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, 2025

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: 001-39617

Aligos Therapeutics, Inc.
(Exact name of Registrant as specified in its Charter)

Delaware	82-4724808
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
One Corporate Drive, 2nd Floor South San Francisco, California	94080
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (800) 466-6059

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, par value, $0.0001 per share	ALGS	The Nasdaq Stock Market LLC (Nasdaq Capital 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 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 checkmark 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 recover period pursuant to Section 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 ☒

The aggregate market value of voting and non-voting common stock held by non-affiliates of the Registrant was approximately $19.9 million as of June 30, 2025, the last business day of the Registrant's most recently completed second fiscal quarter, based on (i) 6,151,374 shares of common stock, $0.0001 par value per share, outstanding, comprised of 5,351,374 shares of voting common stock, $0.0001 par value per share and 800,000 shares of non-voting common stock, $0.0001 par value per share, and (ii) the closing sales price for the Registrant's common stock on the Nasdaq Capital Market on such date.

As of March 2, 2026, the Registrant had 6,187,807 shares of common stock, $0.0001 par value per share, outstanding, comprised of 5,387,807 shares of voting common stock, $0.0001 par value per share and 800,000 shares of non-voting common stock, $0.0001 par value per share. This number does not include 4,217,432 shares of common stock issuable upon the exercise of pre-funded warrants outstanding as of March 2, 2026 (which are immediately exercisable at an exercise price of $0.0025 and $0.0001 per share of common stock, respectively, subject to beneficial ownership limitations) sold in the Registrant's private placement on October 23, 2023 and February 13, 2025. See Note 7— Common Warrants and Pre- Funded Warrants to the Registrant's audited financial statements.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Definitive Proxy Statement relating to the 2026 Annual Meeting of Stockholders, which will be filed with the Securities and Exchange Commission within 120 days after the end of the Registrant's fiscal year ended December 31, 2025, are incorporated by reference into Part III of this Report.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business, operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that are in some cases beyond our control and 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.

In some cases, you can identify forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “predict,” “potential,” “positioned,” “seek,” “should,” “target,” “will,” “would,” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the scope, progress, results and costs of developing our drug candidates or any other future drug candidates, including conducting nonclinical studies and clinical trials;
- the scope, progress, results and costs related to the research and development of our pipeline;
- our recurring losses from operations and negative cash flows have raised substantial doubt regarding our ability to continue as a going concern;
- the timing of, and costs involved in, obtaining and maintaining regulatory approval for any of our current or future drug candidates, and any related restrictions or limitations;
- our expectations regarding the potential market size and size of the potential patient populations for our drug candidates and any future drug candidates, if approved for commercial use;
- our ability to maintain existing, and establish new, collaborations, licensing or other arrangements and the financial terms of any such agreements;
- our commercialization, marketing and manufacturing capabilities and expectations;
- the rate and degree of market acceptance of our drug candidates, as well as the pricing and reimbursement of our drug candidates, if approved;
- the implementation of our business model and strategic plans for our business, drug candidates and technology, including additional indications for which we may pursue;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our drug candidates, including the projected term of patent protection;
- any lawsuits related to our drug candidates or commenced against us;
- estimates of our expenses, future revenue, capital requirements, our needs for additional financing, our ability to obtain additional capital and our ability to continue as a going concern;
- developments and projections relating to our competitors and our industry, including competing therapies and procedures;
- regulatory and legal developments in the United States and foreign countries;
- the performance of our third-party suppliers and manufacturers;
- our ability to attract and retain key management, scientific and medical personnel;
- our expectations regarding our ability to obtain, maintain, enforce and defend our intellectual property protection for our drug candidates; and
- other risks and uncertainties, including those listed under the caption “Risk Factors.”

We have based these forward-looking statements largely on management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate as well as management's beliefs and assumptions. These statements are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K and are subject to a number of risks, uncertainties and assumptions described in the section titled "Risk Factors" and elsewhere in this Annual Report on Form 10-K. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein until after we distribute this Annual Report on Form 10-K, whether as a result of any new information, future events or otherwise.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements.

Investors and others should note that we may announce material business and financial information to our investors using our investor relations website, Securities and Exchange Commission, or SEC, filings, webcasts, press releases and conference calls. We use these mediums, including our website, to communicate with our stockholders and the public about our company, our products and other issues. It is possible that the information that we make available may be deemed to be material information. We therefore encourage investors and others interested in our company to review the information that we make available on our website.

Summary of material risks associated with our business

The principal risks and uncertainties affecting our business include the following:

- We are a clinical-stage biotechnology company with a limited operating history and no products approved for commercial sale. We have incurred significant losses since inception. We expect to incur losses for at least the next several years and may never achieve or maintain profitability for a full fiscal year, which, together with our limited operating history, makes it difficult to assess our future viability.
- We have never generated revenue from product sales and may never be profitable for a full fiscal year.
- We will require substantial additional financing to achieve our goals, 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, and our ability to continue as a going concern.
- We are early in our development efforts, and our business is dependent on the successful development of our current and future drug candidates. If we are unable to advance our current or future drug candidates through clinical trials, obtain marketing approval and ultimately commercialize any drug candidates we develop, or experience significant delays in doing so, our business will be materially harmed.
- Our current or future drug candidates may cause undesirable side effects or have other properties when used alone or in combination with other approved products or investigational new drugs that could delay or halt their clinical development, prevent their marketing approval, limit their commercial potential or result in significant negative consequences.
- We depend on collaborations with third parties for the development of certain of our potential drug candidates, and we may depend on additional collaborations in the future for the development and commercialization of these or other potential candidates. If our collaborations are not successful, we may not be able to capitalize on the market potential of these drug candidates.
- We intend to develop our current drug candidates, and expect to develop other future drug candidates, in combination with other therapies, which exposes us to additional risks.
- We face significant competition, and if our competitors develop and market products that are more effective, safer or less expensive than the drug candidates we develop, our commercial opportunities will be negatively impacted.
- If we and our collaborators are unable to obtain, maintain, protect and enforce sufficient patent and other intellectual property protection for our drug candidates and technology, our competitors could develop and commercialize products and technology similar or identical to ours, and we may not be able to compete effectively in our market or successfully commercialize any drug candidates we may develop.

- Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could negatively impact the success of our business.
- We have entered into licensing and collaboration agreements with third parties. If we fail to comply with our obligations in the agreements under which we license intellectual property rights to or from third parties, or these agreements are terminated, or we otherwise experience disruptions to our business relationships with our licensors or licensees, our competitive position, business, financial condition, results of operations and prospects could be harmed.
- We are highly dependent on our key personnel, and if we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

The summary risk factors described above should be read together with the text of the full risk factors below in the section entitled “Risk Factors” and the other information set forth in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes, as well as in other documents that we file with the SEC. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not precisely known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations, and future growth prospects.

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PART I

Item 1. Business.

Overview

We are a clinical-stage biotechnology company focused on developing novel therapeutics to address unmet medical needs in liver diseases and viral infections, including in the areas of chronic hepatitis B virus (HBV) infection, metabolic dysfunction-associated steatohepatitis (MASH), obesity, and coronavirus infections (e.g., SARS-CoV-2, SARS-CoV, MERS-CoV, and other related infections). The Aligos team has a demonstrated track record of success in drug development and medicinal chemistry in liver and viral diseases, resulting in three potential best-in-class drug candidates.

