharmacokinetics ("PK") of combined bemnifosbuvir and ruzasvir have been evaluated in studies conducted in healthy subjects, both as individual formulations and as the fixed dose combination ("FDC") tablet that will be used in the Phase 3 clinical trials. In addition, the PK of bemnifosbuvir and ruzasvir administered separately and in combination with other concomitant medications has been studied in multiple phase 1 studies.

To date, over 2,300 human subjects have been exposed to bemnifosbuvir collectively across the HCV and COVID-19 development programs, at differing doses (single doses up to 1100 mg twice per day ("BID")) and durations up to 12 weeks. Additionally, over 2,100 human subjects have been exposed to ruzasvir in clinical studies conducted to date by Merck initially and more recently by us, including the Phase 2 study of the bemnifosbuvir and ruzasvir combination. Both drugs either alone or in combination have been well-tolerated. Across our completed studies there have been no study drug-related SAEs reported for either bemnifosbuvir or ruzasvir.

Global Phase 3 Clinical Development

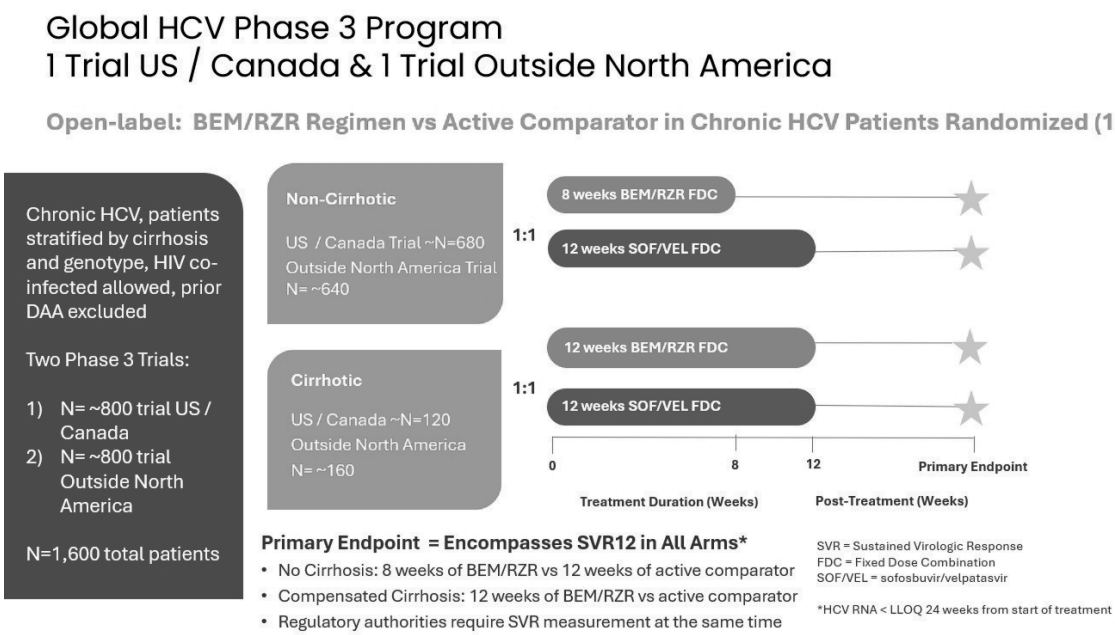
The global HCV Phase 3 program we are currently initiating includes two randomized, open label Phase 3 trials comparing the FDC regimen of bemnifosbuvir and ruzasvir to the FDC regimen of sofosbuvir and

velpatasvir in patients with chronic HCV infection. Currently, we are planning for one trial to be conducted in the U.S and Canada and one trial to be conducted outside of North America. In the Phase 3 trials, we will use a FDC tablet, consisting of 275 mg of bemnifosbuvir and 90 mg of ruzasvir. Two tablets will be administered once daily for a total daily dose of 550 mg of bemnifosbuvir and 180 mg of ruzasvir.

Each Phase 3 trial is expected to enroll approximately 800 treatment-naïve patients, both with and without compensated cirrhosis. Patients will be stratified by GT and cirrhosis status, and patients with controlled HIV co-infection will be allowed to enroll in the trials. For patients without cirrhosis, 8 weeks of the regimen of bemnifosbuvir and ruzasvir will be compared to 12 weeks of the regimen of sofosbuvir and velpatasvir. For patients with compensated cirrhosis, 12 weeks of the regimen of bemnifosbuvir and ruzasvir will be compared to 12 weeks of the regimen of sofosbuvir and velpatasvir.

Each trial in the Phase 3 program will be an open label study. While blinding the clinical trial sites and the patients to the treatment assignment is not possible due to the varying lengths of treatment and the necessity to provide the active comparator in its commercially available packaging, we, at Atea, will remain blinded throughout the study, including during any internal cumulative data reviews, to the individual patient treatment assignment.

The primary efficacy endpoint in each Phase 3 trial is HCV RNA < LLOQ at 24 weeks from the start of treatment. Measurement of sustained response at the Week 24 study visit is selected to ensure the primary endpoint occurs at the same relative timepoint from start of treatment in all patients. As the treatment duration is 8 weeks for patients without cirrhosis in the bemnifosbuvir and ruzasvir study arm and 12 weeks for all other study arms, the primary endpoint encompasses the period at least through the SVR12 timepoint for each treatment arm.



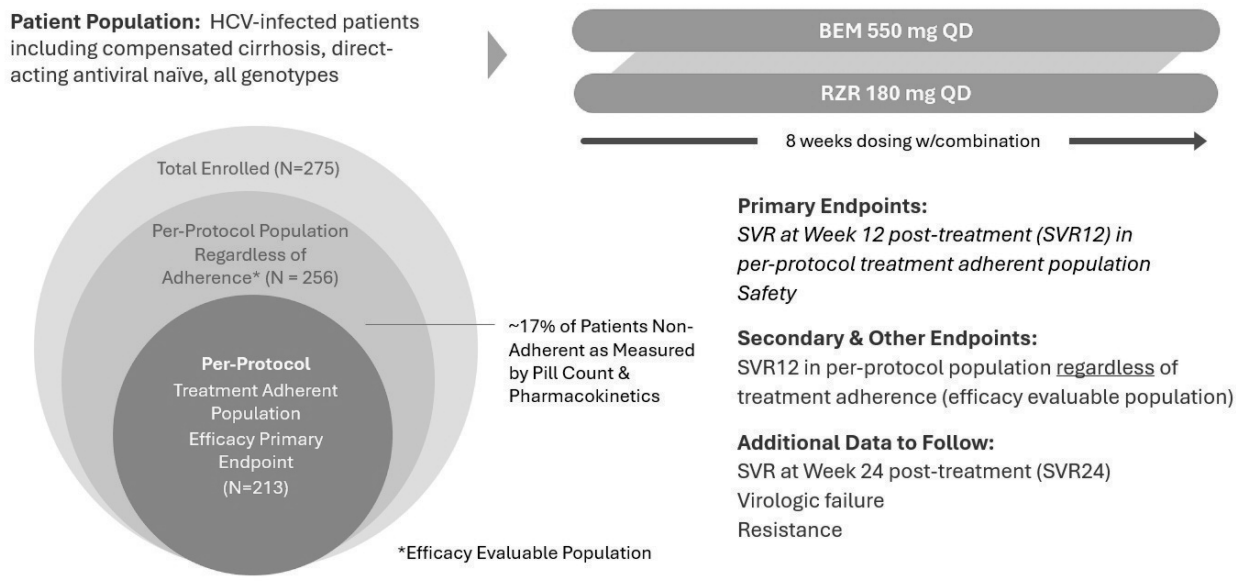
Global Phase 2 Clinical Trial

In June 2023, we initiated enrollment of a global Phase 2 study of bemnifosbuvir in combination with ruzasvir in treatment-naïve, HCV-infected patients, both with and without compensated cirrhosis. This study was designed to evaluate the safety and efficacy of 8 weeks of treatment with the regimen consisting of once daily bemnifosbuvir 550 mg and ruzasvir 180 mg. A lead-in cohort of 60 patients without cirrhosis was initially enrolled and rates of SVR at 4 weeks post treatment ("SVR4") from this cohort served as a gate to allow the enrollment of patients with compensated cirrhosis and continuation of full enrollment in the study. In February 2024, we announced results from the lead-in cohort in which a

98% SVR4 rate was observed. As the SVR4 rate in the lead-in cohort exceeded the protocol-defined efficacy criterion of ≥90% SVR4 for continuing the study, we commenced enrolling the remainder of the study, including patients with cirrhosis.

In total, 275 HCV-infected, treatment-naive patients with GT -1, -2, -3 and -4 were enrolled in this Phase 2 clinical trial. The primary endpoints of the study were safety and SVR12 in the per-protocol treatment adherent population (population which was adherent to the treatment). Secondary and other endpoints included SVR12 in the efficacy evaluable population (a broader analysis population which included treatment non-adherent patients), SVR24, virologic failure and resistance.

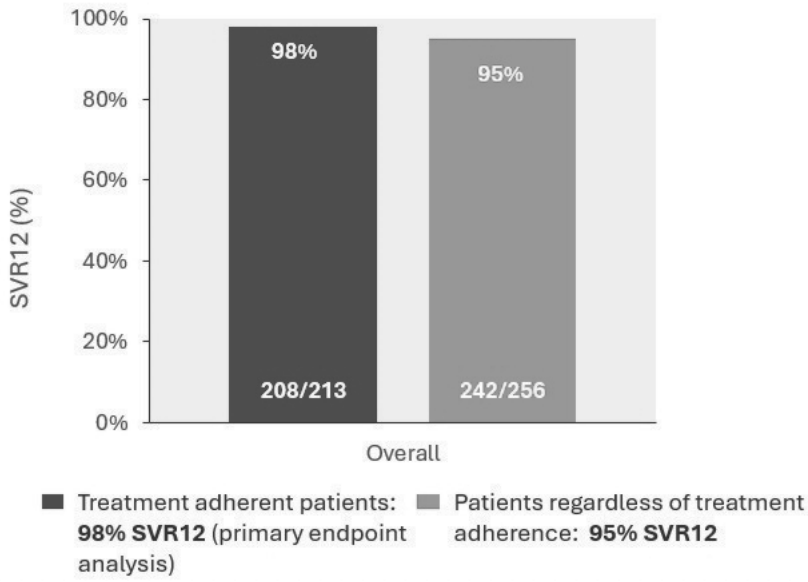
Phase 2 Open Label Study of Bemnifosbuvir + Ruzasvir in HCV-Infected Patients



In December 2024, we announced that this Phase 2 study evaluating the regimen of bemnifosbuvir and ruzasvir met its primary endpoints of safety and SVR12. The regimen was generally well-tolerated with no drug-related SAEs or treatment discontinuations.

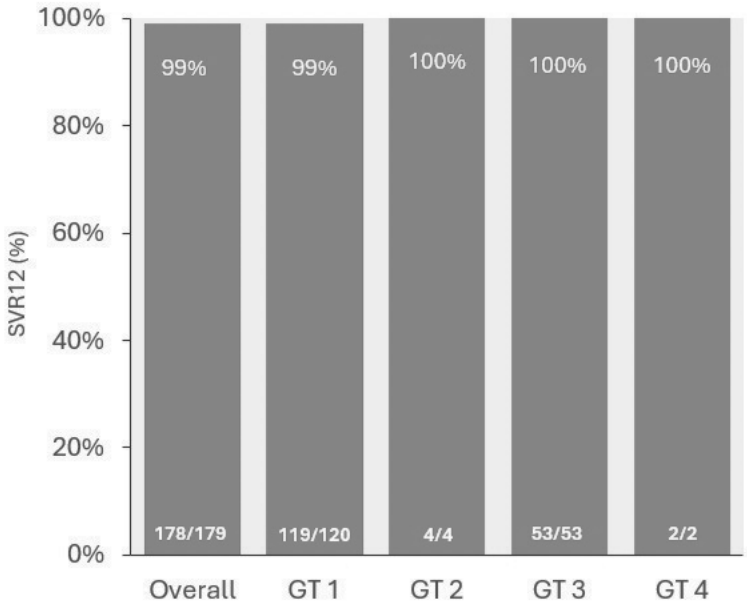
Primary efficacy endpoint results demonstrated a 98% (208/213) SVR12 rate in the per-protocol treatment adherent patient population after 8 weeks of treatment with the regimen of bemnifosbuvir and ruzasvir. The efficacy evaluable patient population, which included 17% treatment non-adherent patients, achieved a 95% (242/256) SVR12 rate.

SVR12 Rates with 8 Weeks Bemnifosbuvir + Ruzasvir in Treatment Adherent Patients (Primary Endpoint Analysis) and Regardless of Treatment Adherence



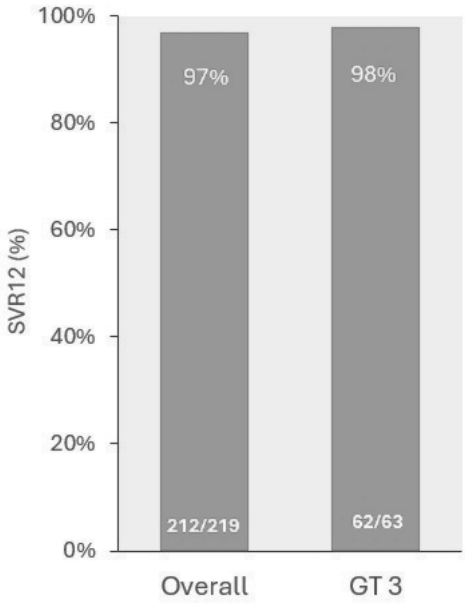
Furthermore, 99% (178/179) of treatment adherent patients who were non-cirrhotic and infected with GT-1, -2, -3, and -4 achieved SVR12, demonstrating the pan-genotypic potency and supporting our selection of an 8-week treatment for non-cirrhotics in the Phase 3 program.

SVR12 Rates by Genotype with 8 Weeks Bemnifosbuvir + Ruzasvir in Non-cirrhotic Treatment Adherent Patients



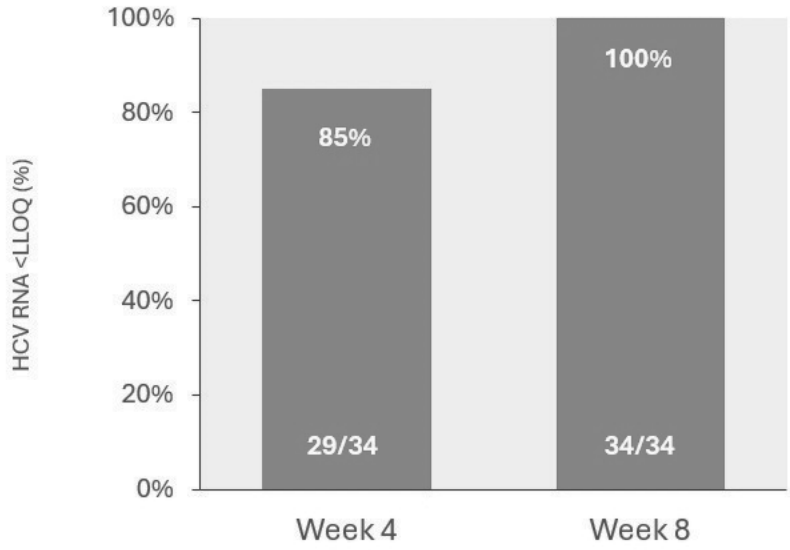
High SVR12 rates were also observed in non-cirrhotic patients regardless of treatment adherence, including in patients with GT-3 infection.

SVR12 Rates with 8 Weeks Bemnifosbuvir + Ruzasvir in Non-cirrhotic Patients Regardless of Treatment Adherence (Overall and GT-3)



Treatment adherent patients with cirrhosis achieved an 88% (30/34) SVR12 rate. Viral kinetics were slower in cirrhotic patients, however, all (100%; 34/34) achieved an end of treatment response (at Week 8). Based on these Phase 2 efficacy data, the treatment durations of the regimen of bemnifosbuvir and ruzasvir for the Phase 3 program will be 8 weeks in non-cirrhotic patients and 12 weeks in cirrhotic patients.

Viral Kinetics in Treatment Adherent Patients with Cirrhosis



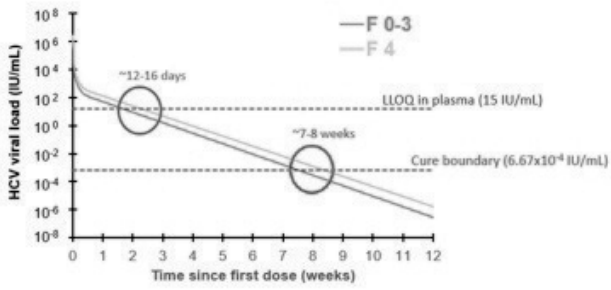
The Phase 2 clinical trial results were further evaluated in a multiscale viral kinetics model of HCV infection and treatment to estimate the efficacy of the regimen of bemnifosbuvir and ruzasvir. In this model, the population estimate for the time to achieve HCV RNA <LLOQ in the blood plasma was

approximately 12 to 16 days while the corresponding time to achieve cure was approximately 7 to 8 weeks. We believe these modeling data provide further support for evaluating the regimen of bemnifosbuvir and ruzasvir in the Phase 3 program with treatment durations of 8 weeks in patients without cirrhosis and 12 weeks in patients with compensated cirrhosis.

Multiscale Viral Kinetics Modeling

Fibrosis Stage	Time to <LLOQ in plasma (≤15 IU/mL) (days)	Time to Cure (≤ 6.67×10^{-4}) (wks)
F 0-3 (no cirrhosis)	12	7.5
F 4 (compensated cirrhosis)	16	8.4

LLOQ=lower limit of quantification



Bemnifosbuvir in Combination with Daclatasvir - Phase 2 Clinical Trial

We conducted a Phase 2, open-label clinical trial to evaluate bemnifosbuvir in combination with daclatasvir, an approved commercially available HCV NS5A inhibitor, in HCV-infected subjects. Ten treatment-naïve, non-cirrhotic HCV GT-1 infected subjects received 550 mg bemnifosbuvir and 60 mg daclatasvir once daily for a period of eight or 12 weeks, depending on viral load at Week 4. The primary efficacy endpoint of the study was SVR12.

Despite the use of a less potent first-generation HCV NS5A inhibitor, daclatasvir, nine of the 10 subjects in the study achieved HCV RNA < LLOQ by Week 4 and stopped treatment at Week 8, as allowed by the protocol. One subject had a slower on-treatment response but achieved < LLOQ by Week 8 and received 12 weeks of treatment. Nine of the ten subjects achieved SVR12. One subject who received eight weeks of treatment, achieved SVR4, and then experienced what was likely virologic relapse at post-treatment Week 12. The single subject who relapsed with GT 1b virus had the following multiple RASs/variants both at baseline and at the SVR12 timepoint: NS5A: R30Q; NS5B: L159F/A218S/C316N. Phenotypic analysis demonstrated that bemnifosbuvir 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_{50} compared to reference). Compared to sofosbuvir, the EC_{50} and EC_{90} 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 RASs at baseline.

The rapid early clearance of HCV RNA observed in this Phase 2 clinical trial evaluating bemnifosbuvir in combination with daclatasvir supported continued evaluation of bemnifosbuvir with ruzasvir, a more potent HCV NS5A inhibitor.

Bemnifosbuvir as a Single Agent – Phase 1 Clinical Trial

We conducted a Phase 1 trial to evaluate single and multiple doses of bemnifosbuvir 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 ≥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 bemnifosbuvir 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 HCV GT-1b infected subjects (Part C). Additional cohorts evaluated 600 mg salt form (553 mg free base) once daily for seven days in non-cirrhotic GT-3, (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, bemnifosbuvir 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 bemnifosbuvir 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 bemnifosbuvir at 553 mg free base in non-cirrhotic GT-1b HCV-infected subjects, and a mean reduction of 4.5 log_{10} IU/mL after seven days of dosing in non-cirrhotic GT-3 HCV-infected subjects. The PK data in cirrhotic subjects was similar to non-cirrhotic subjects. E_{max} modeling predicted that a dose of 553 mg free base of bemnifosbuvir once daily would result in maximum viral load reduction.

Maximum HCV RNA change in Part B (single dose in non-cirrhotic, HCV GT-1 infected subjects)

Maximum Reduction (log_{10} IU/mL) Bemnifosbuvir dose (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, HCV GT-1 infected subjects)

Maximum Reduction (log_{10} 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, HCV GT-3 infected subjects) and Part E (multiple dose in cirrhotic HCV-infected subjects)

Maximum Reduction (log_{10} IU/mL)	Part D – GT-3	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

In November 2024, we announced data from next generation sequencing that was performed to evaluate bemnifosbuvir resistant substitutions in the above referenced Phase 1b study (n=42). The pre-existing NS5B non-nucleoside resistance-associated substitutions at baseline did not correlate to bemnifosbuvir antiviral activity based on the maximum HCV RNA reduction of each subject. The changes of amino acid percentage in on-treatment samples were generally minimal, within 1-2% compared with baseline samples, indicating no development of viral resistance.