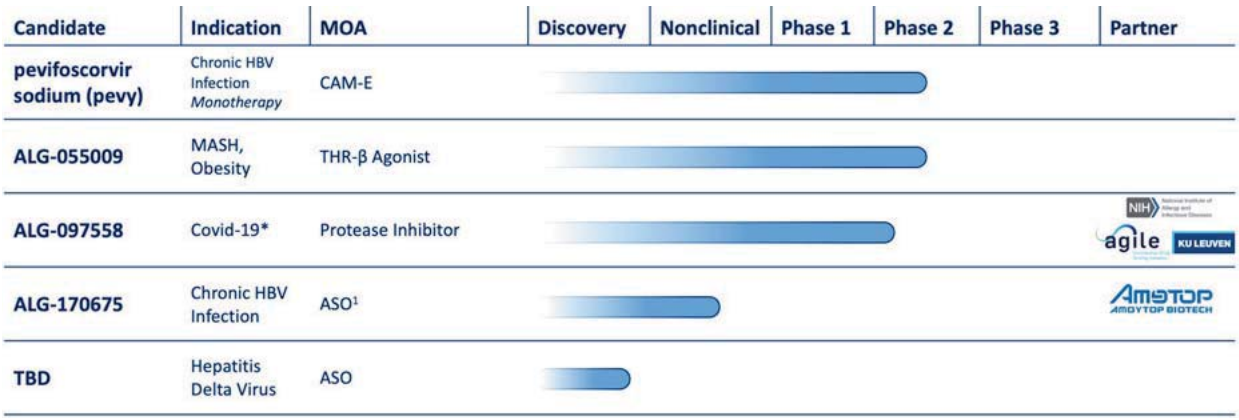
Our pipeline of drug candidates includes pevifoscorvir sodium (previously known as ALG-000184) for chronic HBV infection, ALG-055009 for MASH and obesity, ALG-097558 for coronavirus infections, and a portfolio of preclinical programs.

Pevifoscorvir sodium is our potential best-/first-in-class Capsid Assembly Modulator (CAM-E) for chronic HBV infection which has shown in preclinical testing to have enhanced pharmacologic properties vs. competitor CAM-E drugs and greater hepatitis B virus deoxyribonucleic acid (HBV DNA) suppression compared to the standard of care, nucleos(t)ide analogs (NAs), and has shown multi-$\log_{10}$ reductions in viral antigens in a multi-part Phase 1 clinical trial spanning up to 96 weeks of treatment. ALG-055009 is our potential best-in-class thyroid hormone receptor beta (THR-β) agonist for MASH and obesity with pharmacologic properties that appear to be enhanced based on data to date vs. competitor THR-β agonists. Phase 2a topline data demonstrated that ALG-055009 dose groups met the primary endpoint with statistically significant reductions in liver fat at Week 12 as measured by Magnetic Resonance Imaging Proton Density Fat Fraction (MRI-PDFF) in subjects with presumed MASH. Recently presented nonclinical data suggests synergistic fat mass loss in combination with incretin receptor agonists in diet induced obese (DIO) mice. ALG-097558 is our potential best-in-class small molecule coronavirus 3CL protease inhibitor (PI) which is at least 3-fold more potent in cell-based assays of coronavirus infection than other approved CoV PIs and we believe can be dosed twice daily without the requirement for ritonavir co-dosing based on Phase 1 clinical studies conducted to date.

Our Pipeline

We are focused on liver and viral diseases, areas in which our employees have expertise and decades of experience. In the area of chronic HBV infection, our most advanced drug candidate, pevifoscorvir sodium, is currently in the global Phase 2 B-Supreme study in subjects with chronic HBV infection. We believe pevifoscorvir sodium has the potential to replace standard of care NAs and become the backbone of next-generation treatments. We have advanced our THR-β agonist in MASH through a Phase 2a study in subjects with presumed MASH and in obesity through certain preclinical studies. We are evaluating a variety of options to fund continued development, including potential out-licensing. Our ritonavir-free pan-coronavirus protease inhibitor (PI) for the treatment of COVID-19 also appears to be favorably differentiated in a Phase 1 study and is currently in a Phase 2 clinical study in standard and high-risk COVID-19 patients.

Figure 1: Aligos Development Pipeline



*Our Covid-19 protease inhibitor programs are partly funded ($13.8M USD awarded) by the NIH and NIAID's AViDD Centers for Pathogens of Pandemic Concern program through the MAVDA consortium and our recently awarded NIAID Contract. HBV = hepatitis B virus; CAM-E = capsid assembly modulator (empty); Covid-19 = coronavirus disease of 2019 (SARS-CoV-2); MASH = metabolic dysfunction-associated steatohepatitis; THR-β = thyroid hormone receptor beta. ASO= antisense oligonucleotide. All timelines are approximate and subject to change based on enrollment and operational considerations. [1]Amoytop has rights in China, Taiwan, Hong Kong, and Macau. Pevifoscorvir sodium formerly known as ALG-000184.

Chronic HBV Infection

Chronic HBV infection is the most common viral infection in the world and an area of substantial unmet medical need. There are approximately 254 million chronic carriers worldwide with 1.2 million individuals becoming infected every year despite the availability of an efficacious prophylactic vaccine. In 2022, there were more than 90 million cases of chronic HBV infection in China alone, while the European Union (EU) and United States accounted for nearly 15 million cases. Complications from chronic HBV infection include cirrhosis, end-stage liver disease, and hepatocellular carcinoma (HCC), which collectively resulted in approximately 1.1 million deaths according to the World Health Organization (WHO) in 2019. Chronic HBV infection is the primary cause of liver cancer worldwide, and the mortality associated with HBV‑related liver cancer continues to increase. Liver cancer is the 6th most diagnosed form of cancer worldwide, but results in the 3rd most deaths of all cancers (Bray et. al. CA J Clin. 2024).

The primary treatment goals are to reduce HBV DNA to undetectable levels, normalize liver enzymes, prevent liver damage, and reduce the risk of developing HCC. The WHO 2024 guidelines currently recommend treatment in the presence of significant fibrosis, or HBV DNA >2,000 IU/mL and ALT>ULN, or the presence of special risk factors. Current therapy for chronic HBV infection may entail life-long treatment and does not eliminate the virus in a meaningful number of patients. In the case of NAs, long-term treatment can lower the amount of HBV DNA in systemic circulation, resulting in improvements in long-term disease outcomes, but virological relapse is common after treatment cessation. In addition, certain patients continue to progress to liver disease while on NA treatment.

Our goal for pevifoscorvir sodium is to achieve superior rates of viral suppression (as measured by HBV DNA). Chronic suppressive therapy is an established regulatory pathway for approval according to the FDA, the Committee for Medicinal Products for Human Use (CHMP: EU) and the National Medical Products Administration (NMPA: China). Based on the Phase 1 data to date, we believe pevifoscorvir sodium has the potential to replace standard of care NA treatment and become the backbone of next-generation treatments. Furthermore, when combined with other mechanisms of action, including other candidates in our chronic HBV infection portfolio, pevifoscorvir sodium dosing regimens have the potential to contribute to achieving higher rates of functional cure, subject to testing such endpoint, as compared with currently approved agents. In addition, we believe that pevifoscorvir sodium has the potential to treat chronic HBV infection patients that may not qualify for treatment with currently available therapies. This could include the possibility of lowering HBsAg, which may allow more patients to be eligible for curative therapies.

We are also exploring additional ways to potentially treat patients with chronic HBV infection, including our antisense oligonucleotide (ASO) platform which utilizes novel monomers that could potentially reduce ASO toxicity and improve ASO liver to kidney ratios. Along with our partner Xiamen Amoytop Biotech Co., Ltd. (Amoytop), ALG-170675 was recently selected to proceed into IND-enabling studies. Current costs for development in China are being funded by Amoytop, who maintain rights in China, Taiwan, Hong Kong and Macau. This next-generation

ASO works via two mechanisms of action. It targets and destroys HBsAg mRNA and activates the immune response through TLR-8 agonism.

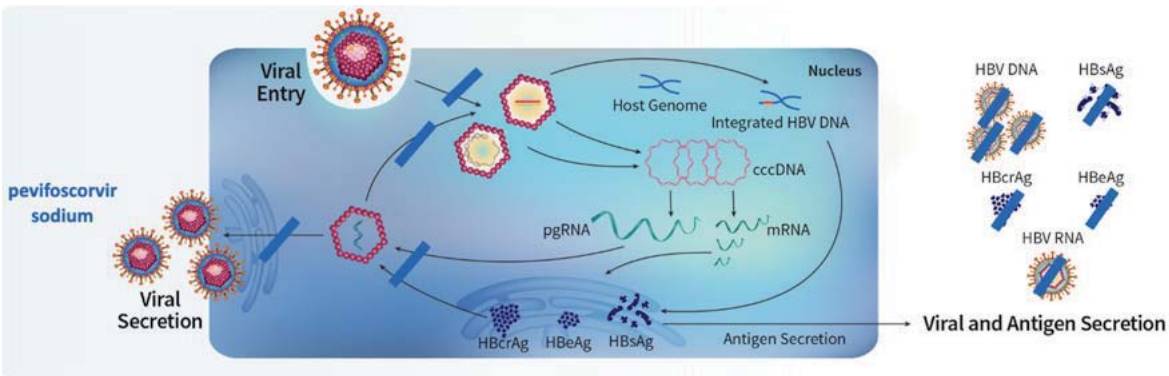
Additionally, we are pursuing a novel strategy for a potential cure for hepatitis delta virus (HDV) coinfection by utilizing a proprietary ASO approach targeting the destruction of the viral genome. Ongoing work is aimed at the selection of a clinical development candidate.

Pevifoscorvir sodium: Potential best-in-class small molecule CAM‑E for chronic hepatitis B virus infection

In 2018, we in‑licensed a lead drug candidate (GLP‑26) and the associated IP for a CAM‑E from the laboratory of Professor Raymond Schinazi at Emory University. Our scientists optimized this lead drug candidate to discover the highly potent CAM‑E, ALG‑001075, which was further optimized to the prodrug pevifoscorvir sodium. Based on preclinical data to date, pevifoscorvir sodium has superior DMPK properties with enhanced absorption and high liver uptake, with a ~200-to 300-fold improvement in in vitro potency compared to other known CAMs.

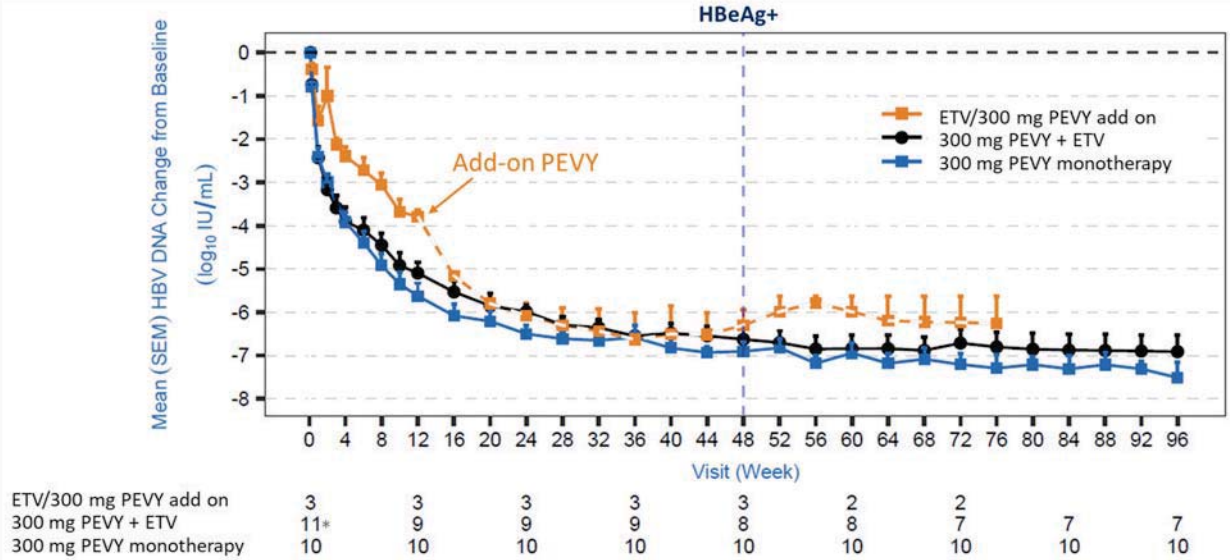
CAM‑Es are a class of small molecule antiviral agents that accelerate HBV capsid assembly and inhibit pgRNA encapsidation (1st MOA), resulting in empty viral capsids and lower circulating HBV DNA and RNA levels (Figure 2). CAM‑Es are also believed to prevent the establishment of cccDNA (2nd MOA), a major factor for the persistence of HBV infection which can be assessed by circulating HBV antigen levels (HBsAg, HBcrAg, and HBeAg). In clinical trials, competitor CAM‑Es have shown reductions in HBV DNA and RNA (1st MOA), but have rarely or inconsistently shown reductions in HBV antigens (2nd MOA). There have also been observations of the emergence of viral CAM-E drug resistance.

Figure 2 – Mechanism of Action: Pevifoscorvir sodium (CAM-E)



A multipart Phase 1 study is complete with the evaluation of the safety, tolerability, and pharmacokinetic profile of pevifoscorvir sodium in healthy volunteers (HVs). Additionally, a dose-ranging Phase 1 study assessing the safety, pharmacokinetics, and antiviral activity of 10-300 mg doses of pevifoscorvir sodium administered over 28 days in untreated HBeAg+/- subjects with chronic HBV infection has also been completed. Pevifoscorvir sodium was found to be well tolerated with a favorable PK profile and demonstrated substantial HBV DNA and RNA reductions at all doses tested as well as HBsAg reductions in a subset of HBeAg+ subjects receiving 100 mg and 300 mg of pevifoscorvir sodium (Hou et al., AASLD 2022).

Figure 3 – Antiviral Effect in Subjects (HBeAg+) with Chronic HBV Infection
Mean HBV DNA Change from Baseline



Based on the favorable profile after dosing up to 300 mg pevifoscorvir sodium for 28 days, additional cohorts have been completed, which evaluated the safety and efficacy of 300 mg oral daily doses of pevifoscorvir sodium, with or without entecavir (ETV) for ≤96 weeks in HBeAg+/- subjects. Data from these cohorts (Yuen et al., AASLD 2025) have been presented, showing that pevifoscorvir sodium (± ETV), administered for up to 96 weeks, was well tolerated, exhibited a favorable PK profile, and suggesting a potential for best-in-class antiviral activity. Specifically, antiviral activity data demonstrated that 300 mg pevifoscorvir sodium monotherapy resulted in profound reductions in HBV DNA which were greater than achieved with ETV alone (Figure 3). Furthermore, the extent of HBV DNA suppression was similar whether pevifoscorvir sodium was dosed alone or in combination with ETV, potentially indicating ETV did not meaningfully contribute to observed HBV DNA lowering effects. These data indicate robust antiviral effects occur through the CAM-E 1st MOA.

Also of note, pevifoscorvir sodium monotherapy was not associated with viral breakthrough as assessed by HBV DNA levels (Figure 3) and demonstrated a favorable tolerability profile in subjects dosed for up to 96 weeks with pevifoscorvir sodium monotherapy. Grade ≥3 TEAEs of ALT/AST elevation were observed in 3 HBeAg+ and 1 HBeAg- subjects with preserved synthetic and excretory functions. All events resolved in the setting of continued pevifoscorvir sodium dosing and were not considered clinically concerning by the ALT Flare Committee. Grade 3 cholesterol/triglycerides increase in HBeAg- subject resolved in the setting of continued pevifoscorvir sodium dosing.