Ruzasvir

Ruzasvir is an investigational oral, 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_{50} in the sub- to low picomolar range against all GTs (<10 pM against GTs 1-7). The antiviral activity of ruzasvir was evaluated in POC study in HCV-infected patients, where viral load reductions >3 log_{10} were observed in HCV GT-1, GT-2 and GT-3 infected patients after treatment with monotherapy. This clinical antiviral activity is on par with what was achieved, as single agents, with

pibrentasvir and velpatasvir, the NS5A inhibitor components of Mavyret and Epclusa, respectively. These POC data supported evaluation of ruzasvir in larger phase 2 multiple drug combination studies (including two and three 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 two-drug combination studies (ruzasvir plus uprifosbuvir, a pyrimidine nucleotide prodrug, for 12 weeks) conducted by Merck in GT-1, -2, -4 and -6-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). We believe 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 observed dose-related clinical antiviral activity of ruzasvir in GT-3 subjects with cirrhosis.

In studies conducted by Merck, over 1,200 HCV-infected participants received ruzasvir at daily doses up to 180 mg for durations up to 12 weeks as part of 2-drug and 3-drug regimens with or without ribavirin. The overall safety data indicates that ruzasvir was generally well-tolerated with no consistent treatment-related changes in laboratory, vital signs, or electrocardiogram parameter values. SAEs and discontinuations due to AEs were rare in all studies conducted by Merck.

Other Phase 1 Trials

Bemnifosbuvir in Combination with Ruzasvir

In 2023, we conducted a Phase 1 clinical study in healthy subjects to evaluate the potential drug-drug interaction between bemnifosbuvir and ruzasvir and the effect of food on the PK of the study drugs. The study dugs were well-tolerated and plasma PK profiles were not substantially affected by food nor concomitant dosing, the latter indicating lack of drug-drug interaction between bemnifosbuvir and ruzasvir. These data supported the evaluation of the combination regimen in HCV-infected patients.

Other Drug-Drug Interaction Studies with Bemnifosbuvir

A series of Phase 1 studies demonstrated an overall low drug-drug interaction potential associated with bemnifosbuvir, including no dosage adjustment needed for co-administration of bemnifosbuvir with drugs that are CYP3A substrates or for drugs that are sensitive substrates of efflux and hepatic uptake transporters. CYP3A is an enzyme that metabolizes many classes of medicines and supplements, and the sensitive substrates of efflux and hepatic uptake transporters regulate cellular trafficking of drugs that are commonly prescribed.

In these studies, bemnifosbuvir was administered with index drugs for CYP3A4 (midazolam), P-glycoprotein (digoxin, cyclosporine, carbamazepine), breast cancer resistance protein and organic anion transporter polypeptide 1B1 (rosuvastatin). Based on low potential for drug-drug interaction, we believe bemnifosbuvir has the potential to be co-administered with commonly prescribed therapeutics that are often taken for other conditions.

Thorough QT Study - Bemnifosbuvir

A dedicated thorough QT Phase 1 trial was conducted in healthy participants who were randomized to receive a single oral dose of bemnifosbuvir 550 mg (clinical dose), 1100 mg (supratherapeutic dose), matching placebo (negative control) and open-label moxifloxacin 400 mg (positive control), in a four-way crossover design. Results, announced in November 2024, showed that bemnifosbuvir had no clinically relevant effects on cardiac repolarization, heart rate, PR interval, or QRS duration, which are all related to heart function. A QTc effect exceeding 10 milliseconds, the established threshold of concern, can be excluded across the observed plasma concentrations of bemnifosbuvir and its metabolites at the therapeutic and supratherapeutic doses.

Collectively, clinical data were consistent with the preclinical *in vitro* and *in vivo* study results, which demonstrated bemnifosbuvir has a low potential for cardiotoxicity with no predicted arrhythmic QTc-interval prolongation (a heart condition that occurs when the heart's ventricles take longer than normal to repolarize) or inhibition of the human mitochondrial DNA-directed RNA polymerase.

Safety Results for Bemnifosbuvir, Ruzasvir and the Regimen of Bemnifosbuvir and Ruzasvir

Over 2,300 human subjects have been exposed to bemnifosbuvir collectively across the HCV and COVID-19 development programs, at differing doses including single doses up to 1100 mg BID and durations (up to 12 weeks). Over 2,100 human subjects have been exposed to ruzasvir in clinical studies conducted to date. In the Phase 2 study evaluating the regimen of bemnifosbuvir and ruzasvir, 275 HCV-infected subjects with GT 1-4 received the combination of bemnifosbuvir 550 mg and ruzasvir 180 mg once daily for 8 weeks. In this Phase 2 study, there were no drug-related SAEs or treatment discontinuations due to drug-related AEs. AEs were generally mild to moderate in intensity. In addition, no trends were observed in AEs or safety laboratory parameters. At higher bemnifosbuvir doses (>550 mg BID) which were evaluated in the prior COVID-19 program, an increased incidence of mild to moderate gastrointestinal related non-serious adverse events, specifically nausea and to a lesser extent vomiting, were observed. However, treatment-limiting, bemnifosbuvir-related gastrointestinal AEs were not apparent at the 550 mg once daily dose being evaluated for HCV.

Both bemnifosbuvir and ruzasvir, alone and in combination have been well-tolerated and have favorable safety profiles, including in Phase 1 studies in healthy subjects. To date, there have been no study drug-related SAEs reported for bemnifosbuvir, ruzasvir or the combination of bemnifosbuvir and ruzasvir.

COVID-19

In September 2024, we announced results from the Phase 3 SUNRISE-3 trial, a global, multicenter, randomized, double-blind, placebo-controlled study evaluating bemnifosbuvir in patients with mild to moderate COVID-19. The trial did not meet its primary endpoint of a statistically significant reduction in all-cause hospitalization or death through Day 29. Total enrollment for the monotherapy cohort consisted of 2,221 high-risk patients randomized 1:1 to receive bemnifosbuvir 550 mg twice-daily (BID) or placebo BID for five days. In the trial, bemnifosbuvir was generally well tolerated.

The evolving nature of COVID-19, including milder disease presentations and a reduction in hospitalizations due to COVID-19 related severe respiratory disease, pose significant challenges in demonstrating a clinical impact with a direct-acting antiviral such as bemnifosbuvir. Given the trial results and the changing landscape of the pandemic, we are not pursuing a regulatory pathway forward for bemnifosbuvir for COVID-19.

Respiratory and other RNA virus infections

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

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

Roche License Agreement

In October 2020, we entered into a license agreement (“Roche License Agreement”) with Roche in connection with the global development, manufacture and commercialization of bemnifosbuvir, products containing bemnifosbuvir or AT-511, the free base of bemnifosbuvir, and related companion diagnostics.

As partial consideration for 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.

During the term of the Roche License Agreement, Roche and we jointly developed bemnifosbuvir for COVID-19 on a worldwide-basis and equally shared the costs associated with such development activities. On February 10, 2022, the Roche License Agreement terminated.

As a result of the Roche License Agreement termination, we regained worldwide exclusive rights from Roche to research, develop, manufacture and commercialize bemnifosbuvir, products containing

bemnifosbuvir or AT-511, the free base of bemnifosbuvir and related companion diagnostics in all fields of use.

Merck License Agreement

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

Pursuant to the terms of the Merck License Agreement, we obtained from Merck an exclusive (subject to certain reserved rights to conduct internal research), sublicensable, and worldwide license under certain Merck patents and know-how to research, develop, manufacture, have manufactured, use, import, export, sell, offer for sale, and otherwise commercialize ruzasvir ("Compound"), or products containing the Compound (each a "Product") for all therapeutic or prophylactic uses in humans ("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. The first milestone, in the amount of $5.0 million, is payable upon initiation of the first clinical trial in our Phase 3 program. The related expense will be recorded when the contingency is resolved and the milestone becomes payable. We currently anticipate enrollment of patients to commence in the Phase 3 program in April 2025. 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 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 bemnifosbuvir, 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 and anticipate relying upon these or other CMOs or other third parties for commercial supply if any of our product candidates is successfully developed and

approved for sale. While we expect that we will be able to enter into such arrangements, we do not currently have long-term agreements in place for manufacture of product at commercial scale quantities. As a result, there are no assurances that our manufacturing and supply chain infrastructure will remain uninterrupted and reliable or that our CMOs or other third parties will be able to satisfy demand in a timely manner. While there are a limited number of companies that can produce raw materials and active pharmaceutical ingredients in the quantities and with the quality and purity that we require for our product candidates, based on our diligence to date, we believe our current network of manufacturing partners are able to fulfill these requirements, can continue to expand capacity as needed. Additionally, we have, and will continue to evaluate further relationships with additional suppliers to increase overall capacity as well as further reduce risks associated with reliance on a limited number of suppliers for manufacturing.

Our employees who have extensive manufacturing and supply chain experience oversee the relationships with our CMOs.

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. The commercial opportunity for any product candidate we develop, if any are approved, could be reduced or eliminated if such product fails to achieve market acceptance from patients, prescribers and payors, 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.

HCV

Since 2014, many direct-acting antiviral therapies have been approved for use for the treatment of HCV in the US and globally. Orally administered, FDA-approved treatments for patients with chronic HCV include:

- Sovaldi® (sofosbuvir) (Gilead Sciences, Inc.), an HCV nucleotide analog NS5B polymerase inhibitor approved for the treatment of adult patients with GT-1, -2, -3, -4, -5, -6 chronic HCV infection without cirrhosis or with compensated cirrhosis as a component of a combination antiviral treatment regimen; pediatric patients ≥3 years old with HCV GT-2 or -3 infection without cirrhosis or with compensated cirrhosis in combination with ribavirin.
- Epclusa® (sofosbuvir and velpatasvir) (Gilead Sciences, Inc.), a fixed dose combination regimen of sofosbuvir and velpatasvir, an HCV NS5A inhibitor, approved for the treatment of adults and pediatric patients ≥3 years old with chronic HCV GT-1, -2, -3, -4, -5, or -6 infection without cirrhosis or with compensated cirrhosis, or for use in combination with ribavirin with decompensated cirrhosis.

- Harvoni® (ledipasvir and sofosbuvir) (Gilead Sciences, Inc.) a fixed dose combination of ledipasvir, an HCV NS5A inhibitor, and sofosbuvir approved for the treatment of adult and pediatric patients ≥3 years old with HCV GT-1, -4, -5 or -6 infection without cirrhosis or with compensated cirrhosis.
- Vosevi® (sofosbuvir, velpatasvir, and voxilaprevir) (Gilead Sciences, Inc.) a fixed dose triple combination of sofosbuvir, velpatasvir and voxilaprevir, an HCV NS3/4A protease inhibitor approved for the treatment of adult patients with chronic HCV infection without cirrhosis or with compensated cirrhosis who have HCV GT-1, -2, -3, -4, -5, or -6 infection and have previously been treated with an HCV regimen containing an HCV NS5A inhibitor; HCV GT-1a or -3 infection who have previously been treated with an HCV regimen containing sofosbuvir without an HCV NS5A inhibitor.
- Mavyret® (glecaprevir and pibrentasvir) (AbbVie, Inc.) a fixed-dose combination of glecaprevir, an HCV NS3/4A protease inhibitor and pibrentasvir, an HCV NS5A inhibitor, approved for the treatment of adult and pediatric patients ≥3 years old with chronic HCV GT-1, -2, -3, -4, -5, or -6 infection without cirrhosis or with compensated cirrhosis. Mavyret as an eight-week treatment is approved for patients who have not been previously treated. Longer treatment durations (up to 16 weeks) are indicated for some treatment-experienced populations. It is recommended that Mavyret be taken with food. Mavyret is not approved for use in patients with decompensated cirrhosis.
- Zepatier® (elbasvir and grazoprevir) (Merck) a fixed-dose combination of elbasvir, an HCV NS5A inhibitor and grazoprevir, an HCV NS3/4A protease inhibitor approved for the treatment of chronic HCV GT-1 or -4 infection in adult and pediatric patients ≥12 years old or weighing at least 30 kg. Zepatier is indicated for use with ribavirin in certain patient populations.

In addition to the branded products, Gilead Sciences, Inc. markets authorized generic copies of Epclusa and Harvoni through its subsidiary, Asegua Therapeutics, LLC. We are not aware of any investigational agents in late-stage development in the US although there may be other investigational agents for HCV in various stages of clinical development in other parts of the world.

Commercialization

We currently believe that we can maximize the value of our product portfolio by retaining global development rights to our product candidates. However, to further maximize the value of product candidates that are authorized or approved for sale, we may seek collaborations that allow us to access and leverage commercialization expertise and resources of collaborators in certain markets. To assist in the commercialization in the US of any product candidates we successfully develop, we may enter into arrangements with third parties that have existing commercial infrastructure including a pharmaceutical sales force and expertise in managed care. Outside the US, we anticipate that commercialization of our products, if approved or authorized for use, would be undertaken by third party collaborators. Currently, we do not have any sales, marketing or commercial product distribution infrastructure and we do not have any existing arrangements with third parties to commercialize our product candidates in the US or elsewhere. In December 2024, we announced that we had engaged Evercore LLC, an independent global investment bank, to assist us in identifying and exploring potential strategic partnerships related to our lead product candidate, the regimen of the bemnifosbuvir and ruzasvir for the treatment of HCV infection. That effort remains ongoing.

Intellectual Property

Our commercial success will depend in part on our ability to obtain and maintain proprietary protection for our therapeutic products for viral diseases. We seek to protect our proprietary compounds and methods of treatment for viral diseases using our 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 compounds. Our success also depends on our ability to operate without infringing, misappropriating or otherwise violating 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 US 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 US, 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 US, 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 March 1, 2025, we are the sole owner of seventeen patent families covering our product candidates and proprietary 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 March 1, 2025, on a worldwide basis, includes more than 300 pending, granted, or allowed patent applications with twenty two issued US patents, ten pending US non-provisional applications and more than 250 pending or granted patent applications that have entered the national phase of prosecution in countries outside the US.

As of March 1, 2025, we are the exclusive licensee of three patent families from Merck covering composition of matter, process of preparation, and formulations of ruzasvir, the NS5A inhibitor which we are developing in combination with bemnifosbuvir for the treatment of HCV. These three patent families collectively include two issued US patents, granted patents in France, Great Britain, and Germany and one pending US patent application and one pending patent application in the European Patent Office ("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 US 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 US 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 US 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 the European Union ("EU"). 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 US, 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 US or a foreign country.

Current issued patents and patent applications covering the composition of matter for AT-511, the free base of bemnifosbuvir, and our product candidate, bemnifosbuvir, 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, and without regard to any possible patent term adjustments or extensions. Current issued patents and patent applications covering the use of AT-511 and bemnifosbuvir for the treatment of HCV will expire on dates ranging from 2036 to 2046, if the applications are issued and held valid by a court of final jurisdiction if challenged, and without regard to any possible patent term adjustments or extensions. Current patent applications covering the use of AT-511 and bemnifosbuvir for the treatment of SARS-CoV-2 will expire on dates ranging from 2040 to 2041, if the applications are issued and held valid by a court of final jurisdiction if challenged, and without regard to any possible patent term adjustments or extensions.

However, any of our patents, including patents that we may rely on to protect our market for products if any are approved, 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 US 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 biopharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Our ability to obtain and maintain our proprietary position for our 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 the section titled *"Risk Factors—Risks Related to Intellectual Property."*

Our patent families, as of March 1, 2025, are further described below.

AT-511 and Bemnifosbuvir

We own a first patent family that describes AT-511 or a pharmaceutically acceptable salt thereof (for example, bemnifosbuvir), 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 seven issued US patents (US Patent Nos. 9,828,410; 10,000,523; 10,005,811; 10,239,911; 10,815,266; 10,870,672; 10,870,673) covering AT-511 or a pharmaceutically acceptable salt thereof, related compounds and their 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 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 40 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 bemnifosbuvir (the hemisulfate salt of AT-511), pharmaceutical compositions, process of preparation, and methods to treat HCV using bemnifosbuvir. This family includes three issued US patents (US Patent Nos. 10,519,186; 10,906,928; and 12,006,340) covering bemnifosbuvir or a process to prepare bemnifosbuvir. This family is currently in the national phase of prosecution in Argentina, ARIPO, Australia, Brazil, Canada, China, Colombia, the EAPO, 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. The patent has now been granted by the European Patent Office. We have over 30 granted foreign patents and over 20 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 US or other national laws.

We own two patent families that disclose methods for the treatment of SARS-CoV-2 using AT-511 or bemnifosbuvir. These families include five granted US patents (US Patent Nos. 10,874,687, 11,707,480, 11,783,038, 11,813,278 and 12,226,429) and one pending US applications. Patent applications in this family have been allowed in Japan and the EPO, and applications are pending in Australia, Canada, China, the EPO, and Japan. 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 US 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 *Flaviviridae* viral infection such as dengue, West Nile, or yellow fever. This family consists of two issued US patents (US Patent Nos. 10,946,033 and 11,975,016) 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 US or other national laws.

We own a sixth patent family that discloses the use of AT-511 and bemnifosbuvir for the treatment of HCV in patients with cirrhosis of the liver. This family includes one granted US patent (US Patent No. 11,690,860). 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 US or other national laws.

We own a seventh patent family that describes methods to treat mutant or resistant forms of the SARS-CoV-2 virus. This family consists of one pending application in the US. 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 US or other national laws.

We also own an eighth patent family that discloses methods for manufacturing AT-511 and bemnifosbuvir. This family consists of one pending US application. 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 US or other national laws.

We also own a ninth patent family that discloses additional processes for the manufacture of AT-511 and bemnifosbuvir. This family consists of one pending patent application in the US in addition to pending applications in Argentina, Australia, Canada, China, the EPO Hong Kong, India, Japan, Korea, Mexico, New Zealand, and Taiwan. The expected year of expiration for patents issuing from these non-provisional patent applications, if valid and enforceable, is 2041, without regard to any adjustments of term that may be available under US or other national law.

We also own a tenth patent family that discloses new morphic forms of bemnifosbuvir. This family consists of one pending patent application in the US, as well as pending applications in Australia, Brazil, Canada, China, the EAPO, the EPO, Israel, India, Japan, Korea, Mexico, Russia, and 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 2042, without regard to adjustments of term that may be available under US or other national laws.

Ruzasvir and the Combination of Bemnifosbuvir and Ruzasvir

We have exclusively licensed three patent families from Merck covering composition of matter, process of preparation, and formulations of ruzasvir, a pan-genotypic NS5A inhibitor which we are combining with bemnifosbuvir in the regimen we are developing to treat HCV. The family covering the ruzasvir composition of matter includes one granted US patent (US 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 US patent (US Patent No. 10,457,690), with an expected expiration date in 2036. The family describing formulations includes one pending US patent application and one pending patent application in the EPO, which if granted, is expected to expire in 2039.

We also solely own an eleventh patent family covering the combination of bemnifosbuvir and ruzasvir. This family consists of one patent application in the US, in addition to patent applications in the United Arab Emirates, Argentina, Australia, Brazil, Canada, China, Colombia, the EAPO, the EPO, Indonesia, Israel, India, Japan, Korea, Mexico, Malaysia, New Zealand, the Philippines, Qatar, Russia, Saudi Arabia,

Singapore, Thailand, Taiwan, and South Africa. These patent applications, if granted, will have an expiration date in 2042.

We also solely own a twelfth patent application covering our fixed-dose combination of bemnifosbuvir and ruzasvir. The expected year of expiration for patents issuing from this application, if valid and enforceable, is 2046, without regard to any adjustments of term that may be available under US or other national law.

Government Regulation and Product Approval

Government authorities in the US, 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 US.

US Drug Development Process

In the US, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act ("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 US generally involves the following:

- completion of certain 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 satisfactory completion of potential inspections 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 US.

Prior to beginning the first clinical trial with a product candidate in the US, a sponsor must submit an IND to the FDA. An IND is a request for allowance from the FDA to administer an investigational drug 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 investigational 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 allowance 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 among other things 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 investigational product 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 labeling.

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 approved 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 alignment on the next phase of development.

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.

US Review and Approval Process

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, including results from 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.

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 certain 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 deemed 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.

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 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 may 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 ("CRL"). An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A CRL 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 CRL is issued, the sponsor must resubmit the NDA 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. The FDA may also require one or more post-approval 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-approval studies.

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, investigational 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. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the application may be eligible for priority review. 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.

Moreover, 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, depending on the design of the applicable clinical trials, 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 generally requires that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled confirmatory clinical trials to verify and describe the predicted clinical benefit and may require that such confirmatory trials be underway prior to granting any accelerated approval. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required clinical trials in a timely manner, 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.

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 NDA holders and any third-party manufacturers that NDA holders 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 labeling.

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 US 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 non-patent 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 US. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to any existing periods of regulatory exclusivity or patent terms 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, and a grant of pediatric exclusivity does not require the sponsor to obtain approval for the product candidate for pediatric use.