The complete 96-week data from the Phase 1 monotherapy (NCT04536337) demonstrated that in all 10 HBeAg+ subjects with very high mean baseline HBV DNA level of 8.0 log10 IU/mL, a rapid, profound, and durable HBV DNA reduction was noted following daily oral dose of 300 mg pevifoscorvir sodium monotherapy. At Week 48, 6 of 10 subjects (60%) achieved HBV DNA < LLOQ (10 IU/mL, TD or TND). With treatment extension, this rate increased to 10 of 10 subjects (100%) at Week 96. Additionally, HBV DNA level declined below the undetectable level (< LLOQ (TND, ≤4.29 IU/mL)) in 5 of 10 (50%) subjects at Week 96.

In HBeAg- subjects receiving daily dose of 300 mg pevifoscorvir sodium monotherapy, all 11 (100%) had rapid decline in HBV DNA levels < LLOQ (TD or TND) by Week 24 with HBV DNA suppression maintained for up to 96 weeks of treatment; further decline in 8 of 9 (89%) subjects below the undetectable level of HBV DNA to < LLOQ (10 IU/mL, TND) was noted at Week 96.

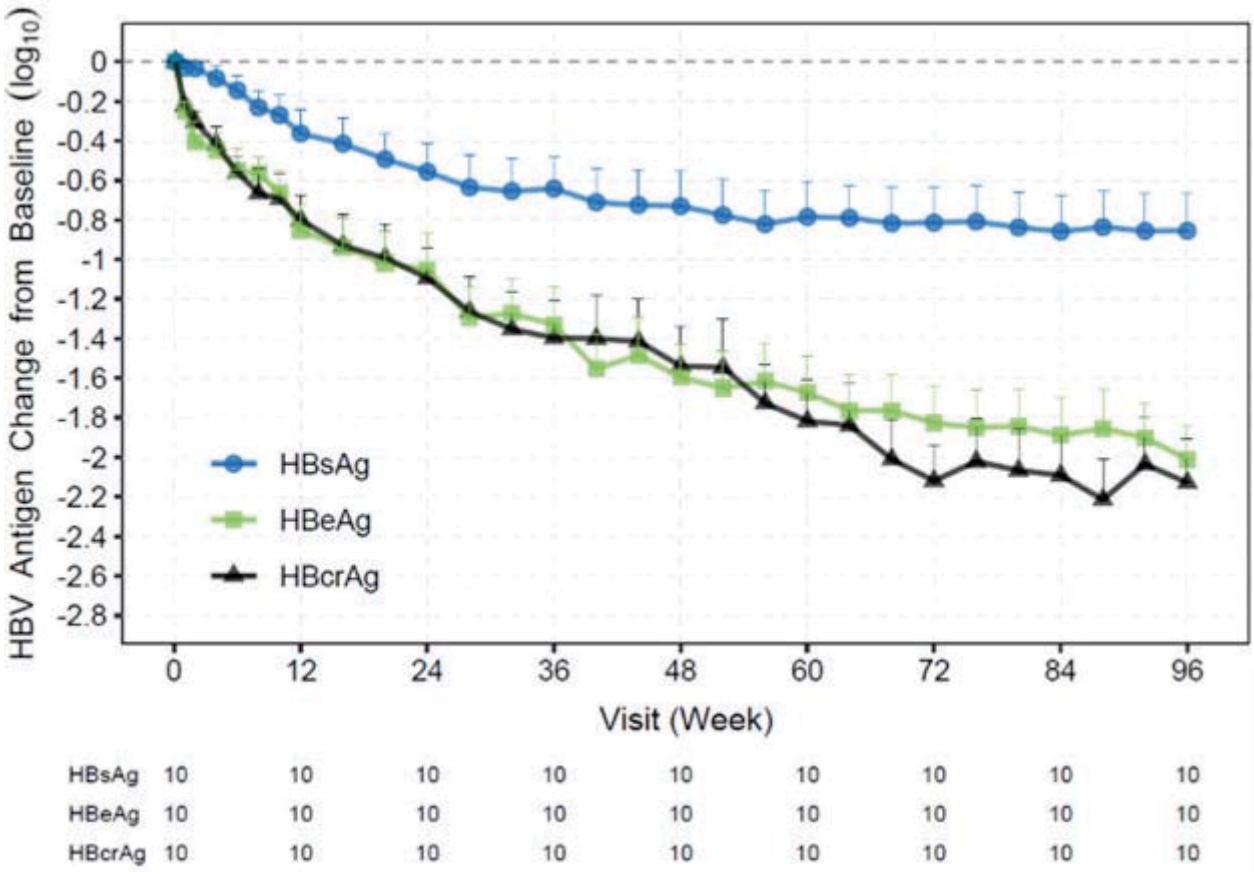
Furthermore, concurrent multi-log_{10} reductions in HBV antigens (HBsAg, HBeAg, and HBcrAg) in HBeAg+ subjects and HBcrAg decline in HBeAg- subjects were observed, suggesting the potential inhibition of cccDNA establishment by CAM-E secondary mechanism of action of pevifoscorvir sodium (Figure 4; Yuen et al., AASLD

2025). The disruption of the replication, integration, and cccDNA reservoir may also enhance the rates of functional cure.

Further, data presented at AASLD's The Liver Meeting® 2025 highlighted outcomes for treatment-naïve or currently not treated HBeAg+ and HBeAg- subjects who completed 96 weeks of 300 mg pevifoscorvir sodium monotherapy, followed by 8 weeks of nucleos(t)ide analog (NA) monotherapy. Reductions in HBV DNA, HBV antigens, and HBV RNA were largely maintained during the NA-only 8-week follow-up period. Notably, viral biomarkers such as HBV antigens and HBV RNA are typically unaffected by NA therapy, suggesting that pevifoscorvir sodium may reduce the cccDNA pool through engagement of its secondary mechanism of action (Yuen et al., AASLD 2025).

Additionally, preclinical in vitro data demonstrated that ALG-001075, the active parent moiety of pevifoscorvir sodium, can prevent cccDNA formation and HBV DNA integration. This finding is further supported by cell-based studies, which showed prevention of cccDNA establishment and HBV DNA integration following treatment with ALG-001075 (Verheyen, et. al. AASLD 2025).

Figure 4 – Antiviral Effect of 300mg Pevifoscorvir Sodium Monotherapy in Subjects (HBeAg+) with Chronic HBV Infection
Mean HBV Antigen Change from Baseline



With the completion of the 96 week Phase 1 study, we initiated the Phase 2 B-SUPREME study (NCT06963710), which is designed as a randomized, double-blind, active-controlled multicenter study evaluating the safety and efficacy of pevifoscorvir sodium monotherapy compared with tenofovir disoproxil fumarate for 48 weeks in approximately 200 currently untreated HBeAg+ and HBeAg- adult subjects with chronic HBV infection. The primary endpoint in the HBeAg+ arm is HBV DNA <LLOQ (10 IU/mL, TD or TND) and the primary endpoint in the HBeAg- arm is HBV DNA <LLOQ (10 IU/mL, TND). The study is also evaluating safety, PK, and other secondary and exploratory HBV biomarkers, including reductions in HBV antigens and other markers of HBV

infection.

The Phase 2 study has obtained regulatory approvals to move forward in every country included in the study and has reached the planned number of subjects enrolled in the HBeAg- cohort and is currently enrolling subjects in the HBeAg+ cohort.

The first interim analysis is expected to occur in the first half of 2026. The first protocol defined interim analysis includes approximately 60% (or 36) HBeAg- participants that complete 12 weeks of the treatment period. This enrollment milestone occurred in Q4 2025.

A second protocol defined interim analysis is planned when approximately 50% (or 55) HBeAg+ participants complete 24 weeks of the treatment period. This enrollment milestone occurred in January 2026. This interim analysis is expected to occur in the second half of 2026.

To preserve study integrity and comply with FDA regulatory requirements, we will remain blinded to subject-level data and will receive insights from the Data Safety Monitoring Board on protocol-specified assessments, including the potential for sample size re-estimation at each interim analysis.

Topline data for the Phase 2 B-SUPREME study are expected in 2027.

MASH, Obesity

According to the WHO, one in eight people worldwide are living with obesity as of 2022. Obesity is a complex disease caused by an overabundance of body fat that increases the risk of other comorbidities, such as MASH. The accumulation of fatty deposits in the liver, referred to as metabolic dysfunction-associated steatotic liver disease (MASLD), was estimated to occur in approximately 30% of the worldwide population as of 2019 (Younossi, et. al. Hep. 2023). An estimated 1.5% to 4.8% of the global population was estimated to have an ongoing inflammatory response to these excess fat deposits, which was previously referred to as NASH (non-alcoholic steatohepatitis), and is now called MASH (Fishman, et. al. Neph. Hep C. 2024). Over the past several years, the prevalence of MASH and obesity have continued to rise. In the absence of changes in diet and exercise, the inflammation inherent in MASH persists and may result in progressive fibrosis of the liver, which may result in cirrhosis. These fibrotic changes are associated with numerous morbidities including recurrent hospitalization for complications of cirrhosis, HCC, need for liver transplant, and death.

There are currently two approved drugs to treat MASH, a THR-β agonist, resmetirom, and an incretin receptor agonist, semaglutide.

ALG-055009: Potential best-in-class small molecule THR-β agonist for MASH and obesity

MASH

The thyroid hormone triiodothyronine (T3) has many physiological effects throughout the body, ranging from increasing metabolism, including fat metabolism, to stimulating growth and development. T3 exerts its effects by binding to the thyroid hormone receptor (THR), which has two subtypes: alpha (THR-α) and beta (THR-β). The distribution of the two THR subtypes varies by organ, with THR-β predominantly expressed in the liver and THR-α predominantly expressed in other tissues (e.g., heart, skeletal muscles and bone). Drugs like resmetirom, which preferentially binds the THR-β subtype, have been shown in clinical trials to lower lipid levels in serum and the liver, while avoiding the unwanted effects associated with THR-α stimulation. In addition to the intended effect of lowering liver lipid levels in MASH patients, lowering serum lipid levels via THR-β agonism may also have favorable cardiovascular consequences in this population, which has a high rate of underlying cardiovascular disease.

The most advanced THR-β agonist is resmetirom, which received FDA approval in MASH in March 2024 based on favorable Phase 3 data (Harrison et al., EASL 2023). This drug has demonstrated significant reductions in lipid levels in the liver and serum and, to date, has an acceptable risk-benefit profile. In addition, resmetirom has demonstrated histologic evidence of MASH resolution and fibrosis improvement in Phase 3, which are both FDA approvable MASH endpoints. Recently, resmetirom has presented data demonstrating improvements in subjects with cirrhosis. Our THR-β drug candidate ALG-055009 may have important advantages over this compound. Side-

by-side cell-based experiments in HEK293T cells indicate that ALG‑055009 is 50-fold more potent and 2-fold more selective for the β receptor compared to resmetirom.

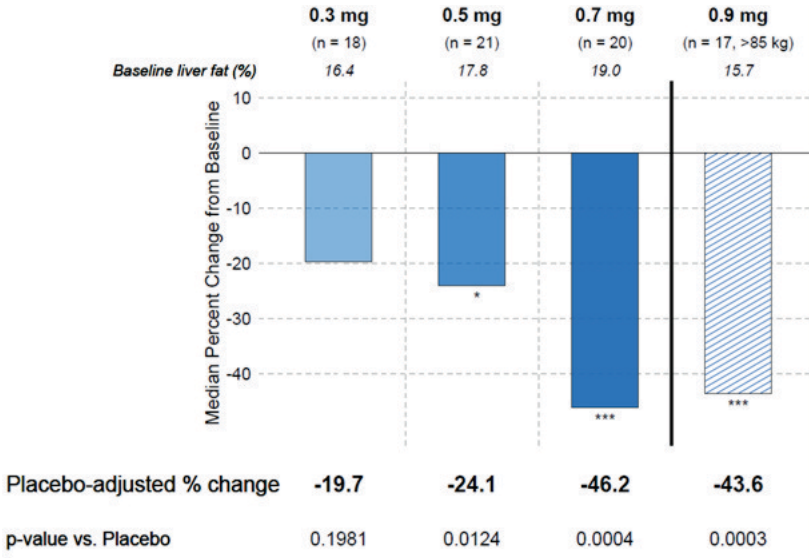
A Phase 1 first in human study of ALG‑055009 in HVs (oral single doses) and subjects with hyperlipidemia (14 oral daily doses) has been completed. Data after single doses up to 4 mg and multiple daily doses up to 1 mg have previously been reported at EASL 2022 and AASLD 2023, respectively. At these conferences, data were presented that showed ALG‑055009 was well tolerated, had dose proportional PK and low variability, and demonstrated expected thyromimetic effects (i.e., generally dose proportional increases in sex hormone binding globulin and decreases in various atherogenic lipids and thyroid hormones without any clinical evidence of thyroid dysfunction).

A second Phase 1 study evaluating whether there is the potential for a drug-drug interaction (DDI) between ALG-055009 and atorvastatin has also been completed, with data demonstrating no clinically meaningful safety concerns or evidence of a DDI with atorvastatin.

We completed a Phase 2a proof of concept study (HERALD) under an amendment to an open investigational new drug application (IND) in 2024 (NCT06342947). The study was designed as a 12‑week randomized, double‑blind, placebo‑controlled trial evaluating 4 doses of ALG‑055009 vs. placebo in 102 subjects with presumed liver fibrosis stage 1-3 (F1-F3) MASH. The primary endpoint of this study was percent relative change in liver fat content by MRI-PDFF at Week 12. This study also evaluated the safety and PK of ALG‑055009 treatment and its effect on multiple other efficacy biomarkers.

Twelve weeks of once daily oral dose of ALG‑055009 treatment in subjects with presumed MASH met the primary endpoint, with robust reductions in liver fat content at Week 12. Doses of 0.5 mg to 0.9 mg ALG‑055009 demonstrated statistically significant reductions in liver fat at Week 12, with placebo-adjusted median relative reductions up to 46.2% as measured by MRI-PDFF (Figure 5). Up to 70% of subjects achieved ≥30% relative reduction in liver fat compared to baseline, a positive prognostic indicator of histological improvements in MASH resolution and fibrosis reduction. Eighteen subjects who were on stable GLP-1 agonist therapy qualified for enrollment in the study, with liver fat content meeting the inclusion criteria of ≥10% at baseline as measured by MRI-PDFF. Notably, 11 out of 14 subjects on stable GLP-1 agonists treated with ALG‑055009 had liver fat decreases, whereas 4 out of 4 subjects on stable GLP-1 agonists treated with placebo had increases in liver fat over the 12-week dosing period (Figure 6).

Figure 5 – Placebo-Adjusted Median Relative Change in Liver Fat at Week 12

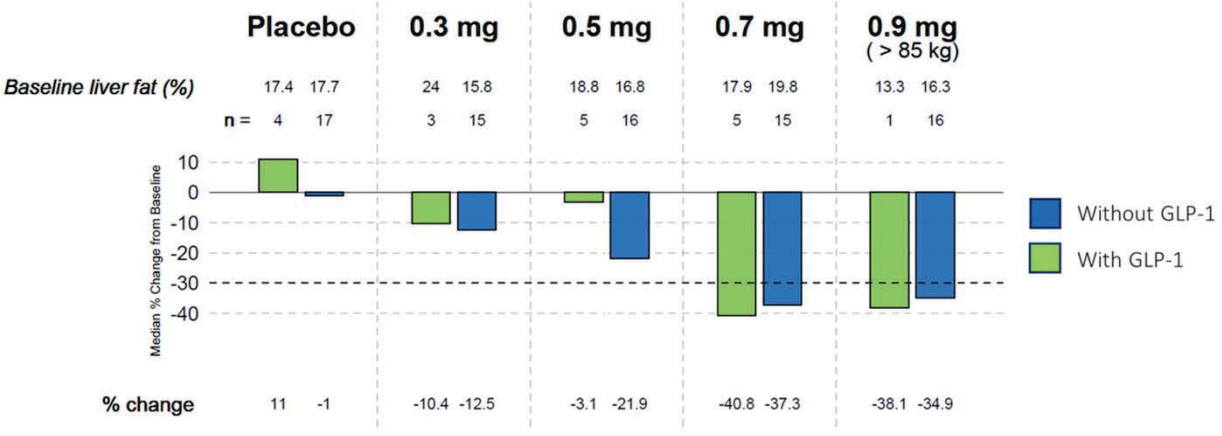


Note: Only subjects weighing >85kg were enrolled in the 0.9 mg dose group, no body weight restrictions were implemented in other dose groups. Data from MRI-PDFF analysis dataset, defined as all randomized subjects who have MRI-PDFF measurements available at both baseline and Week 12; median % change in placebo was +7.2%; *p<0.05 ***p<0.001.