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, US 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 US. Such foreign laws and regulations may be broader in scope than the provisions described above and may apply regardless of payor. These laws and regulations may differ from one another in significant ways, thus further complicating compliance efforts. For instance, in the EU, many EU member states have adopted specific anti-gift statutes that further limit commercial practices for medicinal products, in particular vis-à-vis healthcare professionals and organizations. Additionally, there has been a recent trend of increased regulation of payments and transfers of value provided to healthcare professionals or entities and many EU member states have adopted national “Sunshine Acts” which impose reporting and transparency requirements (often on an annual basis), similar to the requirements in the US, on pharmaceutical companies. Certain countries also mandate implementation of commercial compliance programs, or require disclosure of marketing expenditures and pricing information. 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 US 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 US, 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 US 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 US, 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 US, 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; 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 and Medicaid 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.

Since its enactment, there have been judicial and political challenges to certain aspects of the ACA. On June 17, 2021, the US Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of 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, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, 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. In addition, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price.

Moreover, 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. On August 16, 2022, the Inflation Reduction Act of 2022, or ("IRA"), was enacted into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023), and replaces the Part D coverage gap discount program with a new discounting program (which began in 2025). The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has issued and will continue to issue guidance implementing the IRA. CMS has published the negotiated prices for the initial ten drugs, which will first be effective in 2026, and the list of the subsequent 15 drugs that will be subject to negotiation, although the Medicare drug price negotiation program is currently subject to legal challenges. While the impact of the IRA on the pharmaceutical industry cannot yet be fully determined, it is likely to be significant.

Individual states in the US 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, drug price reporting and other transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states. In addition, certain individual states as well as regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which drugs and suppliers will be included in their healthcare programs. The states of Louisiana and Washington used bidding procedures in 2019 and more recently Minnesota did so in 2021 to secure contracts with suppliers of HCV antiviral therapeutics for certain populations including those covered by Medicare and those in correctional institutions. Other states are currently engaged in similar discussions. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

In the EU, on December 13, 2021, Regulation No 2021/2282 on Health Technology Assessment ("HTA") was adopted. The Regulation entered into force in January 2022 and has been applicable since January 2025, with phased implementation based on the type of product, i.e. oncology and advanced therapy medicinal products as of 2025, orphan medicinal products as of 2028, and all other medicinal products by 2030. The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

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

Data Privacy and 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 US, 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. Further, certain foreign laws govern the privacy and security of personal data, including health-related data. 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. For additional information, see Part I, Item 1A, "Risk Factors".

Government Regulation Outside of the US

In addition to regulations in the US, we are subject to a variety of regulations in other jurisdictions, such as the EU, 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 processes 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

Similar to the US, 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 (pharmaco-toxicological) studies must be conducted in compliance with the principles of good laboratory practice ("GLP") as set forth in EU Directive 2004/10/EC (unless otherwise justified for certain particular medicinal products – e.g., radio-pharmaceutical precursors for radio-labeling purposes). 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 Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use ("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 EU Clinical Trials Directive required a separate clinical trial application ("CTA") to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, much like the FDA and IRB respectively, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The 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.

As of January 31, 2025, all clinical trials (and related applications) are 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 Products 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.

In the EU, innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the PRIority MEdicines ("PRIME") scheme, which provides incentives similar to the breakthrough therapy designation in the US. In March 2016, the EMA launched an initiative, the PRIME scheme, a voluntary scheme aimed at enhancing the EMA's support for the development of medicines that target unmet medical needs. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. Product developers that benefit from PRIME designation can expect to be eligible for accelerated assessment, but this is not guaranteed. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated MAA assessment once a dossier has been submitted. Importantly, a dedicated contact and rapporteur from the CHMP is appointed early in the PRIME scheme facilitating increased understanding of the product at EMA's committee level. An initial meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies.

Moreover, in the EU, a "conditional" MA may be granted in cases where all the required safety and efficacy data are not yet available. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and has to be renewed annually until fulfillment of all the conditions. Once the pending studies are provided, it can become a "standard" MA. However, if the conditions are not fulfilled within the timeframe set by the EMA, the MA ceases to be renewed. Furthermore, MA may also be granted "under exceptional circumstances" when the applicant can show that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. This may arise in particular when the intended indications are very rare and, in the present state of scientific knowledge, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. This MA is close to the conditional MA as it is reserved 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 MA. However, unlike the conditional MA, the applicant does not have to provide the missing data and will never have to. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit

balance of the medicinal product is reviewed annually, and the MA is withdrawn in case the risk-benefit ratio is no longer favorable.

Under the above-described procedures, in order to grant the MA, the EMA or the competent authorities of the EU member states make an assessment of the risk benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. 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 data and 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.

Pediatric Development

In the EU, MAAs for new medicinal products have to include the results of studies conducted in the pediatric population, in compliance with a pediatric investigational plan ("PIP") agreed with the EMA's Pediatric Committee ("PDCO"). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data is not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all the EU member states and study results are included in the product information, even when negative, the product is eligible for six months' supplementary protection certificate extension (if any is in effect at the time of approval) or, in the case of orphan pharmaceutical products, a two-year extension of the orphan market exclusivity is granted.

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

Since the end of the Brexit transition period on January 1,2021, and the implementation on January 1, 2025 of the Windsor Framework (as defined below), the United Kingdom ("UK") has not generally been directly subject to EU laws with respect to medicinal products. The EU laws that have been transposed into UK law through secondary legislation remain applicable in Great Britain (England, Scotland and

Wales), however, new legislation such as the (EU) CTR is not applicable in Great Britain ("GB"). Under the Medicines and Medical Devices Act 2021, the Secretary of State or an 'appropriate authority' has delegated powers 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.

Since January 1, 2021, the Medicines and Healthcare products Regulatory Agency ("MHRA") has been the UK's standalone medicines and medical devices regulator. As a result of the Northern Ireland Protocol, different rules applied in Northern Ireland than in GB; broadly, Northern Ireland continued to follow the EU regulatory regime. However, on January 1, 2025, a new arrangement called the "Windsor Framework" came into effect and reintegrated Northern Ireland under the regulatory authority of the MHRA with respect to medicinal products. The Windsor Framework removes EU licensing processes, and EU labelling and serialization requirements in relation to Northern Ireland, and introduces a UK-wide licensing process for medicinal products.

The UK regulatory framework in relation to clinical trials is derived from pre-existing EU legislation (as implemented into UK law, through secondary legislation). The extent to which the regulation of clinical trials in the UK will mirror the (EU) CTR in the long term is not yet certain, however, on December 12, 2024, the UK government introduced a legislative proposal - the Medicines for Human Use (Clinical Trials) Amendment Regulations 2024 - that, if implemented, will replace the current regulatory framework for clinical trials in the UK. The legislative proposal aims to provide a more flexible regime to make it easier to conduct clinical trials in the UK, increase the transparency of clinical trials conducted in the UK and make clinical trials more patient centered. If the legislative proposal is approved (with or without amendment), it would be adopted into UK law, which is expected in early 2026.

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 opted 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, since 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. An international recognition framework has been in place from January 1, 2024, whereby the MHRA will have regard to decisions on the approval of MAs made by the EMA and certain other regulators when determining an application for a new UK MA.

There is 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 the UK, 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 the UK.

Human Capital Resources

As of March 4, 2025, we had 56 full-time employees, including 17 employees with M.D., Ph.D. or Pharm.D. degrees. Of these full-time employees, 39 employees are engaged in research and development activities. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Our top priorities for human capital resources are to attract, recruit, retain, incentivize, and seamlessly integrate both our current and new employees in an engaging manner. 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.

Organization

Atea Pharmaceuticals, Inc. was incorporated in July 2012 and began principal operations in March 2014. Our principal office facilities are in Boston, Massachusetts. Atea Pharmaceuticals Securities Corporation, a Massachusetts corporation incorporated in 2016, is a wholly owned subsidiary of Atea Pharmaceuticals, Inc. Our website is www.ateapharma.com. Information that is contained on, or that can be accessed through, our website is not incorporated by reference into this Annual Report on Form 10-K, and you should not consider information on our website to be part of this Annual Report on Form 10-K.

Available Information

We make available free of charge on the investor relations portion of our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, Proxy Statements for our annual meetings of stockholders, and amendments to those reports, as soon as reasonably practicable after we file such material with, or furnish it to, the Securities and Exchange Commission ("SEC"). These filings are available for download free of charge on the investor relations portion of our website located at https://ir.ateapharma.com. The SEC also maintains a website that contains reports, proxy statements and other information that we and other issuers file electronically with the SEC. The address of that website is https://www.sec.gov.

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
Executive Officers		
Jean-Pierre Sommadossi, Ph.D.	68	President and Chief Executive Officer and Chairman of the Board of Directors
Andrea Corcoran	62	Chief Financial Officer, Executive Vice President, Legal and Secretary
Janet Hammond, M.D., Ph.D.	64	Chief Development Officer
Maria Arantxa Horga, M.D.	56	Chief Medical Officer
John Vavricka	61	Chief Commercial Officer
Wayne Foster	56	Executive Vice President and Chief Accounting Officer
Directors		
Franklin Berger (1)(2)	75	Director (Lead Director)
Jerome Adams, M.D. (3)(4)	50	Director
Barbara Duncan (1)(3)	60	Director
Arthur Kirsch	73	Director
Bruno Lucidi (1)(2)	65	Director
Polly A. Murphy, D.V.M., Ph.D. (3)(4)	60	Director
Bruce Polsky, M.D. (2)(4)	70	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 has also served on the board as Chairman of the board of directors of Panchrest, Inc., a privately held marketing authorized representative in healthcare, since 2013, and Chairman of the board of directors of Biothea Pharma, Inc., a privately held biotechnology company, since 2021. Dr. Sommadossi has also served as a member of the board of directors of The BioExec Institute since 2004. Previously, Dr. Sommadossi served on the board of directors of ABG Acquisition Corporation from February 2021 to February 2023, as Chairman of the board of directors of Kezar Life Sciences, Inc., a biopharmaceutical company, from June 2015 to May 2022, Vice Chairman 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 biopharmaceutical industry qualifies him to serve on our Board.

Andrea Corcoran has served as our Chief Financial Officer since October 2020, Secretary since September 2014 and Executive Vice President, Legal since December 2013 and served as our 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 privately held 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 as Vice President and Therapeutic Area Head for General Medicine and Infectious Disease Development at AbbVie, Inc., a biopharmaceutical company, from November 2016 to August 2020, and as Senior Vice President, Global Head of Infectious Diseases and Head of Pharmaceutical Research and Early Development China at F. Hoffmann-La Roche from March 2011 to November 2016. Dr. Hammond has also served on the board of directors of Enterprise Therapeutics Ltd., a privately held biopharmaceutical company, since May 2024. 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, Inc. 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 co-founded and served as the Chief Executive Officer of Biothea Pharma, Inc., a privately held 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 and previously served as Senior Vice President, Finance and Administration from December 2019 to January 2022. Prior to 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 Satellos Bioscience Inc. since September 2023, ESSA Pharma Inc. since March 2015, and Kezar Life Sciences, Inc. since January 2016. Mr. Berger previously served on the boards of directors of Rain Therapeutics Inc. from May 2020 to January 2024, Atreca Inc. from October 2014 to May 2024, BELLUS Health, Inc. from May 2010 to June 2023, Tocagen, Inc. from October 2014 to December 2020, Proteostasis Therapeutics, Inc. from February 2016 to December 2020, and 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 has served as Director of Health Equity Initiatives at Purdue University since October 2021. Dr. Adams served as the 20th Surgeon General of the US 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 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 service as a Surgeon General and 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 as Chief Financial Officer and Treasurer at Intercept Pharmaceuticals, Inc. from May 2009 to June 2016. Ms. Duncan also serves on the boards of directors of Ovid Therapeutics, Inc. since June 2017, Halozyme Therapeutics, Inc. since February 2023, and Convergent Therapeutics, a privately held biopharmaceutical company, since December 2024. Previously, Ms. Duncan served on the boards of directors of Fusion Pharmaceuticals Inc. from November 2020 to May 2024, Jounce Therapeutics, Inc. from June 2016 to May 2023, Adaptimmune Therapeutics plc from June 2016 to June 2023, 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 financial expertise, experience in the biotechnology industry and service as a public company executive and board member.

Arthur Kirsch has served as a member of our Board of Directors since February 2025. Mr. Kirsch has served as a Senior Advisor to Alvarez & Marsal's Life Science Industry Group, a global professional services firm, since 2019. Prior to such role, Mr. Kirsch was a Senior Advisor and Managing Director for GCA Savvian, an investment bank, from 2005 to 2018, where he was responsible for healthcare investment banking activities. Prior to 2005, Mr. Kirsch had a number of other leadership roles in investment banking at Vector Securities/Prudential Vector Healthcare, NatWest Markets and Drexel Burnham Lambert. Mr. Kirsch has served on the board of directors of Liquidia Corporation, a biopharmaceutical company, since December 2016 and previously served on the boards of directors of a number of other public companies in the biopharmaceutical and pharmaceutical industries, including Kadmon Holdings, Inc. from May 2019 to November 2021, Immunomedics, Inc. from August 2015 to October 2016, POZEN Inc. from April 2004 to May 2015 and Aralez, Inc. from February 2016 to May 2019. The Company believes Mr. Kirsch's extensive experience in the healthcare and life sciences industries and as a strategic advisor will be valuable additions to the Board.

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 has more than 40 years of experience in the pharmaceutical industry. He held Senior Executive positions at Bristol-Myers Squibb, Johnson and Johnson and GSK and he has been CEO and Chairman of the board of several biopharmaceutical companies in Europe and the US. Mr. Lucidi was trained in Oncology at the Gustave Roussy Institute, Villejuif, France, in Marketing and Strategic Management of Companies at the Ecole Superieure de Commerce, Paris, France, and in Finance, Merger and Acquisitions at the Investment Banking Institute in New York. We believe that Mr. Lucidi is qualified to serve on our board due to his extensive leadership experience in the life science industry as an executive of pharmaceutical companies and other organizations at various stages of development and his expertise commercializing antiviral and other drug products on a global basis.

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 Avadel Pharmaceuticals plc since May 2024. Previously, Dr. Murphy served as the Chief Business Officer of Urogen, Inc. from August 2020 to May 2024. Dr. Murphy also previously served in various leadership roles at Pfizer, Inc. from September 2008 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 has served on the board of directors of Celcuity Inc. since September 2022. 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., *MACP, FIDSA,* 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 has served as professor and Chair of the Department of Medicine and as an Associate Dean at NYU Grossman 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 that Dr. Polsky is qualified to serve on our Board due to his extensive medical and scientific knowledge and the depth and breadth of his experience as a leading practicing infectious disease physician.

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 consolidated financial statements and the related notes and "Management's Discussion and Analysis of Results of Operations and Financial Condition." Our business, financial condition, results of operations or prospects could be materially and adversely affected if any of these risks occurs, and as a result, the market price of our common stock could decline and you could lose all or part of your investment. Our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain factors, including those set forth below.

Risks Related to 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 successfully develop, obtain marketing approval, manufacture a product at commercial-scale, or conduct sales and marketing activities necessary for successful product commercialization, or have third parties to do these activities on our behalf. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing, obtaining marketing approval for and commercializing antiviral therapies.

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

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

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

We have incurred significant operating expenses since inception and expect to incur significant additional operating expenses for the foreseeable future. We have no products that have generated any commercial revenue. We expect to incur operating losses in 2025 and for the foreseeable future.

We have incurred significant operating expenses since our inception. For the years ended December 31, 2024 and 2023, our operating expenses were $192.9 million and $164.2 million, respectively. As of December 31, 2024, we had an accumulated deficit of $364.2 million.

We have not commercialized any products and have never generated any revenue from product sales. We have devoted almost all of our financial resources to research and development, including our clinical trials and preclinical development and manufacturing activities. We expect to continue to incur significant additional operating expenses and to incur operating losses for the foreseeable future as we seek to advance product candidates through clinical development, continue preclinical development, pursue research and development activities, discover or acquire and develop product candidates, complete

preclinical studies and clinical trials, scale up and complete manufacturing and supply chain activities, seek regulatory approval and, if we receive regulatory approval, commercialize our products.

In order to obtain the FDA's or a foreign regulatory authority's approval to market any product candidate in the US or abroad, respectively, we must submit to the FDA a New Drug Application ("NDA") or similar application to the foreign regulatory authority demonstrating to the FDA's or foreign regulatory authority's satisfaction that the product candidate is safe and effective for its intended use(s). This demonstration requires significant research and extensive data from 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. For example, as we advanced and completed the enrollment of our COVID-19 Phase 3 SUNRISE-3 clinical trial, our operating expenses increased. We anticipate that operating expenses will also increase in the future as we advance and complete Phase 3 clinical trials evaluating the regimen of bemnifosbuvir and ruzasvir for the treatment of HCV as well as any additional late stage clinical trials. Because of the numerous risks and uncertainties associated with the development of our product candidates, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to begin generating revenue from the commercialization of products or again achieve profitability.

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

- continue to discover and develop additional product candidates;
- successfully complete clinical trials and seek regulatory approval for our regimen of bemnifosbuvir and ruzasvir or other product candidates, 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 collaborators;
- maintain, expand, protect and enforce our intellectual property portfolio;
- hire additional staff, including clinical, scientific, technical, regulatory, operational, financial, commercial and support personnel, to execute our business plan and support our product development and potential future commercialization efforts;
- more extensively utilize external vendors for support with respect to research, development, manufacturing, commercialization, regulatory, pharmacovigilance and other functions;
- acquire or in-license commercial products or additional product candidates and technologies;
- make milestone, royalty or other payments under the Merck License Agreement with respect to the development and commercialization of ruzasvir in combination with bemnifosbuvir for the treatment of HCV;
- make upfront, milestone, royalty or other payments in connection with any future in-license agreements relating to other product candidates; and
- incur continuing and increasing legal, accounting and other expenses in operating our business as a public company.

Furthermore, our ability to successfully develop, commercialize and license any products and generate product revenue is subject to substantial additional risks and uncertainties. Our HCV product candidate and any future product candidates we may discover, license or otherwise acquire, will require regulatory approval in not less than one jurisdiction, the securing of manufacturing supply, capacity, distribution channels and expertise, the use of external vendors, the building of or other access to a commercial organization, substantial investment and significant marketing efforts before we generate any revenue from product sales. Additionally, our HCV product candidate and any future product candidates will

require additional preclinical and clinical development. As a result, we expect to continue to use cash for operating activities and incur operating expenses and operating losses for the foreseeable future. The use of cash and incurrence of operating expenses and operating losses has had, and we expect will continue to have, an adverse effect on our working capital.

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

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

Since inception, we have incurred substantial operating expenses. We expect to incur substantial expenses in connection with our current and planned business activities, particularly the late stage development of the regimen of bemnifosbuvir and ruzasvir. Also, we anticipate that we may incur substantial expenses in connection with the discovery, license or other acquisition and potential development of other product candidates, if any, and, if we successfully develop one or more product candidates, in connection with the establishment of sales, marketing, internal systems and distribution infrastructure to commercialize any products for which we may obtain regulatory approval.

If our cash, cash equivalents and marketable securities are not sufficient to fund our future operations, we will need additional capital to fund these activities, which we may raise through equity offerings, 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 for our product candidates from the FDA, or any foreign regulatory authorities, and could be forced to discontinue product development. In addition, attempting to secure additional financing could divert the time and attention of our management from day-to-day activities and may harm our product candidate development efforts.

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

- the scope, progress, results and costs of our preclinical studies and clinical trials, in particular the Phase 3 development of the regimen of bemnifosbuvir and ruzasvir for the treatment of HCV;
- the timing of and costs associated with discovery, license or acquisition of a product candidate for the treatment of respiratory or other diseases resulting from infection with single stranded RNA viruses;
- the timing of, and the costs involved in, obtaining marketing approvals for our current and future product candidates in regions where we choose to commercialize any products;
- 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 manufacturing and commercialization activities for any approved product candidate to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of manufacturing commercial supply at a scale to meet demand and the costs and timing of establishing commercialization capabilities for and conducting product sales, marketing, distribution activities;
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- the costs, timing and changes in pharmaceutical pricing and reimbursement infrastructure resulting from, among other things, the enactment of the Inflation Reduction Act ("IRA") and other legislation and regulations that may be subsequently enacted;
- our ability to compete with other therapies in the indications we target;
- the extent to which we in-license or acquire rights to products, product candidates or technologies in addition to ruzasvir;
- growth of our headcount and associated costs if and as we establish a commercial infrastructure;
- the costs of preparing, filing and prosecuting patent applications and maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property-related claims; and
- the continued costs of operating as a public company.

Currently, we do not have any committed external source of funds or other support and we cannot be certain that additional funding will be available on acceptable terms, if needed. Our ability to access potential sources of future liquidity and raise funds will depend upon financial, economic and geopolitical conditions and other factors, many of which are beyond our control. These external factors, including rates of interest and inflation, will also impact and may increase substantially costs we incur in connection with any potential fundraising. If we are unable to raise additional capital in sufficient amounts, on terms acceptable to us, or on a timely basis, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives.