Significant reductions in atherogenic lipids, including LDL-C, lipoprotein (a) and apolipoprotein B and dose-dependent increases in sex hormone binding globulin were observed. In particular, ALG-055009 demonstrated a dose-dependent reduction from baseline of up to 26.8% at Week 12 for lipoprotein (a), which is an established risk factor for cardiovascular disease that has been resistant to treatment with statin therapy. Treatment with ALG-055009 was well-tolerated, with no serious adverse events in subjects receiving ALG-055009. There was one discontinuation due to a treatment emergent adverse event (TEAE) of worsening insomnia in a subject with pre-existing insomnia. The majority of TEAEs were mild or moderate with no clinical hypo/hyperthyroidism. No clinically concerning laboratory, ECG, physical exam, or vital sign trends/findings were observed. Similar rates of diarrhea were noted for active dose groups compared to placebo, with no dose-response.

Figure 6 – Additional Fat Reduction in Subjects with Stable Use of GLP-1 Agonists

Median Relative Percent Change in Liver Fat at Week 12



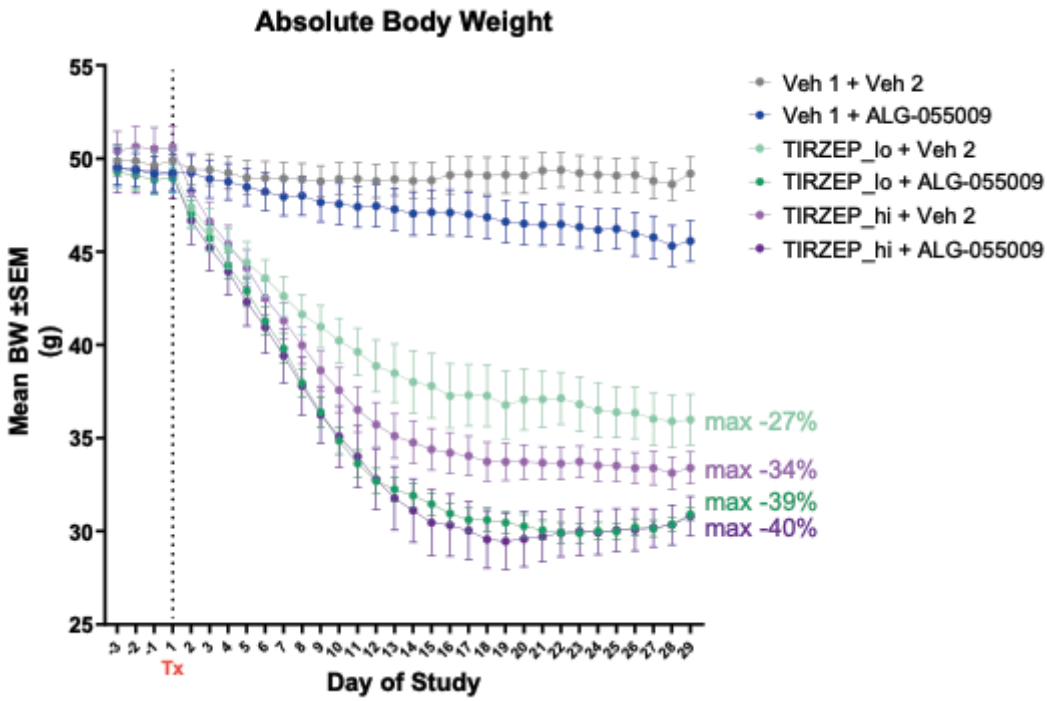
Note: Subjects on GLP-1 agonists (semaglutide (n=12), liraglutide (n=4) or dulaglutide(n=2)) at baseline were required to have stable use for ≥12 weeks prior to randomization; for derivation of duration of use, if a month and/or day for the start of GLP-1 agonist use was unknown, it was imputed as January and/or the 1st of the month, respectively. Bolded dashed line indicates 30% relative reduction in liver fat.

Obesity

Recently presented in vivo data in diet induced obese (DIO) mice treated with semaglutide (SEMA), tirzepatide (TIRZEP), or a combination of ALG-055009 and SEMA or TIRZEP for 28 days demonstrated synergistic weight loss in the combination groups compared to monotherapy groups. SEMA monotherapy resulted in a maximum of 23.9 ±2.6% body weight loss, while the combination of SEMA and ALG-055009 had an additional 8.6% decrease for a maximum 33% body weight loss. The low and high doses of TIRZEP led to maximum of 27.1 ±2.7% and 34.4 ±1.6% body weight loss, respectively. Combination of TIRZEP (low) or TIRZEP (high) with ALG-055009 induced an additional 11.7% and 5.8% decrease for a maximum of 39% and 40% body weight loss, respectively (Figure 7).

Furthermore, the additional weight loss in the combination therapy of either incretin receptor agonist and ALG-055009 was mainly due to additional loss of fat mass, with no significant effect on lean mass or food consumption as compared to incretin receptor agonist monotherapy. These preclinical data suggest a potentially significant benefit of adding ALG-055009 to an incretin receptor agonist therapy for weight loss, especially in combination with a low-dose of a potent molecule, such as tirzepatide.

Figure 7 – ALG-055009 + Tirzepatide: Combination Therapy Enhances Body Weight Loss in Diet-Induced Obese (DIO) Mice



Based on its favorable potency/selectivity and PK, we believe ALG‑055009 has the potential to become a best-in-class THR‑β agonist and could play an integral role in future combination regimens for MASH and obesity. We are currently evaluating a variety of options to fund continued development including potential out-licensing.

Coronavirus

SARS-CoV-2 is responsible for the COVID-19 pandemic, which has infected more than 760 million individuals and is responsible for the death of more than 7 million individuals worldwide (WHO – 14 January 2025), including approximately 1.2 million in the US. After Middle East Respiratory Syndrome (MERS) and SARS (SARS‑CoV‑1), SARS‑CoV‑2 is the third known coronavirus to cross over from animal species to humans and cause significant morbidity and mortality in the past 20 years. Due to the COVID-19 pandemic and the risk of additional novel coronaviruses emerging in the future, there is a need to develop novel therapeutics with

pan-coronavirus activity that have a high barrier to resistance. Two orally available therapeutics have been authorized for the outpatient treatment of COVID-19, but both have important limitations related to sub-optimal efficacy (molnupiravir, a nucleoside analog; Merck) or the need for ritonavir boosting (PF-07321332/nirmatrelvir, a viral protease inhibitor; Pfizer). Our drug candidate, ALG-097558, has shown in preclinical studies to be 3-fold more potent in cell-based assays than nirmatrelvir against a panel of SARS-CoV-2 variants (including Omicron), has broad pan-coronavirus activity, and does not require ritonavir boosting based on preclinical studies.

ALG-097558: Potential best-in-class small molecule ritonavir-free pan-coronavirus protease inhibitor

In 2024 we completed evaluation of the safety and pharmacokinetics of ALG-097558 after single and multiple (twice daily dosing x 7 days) doses in HVs. In this first-in-human Phase 1 clinical study, single doses up to 2000 mg and multiple doses up to 800 mg Q12H for 7 days were well tolerated with an acceptable PK profile that indicated (1) ritonavir boosting is not required and (2) the absence of a clinically relevant DDI with midazolam, suggesting ALG-097558 may be shown to be appropriate for co-administration with CYP3A4 substrates. Based on these Phase 1 data (Wilkes et al, RespiDart, 2024), the projected efficacious dose range to treat SARS-CoV-2 is 200-600 mg ALG-097558 Q12H x 5 days.

AGILE University of Liverpool, a UK government supported platform trial (MRC and Wellcome Trust funding), is sponsoring and performing a Phase 2 study in standard and high-risk COVID-19 patients evaluating ALG-097558 as monotherapy or in combination with remdesivir (NCT04746183).

Preclinical activities for our coronavirus program were partially funded through a grant from the National Institutes of Health (NIH) and the National Institute of Allergy and Infectious Diseases (NIAID) Antiviral Drug Discovery (AViDD) Centers for Pathogens of Pandemic Concern program through the Metropolitan AntiViral Drug Accelerator (MAVDA) consortium. Specific clinical and nonclinical studies for the ALG-097558 program and the follow up compound are now also being funded with federal funds from the NIAID, NIH, Department of Health and Human Services, under Contract No. 75N93023C00052. We submitted an IND in the third quarter of 2024 and clinical studies in special populations were initiated in the second half of 2024 as part of this NIAID contract. We expect to receive approximately $15.3 million in funds across these two NIH awards and contracts to support these activities. We are also seeking additional external funding (e.g., from governmental agencies) to support future studies as we advance ALG-097558 for the treatment of COVID-19 and future coronavirus pandemics.

Early-stage discovery efforts

In addition to our development stage drug candidates, we are targeting additional novel liver and viral targets with our drug discovery platform, including our antisense oligonucleotide programs for chronic HBV infection and hepatitis delta infection. We are also pursuing backup candidates in order to create a robust portfolio of assets which we can draw upon to create an optimized regimen for treatment in all of our disease areas of interest.

Management

Our management team consists of a group of highly collaborative executives with decades of drug discovery and development experience and a proven track record of success in the areas of viral infections and liver diseases. Members of our management team have worked together across multiple companies, many for over a decade, and have been collectively involved in the discovery and/or development of a number of drugs that have been successfully commercialized, including Ganovo, Sovaldi, Infergen, Neupogen, Andexxa, Esbriet, Pegasys and Incivo among others. In support of our management team, we also have assembled an industry-leading board of directors and a world-class group of scientific advisors with significant experience in drug development for liver diseases and viral infections.

Our team’s collective experience and success in discovering and developing drugs targeting liver and viral diseases, combined with our in-house expertise in drug discovery, gives us a differentiated set of capabilities, which has enabled us to rapidly establish a robust pipeline consisting of multiple novel drug candidates.

Our Strategy

Our strategy is to develop pharmacologically optimized drug candidates designed to achieve improved treatment outcomes. Our areas of focus are liver and viral diseases, where our team is leveraging their in-depth knowledge and expertise to develop potential regimens addressing large areas of unmet medical need. The core elements of our business strategy include:

- ***Maximizing the value of our drug candidates.*** We currently hold worldwide development and commercialization rights, including through exclusive licenses, to all our clinical drug candidates. We intend to pursue independent development and commercialization in select indications and markets that we can address with a specialty sales and marketing organization. We may opportunistically explore additional licensing agreements, collaborations or partnerships to develop our drug candidates in larger market indications where we could accelerate development utilizing the resources of larger biopharmaceutical companies, or to commercialize them in specific geographies.
- ***Expanding our development capabilities and pipeline.*** We utilize our in-house discovery expertise to evaluate novel mechanisms of action with the potential to complement our current pipeline and work to continually improve upon our existing drug candidates. To further supplement our internal discovery and development efforts, we actively evaluate external technology platforms and assets for future development candidates for liver and viral diseases. To date, we have secured licenses for technology, including from Emory and KU Leuven.

Our Approach to Research and Development

Our small molecule and oligonucleotide platforms are designed to allow us to discover drug candidates that can be used to develop potentially best-in-class regimens. We believe we have a differentiated set of in-house capabilities to use in developing novel, optimized combination regimens across all of our current areas of focus.

Our team has extensive end-to-end drug discovery and development experience across multiple therapeutic areas and disciplines. Our clinical development strategy leverages past experiences to rapidly advance drug candidates towards optimized regimens. We have strengthened our platforms by in-licensing select intellectual property, which, together with our in-house expertise, allows us to develop novel and proprietary drug candidates.

Small molecule platform

Our team has the capability and experience to rapidly identify and optimize small molecules, including traditional small molecules, peptidomimetics and prodrugs. Our team has a strong track record of developing and commercializing small molecule drug candidates. We use state-of-the-art computational chemistry and crystallography to enable structure-guided drug design. We have applied this approach to the multidimensional optimization of potential drug candidates in multiple therapeutic areas, including for liver diseases and viral infections.

Traditional small molecules

To date, traditional small molecules represent the vast majority of approved drugs and are the primary chemistry approach used for drug discovery.

CAM-Es are small molecules that have been shown to significantly reduce HBV DNA and RNA levels in subjects with chronic HBV infection. We have identified ALG-001075, which has demonstrated potentially best-in-class in vitro potency. The prodrug of ALG-001075, pevifoscorvir sodium, has been evaluated as single and multiple doses in HVs and subjects with chronic HBV infection and been found to be well tolerated, with favorable PK, and substantial antiviral activity in subjects up to 96 weeks. Pevifoscorvir sodium is currently being evaluated in the Phase 2 B-Supreme study.

THR-β agonists are small molecules that have been shown to significantly reduce circulating lipid levels and improve liver histology in patients with MASH. Based on publicly available and/or internally collected in vitro data for THR-β agonists currently in clinical development, our drug candidate ALG-055009 has demonstrated the greatest beta selectivity and highest potency for the THR-β receptor to date. ALG-055009 also demonstrated dose proportional pharmacokinetics with low variability and expected thyromimetic effects in a completed Phase 1 study evaluating dosing for up to 14 days. ALG-055009 completed a Phase 2a study in 2024, which met the primary

endpoint with statistically significant reductions in liver fat at Week 12 as measured by MRI-PDFF in subjects with presumed MASH.

Small molecule prodrugs

A prodrug is a compound that, after administration, is metabolized into the pharmacologically active parent drug. We use small molecule prodrug chemistry to optimize the drug-like properties of drug candidates to improve their solubility and pharmacokinetics. We have applied this approach to ALG-001075 to create pevifoscorvir sodium, our lead CAM-E drug candidate, which is currently being evaluated in the clinic for the treatment of chronic HBV infection.

We are engaged in multiple other small molecule discovery efforts to identify additional potentially best-in-class drug candidates for the treatment of liver and viral diseases.

Peptidomimetics

Peptidomimetics are small molecules derived from short polypeptides that can be used as drug candidates against multiple targets. The peptidomimetic approach has been successfully used in the antiviral field to develop protease inhibitor drugs against Hepatitis C virus (HCV) and human immunodeficiency virus (HIV). Working in collaboration with KU Leuven, CISTIM, and the CD3, our team has discovered multiple potent potential drug candidates targeting the 3C-like protease of coronaviruses, which have shown pan-coronavirus activity and do not require ritonavir boosting based on nonclinical studies. ALG-097558 is our lead protease inhibitor (PI) and has shown in clinical studies to be 3-fold more potent than nirmatrelvir and other PIs in clinical development in cell-based assays against a panel of SARS-CoV-2 variants (including Omicron). It also demonstrates broad pan-coronavirus activity, and based on clinical data to date, appears to not require ritonavir boosting. The safety and PK properties of ALG-097558 were assessed in a Phase 1 study in HVs. Single doses up to 2000 mg and multiple doses up to 800 mg Q12H for 7 days were well tolerated with an acceptable PK profile that indicated (1) ritonavir boosting is not required and (2) the absence of a clinically relevant DDI with midazolam, suggesting ALG-097558 may be shown to be appropriate for co-administration with CYP3A4 substrates. ALG-097558 is currently being evaluated in a clinical study of standard and high-risk COVID-19 patients.