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

In the future, we may enter into strategic collaborations or other transactions. In the fourth quarter of 2024, we announced that we had engaged Evercore LLC, a global independent investment bank, to assist us in identifying and exploring potential strategic partnerships related to our regimen of the bemnifosbuvir and ruzasvir. While this process is ongoing, there is no assurance that it will result in the completion of any specific transaction or outcome. If we do identify suitable collaboration candidates or strategic partners, we may not be able to complete such collaborations or other strategic transactions on favorable terms, or at all. Any collaborations or other strategic transactions may not strengthen our competitive position, and these transactions may be viewed negatively by stock research analysts or investors, and we may never realize the anticipated benefits of such transactions. We may decide to issue our common stock or other equity securities to a strategic partner or collaborator which would reduce the percentage ownership of our existing stockholders. In addition, we may not be able to successfully integrate with any collaborator or strategic partner in an effective, timely and non-disruptive manner. Collaborations or other strategic transactions may also divert management attention from day-to-day responsibilities, lead to a loss of key personnel, increase our expenses and reduce our cash and cash equivalents available for operations and other uses. We cannot predict the number, timing or size of future collaborations or strategic partnerships or the effect that any such transactions might have on our operating results.

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

We incurred a net loss of $168.4 million for the year ended December 31, 2024. Our ability to achieve and sustain future profitability depends upon our ability to generate revenue from product sales. We have not generated product revenue and we do not expect to generate product revenue unless or until we successfully complete clinical development and obtain regulatory approval of, and then successfully commercialize, at least one of our product candidates. Our HCV product candidate and future product candidates, if any, will require additional preclinical and clinical development, regulatory review and approval, substantial investment in and access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. Currently, we do not anticipate generating revenue from product sales for at least the next few years. Our ability to generate revenue depends on a number of factors, including, but not limited to:

- timely completion of our clinical trials, including the Phase 3 clinical trials evaluating the regimen of bemnifosbuvir and ruzasvir for the treatment of HCV, as well as our preclinical studies and other clinical trials, each of which may be significantly slower or more costly than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- our ability to complete additional investigational drug application ("IND") enabling studies and successfully submit INDs, clinical trial application ("CTAs") or comparable applications to allow us to initiate clinical trials for any other product candidates;
- whether we are required by the FDA or similar foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our HCV product candidate or any future product candidates;
- our ability to demonstrate to the satisfaction of the FDA or similar foreign regulatory authorities the safety and efficacy of our HCV product candidate or any future product candidates;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our HCV product candidate or future product candidates, if any;
- the timely receipt of necessary marketing approvals from the FDA or similar foreign regulatory authorities;
- the availability, actual and perceived advantages and relative cost, convenience, safety and efficacy of our HCV product candidate or other product candidates we may be able to commercialize, compared to other commercially available therapies for the targeted indications, as well as the accuracy and sufficiency of clinical evidence supporting any such advantages of our product candidates;
- the willingness of physicians, operators of clinics and patients to conduct or participate in clinical trials evaluating our product candidates and, if successfully developed, to utilize or adopt our HCV product candidate or any future product candidates, if approved as antiviral therapies;
- our ability and the ability of third parties with whom we contract to manufacture adequate clinical and commercial supplies of our HCV or future product candidates, remain in good standing with regulatory authorities and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices ("cGMP") or similar requirements outside the US;
- our ability to successfully establish a commercial strategy and thereafter commercialize our HCV product candidate or any future product candidates, in the US and internationally, if approved for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others; and

- our ability to establish, maintain, protect and enforce intellectual property rights in and to our HCV product candidate or any future product candidates.

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

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

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

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

As of December 31, 2024, we had US federal and state net operating loss carryforwards ("NOLs"), of $63.3 million and $98.7 million, respectively.

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

For the years ended December 31, 2024 and 2023, we have completed a Section 382 study, the results of which indicated that no ownership shift occurred during such respective period. However, this conclusion could be challenged by tax authorities. In addition, future changes in our stock ownership, some of which might be beyond our control, could result in an ownership change under Sections 382 and 383 of the Code. For these reasons, we may not be able to utilize existing NOLs or research and development credit carryforwards or net operating losses and research and development credits that may be generated in the future.

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

Even if the results of preclinical studies and clinical trials that we have conducted or may conduct in the future may support further development of one or more of our product candidates, we may delay, suspend or terminate the future development of a product candidate at any time for strategic, business, financial or other reasons, including the determination or belief that the emerging profile of the product candidate is such that it may not receive regulatory approvals in key markets, gain meaningful market acceptance, otherwise provide any competitive advantages in its intended indication or market or generate a significant return to stockholders. For example, in September 2024, after the SUNRISE-3

Phase 3 clinical trial failed to reach its primary endpoint, we discontinued the development of bemnifosbuvir for the treatment of COVID-19. Any similar delays, suspensions or terminations of other clinical programs or product candidates, particularly our HCV product candidate, could materially harm our business, results of operations or financial condition.

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

Our business is highly dependent on the success of our product candidate, the regimen of bemnifosbuvir and ruzasvir for the treatment of HCV, which will require significant additional clinical testing, including successful Phase 3 clinical testing, before we can seek regulatory approval and potentially launch commercial sales. If this product candidate fails in clinical development, does not receive regulatory approval or is not successfully commercialized, or is significantly delayed in doing so, our business will be harmed.

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

During the near term we expect that a substantial portion of our efforts and expenditures will be devoted to developing the regimen of bemnifosbuvir and ruzasvir for the treatment of HCV which will require additional clinical development, management of clinical, medical affairs and manufacturing activities, obtaining regulatory approvals in multiple jurisdictions, securing of manufacturing supply, building of or otherwise accessing a commercial organization, substantial investment and significant marketing efforts.

We cannot be certain that our HCV product candidate or any future product candidates will be successful in clinical trials, receive regulatory approval or be successfully commercialized even if we receive regulatory approval. Further, our development of any product candidate may be delayed or suspended, which may affect our ability to successfully commercialize such product candidate. Additionally, our ability to successfully commercialize a product will also be dependent upon our ability to timely manufacture at commercial scale the quantities of product that will satisfy market demand.

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

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

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

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

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

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

We have not submitted an NDA for, or obtained regulatory approval of, any product candidate. We must complete additional clinical and preclinical studies to demonstrate the safety and efficacy of our product candidates in humans to the satisfaction of the regulatory authorities before we will be able to obtain these approvals, and it is possible that neither our HCV product candidate nor any product candidates we may seek to develop in the future will ever obtain regulatory approval. Applications for our product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

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

The lengthy regulatory process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market our HCV product candidate and any future product candidates, which may seriously harm our business. In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may impose significant limitations in the form of narrow indications, warnings, or a Risk Evaluation and Mitigation Strategy ("REMS") or similar risk management measures. Regulatory authorities may not approve the price we intend to charge for products we may develop, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could seriously harm our business.

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

Before obtaining marketing approval from the FDA or other comparable foreign regulatory authorities for the sale of our product candidates, we must complete preclinical development and extensive clinical trials

to demonstrate the safety and efficacy of our product candidates. Clinical testing is expensive, time-consuming and subject to uncertainty. A failure of one or more clinical trials can occur at any stage of the process, such as the failure in September 2024 of bemnifosbuvir to meet the primary endpoint in the COVID-19 Phase 3 SUNRISE-3 clinical trial. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. Moreover, preclinical and clinical data, particularly the analysis of exploratory endpoints and analysis of data derived from patient subgroups, including in the case of HCV, patients infected with varying viral genotypes are often susceptible to varying interpretations, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and varying stages of clinical trials have nonetheless failed to obtain marketing approval of their drugs.

To date, we have not successfully concluded 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.

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

- inability to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- delays in reaching a consensus with regulatory authorities on study design or implementation of the clinical trials;
- delays or failure in obtaining regulatory allowance to commence or amend a clinical trial;
- delays in reaching agreement on acceptable terms with prospective 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 or positive opinion at each clinical trial site;
- delays in recruiting, screening and enrolling a suitable number and diversity of patients to participate in our clinical trials;
- subjects enrolled in our clinical trials or clinical sites deviating from the clinical trial protocol or dropping out of a trial;
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing;
- insufficient or inadequate supply or quality of product candidates or other materials necessary for use in clinical trials, or delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials;
- imposition of a temporary or permanent clinical hold by regulatory authorities for a number of reasons, including after review of an IND or amendment or equivalent foreign application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; or a negative finding from an inspection of our clinical trial operations or study sites;
- developments on trials conducted by competitors for related technology that raises FDA or foreign regulatory authority concerns about risk to patients of the technology broadly;

- developments during the course of a clinical trial that cause the FDA, a foreign regulatory authority or the clinical trial DSMB to find that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties or us to adhere to clinical trial protocols; failure to perform in accordance with the FDA's or any other regulatory authority's good clinical practices ("GCPs"), or applicable regulatory guidelines in other countries;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits, or occurrence of adverse events in trial of the same class of agents conducted by other companies;
- changes to the clinical trial protocols;
- delays caused by patients withdrawing from clinical trials or failing to return for post-treatment follow-up;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols or otherwise impact the conduct of the clinical trial;
- changes in the standard of care or rate of event occurrence upon which a clinical development plan was based, which may require discontinuation of current trials or new or additional trials;
- selection of clinical endpoints that require prolonged periods of observation or analyses of resulting data;
- the cost of clinical trials of our product candidates being greater than we anticipate;
- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development of such product candidates;
- transfer of manufacturing processes to larger-scale facilities operated by a CMO and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process; and
- third parties being unwilling or unable to satisfy their contractual obligations to us.

Any inability to successfully complete our Phase 3 clinical trials evaluating the regimen of bemnifosbuvir and ruzasvir for the treatment of HCV or the completion of any other planned clinical trials we may initiate could result in additional costs to us or impair our ability to seek approval for our HCV product candidate or any future product candidates and ultimately generate revenue from product sales.

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

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

Further, conducting clinical trials in foreign countries, as we are currently doing for our HCV product candidate and otherwise expect to do for other product candidates, if any, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate product revenue. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to further strengthen the market position of their current products or bring new or additional products to market before we do, which could significantly reduce the commercial viability of our product candidates. Any of these occurrences may harm our business, financial condition and prospects significantly.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the EU recently evolved. The EU CTR which was adopted in April 2014 and repeals the EU Clinical Trials Directive ("Clinical Trial Directive"), became applicable on January 31, 2022. While the EU Clinical Trials Directive required a separate CTA to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. As of January 31, 2025, all CTAs and clinical trials conducted in the EU (including those which are ongoing) are subject to the provisions of the CTR. As a result, the CTAs we submit in connection with the proposed conduct of our HCV Phase 3 clinical trial in the EU must be in compliance with the CTR requirements. We have limited experience submitting applications under the CTR. If we or our third-party service providers, such as CROs, encounter difficulties or are unable to comply with the CTR requirements our developments plans would be adversely impacted.

It is currently unclear to what extent the UK will seek to align its regulations with the EU. The extent to which the regulation of clinical trials in the UK will mirror the (EU) CTR in the long term is not yet certain, however, on December 12, 2024, the UK government introduced a legislative proposal - the Medicines for Human Use (Clinical Trials) Amendment Regulations 2024 - that, if implemented, will replace the current regulatory framework for clinical trials in the UK. The legislative proposal aims to provide a more flexible regime to make it easier to conduct clinical trials in the UK, increase the transparency of clinical trials conducted in the UK and make clinical trials more patient centered. The UK government has provided the legislative proposal to the UK Parliament for its review and approval. Once the legislative proposal is approved (with or without amendment), it will be adopted into UK law which is expected in early 2026. A decision by the UK not to closely align its regulations with the new approach that has been adopted in the EU may have an effect on the cost of conducting clinical trials in the UK as opposed to other countries.

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

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

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

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

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

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

Our product candidates may be associated with serious adverse events, 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 we successfully develop could be suspended or terminated, and our business could be seriously harmed. Treatment-related side effects could also affect patient recruitment and the ability of enrolled patients to complete the trial or result in potential liability claims. Regulatory authorities could order us to cease further development of, deny approval of, or require us to cease selling any product candidate or product for any or all targeted indications. If we are required to delay, suspend or terminate any clinical trial or commercialization efforts, the commercial prospects of such product candidate or product may be harmed, and our ability to generate revenues from such product or 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 and retaining enrolled patients in our clinical trials and having patients comply with the clinical trial protocol, our clinical development activities could be delayed or otherwise adversely affected.

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

Enrollment of patients depends on many factors, including but not limited to:

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

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

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

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

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

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

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

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

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

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

- regulatory and administrative requirements of the jurisdiction where the trial is conducted that could burden or limit our ability to conduct our clinical trials;
- foreign exchange fluctuations;
- manufacturing, customs, shipment and storage requirements for clinical trial materials and supplies as well as shipment and storage of biological samples;
- cultural differences in medical practice and clinical research; and

- the risk that the patient populations in such trials are not considered representative as compared to the patient population in the target markets where approval is being sought.

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

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

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

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

In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top-line, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

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

Part of our strategy involves identifying novel product candidates. For example, we are currently engaged in internal efforts to identify product candidates for the treatment of respiratory and other diseases resulting from infection with single stranded RNA viruses.

Our efforts to discover such product candidates and any subsequent discovery efforts we initiate to identify other novel product candidates may fail to yield product candidates for clinical development for a number of reasons, including those discussed in these risk factors and also:

- we may not be able to assemble sufficient resources to acquire or discover additional product candidates;
- competitors may develop alternatives that render our potential product candidates obsolete or less attractive;
- potential product candidates we develop may nevertheless be covered by third-parties' patent or other intellectual property or exclusive rights;

- potential product candidates may, on further study, be shown to have harmful side effects, toxicities or other characteristics that indicate that they are unlikely to be products that will receive marketing approval or achieve market acceptance, if approved;
- potential product candidates may not be effective in treating their targeted diseases or symptoms;
- the market for a potential product candidate may change so that the continued development of that product candidate is no longer reasonable;
- a potential product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; or
- the regulatory pathway for a potential product candidate is highly complex and difficult to navigate successfully or economically.

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

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

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

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

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

We are developing our product candidates for the treatment of serious conditions, and therefore may decide to seek approval of such product candidates under the FDA's accelerated approval pathway. A product candidate may be eligible for accelerated approval if it is designed to treat a serious or life-threatening disease or condition and generally provides a meaningful advantage over available therapies, upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as

irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit.

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

In the EU, a "conditional" 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 EMA, the marketing authorization will cease to be renewed. Furthermore, marketing authorizations may also be granted "under exceptional circumstances" when the applicant can show that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use even after the product has been authorized and subject to the introduction of specific procedures. This may arise when the intended indications are very rare and, in the present state of scientific knowledge, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. This type of marketing authorization is close to a conditional marketing authorization as it is reserved to medicinal products to be approved for severe diseases or unmet medical needs and the applicant does not hold the complete data set legally required for the grant of a marketing authorization. However, unlike a conditional marketing authorization, the applicant does not have to provide the missing data and will never have to. Although a marketing authorization "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually and the marketing authorization may be withdrawn where the risk-benefit ratio is no longer favorable.

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

If we decide to submit an NDA seeking accelerated approval or receive an expedited regulatory designation for our product candidates, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. Failure to obtain accelerated approval or any other form of expedited development, review or approval for a product candidate would result in a longer time period prior to commercialization of such product candidate, if any, and could increase the cost of development of such product candidate, which could harm our competitive position in the marketplace.

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

Any product candidates we may develop and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the US and by comparable authorities in other countries. Any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction. It is possible that none of the HCV product candidate we are developing or product candidates, if any, that we may seek to develop in the future will ever obtain regulatory approval. We, as a company, have no experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs, suppliers, vendors or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority.

The process of obtaining marketing approvals, both in the US and abroad, is expensive, may take many years if numerous clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application**.** For instance, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products (potentially reducing the duration of regulatory data protection, revising the eligibility for expedited pathways, etc.) was published on April 26, 2023. The proposed revisions have yet to be agreed and adopted by the European Parliament and European Council and the proposal may therefore be substantially revised before adoption, which is not anticipated before early 2026. The revisions may however have a significant impact on the pharmaceutical industry and our business in the long term.

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

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

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

In order to market any products outside of the US, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional

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

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

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

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

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

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

We currently focus on the discovery and development of product candidates for the treatment of serious viral diseases. Our eligible patient population, pricing estimates and available coverage and reimbursement may differ significantly from the actual market addressable by our product candidates. Our estimates of the number of people who have these diseases, the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, and the market demand for our product candidates are based on our beliefs and analyses. These estimates have been derived from a variety of sources, including the scientific literature, current third-party data regarding prescriptions dispensed, and market research, and may prove to be incorrect. The number of patients may turn out to be lower than expected. Likewise, the potentially addressable patient population for our product candidates may be limited or may not be receptive to treatment with our product candidates, and new

patients may become increasingly difficult to identify or access. Additionally, the availability of superior or competitive therapies from our competitors could negatively impact or eliminate market demand for our product candidates. If the market opportunities for our product candidates are smaller than we estimate, it could have an adverse effect on our business, financial condition, results of operations and prospects.

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

The ability of the FDA and foreign regulatory authorities to review or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions including a rapid substantial influx of applications from numerous sponsors as occurred with COVID-19. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, the US government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. If a prolonged government shutdown occurs, or funding shortages, staffing limitations, or renewed global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities on a timely basis, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

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

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

Any additional product liability insurance coverage we acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for any of our product candidates, we intend to acquire insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments are for claims not covered by or are in amounts that exceed our insurance coverage, could adversely affect our results of operations and

business, including preventing or limiting the development and commercialization of any product candidates we develop. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury from biological or hazardous waste, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

Operating as a public company has in the past and may in the future make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits 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 if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash and cash equivalents position and results of operations.

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

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

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

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product candidate development programs. For example, the loss of data from completed, ongoing or planned preclinical studies or clinical trials could result in delays in our

regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

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

Risks Related to Healthcare Laws and Other Legal Compliance Matters

We are subject to extensive and costly government regulation.

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

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

Even if we are able to obtain regulatory approval for a particular product, the approval may limit the indicated medical uses for the product, may otherwise limit our ability to promote, sell and distribute the product, may require that we conduct costly post-marketing surveillance, and/or may require that we conduct ongoing post-marketing studies. Material changes to an approved product, such as, for example, manufacturing changes or revised labeling, may require further regulatory review and approval. Once obtained, any approvals may be withdrawn, including, for example, if there is a later discovery of previously unknown problems with the product, such as a previously unknown safety issue.

If we, our consultants, CMOs, CROs or other vendors, fail to comply with applicable regulatory requirements at any stage during the regulatory process, such noncompliance could result in, among other things, delays in the approval of applications or supplements to approved applications; refusal of a regulatory authority, including the FDA, to review pending market approval applications or supplements to approved applications; warning letters; fines; import and/or export restrictions; product recalls or seizures; injunctions; total or partial suspension of production; civil penalties; withdrawals of previously approved marketing applications or licenses; recommendations by the FDA or other regulatory authorities against governmental contracts; and/or criminal prosecutions.

Moreover, our operations are broadly subject to an evolving regulatory environment. New and changing laws, regulations, executive orders and enforcement priorities can also create uncertainty about how such

laws and regulations will be interpreted and applied, which may increase our costs or otherwise adversely impact our business and results of operations.

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

In the US, the EU and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities involving any product candidates for which we obtain marketing approval, impact pricing and reimbursement and impact our ability to sell any such products profitably. In particular, there have been and continue to be a number of initiatives at the US federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. In addition, new regulations and interpretations of existing healthcare statutes and regulations are frequently adopted.

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

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

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

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

Moreover, payment methodologies may be subject to other changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as outcomes-based reimbursement. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several US Congressional inquiries and proposed and enacted federal legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs. Most recently, on August 16, 2022, the IRA was signed into law. Among other things, the IRA requires manufacturers of

certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (which began in 2025). The IRA permits the HHS Secretary to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. CMS has published the negotiated prices for the initial ten drugs, which will first be effective in 2026, and the list of the subsequent 15 drugs that will be subject to negotiation, although the Medicare drug price negotiation program is currently subject to legal challenges. For that and other reasons, it is currently unclear how the IRA will be effectuated. We expect that additional US federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the US federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Individual states in the US have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure, drug price reporting and other transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, states and other regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates or put pressure on our product pricing.

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

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

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

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

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the US, the EU or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new

requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

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

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

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

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

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if any regulatory approval is withdrawn, our business will be seriously harmed.

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

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

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

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

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

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

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

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

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

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

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

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

Our operations abroad may also be subject to increased scrutiny or attention from data protection authorities. For example, the EU General Data Protection Regulation ("GDPR") went into effect in May 2018, and imposes strict requirements for processing the personal data of individuals within the EEA or in the context of our activities in the EEA. The GDPR and related implementing laws in individual EU member states govern the collection and use of health data and other personal data in the EU including the personal data processed by companies outside the EU in connection with the offering of goods or services to individuals in the EU or the monitoring of their behavior (including in the context of clinical trials). Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. In addition to the foregoing, a breach of the GDPR could result in regulatory investigations, reputational damage, orders to cease / change our processing of our data, enforcement

notices, and/ or assessment notices (for a compulsory audit). Companies may also face civil claims including representative actions and other class action type litigation (where individuals have suffered harm), potentially amounting to significant compensation or damages liabilities, as well as associated costs, diversion of internal resources, and reputational harm.

Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the US, and the efficacy and longevity of current transfer mechanisms between the EEA, and the US remains uncertain. On July 10, 2023, the European Commission adopted its Adequacy Decision in relation to the new EU-US Data Privacy Framework ("DPF"), rendering the DPF effective as a GDPR transfer mechanism to US entities self-certified under the DPF. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the 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 conduct our business, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

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

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

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

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

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

Our activities outside the US impose additional compliance requirements and generate additional risks of enforcement for noncompliance. Failure by our CROs and other third-party contractors to comply with the strict rules on the transfer of personal data outside of the EU into the US may result in the imposition of criminal and administrative sanctions on such collaborators, which could adversely affect our business. Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws and genetic testing laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our collection, use and dissemination of individuals' health information.

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

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

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

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

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

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

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

Risks Related to Commercialization

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

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

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

Additionally, many of these competitors have greater experience in:

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

If these competitors access the marketplace before we do with safer, more effective, or less expensive therapeutics or vaccines, our product candidates, if approved for commercialization, may not be profitable to sell or worthwhile to continue to develop. Technology in the pharmaceutical industry has undergone rapid and significant change, and we expect that it will continue to do so. Any compounds, products or processes that we develop may become obsolete or uneconomical before we recover any expenses incurred in connection with their development. The success of our product candidates will depend upon factors such as product efficacy, safety, reliability, availability, timing, scope of regulatory approval, acceptance and price, among other things. Other important factors to our success include speed in developing product candidates, completing clinical development and laboratory testing, obtaining regulatory approvals and manufacturing and selling commercial quantities of potential products.

For the diseases that we are targeting, significant competition exists from approved and authorized oral treatments as well as other treatments in development. The approved drugs, particularly for HCV, are well-established products and are widely-accepted by physicians, patients and third-party payors.

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

Many of our competitors have substantially greater capital resources, access to larger pools of capital, robust product candidate pipelines, established presence in the market, deep and broad commercial infrastructures and greater expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. As a result, our competitors may be able to maintain market share or achieve product commercialization or patent or other intellectual property protection earlier than we can. For example, in each of May 2023 and October 2024, the US Patent and Trademark Office ("USPTO") granted Gilead Sciences patents in the US that may cover our compound bemnifosbuvir. If Gilead Sciences asserts either of these patents in an infringement suit, we may not be successful in convincing a trial court that the patent is invalid and unenforceable. In that circumstance, we would need to obtain a license from Gilead Sciences, which may not be available on reasonable terms, if at all. If a license is required and we are unable to obtain such license, commercialization of approved product candidates, if any, using bemnifosbuvir may not be able to continue without infringement, which could result in significant cost or prevent us from commercializing bemnifosbuvir or regimens containing bemnifosbuvir such as our HCV product candidate.

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

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

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

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

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

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

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

We expect to experience pricing pressures in connection with the sale of our product candidates due to the presence of approved, and in the case of HCV, authorized generic, products already in many marketplaces, the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes resulting from legislative actions, including the IRA. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and

surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products.

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

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

Currently, we anticipate to establish our own commercial organization in the US to commercialize, together with a collaborator, our HCV product candidate, if approved. Outside the US, we anticipate to rely on a collaborator to commercialize our HCV product candidate if approved. We do not currently have any commercialization arrangements in place with any collaborator either within or outside the US and we may be unable to enter into acceptable arrangements to do so.

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

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

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

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

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

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

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

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

Our future profitability may depend, in part, on our ability to commercialize our product candidates in foreign markets. Currently, we anticipate to rely on third party collaborators for such foreign market commercialization. We are evaluating potential collaborations and opportunities for the commercialization of our product candidates in foreign markets but currently we do not have any collaboration agreements or arrangements in place. Neither we or any third party with which we may collaborate is permitted to market or promote any of our product candidates before regulatory approval of such product candidate is received from the applicable regulatory authority in that foreign market, and such regulatory approval for any of our product candidates may never result. To obtain regulatory approvals in countries outside the US, it will be necessary to comply with numerous and varying regulatory requirements of such countries regarding the safety and efficacy of our product candidates and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions. If we obtain approval of our product candidates and ultimately commercialize 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 of any third parties upon which we are relying;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- our ability, or the ability of our collaborators, to supply our 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;
- longer accounts receivable collection times;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

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

If any of our product candidates is approved for commercialization, we currently anticipate to selectively partner with third parties to market such product candidate both within and outside the US. If we or a collaborator market a product candidate outside the US, we expect that we will be subject to additional risks related to international pharmaceutical operations, including but not limited to:

- different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries;
- reduced protection for patent and other intellectual property rights;
- foreign reimbursement, pricing and insurance regimes;
- potential noncompliance with the US Foreign Corrupt Practices Act, the U.K. Bribery Act 2010 and similar anti-bribery and anticorruption laws in other jurisdictions; and
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad.

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

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

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

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

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

Currently, we face an inherent risk of product liability claims as a result of the testing our product candidates and we will face product liability risks if we, or a collaborator, commercialize any of our product candidates that are approved. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with

our products. On occasion, large judgments have been awarded in class action lawsuits based on products that had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs, which may not be covered by insurance. In addition, regardless of merit or eventual outcome, product liability claims may result in:

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

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

Risks Related to Manufacturing and our Dependence on Third Parties

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

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

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

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

Any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or changes in global, political, regulatory and economic conditions affecting US trade, manufacturing, development or investment, could result in additional restrictions on our ability to manufacture materials for our research programs, preclinical studies and clinical trials. In recent years, the U.S has instituted or proposed changes in trade policies that include the negotiation or termination of trade agreements, the imposition of higher tariffs on imports into the US, economic sanctions on individuals, corporations or countries, and other government regulations affecting trade between the US and other countries where we conduct our business, in particular China, Mexico and Canada. A number of other nations have proposed or instituted similar measures directed at trade with the United States in response. As a result of these developments, there may be greater restrictions and economic disincentives on international trade that could adversely affect our business. As additional trade-related policies are instituted, we may need to modify our business operations to comply and adapt to such developments, which may be time-consuming and expensive.

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

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

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

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

We do not have multiple sources of supply for all of the components used in our product candidates, nor long-term supply contracts, and certain of our suppliers are critical to our production. If we were to lose a critical supplier, it could have a material adverse effect on our ability to complete the development of our product candidates. If we obtain regulatory approval for any of our product candidates, we would need to expand the supply of their components in order to commercialize them.

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

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

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

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

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

We are dependent on third parties to conduct critical aspects of the Phase 3 development activities for our HCV product candidate, the regimen of bemnifosbuvir and ruzasvir, and we expect to rely on third parties to conduct future clinical trials and preclinical studies for our other product candidates, if any. Specifically, we have used and relied on, and intend to continue to use and rely on, medical institutions, clinical investigators, CROs and consultants to conduct our clinical trials in accordance with our clinical protocols and regulatory requirements. These CROs, investigators and other third parties play a significant role in the conduct and timing of these trials and subsequent collection and analysis of data. While we have agreements governing the activities of our third-party contractors, we have limited influence over their actual performance. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs or trial sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials or research activities complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP or similar regulations outside the US. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

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

entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position.

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

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

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

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

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

Collaborations involving our product candidates involve many risks, including:

- collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not properly obtain, maintain, enforce or defend intellectual property or proprietary rights relating to our product candidates or may use our proprietary information inappropriately or in such a way as to expose us to potential litigation or other intellectual property-related proceedings, including proceedings challenging the scope, ownership, validity and enforceability of our intellectual property;
- collaborators may own or co-own intellectual property rights covering our product candidates that result from our collaboration with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property or such product candidates;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to collaborations;

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

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

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

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

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

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

Misconduct by our employees and independent contractors, including principal investigators, CROs, consultants, vendors and any third parties we may engage in connection with research, development, regulatory, manufacturing, quality assurance and other pharmaceutical functions and commercialization, could include intentional, reckless or negligent conduct or unauthorized activities that violate: (i) the laws and regulations of the FDA, and other similar regulatory authorities, including those laws that require the reporting of true, complete and accurate information to such authorities; (ii) manufacturing standards; (iii) data privacy, security, anti-corruption, fraud and abuse and other healthcare laws and regulations; or (iv) laws that require the reporting of true, complete and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of preclinical studies or clinical trials, creation of fraudulent data in preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid, other US federal healthcare programs or healthcare programs in other jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

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

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

Risks Related to Intellectual Property

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

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

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

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

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

If the patent applications we hold with respect to our programs or product candidates fail to issue, if the breadth or strength of protection of our current or future issued patents is threatened, or if they fail to provide meaningful exclusivity for our product candidates, it could dissuade companies from collaborating with us to develop product candidates, or threaten our ability to commercialize our current or future

product candidates. Several patent applications covering our HCV product candidate have been filed recently by us. We cannot offer any assurances about which, if any, will result in issued patents, the breadth of any such patents or whether any issued patents will be found invalid or unenforceable or will be threatened by third parties. Any successful opposition to these patents or any other patents owned by us could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop.

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

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

The Leahy-Smith Act created for the first time new procedures to challenge issued patents in the US, including post-grant review, inter partes review and derivation proceedings, which are adversarial proceedings conducted at the USPTO, which some third parties have been using to cause the cancellation of selected or all claims of issued patents of competitors. For a patent with a priority date of March 16, 2013 or later, which all of our patent filings have, a petition for post-grant review can be filed by a third-party in a nine-month window from issuance of the patent. A petition for inter partes review can be filed immediately following the issuance of a patent if the patent was filed prior to March 16, 2013. A petition for inter partes review can be filed after the nine-month period for filing a post-grant review petition has expired for a patent with a priority date of March 16, 2013 or later. Post-grant review proceedings can be brought on any ground of challenge, whereas inter partes review proceedings can only be brought to raise a challenge based on published prior art. These adversarial actions at the USPTO include review of patent claims without the presumption of validity afforded to US patents in lawsuits in US federal courts. The USPTO issued a final rule effective November 13, 2018 announcing that it will now use the same claim construction standard currently used in the US federal courts to interpret patent claims in USPTO proceedings, which is the plain and ordinary meaning of words used. If any of our patents are challenged by a third-party in such a USPTO proceeding, there is no guarantee that we will be successful in defending the patent, which would result in a loss of the challenged patent right to us, including loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

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

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

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

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

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

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

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

present claims in a manner that could cover our product candidates or the use of our product candidates. After issuance, the scope of patent claims remains subject to construction as determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history.

Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. To challenge the validity of a US patent, we would need to initiate an action either in federal court or at the PTAB as we have done against the '361 patent. An action brought before the PTAB must be timely submitted within nine months of the issuance of the patent we are seeking to challenge unless based on published prior art. In either a PTAB or federal court proceeding, there is no assurance that the PTAB or a court of competent jurisdiction would invalidate the claims of any such US patent or, if a PTAB decision is appealed, that a federal court would uphold a PTAB determination of invalidity. If any third-party patents were held by a court of competent jurisdiction to cover the composition of matter of any of our product candidates, the manufacturing process of any of our product candidates or the method of use for any of our product candidates, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtain a license under the applicable patents, which may not be available at all or on commercially reasonable terms, or until such patents expire.

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

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

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

Our HCV product candidate does include and other product candidates we may develop, may include nucleotide prodrugs, or nucleotide phosphoramidates. A number of companies and universities have patent applications and issued patents in this general area, including for viral indications, such as, for example, Gilead Pharmasset, LLC; Gilead Sciences; Merck & Co.; Bristol Myers Squibb; Roche;

University of Cardiff; University College Cardiff Consultants; NuCana, plc; Janssen Pharmaceutical Companies; Medivir AB; and others. If any of these companies or universities, or others, assert that a patent it holds is infringed by any of our product candidates or their use or manufacture, we may be drawn into expensive litigation, which may affect our business, take the time of and distract the attention of our employees, and if the litigation is successful, could affect the profitability of our products or prohibit their sale.

For example, we note that Gilead Sciences has obtained the US '361 patent that includes a Claim that purportedly covers bemnifosbuvir. We requested the PTAB Board to institute a post grant review of this patent and it declined to exercise its discretion to do so. This denial does not stop us from making the same or similar arguments, or additional arguments, nor from bringing the same or new evidence of invalidity or unenforceability in court if Gilead files an infringement suit. While we believe this Claim is invalid and unenforceable, a trial court or an appellate court may disagree and uphold the Claim of the '361 patent, which would require us, prior to commercialization of a bemnifosbuvir product candidate to obtain a license from Gilead Sciences to the ‘361 patent. Such a license may not be available on reasonable terms or at all. If a license is required and we are unable to obtain such license, commercialization of approved product candidates, if any, containing bemnifosbuvir may not be able to continue without infringement which could result in significant cost or prevent us from commercializing such product candidate.

Additionally, on October 22, 2024, seventeen years after its priority date, Gilead Sciences obtained US ‘529 patent with claims that also purport to cover bemnifosbuvir. While we believe these claims are also invalid and unenforceable, a trial court or an appellate court may disagree and uphold one or more claims of the '529 patent, which would require us to obtain a license from Gilead Sciences to the ‘529 patent. Such a license may not be available on reasonable terms or at all. If a license is required and we are unable to obtain such license, commercialization of approved product candidates, if any, containing bemnifosbuvir may not be able to continue without infringement which could result in significant cost or prevent us from commercializing such product candidate.

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

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

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

generic. Further, even if we do correctly list our relevant patents in the Orange Book, bring a lawsuit in a timely manner and prevail in that lawsuit, the generic litigation may be at a very significant cost to us of attorneys' fees and employee time and distraction over a long period. Further, it is common for more than one generic company to try to sell an innovator drug at the same time, and so we may be faced with the cost and distraction of multiple lawsuits. We may also determine it is necessary to settle the lawsuit in a manner that allows the generic company to enter our market prior to the expiration of our patent or otherwise in a manner that adversely affects the strength, validity or enforceability of our patent.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

On June 3, 2019, we received an anonymous third-party Observation filed in connection with our international Patent Cooperation Treaty patent application for our second patent family, which covers the hemisulfate salt form of AT-511, or bemnifosbuvir. The Observation generally challenges the patentability of the hemisulfate salt bemnifosbuvir over the free base AT-511 described in our first patent family. On August 1, 2019, we filed a response to the Observation describing that the bemnifosbuvir hemisulfate salt of AT-511 is not obvious in view of the AT-511 free base because bemnifosbuvir disproportionately concentrates in the liver over the heart, as shown in vivo in a dog model, which can provide an increased therapeutic effect to treat HCV, and decreased toxicity because HCV is a disease of the liver. Further, while not raised in the response to the Observation, we have now also shown that bemnifosbuvir has a longer half-life and higher concentration in the lung than in the liver *in vivo* in monkeys, which is relevant to our COVID-19 indication. The Observations by anonymous third parties as well as our responses are placed in the file and available to be read and considered by any country examining our respective patent applications.

In December 2019, the US Patent Office issued a patent to us covering the composition of matter of bemnifosbuvir. Our composition of matter patent on bemnifosbuvir has also been granted in Europe, China, Japan, Korea, Australia, Brazil, Eurasia, Canada, Israel, New Zealand, South Africa, Russia and Mexico, and is pending in certain other countries and regions.

Our patent on AT-511 or its pharmaceutically acceptable salt, which includes bemnifosbuvir, has been granted in United States, China, Japan, Korea, Australia, Eurasia, Canada, Israel, Singapore, Malaysia, Indonesia, Georgia, Russia, Ukraine, Columbia and Mexico, and is also pending in certain other countries and regions. The European Patent Office has also indicated allowability of the claims.

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.

On April 12, 2022, we received notification of a Pre-Grant Opposition from the Controller General of Patents, Designs, and Trademarks at the Indian Patent Office. The Opposition was filed by Sankalp Rehabilitation Trust and challenges our pending patent claims to AT-511 or a pharmaceutically acceptable salt thereof. In February 2023, we responded to this Pre-Grant Opposition. We are currently awaiting further action on this matter by the Indian Patent Office. In addition to the Pre-Grant Opposition related to AT-511 or a pharmaceutically acceptable salt thereof (which bemnifosbuvir would fall under), we have received notification of a second Pre-Grant Opposition filed by the Sankalp Rehabilitation Trust. This second Pre-Grant Opposition challenges our pending patent claims to bemnifosbuvir. In October 2023, we responded to this second Pre-Grant Opposition. A hearing on the matter was held in April 2024. In June 2024, the Indian Patent Office issued a decision refusing the claims to bemnifosbuvir on the basis that a new salt of a known compound is not patentable under section 3(d) of the Indian Patent Act. This decision was not appealed. While we intend to vigorously defend our patent claims on AT-511 or a pharmaceutically acceptable salt thereof and their use to treat HCV in India, we cannot

guarantee that the Indian Patent Office will decide in our favor with respect to the pending Pre-Grant Opposition and allow our patent claims to AT-511 or a pharmaceutically acceptable salt thereof (which bemnifosbuvir would fall under). In addition, Pre-Grant Oppositions in India can proceed very slowly, and therefore these proceedings may not be resolved for several years. Our patent applications will not issue as a patent on AT-511 or a pharmaceutically acceptable salt thereof or their use to treat HCV in India unless and until the Pre-Grant Opposition is resolved in our favor. If it is not resolved in our favor, we may not receive patents on AT-511, bemnifosbuvir or their use to treat HCV in India. Further, there is no guarantee that other companies will not also file Pre-Grant Opposition Proceedings, or if the patent issues, one or more Post-Grant Oppositions, challenging our patent rights in AT-511.

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

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

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

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

foreign adversarial proceedings can also be substantial, and in many foreign jurisdictions, the losing party must pay the attorney fees of the winning party.

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

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

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

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

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

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

be affected by the influence of current public policy on patent issuance, enforcement or involuntary licensing in the healthcare area.

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

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

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

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

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

Further, we cannot provide any assurances that competitors or other third parties will not otherwise gain access to our trade secrets and other confidential proprietary information or independently discover or develop substantially equivalent technology and processes. If we are unable to prevent disclosure of the

trade secrets and other non-patented intellectual property related to our product candidates and technologies to third parties, there is no guarantee that we will have any such enforceable trade secret protection and we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

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

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

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

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

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make products that are the same as or similar to our product candidates but that are not covered by the claims of our patents;
- others, including inventors or developers of our patented technologies who may become involved with competitors, may independently develop similar technologies that function as alternatives or replacements for any of our technologies without infringing, misappropriating or otherwise violating our intellectual property rights;
- we might not have been the first to conceive and reduce to practice the inventions covered by our patents or patent applications;
- we might not have been the first to file patent applications covering certain of our inventions;
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third-party may subsequently file a patent covering such intellectual property;
- our pending patent applications might not result in issued patents;
- there might be prior public disclosures that could invalidate our patents;

- our issued patents may not provide us with any commercially viable products or competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors or other third parties;
- the Supreme Court of the US, other US federal courts, Congress, the USPTO or similar foreign authorities may change the standards of patentability and any such changes could narrow or invalidate, or change the scope of, our patents;
- patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- ownership, validity or enforceability of our patents or patent applications may be challenged by third parties; and
- the patents or pending or future applications of third parties, if issued, may have an adverse effect on our business.

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

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

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

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

These types of cost reduction activities are complex and may result in unintended consequences and costs, such as unforeseen delays in the implementation of our strategic initiatives, business and operational disruptions, decreased employee morale, loss of institutional knowledge and expertise, and potential impacts on financial reporting and the related internal controls. In addition, while positions have been eliminated, certain functions necessary to our operations remain, and we may be unsuccessful in distributing the duties and obligations of departed employees among our remaining employees. This reduction in workforce could also make it difficult for us to pursue, or prevent us from pursuing, new opportunities and initiatives due to insufficient personnel, or require us to incur additional and unanticipated costs to hire new personnel to pursue such opportunities or initiatives. If we do not successfully manage our current initiatives or any other similar activities that we may undertake in the future, expected efficiencies and benefits might be delayed or not realized, and our business, financial condition, and results of operations may be materially adversely affected.

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

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

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

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

Our reduction in force in January 2025 may make it more difficult for us to retain or hire qualified personnel.

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

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

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

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

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

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

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

Risks Related to Our Common Stock

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

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

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

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

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from filling vacancies on our board of directors;

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

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

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

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

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

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

General Risk Factors

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

Until such time, if ever, as we can generate substantial revenue from product sales, we may finance our cash needs through a combination of equity offerings, 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.

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

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

Increased scrutiny of, and evolving expectations for ESG initiatives could increase our costs, harm our reputation, or otherwise adversely impact our business.

Companies across industries are facing increasing and evolving scrutiny related to their ESG and sustainability practices from certain investors, government entities, customers, employees, and other stakeholders or third parties. Expectations regarding voluntary ESG initiatives and disclosures may result in increased costs (including but not limited to increased costs related to compliance, stakeholder engagement, contracting and insurance), enhanced compliance or disclosure obligations, increased litigation or reputational damage relating to ESG practices or performance, or other adverse impacts to our business, financial condition, or results of operations.

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

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

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

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

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

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

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

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

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

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

- general economic, industry and market conditions, including rising inflation and interest rates; and
- the other factors described in this “Risk Factors” section.

Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company’s securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management’s attention and resources, which would harm our business, financial condition and results of operations.

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

We are required to comply with the SEC’s rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act, which require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of controls over financial reporting. In addition, we have in the past and may for future fiscal years beginning after January 1, 2026, be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm and our independent registered public accounting firm has in the past and may be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. Our independent registered public accounting firm may issue a report that is adverse in the event material weaknesses have been identified in our internal control over financial reporting.

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

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

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

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of

the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

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 1C. Cybersecurity.

Cybersecurity Risk Management and Strategy

We have developed and implemented a cybersecurity risk management program intended to protect the confidentiality, integrity, and availability of our critical systems and information.

We design and assess our program based on the National Institute of Standards and Technology Cybersecurity Framework (NIST CSF). This does not imply that we meet any particular technical standards, specifications, or requirements, only that we use the NIST CSF as a guide to help us identify, assess, and manage cybersecurity risks relevant to our business.

Our cybersecurity risk management program is integrated into our overall enterprise risk management program, and shares common methodologies, reporting channels and governance processes that apply across the risk management program to other legal, compliance, strategic, operational, and financial risk areas.

Key elements of our cybersecurity risk management program include, but are not limited to, the following:

- risk assessments designed to help identify material risks from cybersecurity threats to our critical systems and information;
- a security team principally responsible for managing (1) our cybersecurity risk assessment processes, (2) our security controls, and (3) our response to cybersecurity incidents;
- the use of external service providers, where appropriate, to monitor, assess, test or otherwise assist with aspects of our security processes;
- cybersecurity awareness training of our employees, including incident response personnel, and senior management;
- a cybersecurity incident response plan that includes procedures for responding to cybersecurity incidents; and
- a third-party risk management process for key service providers based on our assessment of their criticality to our operation and respective risk profiles.

We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected us, including our operations, business strategy, results of operations or financial condition. We face risks from cybersecurity threats that, if realized, are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. For more information, see the section titled "*Risk Factors — Our business and operations may suffer in the event of information technology system failures, cyberattacks, or deficiencies, which could materially affect our results.*"

Cybersecurity Governance

Our Board considers cybersecurity risk as part of its risk oversight function and has delegated to the Audit Committee (the "Audit Committee") oversight of cybersecurity risks. The Audit Committee oversees management's implementation of our cybersecurity risk management program.

The Audit Committee receives periodic reports from management on our cybersecurity risks. These reports include updates on our processes for preparing for, preventing and detecting cybersecurity incidents. Between such regular updates, the Audit Committee would be notified regarding any significant cybersecurity threat or incident, if applicable. The Audit Committee reports to the full Board regarding its activities, including those related to cybersecurity.

Our information technology ("IT") team, which includes both our internal staff and retained consultants with IT and cybersecurity expertise, is led by our Vice President of IT who has more than 25 years of

experience managing and securing technology infrastructure and is certified in cybersecurity by the Information System Security Certification Consortium. The IT team has responsibility for, among other things, developing and implementing practices, procedures and controls designed to identify, assess and manage cybersecurity programs and risks. The IT team takes steps to stay informed about and monitor efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include briefings from internal security personnel; threat intelligence and other information obtained from governmental, public or private sources, including external consultants engaged by us; and alerts and reports produced by security tools deployed in the IT environment. Our IT team is supplemented by a security committee, comprised of representatives from key functional areas of our business and includes both our CFO and our Sr. VP of Human Resources to whom the Vice President of IT reports.

Item 2. Properties.

Our principal office is located at 225 Franklin Street, Boston, Massachusetts, where we lease 17,544 square feet of office space. We lease this space under a sublease agreement, with the term January 1, 2022 through 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.

PART II

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 March 4, 2025 there were 18 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.

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 leveraging our deep understanding of antiviral drug development, medicinal chemistry, biology, biochemistry and virology to discover and develop novel orally administered product candidates to treat serious viral diseases. Our lead product candidate is a the regimen consisting of bemnifosbuvir and ruzasvir, which we are developing for the treatment of hepatitis C virus ("HCV") infection. Currently, we expect to commence enrollment of patients in an HCV Phase 3 program evaluating the regimen in April 2025.

HCV

HCV is a blood-borne, positive-sense, single-stranded ribonucleic acid ("RNA") virus that primarily infects liver cells. HCV is a leading cause of chronic liver disease, liver transplants and liver cancer in the United States ("US"), Europe and Japan.

Despite the availability of direct-acting antiviral ("DAA") oral combination treatment regimens and eradication efforts by the World Health Organization and others, HCV continues to be a serious viral disease. An estimated 50 million people globally live with chronic HCV infection, with approximately 1 million new infections occurring each year. In 2022, HCV led to an estimated 242,000 deaths. These deaths are primarily attributable to cirrhosis and hepatocellular cancer, each of which are serious long-term consequences resulting from prolonged exposure, generally up to 20 years of HCV infection.

In the US, it is estimated that there are between 2.4 and 4.0 million persons infected with untreated HCV. Further it is reported that on an annual basis in the US, there are greater than 160,000 newly reported HCV infections. This incidence of newly reported infections outpaces substantially stagnant rates of treatment.

In the US and elsewhere, HCV is increasingly affecting younger people, with high case rates among those between 20 to 49 years of age. Since recently infected and younger patient populations are less likely to have developed cirrhosis given the relatively shorter cumulative exposure to the virus, there has been a trend in the US of decreasing incidence of cirrhosis among individuals with HCV infection. It is estimated by that less than 10% of the HCV-infected population in the US has cirrhosis.

Our Goal

The objective of our HCV development program is to improve upon the current standard of care ("SOC") by offering, the regimen of bemnifosbuvir and ruzasvir, if successfully developed and approved, as a differentiated pan-genotypic protease inhibitor-free therapeutic for HCV-infected patients. We believe that a novel treatment, with a profile that can be easily prescribed for and administered to today's population of HCV-infected patients (e.g. young, newly infected, non-cirrhotic) would be a significant improvement to the current SOC.

Presently, there are no short-course (i.e., 8 week) nucleoside inhibitor-based, pan-genotypic HCV treatment regimens. Results from the clinical and nonclinical studies we have conducted to date, including a global Phase 2 clinical trial which enrolled 275 HCV infected patients, have shown that the regimen of bemnifosbuvir and ruzasvir offers high potency, a low risk for drug-drug interactions, good tolerability and convenience in that it can be taken with or without food which we believe would offer a significant improvement to the current SOC, if approved.

Based upon the encouraging clinical and nonclinical results to date, we are advancing the regimen of bemnifosbuvir and ruzasvir to Phase 3 clinical development. In the Phase 3 clinical trials, we will evaluate the regimen as an 8-week treatment duration for patients without cirrhosis and a 12-week treatment duration for patients with compensated cirrhosis. We believe that the regimen of bemnifosbuvir and ruzasvir, if approved, will rapidly become a therapy preferred by both HCV prescribers and patients.

Key Clinical Trial Results

In December 2024, we announced that the global Phase 2 study evaluating the regimen of bemnifosbuvir and ruzasvir had met its primary endpoints of safety and sustained virologic response ("SVR") at 12 weeks post treatment ("SVR12"). The regimen of bemnifosbuvir and ruzasvir was generally well-tolerated with no drug-related serious adverse events ("SAEs") or treatment discontinuations.

Primary efficacy endpoint results showed a 98% (208/213) SVR12 rate in the per-protocol treatment adherent patient population after 8 weeks of treatment with the regimen. The efficacy evaluable patient population, which included 17% treatment non-adherent patients, achieved a 95% (242/256) SVR12 rate. Additional results from the Phase 2 study showed in treatment adherent patients who were non-cirrhotic and infected with genotypes 1-4, an SVR12 rate of 99% (178/179) was achieved, demonstrating pan-genotypic potency. Treatment adherent patients with cirrhosis achieved an 88% (30/34) SVR12 rate. Although viral kinetics were slower in cirrhotic patients, all cirrhotic patients (100%; 34/34) achieved an end of treatment response at Week 8.

The global Phase 2 study enrolled 275 HCV treatment-naïve patients, both with and without compensated cirrhosis. The study was designed to evaluate the safety and efficacy of 8 weeks of treatment with the regimen consisting of once-daily bemnifosbuvir 550 mg and ruzasvir 180 mg. The primary endpoints were safety and SVR12 in the per-protocol treatment adherent population. Secondary and other endpoints included SVR12 in the efficacy evaluable population (a broader analysis population which included treatment non-adherent patients), SVR at 24 weeks post treatment ("SVR24"), virologic failure and resistance.

Phase 3 Clinical Development

In January 2025, we met with the U.S. Food and Drug Administration ("FDA") at an End-of-Phase 2 meeting to seek feedback on the design of the Phase 3 clinical trials. The End-of-Phase 2 feedback from the FDA supported our decision to advance the program to Phase 3 clinical development.

The global HCV Phase 3 program we are currently initiating includes two randomized, open label Phase 3 trials comparing the regimen of bemnifosbuvir and ruzasvir to sofosbuvir and velpatasvir in patients with chronic HCV infection. The overall clinical trial design is identical for each trial. Currently, we are planning for one trial to be conducted in the U.S and Canada and one trial to be conducted outside of North America. This global geographic footprint is intended to assist us in enrolling patients with varied HCV genotypes.

Each trial is expected to enroll approximately 800 treatment-naïve patients, both with and without compensated cirrhosis. Patients will be stratified by genotype and cirrhosis status, and patients with human immunodeficiency virus ("HIV") co-infection will be allowed. For non-cirrhotic patients, 8 weeks of treatment with the regimen of bemnifosbuvir and ruzasvir will be compared to 12 weeks of sofosbuvir and velpatasvir. For cirrhotic patients, 12 weeks of bemnifosbuvir and ruzasvir will be compared to 12 weeks of sofosbuvir and velpatasvir.

The primary efficacy endpoint in each Phase 3 trial is HCV RNA < LLOQ at 24 weeks from the start of treatment. Measurement of sustained response at the Week 24 study visit is selected to ensure the primary endpoint occurs at the same relative timepoint from start of treatment in all patients. As the treatment duration is 8 weeks for patients without cirrhosis in the bemnifosbuvir and ruzasvir study arm and 12 weeks for all other study arms, the primary endpoint encompasses the period at least through the SVR12 timepoint for each treatment arm.

COVID-19

In September 2024 we announced the outcome of the global Phase 3 SUNRISE-3 trial evaluating bemnifosbuvir versus placebo for the treatment of Coronavirus Disease 2019 ("COVID-19"). The trial did not meet the primary endpoint of a statistically significant reduction in all-cause hospitalization or death through Day 29 in the monotherapy cohort of 2,221 high-risk patients with mild to moderate COVID-19. We believe that the unfavorable results from this study were impacted by the constantly evolving variants of COVID-19 and rapidly changing natural history of the disease, which during the study period trended toward a milder disease. This has led us to discontinue efforts to develop bemnifosbuvir for the treatment of COVID-19. In SUNRISE-3, bemnifosbuvir was generally safe and well tolerated. Currently, we are continuing to wind down and close out the study.

Respiratory and Other RNA Virus Infections

Separately, we are engaged in efforts to discover a product candidate for the treatment of respiratory diseases resulting from infection with single stranded RNA viruses. Additionally, we engaged in efforts to screen compounds which are a part of our compound library to assess antiviral activity against other RNA viral infections. Each of these efforts are at early stages and no clinical candidates have yet to be nominated.

Financial Resources

We believe we are well capitalized to advance our current programs. We had $454.7 million in cash, cash equivalents and marketable securities at December 31, 2024. Based on our current plans, we anticipate these financial resources will allow us to advance our current and planned clinical programs to and through key inflection points including the completion of clinical development of the regimen of bemnifosbuvir and ruzasvir for the treatment of HCV and to fund our activities into 2028. We have based this estimate on assumptions that may prove to be wrong and we could exhaust our available capital resources sooner than we expect.

We do not have any products approved for sale and have not generated any product revenue since inception. We do not anticipate generating any revenue from product sales for the foreseeable future. Our ability to generate product revenue will depend on the successful development, regulatory approval and eventual commercialization of one or more of our product candidates. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through private or public equity or debt financings, collaborative or other arrangements with third parties, or through other sources of financing. Our failure to meet the primary efficacy endpoint of our COVID-19 SUNRISE-3 Phase 3 clinical trial may make such financing more difficult. 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.

Roche License Agreement

In October 2020, with Roche, we entered into a License Agreement (“Roche License Agreement”) with F. Hoffmann-LaRoche Ltd. and Genentech, Inc. (together, “Roche”) in connection with the global development, manufacture and commercialization of bemnifosbuvir, products containing bemnifosbuvir or AT-511, the free base of bemnifosbuvir, and related companion diagnostics. During the term of the Roche License Agreement, Roche and we jointly developed bemnifosbuvir for COVID-19 on a worldwide-basis and equally shared the costs associated with such development activities.

The Roche License Agreement terminated on February 10, 2022, and, accordingly, our obligations to share costs with Roche also ended. As a result of the termination of the Roche License Agreement, we regained worldwide exclusive rights from Roche to research, develop, manufacture and commercialize bemnifosbuvir, products containing bemnifosbuvir or AT-511 and related companion diagnostics in all fields of use.

Merck License Agreement

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

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

In addition to a non-refundable upfront payment that we made in February 2022, we will be required to pay Merck milestone payments upon our achievement of certain development, regulatory and sales-based milestones. Additionally, we will pay Merck tiered royalties based on annual net sales of Products ranging from high single digits to mid-teens percentages. Our royalty payment obligations will continue until the later of (i) the expiration of the last to expire valid claim of a licensed Merck patent claiming such Product and (ii) a period of years after the first commercial sale of such Product in such country. We may terminate the Merck License Agreement for convenience upon prior written notice. The first milestone, in the amount of $5.0 million, is payable upon initiation of the first clinical trial in our Phase 3 program. We currently anticipate enrollment of patients to commence in the Phase 3 program in April 2025 and we expect this milestone to become payable in conjunction with such event.

Financial Operations Overview

As of December 31, 2024, we had cash, cash equivalents and marketable securities of $454.7 million. Net cash used in operating activities was $135.5 million for the year ended December 31, 2024.

We expect that our net cash used in operating activities will remain significant as we advance our HCV product candidate through preclinical and clinical development, seek regulatory approval, and prepare for and, if approved, manufacture such product at commercial scale and otherwise pursue commercialization activities; acquire, discover, validate and develop additional product candidates; obtain, maintain, protect and enforce our intellectual property portfolio; and, if necessary, hire additional personnel. In addition, we may incur additional costs as we continue to operate as a public company. We believe that our available cash, cash equivalents and marketable securities will be sufficient to fund our planned operations into 2028. We have based this estimate on assumptions that may prove to be wrong and we could exhaust our available capital resources sooner than we expect.

We do not have any products approved for sale and have not generated any product revenue since inception. We do not anticipate generating any revenue from product sales for the foreseeable future. Our ability to generate product revenue will depend on the successful development, regulatory approval and eventual commercialization of one or more of our product candidates. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through private or public equity or debt financings, collaborative or other arrangements with third parties, or through other sources of financing. Our failure to meet the primary endpoint of our COVID-19 SUNRISE-3 Phase 3 clinical trial may make such financing more difficult. Adequate funding may not be available to us on acceptable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of our product candidates.

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

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

- conduct Phase 3 clinical development of the regimen of bemnifosbuvir and ruzasvir for the treatment of HCV;
- continue discovery and IND-enabling activities in anticipation of nominating a protease inhibitor product candidate for the treatment of respiratory diseases resulting from infection with single stranded RNA viruses;
- continue discovery activities to identify within our compound library other potential product candidates for the treatment of diseases caused by single stranded RNA viruses;
- initiate clinical development of a protease inhibitor for the treatment of respiratory and other diseases resulting from infection with single stranded RNA viruses;
- manufacture the combination of bemnifosbuvir and ruzasvir in a fixed dose tablets for use in the Phase 3 clinical trials, and, if approved, for potential commercialization, for the treatment of HCV;
- seek market approval and prepare for potential commercialization of any product candidates that we may successfully develop;
- acquire or in-license clinical stage drug candidates, form strategic alliances or establish collaborations with third parties;
- maintain, expand, protect and enforce our intellectual property portfolio;
- hire additional personnel, if necessary, to support our activities; and
- establish commercialization capabilities if we are successful in developing our product candidates.

Components of Results of Operations

Revenue

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

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

Operating Expenses

Research and Development Expenses

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

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

As discussed in Note 3 to our consolidated financial statements, during the term of the Roche License Agreement which terminated in February 2022, we and Roche shared certain COVID-19 manufacturing

and clinical development costs on a 50/50 basis. Billings to us by Roche for our percentage share of such expenses were recorded in research and development expenses. During the years ended December 31, 2024 and 2023, we recorded a net reduction to research and development expenses of $1.3 million and $18.6 million, respectively, related to credits received from Roche. These credits were the result, following the termination of the Roche License Agreement, of changes and adjustments by Roche in estimated amounts of expenses reported by Roche during the period in which we and Roche shared costs associated with the development of bemnifosbuvir for the treatment of COVID-19. We do not anticipate to receive any additional credits from Roche or record any related additional net reductions to research and development expenses.

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

	Years Ended December 31,	
	2024	2023
	(in thousands)	
COVID-19 external costs	$ 60,734	$ 43,632
HCV external costs	34,106	16,874
Dengue external costs	—	5,550
Early stage discovery external costs	943	521
Internal research and development costs	48,318	47,666
Total research and development expenses	$ 144,101	$ 114,243

Substantially all of our resources are focused on the development of our product candidates. We expect our research and development expenses to vary quarter over quarter particularly as we advance our Phase 3 HCV clinical program and prepare for the possible commercialization of the combination of bemnifosbuvir and ruzasvir if the Phase 3 clinical development is successful. Predicting the timing or cost to complete our clinical programs, validate our commercial manufacturing and supply processes and manufacture of product at commercial scale is difficult and delays may occur because of many factors, including factors outside of our control. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate or the time to complete planned clinical trials is extended due to delays in enrollment or otherwise, we could be required to expend significant additional financial resources and time on the completion of clinical development. Furthermore, we are unable to predict with any certainty when our HCV product candidate or any other product candidate we may develop will, if ever, receive regulatory approval. Early stage activities consist of assessing the antiviral activity and other properties of select compounds derived from our compound library against respiratory and other RNA viral infections.

General and Administrative Expenses

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

We anticipate that our general and administrative expenses may increase, including in connection with any future expansion of our organization for potential commercialization of our product candidates, as a result of increased personnel costs, expanded infrastructure, increased consulting, legal and accounting services, costs associated with complying with Nasdaq and SEC requirements and increased investor relations costs.

Interest Income and Other, Net

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

Income Taxes

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

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023

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

	Years Ended December 31,		
	2024	2023	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 144,101	$ 114,243	$ 29,858
General and administrative	48,849	49,919	(1,070)
Total operating expenses	192,950	164,162	28,788
Loss from operations	(192,950)	(164,162)	(28,788)
Interest income and other, net	25,490	29,224	(3,734)
Loss before income taxes	(167,460)	(134,938)	(32,522)
Income tax expense	(925)	(1,018)	93
Net loss	$ (168,385)	$ (135,956)	$ (32,429)

Research and Development Expenses

Research and development expenses increased by $29.9 million from $114.2 million for the year ended December 31, 2023 to $144.1 million for the year ended December 31, 2024. The net increase was primarily driven by higher external spend related to our COVID-19 Phase 3 SUNRISE-3 clinical trial and our HCV Phase 2 clinical trial of the combination of bemnifosbuvir and ruzasvir. Enrollment in both trials was completed in 2024 and we announced end of study results from the SUNRISE-3 clinical trial in September 2024 and primary endpoint results from our global HCV Phase 2 in December 2024.

General and Administrative Expenses

General and administrative expenses decreased by $1.1 million from $49.9 million for the year ended December 31, 2023 to $48.8 million for the year ended December 31, 2024. The net decrease was primarily related to lower professional fees.

Interest Income and Other, Net

Interest income and other, net, decreased by $3.7 million for the year ended December 31, 2024 compared to the year ended December 31, 2023, primarily due to lower investment balances.

Income Taxes

We recorded an income tax expense of $0.9 million for the year ended December 31, 2024 as compared to an income tax expense of $1.1 million for the year ended December 31, 2023.

Liquidity and Capital Resources

Sources of Liquidity

As of December 31, 2024, we had cash, cash equivalents and marketable securities of $454.7 million. We believe that our available cash, cash equivalents and marketable securities will be sufficient to fund our planned operations into 2028 including the completion of the Phase 3 program evaluating the regimen of bemnifosbuvir and ruzasvir for the treatment of HCV. We have based this estimate on assumptions that may prove to be wrong and we could exhaust our available capital resources sooner than we expect.

We are party to an amended and restated open market sales agreement ("Sales Agreement") with Jefferies LLC ("Jefferies"), pursuant to which we may from time to time offer and sell shares of our common stock for an aggregate offering price of up to $200.0 million, through or to Jefferies, acting as sales agent or principal. We have agreed to pay Jefferies a commission of up to 3.0% of the aggregate gross proceeds from each sale of shares, reimburse legal fees and disbursements and provide Jefferies with customary indemnification and contribution rights. As of December 31, 2024, no shares have been issued under the Sales Agreement. The shares will be offered and sold under the Company's shelf registration statement on Form S-3 declared effective by the SEC on November 19, 2024.

Future Funding Requirements

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

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

- the scope, timing, rate of progress and costs of our Phase 3 program evaluating the combination of bemnifosbuvir and ruzasvir for the treatment of HCV and our other drug discovery efforts, preclinical development activities, laboratory testing and clinical trials for other product candidates;
- the outcome of our search for a strategic partnership to strengthen our commercialization capabilities in the U.S. and enhance our global commercialization reach;
- the number and scope of clinical programs we decide to pursue;
- the cost, timing and outcome of preparing for and undergoing regulatory review of our product candidates;
- the scope and costs of development and commercial manufacturing activities;
- the cost and timing associated with commercializing our product candidates, if they receive marketing approval;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates and, ultimately, the sale of our products, following regulatory approval;
- our implementation of operational, financial and management systems; and
- the costs associated with being a public company.

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

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

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

See *Part 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 and cash equivalents for each of the periods presented below:

	Years Ended December 31,	
	2024	2023
	(in thousands)	
Net cash used in operating activities	$ (135,499)	$ (85,395)
Net cash provided by investing activities	56,105	40,303
Net cash provided by financing activities	267	257
Net decrease in cash and cash equivalents	$ (79,127)	$ (44,835)

Cash Flows from Operating Activities

Net cash used in operating activities for the year ended December 31, 2024 was $135.5 million. Cash used in operating activities was primarily due to a net loss of $168.4 million, accretion of premium and discounts on marketable securities of $11.8 million, and a decrease in accrued expenses of $13.4 million, partially offset by stock-based compensation of $51.8 million and a decrease in prepaid expenses and other assets of $5.9 million.

Net cash used in operating activities for the year ended December 31, 2023 was $85.4 million. Cash used in operating activities was primarily due to a net loss of $136.0 million, accretion of premium and discounts on marketable securities of $15.4 million, partially offset by a decrease in prepaid expenses and other assets of $1.9 million, increase in accounts payable and accrued expenses of $14.4 million and stock-based compensation of $49.4 million.

Cash Flows from Investing Activities

Net cash provided by investing activities for the year ended December 31, 2024 was $56.1 million and consisted of sales and maturities of marketable securities of $517.3 million offset by purchases of marketable securities of $461.2 million.

Net cash provided by investing activities for the year ended December 31, 2023 was $40.3 million and consisted of purchases of marketable securities of $562.4 million offset by sales and maturities of marketable securities of $602.7 million.

Cash Flows from Financing Activities

Net cash provided by financing activities for the year ended December 31, 2024 was $0.3 million and consisted of proceeds from the issuance of our common stock under our Employee Stock Purchase Plan.

Net cash provided by financing activities for the year ended December 31, 2023 was $0.3 million and consisted of proceeds from the issuance of our common stock under our Employee Stock Purchase Plan.

Contractual Obligations and Commitments

We lease our office space in Boston, Massachusetts under a non-cancelable operating sublease . 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, 2024:

	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	$ 838	$ 855	$ —	$ —	$ 1,693

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

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

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

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 million. We are obligated to pay Merck milestone payments of $135 million in the aggregate upon its achievement of certain development and regulatory milestones and up to $300 million 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 and (ii) a period of years after the first commercial sale of such Product in such country. We may terminate the Merck License Agreement for convenience upon prior written notice. The first milestone, in the amount of $5.0 million, is payable upon initiation of the first clinical trial in our Phase 3 program. We currently anticipate enrollment of patients to commence in the Phase 3 program in April 2025 and we expect this milestone to become payable in conjunction with such event.

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.

The table above does not contain any potential amounts we may be obligated to pay under the Merck License Agreement as they will be recorded when the contingency is resolved and the milestone

becomes payable. Additionally, the table above does not include any potential amounts due under the consulting agreement as none are probable and estimable at December 31, 2024.

Critical Accounting Policies and Estimates

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

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

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 services performed, 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 granted stock options 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 our 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 11 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, 2024 and 2023, respectively.

Cash and Cash Equivalents

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

Marketable Securities

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

Fair Value Measurements

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

Concentration of Credit Risk and Off-balance Sheet Risk

Financial instruments that potentially subject us to concentrations of credit risk primarily consist of cash equivalents and marketable securities. Under our investment policy, we limit amounts invested in such securities by credit rating, maturity, industry group, investment type and issuer, except for securities issued by the US government. We do not believe that we are subject to any significant concentrations of credit risk from these financial instruments. We have no financial instruments with off-balance sheet risk, such as foreign exchange contracts, option contracts, or other foreign hedging arrangements.

Indemnification Agreements

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

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

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, 2024, we had cash, cash equivalents and marketable securities of $454.7 million, consisting of interest-bearing money market funds, US treasury obligations, US agency obligations, corporate debt and commercial paper for which the fair value would be affected by changes in the general level of US interest rates. However, due to the short-term maturities and the low-risk profile of our cash equivalents, an immediate 10% relative change in interest rates would not have a material effect on the fair value of our cash equivalents or on our future interest income.

We do not believe that inflation, interest rate changes or foreign currency exchange rate fluctuations have had a 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, 2024. Based upon such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2024, our disclosure controls and procedures were effective at the reasonable assurance level.

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, 2024 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, 2024.

This report does not include an attestation report of our registered public accounting firm regarding our internal control over financial reporting because we do not qualify as an accelerated or a large accelerated filer (as defined in Rule 12b-2 of the Securities Exchange Act of 1934, as amended).

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, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

During the three months ended December 31, 2024, no director or “officer” (as defined in Rule 16a-1(f) under the Exchange Act) of the Company adopted or terminated a “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement”, as each term is defined in Item 408 of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions That Prevent Inspections

Not applicable.

PART III

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 in the “Investors” section under “Corporate Governance.” We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding amendments to, or waivers 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 offers and directors required by this Item 10 is contained under the caption “Information About our 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 2025 Annual Meeting of Stockholders 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 2025 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 2025 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 2025 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 2025 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.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(1) Financial Statements

The following documents are included on pages F-1 through F-23 attached hereto and are filed as part of this Annual Report on Form 10-K.

(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	Restated Certificate of Incorporation.	8-K	001-39661	3.1	11/5/2020	
3.2	Amended and Restated Bylaws.	8-K	001-39661	3.1	6/21/2023	
4.1	Specimen Stock Certificate evidencing the shares of common stock	S-1	333-249404	4.2	10/9/2020	
4.2	Description of Capital Stock	10-K	001-39661	4.2	3/30/2021	
4.3	Fourth Amended and Restated Stockholders Agreement, as amended	S-1/A	333-249404	4.1	10/23/2020	
10.1#	2020 Incentive Award Plan and form of agreements thereunder	S-1/A	333-249404	10.2	10/26/2020	
10.1-1#	Form of 2022 Performance-Based Restricted Stock Unit Award Agreement (CEO) under the 2020 Incentive Award Plan	10-K	001-39661	10.1.1	2/28/2022	
10.1-2#	Form of 2022 Performance-Based Restricted Stock Unit Award Agreement (Non-CEO Executive) under the 2020 Incentive Award Plan	10-K	001-39661	10.1.2	2/28/2022	
10.1(3)#	Form of 2024 Performance-Based Restricted Stock Unit Award Agreement (CEO) under the 2020 Incentive Award Plan	10-K	001-39661	10.1(3)#	2/28/2024	
10.1(4)#	Form of 2024 Performance-Based Restricted Stock Unit Award Agreement (Non-CEO Executive) under the 2020 Incentive Award Plan	10-K	001-39661	10.1(4)#	2/28/2024	
10.1(5)#	Form of 2025 Performance-Based Restricted Stock Unit Award Agreement (CEO) under the 2020 Incentive Award Plan					*

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
10.1(6)#	Form of 2025 Performance-Based Restricted Stock Unit Award Agreement (Non-CEO) under the 2020 Incentive Award Plan					*
10.2#	2020 Employee Stock Purchase Plan	S-1/A	333-249404	10.3	10/26/2020	
10.3#	Non-Employee Director Compensation Program	10-Q	001-39661	10.1	8/7/2024	
10.3-1#	Form of Non-Employee Director Stock Option Award Agreement	10-Q	001-39661	10.2	8/8/2023	
10.3-2#	Form of Non-Employee Director Restricted Stock Unit Award Agreement	10-Q	001-39661	10.3	8/8/2023	
10.4#	Form of Indemnification Agreement for Directors and Officers	S-1/A	333-249404	10.5	10/26/2020	
10.5^	License Agreement, dated as of December 23, 2021, by and between the Registrant and MSD International GMBH	10-K	001-39661	10.5	2/28/2022	
10.6#	Employment Agreement between the Company and Jean-Pierre Sommadossi, Ph.D., dated October 25, 2020	S-1/A	333-249404	10.9	10/26/2020	
10.7#	Employment Agreement between the Company and Andrea Corcoran, dated October 25, 2020	S-1/A	333-249404	10.10	10/26/2020	
10.8#	Employment Agreement between the Company and Janet Hammond, MD, PhD, dated November 3, 2020	10-K	001-39661	10.8	3/30/2021	
10.9#	Employment Agreement between the Company and Arantxa Horga, MD, dated November 3, 2020	10-K	001-39661	10.9	3/30/2021	
10.10#	Employment Agreement between the Company and John Vavricka, dated November 3, 2020	10-K	001-39661	10.10	3/30/2021	
10.11#	Employment Agreement between the Company and Wayne Foster, dated November 3, 2020	10-K	001-39661	10.11	3/30/2021	
10.12#	2013 Stock Incentive Plan, as amended, and form of agreements thereunder	S-1	333-249404	10.1	10/9/2020	
10.13	Sublease Agreement, dated as of July 19, 2021, by and between the Company and DataRobot, Inc.	8-K	001-39661	10.1	7/23/2021	
10.13-1	Amendment to Sublease Agreement dated April 11, 2022 between the Company and DataRobot, Inc.	10-Q	001-39661	10.1	8/8/2022	
10.14#	Consulting Agreement, dated May 18, 2021, by and between the Company and Upstream Wellness and Health LLC.	8-K	001-39661	10.1	5/20/2021	
10.15	Consulting Agreement dated June 10, 2022, by and between the Company and Bruce Polsky, M.D.	10-Q	001-39661	10.2	8/8/2022	
19.1	Insider Trading Compliance Policy					*
21.1	List of Subsidiaries of the Registrant					*
23.1	Consent of Independent Registered Public Accounting Firm					*

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a).					*
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a)					*
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350					**
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350					**
97.1	Policy for Recovery of Erroneously Awarded Compensation	10-K	001-39661	97.1	2/28/2024	
101.INS	Inline XBRL Instance Document - - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.					*
101.SCH	Inline XBRL Taxonomy Extension Schema Document					*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)					*

* Filed herewith.

** Furnished herewith.

^ Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

# Indicates management contract or compensatory plan.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934 the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

ATEA PHARMACEUTICALS, INC.

Date: March 6, 2025

By: /s/ Jean-Pierre Sommadossi
Jean-Pierre Sommadossi, Ph.D.
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Jean-Pierre Sommadossi Jean-Pierre Sommadossi, Ph.D.	President, Chief Executive Officer and Chairman of the Board of Directors (principal executive officer)	March 6, 2025
/s/ Andrea Corcoran Andrea Corcoran	Chief Financial Officer and Executive Vice President, Legal and Secretary (principal financial officer)	March 6, 2025
/s/ Wayne Foster Wayne Foster	Executive Vice President, Chief Accounting Officer (principal accounting officer)	March 6, 2025
/s/ Franklin Berger Franklin Berger	Director (Lead Director)	March 6, 2025
/s/ Jerome Adams Jerome Adams, M.D., M.P.H	Director	March 6, 2025
/s/ Barbara Duncan Barbara Duncan	Director	March 6, 2025
/s/ Arthur Kirsch Arthur Kirsch	Director	March 6, 2025
/s/ Bruno Lucidi Bruno Lucidi	Director	March 6, 2025
/s/ Polly A. Murphy Polly A. Murphy, D.V.M., Ph.D.	Director	March 6, 2025
/s/ Bruce Polsky Bruce Polsky, M.D.	Director	March 6, 2025

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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, 2024 and 2023, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the years then ended, 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, 2024 and 2023, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

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 Public Company Accounting Oversight Board (United States) (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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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 Matters

Critical audit matters are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ KPMG LLP

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

Boston, Massachusetts
March 6, 2025

ATEA PHARMACEUTICALS, INC.
Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	December 31,	
	2024	2023
Assets		
Current assets:		
Cash and cash equivalents	$ 64,696	$ 143,823
Marketable securities	390,025	434,283
Prepaid expenses and other current assets	7,634	12,349
Total current assets	462,355	590,455
Property and equipment, net	873	1,289
Other assets	197	1,396
Operating lease right-of-use assets, net	1,243	1,828
Total assets	$ 464,668	$ 594,968
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,458	$ 4,252
Accrued expenses and other current liabilities	13,345	27,364
Current portion of operating lease liabilities	800	760
Total current liabilities	18,603	32,376
Operating lease liabilities	842	1,642
Income taxes payable	6,356	5,758
Total liabilities	25,801	39,776
Commitments and contingencies (see Note 8)		
Stockholders' equity:		
Preferred stock, $0.001 par value per share; 10,000,000 shares authorized; no shares issued and outstanding as of December 31, 2024 and 2023	—	—
Common stock, $0.001 par value; 300,000,000 shares authorized; 84,463,059 and 83,435,513 shares issued and outstanding as of December 31, 2024 and 2023	84	83
Additional paid-in capital	802,770	750,737
Accumulated other comprehensive gain	233	207
Accumulated deficit	(364,220)	(195,835)
Total stockholders' equity	438,867	555,192
Total liabilities and stockholders' equity	$ 464,668	$ 594,968

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

ATEA PHARMACEUTICALS, INC.
Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share amounts)

	Years Ended December 31,	
	2024	**2023**
Operating expenses:		
Research and development	$ 144,101	$ 114,243
General and administrative	48,849	49,919
Total operating expenses	192,950	164,162
Loss from operations	(192,950)	(164,162)
Interest income and other, net	25,490	29,224
Loss before income taxes	(167,460)	(134,938)
Income tax expense	(925)	(1,018)
Net loss	$ (168,385)	$ (135,956)
Other comprehensive income:		
Unrealized gain on available-for-sale investments	26	891
Comprehensive loss	$ (168,359)	$ (135,065)
Net loss per share - basic and diluted	$ (2.00)	$ (1.63)
Weighted-average number of common shares - basic and diluted	84,264,715	83,389,750

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

ATEA PHARMACEUTICALS, INC.
Consolidated Statements of Stockholders' Equity
(in thousands, except share amounts)

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance – January 1, 2023	83,287,639	$ 83	$ 701,052	$ (684)	$ (59,879)	$ 640,572
Issuance of common stock upon release of restricted stock units	53,935	—	—	—	—	—
Issuance of common stock under ESPP	93,939	—	257	—	—	257
Stock-based compensation expense	—	—	49,428	—	—	49,428
Other comprehensive income	—	—	—	891	—	891
Net loss	—	—	—	—	(135,956)	(135,956)
Balance – December 31, 2023	83,435,513	83	750,737	207	(195,835)	555,192
Issuance of common stock upon release of restricted stock units	927,932	1	(1)	—	—	—
Issuance of common stock under ESPP	99,614	—	267	—	—	267
Stock-based compensation expense	—	—	51,767	—	—	51,767
Other comprehensive income	—	—	—	26	—	26
Net loss	—	—	—	—	(168,385)	(168,385)
Balance – December 31, 2024	84,463,059	$ 84	$ 802,770	$ 233	$ (364,220)	$ 438,867

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,	
	2024	**2023**
Cash flows from operating activities		
Net loss	$ (168,385)	$ (135,956)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation expense	51,767	49,428
Depreciation and amortization expense	416	416
Accretion of premium and discounts on marketable securities	(11,821)	(15,446)
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	5,914	1,864
Other assets	—	98
Accounts payable	206	1,701
Accrued expenses and other liabilities	(13,421)	12,661
Operating lease liabilities	(175)	(161)
Net cash used in operating activities	(135,499)	(85,395)
Cash flows from investing activities		
Purchases of marketable securities	(461,177)	(562,362)
Sales and maturities of marketable securities	517,282	602,665
Net cash provided by investing activities	56,105	40,303
Cash flows from financing activities		
Proceeds from issuance of common stock under ESPP	267	257
Net cash provided by financing activities	267	257
Net decrease in cash and cash equivalents	(79,127)	(44,835)
Cash and cash equivalents at the beginning of period	143,823	188,658
Total cash and cash equivalents	$ 64,696	$ 143,823

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

Business Overview

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

The Company is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing oral antiviral therapeutics to improve the lives of patients suffering from serious viral infections. The Company’s lead product candidate, the regimen of bemnifosbuvir, a nucleotide NS5B inhibitor, and ruzasvir, an NS5A inhibitor is being developed for the treatment of hepatitis C virus (“HCV”). Based upon encouraging results from clinical and nonclinical studies conducted to date, including a global Phase 2 study that enrolled 275 HCV infected patients, the Company is currently advancing the regimen to Phase 3 clinical development.

Liquidity and Capital Resources

As of December 31, 2024, the Company had $454.7 million in cash, cash equivalents and marketable securities, which the Company believes will be sufficient to fund its operations for a period through at least twelve months from the issuance date of these consolidated financial statements.

The Company is a party to an amended and restated open market sales agreement (“Sales Agreement”) with Jefferies LLC (“Jefferies”), under which the Company may from time to time offer and sell shares of its common stock for an aggregate offering price of up to $200.0 million, through or to Jefferies, acting as sales agent or principal. The shares will be offered and sold under the Company’s shelf registration statement on Form S-3 and a related prospectus declared effective by the Securities and Exchange Commission (the “SEC”) on November 19, 2024. The Company has agreed to pay Jefferies a commission of 3.0% of the aggregate gross proceeds from each sale of shares, reimburse legal fees and disbursements and provide Jefferies with customary indemnification and contribution rights. As of December 31, 2024, no shares have been issued under the Sales Agreement.

Risks and Uncertainties

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

The Company may seek additional capital through one or more of a combination of financing through the sale of additional equity securities, debt financing, or funding in connection with any new collaborative relationships it may enter into or other arrangements. There can be no assurance that the Company will be able to obtain such additional funding, on terms acceptable to the Company, on a timely basis or at all. The terms of any financing may adversely affect the holdings or the rights of the Company’s existing

stockholders. Geopolitical events, including civil or political unrest and terrorism, have resulted in a significant disruption of global business and financial markets. In addition, recent or future market volatility, increased inflation and higher interest rates, if sustained, may increase the Company's cost of financing and may restrict our access to potential sources of future liquidity.

2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

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

Principles of Consolidation

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

Cash and Cash Equivalents

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

Marketable Securities

The Company's investment strategy is principally focused on capital preservation. The Company invests in financial instruments that among other things meet the credit quality standards outlined in the Company's investment policy. Marketable securities consist of investments with maturities greater than three months. Investments not classified as cash equivalents with maturities of less than twelve months are classified as current assets on the consolidated balance sheet. Investments with maturities greater than twelve months for which the Company has the intent and ability to hold the investment for greater than twelve months are classified as non-current on the consolidated balance sheet. Marketable securities include US treasury obligations, US agency obligations, corporate debt, commercial paper and asset-backed securities. The Company classifies all of its marketable securities as available-for-sale. Accordingly, these investments are recorded at fair value. Unrealized gains and losses are recorded as a component of accumulated other comprehensive gain (loss) within stockholders' equity. Interest, dividends and amortization and accretion of discounts and premiums are recorded as interest income and other, net. The Company periodically reviews its marketable securities for impairment and adjusts these investments to their fair value when a decline in market value is deemed to be other than temporary. Declines in fair value judged to be other than temporary on marketable securities, if any, are included in interest income and other, net.

Concentrations of Credit Risk and Significant Suppliers

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

The Company is dependent on third-party manufacturers for the supply of products for its research and development activities including its development 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 for preclinical and clinical development activities. The Company also currently anticipates to rely on this small number of manufacturers for commercial supply if any of the current product candidates are approved for sale. The Company's research and development programs, including any potential commercialization efforts, could be adversely affected by a significant interruption in the supply of active pharmaceutical ingredients and formulated drugs.

Fair Value Measurements

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

The carrying amounts of prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair value due to short-term nature of these assets and liabilities.

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:

Asset	Estimated useful life
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 vendor deposits related to research and development activities and a security deposit related to our facility lease.

Impairment of Long-lived Assets

The Company reviews long-lived assets, including property and equipment and right-of-use assets ("ROU") when events or changes in circumstances indicate the carrying value of the assets may not be fully 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, 2024 and 2023.

Leases

The Company accounts for leases in accordance with ASC Topic 842, *Lease Accounting*. At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease. Leases with a term greater than one year are recognized on the consolidated balance sheet as a ROU asset and current and non-current lease liabilities, as applicable. Operating lease liabilities and their corresponding ROU assets are recorded based on the present value of future lease payments over the expected remaining lease term. Lease cost for operating leases is recognized on a straight-line basis over the lease term as an operating expense. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which the Company estimates it 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.

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 drug discovery, 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.

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 and comprehensive loss in the same manner as 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—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 US 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. During the fiscal year ended December 31, 2022 the Company began to incorporate the historical volatility of its own stock price in its calculation of its expected volatility.

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 uses 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).

The purchase price of the Company's common stock under the Company's 2020 Employee Stock Purchase Plan ("ESPP") is equal to 85% of the lesser of (i) the fair market value per share of its common stock on the first business day of an offering period and (ii) the fair market value per share of its common stock on the purchase date (the last business day of an offering period). The fair value of the discounted purchases made under ESPP is calculated using the Black-Scholes valuation model. The fair value of the look-back provision plus the 15% discount is recognized as compensation expense over the 180-day purchase period.

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 Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity that result from transactions and economic events other than those with equity holders. For the years ended December 31, 2024 and 2023, the only components of comprehensive loss other than net loss were unrealized gains and losses on available for sale investments.

Net Loss Per Share

Basic net income loss per share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding for the period. Diluted net loss per share is computed by dividing the diluted net loss by the weighted average number of shares of common stock outstanding for the period, including potential dilutive shares assuming the dilutive effect of outstanding common stock equivalents except where such securities would be antidilutive.

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 ("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. For additional information see Note 16. Segment Information.

New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that the Company adopts as of the specified effective date. Unless otherwise discussed 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.

In November 2023, the FASB issued *ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which is intended to improve reportable segment disclosure requirements, primarily through additional disclosures about significant segment expenses. The standard is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The Company adopted the new standard in fiscal year 2024 for annual and retrospective reporting periods with all interim disclosures to begin in the first quarter of fiscal year 2025. For additional information, see Note 16, Segment Information.

In December 2023, the FASB issued *ASU 2023-09, Improvements to Income Tax Disclosures*, which requires entities to disclose disaggregated information about their effective tax rate reconciliation and income taxes paid. The disclosure requirements will be applied on a prospective basis, with the option to apply them retrospectively. The standard is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the disclosure requirements related to this new standard.

In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures*, which requires disclosure of additional information about specific expense categories in the notes to the financial statements on an interim and annual basis. The standard is effective for fiscal years beginning after December 15, 2026, and for interim periods beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the disclosure requirements related to this new standard.

3. Collaboration Agreement

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

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

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

For the years ended December 31, 2024 and 2023, the Company recorded net credits of $1,292 and $18,576, respectively, from Roche. The credits recorded represent changes in estimate as a result of close out activities and related reporting of amounts incurred by Roche associated with the global development plan. The close out activities were completed by Roche as of March 31, 2024. As a result, the Company does not expect to receive any related amounts from Roche in the future. Included in prepaid expenses and other current assets as of December 31, 2023 is a net balance due from Roche of $5,904. Payment for this amount due was received in February 2024.

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:

	As of December 31, 2024			
	Level 1	**Level 2**	**Level 3**	**Total**
Cash equivalents				
Money market funds	$ 60,984	$ —	$ —	$ 60,984
Marketable Securities				
US Treasury obligations	—	109,036	—	109,036
US Government agency securities	—	25,094	—	25,094
Asset-backed securities	—	60,071	—	60,071
Commercial paper	—	21,857	—	21,857
Corporate bonds	—	173,967	—	173,967
Total	$ 60,984	$ 390,025	$ —	$ 451,009

	As of December 31, 2023			
	Level 1	**Level 2**	**Level 3**	**Total**
Cash equivalents				
Money market funds	$ 143,740	$ —	$ —	$ 143,740
Marketable Securities				
US Treasury obligations	—	155,938	—	155,938
US Government agency securities	—	178,160	—	178,160
Commercial paper	—	39,448	—	39,448
Corporate bonds	—	60,737	—	60,737
Total	$ 143,740	$ 434,283	$ —	$ 578,023

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, 2024 and 2023.

There were no transfers among Level 1, Level 2 or Level 3 categories in the years ended December 31, 2024 and 2023.

5. Marketable Securities

	As of December 31, 2024			
	Amortized Cost	Unrealized Gain	Unrealized Losses	Fair Value
Marketable Securities				
US Treasury obligations	$ 108,967	$ 69	$ —	$ 109,036
US Government agency securities	25,083	19	(8)	25,094
Asset-backed securities	60,002	77	(8)	60,071
Commercial paper	21,850	7	—	21,857
Corporate bonds	173,890	125	(48)	173,967
Total	$ 389,792	$ 297	$ (64)	$ 390,025

	As of December 31, 2023			
	Amortized Cost	Unrealized Gain	Unrealized Losses	Fair Value
Marketable Securities				
US Treasury obligations	$ 155,816	$ 145	$ (23)	$ 155,938
US Government agency securities	178,115	96	(51)	178,160
Commercial paper	39,461	14	(27)	39,448
Corporate bonds	60,684	65	(12)	60,737
Total	$ 434,076	$ 320	$ (113)	$ 434,283

As of December 31, 2024 and 2023, the Company held 21 and 26 securities that were in an unrealized loss position of $64 and $113, respectively. The Company has the intent and ability to hold such securities until recovery. As a result, the Company did not record any charges for credit-related impairments for its marketable debt securities for the years ended December 31, 2024 and 2023.

As of December 31, 2024 and 2023, none of the securities had remaining maturities longer than one year.

The Company received proceeds of $517,282 and $602,665 from sales and maturities of marketable securities during the years ended December 31, 2024 and 2023.

6. Property and Equipment, net

Property and equipment, net, consist of the following:

	As of December 31,	
	2024	2023
Laboratory equipment	$ 5	$ 5
Office furniture and fixtures	396	396
Computer hardware	102	102
Leasehold improvements	1,475	1,475
Total property and equipment, at cost	1,978	1,978
Less: accumulated depreciation and amortization	(1,105)	(689)
Property and equipment, net	$ 873	$ 1,289

Depreciation and amortization expense was $416 for the years ended December 31, 2024 and 2023.

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	As of December 31,	
	2024	2023
Research and development, including manufacturing and clinical expenditures	$ 6,940	$ 20,999
Payroll and payroll related	5,904	5,696
Professional fees and other	501	669
Total accrued expenses and other current liabilities	$ 13,345	$ 27,364

8. Commitments and Contingencies

Operating Lease Agreements

In July 2021, the Company entered into a non-cancelable operating lease agreement pursuant to which the Company leased its principal office facility in Boston, Massachusetts at 225 Franklin Street ("225 Lease"). The 225 Lease commencement date was January 1, 2022 and runs through December 31, 2026. The 225 Lease does not contain any options for renewal or extension.

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

The following assets and liabilities are recorded on the Company’s consolidated balance sheet as of December 31, 2024 and 2023.

	As of December 31,	
	2024	2023
Right-of-use asset	$ 1,243	$ 1,828
Current operating lease liability	800	760
Non-current operating lease liability	842	1,642

The components of the lease expense which are allocated between the general and administrative expenses and the research and development expenses on the consolidated statement of operations for the years ended December 31, 2024 and 2023 were as follows:

	Year Ended December 31,	
	2024	2023
Operating lease costs	$ 646	$ 646
Variable lease costs	56	40
Total lease costs	$ 702	$ 686

The variable lease costs for the years ended December 31, 2024 and 2023 include common area maintenance and other operating charges associated with the 225 Lease. As the 225 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 estimates it 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,	
	2024	**2023**
Remaining lease term (in years)	2.0	3.0
Discount rate	3.1 %	3.1 %

Future minimum payments under the 225 Lease, currently the Company's only operating lease as of December 31, 2024 were as follows:

2025	$	838
2026		855
Total lease payments		1,693
Less amount representing implied interest		51
Total lease liability	$	1,642
Current portion of operating lease liabilities		800
Noncurrent portion of operating lease liabilities	$	842

Rent expense recognized was $646 for the years ended December 31, 2024 and 2023.

The Company maintains a deposit of $197 with the landlord, which is included in other assets in the consolidated balance sheets as of December 31, 2024 and 2023.

License Agreement

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

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

In addition to a non-refundable upfront payment that the Company made in February 2022, the Company will be required to pay Merck milestone payments upon its achievement of certain development, regulatory and sales-based milestones. Additionally, the Company will pay Merck tiered royalties based on annual net sales of Products ranging from high single digits to mid-teens percentages. The Company's royalty payment obligations will continue until the later of (i) the expiration of the last to expire valid claim of a licensed Merck patent claiming such Product and (ii) a period of years after the first commercial sale of such Product in such country. The Company may terminate the Merck License Agreement for convenience upon prior written notice. The first potential milestone in the amount of $5.0 million is payable upon the initiation of a Phase 3 clinical trial and the related expense will be recorded when the contingency is resolved and the milestone becomes payable.

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

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

9. Preferred Stock

As of December 31, 2023 the Company has 10,000,000 shares of preferred stock authorized. None of these shares of preferred stock have been issued.

10. Common Stock

As of December 31, 2024, the authorized capital of the Company included 300,000,000 shares of common stock, of which 84,463,059 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 common stock in the event of liquidation. The holders of common stock have no preemptive, redemption or conversion rights.

As of December 31, 2024, the Company had the following reserved shares of common stock:

Outstanding options	20,166,069
Outstanding restricted stock units	2,523,052
Outstanding performance-based restricted stock units	1,782,870
Shares reserved for future grant under 2020 Incentive Award Plan	5,362,362
Shares reserved under Employee Stock Purchase Plan	2,631,642
	32,465,995

11. Stock-based Compensation

In October 2020, the Company's shareholders approved the Company's 2020 Incentive Award Plan ("2020 Plan"). The 2020 Plan initially provided for the issuance of up to 7,924,000 shares of common stock and for the grant of incentive stock options or other incentive awards to employees, officers, directors and consultants of the Company. The number of shares of common stock that may be issued under the 2020 Plan is also subject to increase on the first day of each calendar year equal to the lesser of i) 5% of the aggregate number of shares of common stock outstanding on the final day of the immediately preceding calendar year or ii) such smaller number of shares as is determined by the board of directors. Through December 31, 2024, the shares available under the plan were increased by 16,622,139 shares. As of December 31, 2024, 5,362,362 shares of common stock were available for

future issuance under the 2020 Plan. In January 2025, the shares of the Company's common stock available under the 2020 Plan were increased by 4,223,152 shares.

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

Stock Options

The following table summarizes stock option activity:

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value ($000s)
Outstanding at January 1, 2024	17,017,319	$ 15.30	7.1	$ 5,080
Granted	3,213,550	$ 4.10		
Exercised	—	$ —		
Cancelled	(64,800)	$ 18.27		
Outstanding at December 31, 2024	20,166,069	$ 13.51	6.6	$ 6,095
Vested and expected to vest at December 31, 2024	20,166,069	$ 13.51	6.6	$ 6,095
Vested and exercisable at December 31, 2024	14,856,586	$ 16.31	6.0	$ 6,077

During the years ended December 31, 2024 and 2023, the Company granted 3,213,550 and 3,777,550 stock options with an aggregate grant date fair value of $9,622 and $12,365, respectively.

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, 2024, total unrecognized compensation expense related to stock option awards was $21,396, which amount is being recognized over a remaining weighted average period of 2.2 years.

The weighted average grant date fair value per option granted during the years ended December 31, 2024 and 2023 was $2.99 and $3.27, respectively. The fair value of each award was estimated using Black-Scholes based on the following weighted average assumptions:

	For the Year Ended December 31,	
	2024	2023
Risk-free interest rate	3.96%	3.65%
Expected term	5.96 years	5.97 years
Expected volatility	84%	85%
Expected dividend yield	0%	0%

Restricted Stock Units

During the year ended December 31, 2024 and 2023, the Company granted 1,126,100 and 2,264,700 restricted stock units to employees and the board of directors with an aggregate grant date fair market value of $4,557 and $10,384, respectively. The restricted stock unit awards vest in three annual installments. During the years ended December 31, 2024 and 2023, the Company issued 927,932 and 53,935 shares of common stock upon the vesting and settlement of restricted stock units. During the year ended December 31, 2024 and 2023, 12,633 and 34,998 restricted stock units were cancelled due to employee terminations.

	Number of Shares		Weighted Average Grant Date Fair Value
Outstanding at January 1, 2024	2,337,517	$	4.69
Granted	1,126,100	$	4.05
Released	(927,932)	$	4.65
Cancelled	(12,633)	$	4.62
Unvested shares at December 31, 2024	2,523,052	$	4.42

As of December 31, 2024, total unrecognized compensation expense related to restricted stock unit awards was $6,445, which amount is being recognized over a remaining weighted average period of 1.4 years.

Performance-based Restricted Stock Units

As of December 31, 2023 the Company had 724,970 performance-based restricted stock units (“2022 PSUs”) outstanding. The 2022 PSUs provide for a performance period from February 1, 2022 through January 31, 2025 to achieve up to six defined performance metrics. The percentage of 2022 PSUs eligible to vest will be determined based on the number of metrics achieved during the performance period and may range from 0% to 200%. The Company did not recognize any compensation expense related to these awards during the year ended December 31, 2023, as achievement of the minimum performance criteria had not been deemed probable. During the year ended December 31, 2024 achievement of two metrics was deemed probable resulting in expense recognition of 50% of the grant date value of the 2022 PSUs. Compensation expense is being recognized from the grant date through the final vest date of January 31, 2026. The vesting of 2022 PSUs for which the performance metrics are determined to have been met will occur in equal installments on January 31, 2025 and January 31, 2026, provided the recipient remains in service to the Company at that time. The Company recorded compensation expense of $2,201 for the year ended December 31, 2024.

During the year ended December 31, 2024, the Company granted 1,057,900 performance-based restricted stock units (“2024 PSUs”) to employees with an aggregate grant date fair value of $4,401. The 2024 PSUs provide for a performance period from February 1, 2024 through January 31, 2027 to achieve up to four defined performance metrics. The percentage of 2024 PSUs eligible to vest will be determined based on the number of metrics achieved during the performance period and may range from 0% to 200%. As of December 31, 2024 two metrics were deemed probable of achievement resulting in expense recognition of 75% of the grant date value of the 2024 PSUs. Compensation expense is being recognized from the grant date through the final vest date of January 31, 2027. The Company recorded compensation expense of $1,009 for the year ended December 31, 2024.

During the years ended December 31, 2024 and 2023, there were no cancellations of performance-based restricted stock units.

	Number of Shares		Weighted Average Grant Date Fair Value
Outstanding at January 1, 2024	724,970	$	7.14
Granted	1,057,900	$	4.16
Released	—	$	—
Cancelled	—	$	—
Unvested shares at December 31, 2024	1,782,870	$	5.37

As of December 31, 2024, total unrecognized compensation expense related to performance-based restricted stock units was $2,679, which amount is being recognized over a remaining weighted average period of 1.5 years.

Employee Stock Purchase Plan

In October 2020, the Company's shareholders approved the ESPP, which became effective upon the closing of the Company's IPO in November 2020. The Company initially reserved a total of 1,187,000 shares of its common stock for issuance under the ESPP. The ESPP provides that the number of shares reserved and available for issuance under the ESPP will be increased on January 1 of each calendar year by 1% of the number of shares of the Company's common stock issued and outstanding on the immediately preceding December 31 or such lesser amount as specified by the board of directors. Through December 31, 2024, the number of shares of the Company's common stock available for issuance under the ESPP was increased by 1,667,231. In January 2025 the number of shares of the Company's common stock available for issuance under the ESPP was increased by 844,630.

The Company issued 99,614 and 93,939 shares for proceeds of $267 and $257 during the years ended December 31, 2024 and 2023, respectively.

Stock-based Compensation Expense

Stock-based compensation expense is classified as follows:

	For the Year Ended December 31,			
		2024		2023
Research and development	$	24,072	$	22,666
General and administrative		27,695		26,762
Total stock-based compensation expense	$	51,767	$	49,428

The components of stock-based compensation expense were:

	For the Year Ended December 31,			
		2024		2023
Restricted stock units	$	5,374	$	3,679
Performance-based restricted stock units		3,209		—
Stock options		43,073		45,626
ESPP		111		123
Total stock-based compensation expense	$	51,767	$	49,428

12. Income Taxes

For the years ended December 31, 2024 and 2023, the Company recorded income tax expense of $925 and $1,018, respectively.

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

	For the Year Ended December 31,	
	2024	2023
Expected income tax benefit at the federal statutory rate	21.0 %	21.0 %
State and local taxes	4.4	4.2
Research and development credits	3.5	3.3
Stock-based compensation	(3.9)	(4.3)
Uncertain tax positions	(0.4)	(0.4)
Other	0.5	(0.1)
Change in valuation allowance	(25.7)	(24.5)
Total	(0.6) %	(0.8) %

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,	
	2024	2023
Deferred tax assets (liabilities)		
Capitalized research and development	$ 56,255	$ 33,692
Net operating loss carryforwards	19,514	9,385
License agreement	5,162	5,609
Stock-based compensation	22,681	17,884
Research and development credits	13,959	8,155
Other	232	143
Prepaid expenses	(589)	(695)
Deferred tax assets (liabilities)	117,214	74,173
Less: valuation allowance	(117,214)	(74,173)
Net deferred tax assets (liabilities)	$ —	$ —

As required by the 2017 Tax Cut and Jobs Act, effective January 1, 2022, taxpayers can no longer immediately expense qualified research and development expenditures. Taxpayers are now required to capitalize and amortize these costs over five years for research conducted in the US or 15 years for research conducted abroad.

As of December 31, 2024, the Company had federal net operating losses of $63,277 and state net operating loss carryforwards of $98,721, which may be used to offset future tax liabilities. The Company has federal and state credit carryforwards of $12,770 and $1,505, respectively. The federal net operating losses and research and development tax credits begin to expire in 2034.

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 2025 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 $117,214 at December 31, 2024.

Under the provisions of Sections 382 and 383 of the Internal Revenue Code ("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 for the years ended December 31, 2024 and 2023 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 there was no impact on the Company's ability to utilize net operating losses or credit carryforwards. To the extent that the Company raises additional equity financing or other changes in the ownership interest of significant

stockholders occurs, 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 ("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.

The following table summarizes the reconciliation of the beginning and ending amount of total unrecognized tax benefits for the year ended December 31, 2024:

Balance beginning of year	$	5,758
Decrease related to current year provision to return adjustment		—
Increase related to accrued interest		598
Balance at end of period	$	6,356

13. Net Loss Per Share

Basic and diluted earnings per share are calculated as follows:

	For the Year Ended December 31,	
	2024	**2023**
Net loss	$ (168,385)	$ (135,956)
Weighted average common shares outstanding, basic and diluted	84,264,715	83,389,750
Net loss per share - basic and diluted	$ (2.00)	$ (1.63)

Stock options for the purchase of 20,166,069 shares, 2,523,052 restricted stock units, 1,782,870 performance-based restricted stock units and 30,062 ESPP shares were excluded from the computation of the net loss per share for the year ended December 31, 2024, due to the net loss during the period as their effect is antidilutive.

Stock options for the purchase of 17,017,319 shares, 2,337,517 restricted stock units, 724,970 performance-based restricted stock units and 30,254 ESPP shares were excluded from the computation of the net loss per share for the year ended December 31, 2023, due to the net loss during the period as their effect is antidilutive.

14. 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 ("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 years ended December 31, 2024 and 2023, the Company recognized expense of $788 and $708, respectively, relating to matching contributions to the 401(k) Plan.

15. 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 $110 in each of the years ended December 31, 2024 and 2023.

In May 2022, the Company entered into a consulting agreement with one of its directors. No expense related to this agreement was recognized during the years ended December 31, 2024 and 2023.

16. Segment Information

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

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

The CODM reviews cash, cash equivalents and marketable securities as a measure of segment assets. As of December 31, 2024 and 2023, the Company's cash, cash equivalents and marketable securities were $454.7 million and $578.1 million, respectively.

The following table illustrates information about significant segment expenses and segment operating loss for the years ended December 31, 2024 and 2023 (in thousands):

	2024	2023
Research and development expense [1]		
COVID-19 external costs [2]	$ 60,734	$ 43,632
HCV external costs [2]	34,106	16,874
Dengue external costs [2]	—	5,550
Early stage discovery external costs [2]	943	521
Compensation and related expenses	20,448	19,495
Consulting and professional fees	1,959	3,591
Other research and development expenses	1,839	1,914
Total research and development expense	120,029	91,577
General and administrative [3]		
Compensation and related expenses	9,279	8,752
Consulting and professional fees	10,031	12,488
Other general and administrative	1,844	1,917
Total general and administrative	21,154	23,157
Stock based compensation	51,767	49,428
Other segment items [4]	(24,564)	(28,207)
Net loss	$ (168,386)	$ (135,955)

[1] Research and development expense for the years ended December 31, 2024 and 2023 excludes stock based compensation of $24,072 and $22,666, respectively.

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

[3] General and administrative expense for the years ended December 31, 2024 and 2023 excludes stock based compensation of $27,695 and $26,762, respectively.

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