Oligonucleotide platform

We have distinct modalities within our oligonucleotide platform, including siRNAs. We have advanced multiple oligonucleotide drug candidates and are currently developing antisense oligonucleotides (ASOs) for the treatment of both chronic HBV infection and hepatitis delta infection.

We have exclusively licensed proprietary technologies that enhance our oligonucleotide platform. These technologies include third generation bridged nucleic acid (BNA) and N-acetylgalactosamine (GalNAc) chemistries, which can improve liver targeting, increase potency, and enhance pharmacokinetic properties.

Sales and marketing

All of our assets are currently pre-commercial, and as such we have not yet established a sales and marketing organization (other than at the senior management level) or distribution capabilities. We intend to pursue independent development and commercialization in select indications and markets, and plan to build a commercial infrastructure to support a specialty sales and marketing organization, as well as distribution capabilities. Similar to our research, clinical and manufacturing operations, we expect to manage sales, marketing and distribution through dedicated staff and third-party contractors and consultants. We may opportunistically explore licensing agreements, collaborations or partnerships with one or more pharmaceutical companies to enhance our commercial capabilities.

Manufacturing

We are currently developing drug candidates in two primary modalities: small molecules and oligonucleotides. We have internal small molecule and oligonucleotide chemistry teams that are able to produce drug candidates at sufficient scale to support discovery activities. In addition, we have a dedicated internal chemistry, manufacturing and control (CMC) team that works with contract development and manufacturing organizations (CDMOs) to produce drug candidates in larger quantities, including to support nonclinical and clinical studies. We have built the teams and infrastructure needed to conduct and manage process development, analytical development, quality, manufacturing and supply chain activities.

Small molecule manufacturing

Small molecule manufacturing is a mature industry and is well supported by an extensive network of contract manufacturers. Our internal CMC team works collaboratively with such contract manufacturers on the pharmaceutical development process research and development, and manufacturing optimization of our drug candidates.

Oligonucleotides manufacturing

Oligonucleotide manufacturing technology has matured significantly over the last several decades, with advanced oligonucleotide synthesizers commercially available to support smaller-scale synthesis, and a network of oligonucleotide contract manufacturers available to support larger-scale syntheses. Our internal CMC team supports our contract manufacturers with process development and optimization, or, where needed, we may collaborate with external consultants and contractors to optimize synthesis and scale-up.

Competition

The life sciences industry is highly competitive and subject to rapid and significant technological change. Our competitors include multinational pharmaceutical companies, established biotechnology companies, universities and other research institutions. Many of our competitors have significantly greater financial, technical, human and other resources than we do and may be better equipped to develop, manufacture and market technologically superior products. In addition, many of these competitors may have significantly greater experience than we have in undertaking nonclinical studies and human clinical trials of new pharmaceutical drug candidates and in obtaining regulatory approvals of human therapeutic candidates. Accordingly, our competitors may develop superior drug candidates and may succeed in obtaining FDA approval for such candidates. Many of our competitors have established distribution channels for the commercialization of their products, whereas we have no such channel or capabilities. In addition, many competitors have greater name recognition and more extensive collaborative relationships.

Any drug candidates that we successfully develop and commercialize may compete with existing therapies and/or new therapies that may become available in the future. Our competitors may obtain regulatory approval of their candidates more rapidly than we do or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our drug candidates or any future drug candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or that have a better safety profile than our drugs (if approved) and these competitors may also be more successful than we are in manufacturing and marketing their products. If we are unable to compete effectively against our competitors, we may not be able to commercialize our drug candidates or any future drug candidates or achieve a competitive position in the market. This would adversely affect our ability to generate revenue. It is likely that our competitors, either working alone or in collaboration with others, will have significantly greater financial resources, an established presence in target markets, expertise in research and development, manufacturing, nonclinical and clinical testing, and experience obtaining regulatory approvals and reimbursement and marketing approved products than we do. We are also in competition for the limited qualified scientific, sales, marketing and management personnel, space at clinical trial sites, for patient registration for clinical trials and technologies complementary to, or necessary for, our programs. New competitors may emerge, smaller or early-stage companies may grow, either on their own or through collaborative arrangements with large and established companies and competitors may concentrate through mergers and acquisitions.

Chronic HBV infection competitors

Current FDA-approved treatments for chronic HBV infection include peg-IFNα, marketed by Roche Holding AG (Roche), and oral antiviral agents such as nucleos(t)ide analogs, marketed by Gilead Sciences, Inc. (Gilead) and Bristol-Myers Squibb Company. These treatments have not been proven to lead to either a functional or a complete cure in the vast majority of patients, and in the case of nucleos(t)ide analogs, may require life-long treatment. Several large and small pharmaceutical companies are developing programs with various mechanisms of action, to be used alone or in combination, with the goal of achieving higher rates of viral suppression or functional cure in patients with chronic HBV infection. Companies with oligonucleotide agents in clinical development include Arbutus Biopharma Corporation, Ionis Pharmaceuticals, Inc. (together with GlaxoSmithKline plc (GSK)), Arrowhead Pharmaceuticals, Inc. (together with Janssen Pharmaceuticals, Inc. (Janssen)), and Precision BioSciences, Inc. Several companies are developing CAM-Es, including Assembly Biosciences Inc. Several companies, including Janssen, are developing therapeutic vaccines for HBV, and several others have approved HBV

vaccines, including Dynavax Technologies, Inc., GSK, Johnson & Johnson, and Merck. Replicor, Inc. is developing nucleic acid polymers (NAPs) for use in patients with chronic HBV infection.

MASH and obesity competitors

There are currently two FDA-approved treatments for MASH: Madrigal Pharmaceuticals, Inc.'s THR-β agonist and Novo Nordisk's GLP-1 receptor agonist semaglutide. A number of pharmaceutical companies, including AbbVie, Inc., AstraZeneca PLC/MedImmune LLC, Bristol‑Myers Squibb Company, Eli Lilly and Company, Merck, Pfizer, Inc., Novo Nordisk, Roche, as well as large and small biotechnology companies such as Gilead and Inventiva Pharma SA, are pursuing the development or marketing of pharmaceuticals that target MASH.

Current FDA approved treatments for obesity include injectable and oral GLP-1 receptor agonists, such as Novo Nordisk’s semaglutide, as well as injectable dual agonists such as Eli Lilly and Company’s tirzepatide. Many companies are developing next-generation incretin receptor agonists, including in oral form, such as Eli Lilly and Company’s orfoglipron. Various other mechanisms are currently under development, including Pfizer’s amylin analog and Novo Nordisk’s CB1 receptor monlunabant.

It is also probable that the number of companies seeking to develop products and therapies for the treatment of obesity as well as serious metabolic diseases, such as MASH, will increase.

Coronaviruses competitors

In addition to remdesivir, which is FDA-approved, Pfizer, Inc. has received approval from the FDA for Paxlovid, an orally administered SARS-CoV-2 protease inhibitor co‑administered with ritonavir. Similarly, Merck (together with Ridgeback Bio), is developing the drug molnupiravir, an oral antiviral drug which was issued an emergency use authorization by the FDA on December 23, 2021.

License agreements and collaborations

License agreement with Emory University

In June 2018, we entered into a license agreement with Emory (the Emory License Agreement), pursuant to which Emory granted us a worldwide, sublicensable license under certain of its intellectual property rights to make, have made, develop, use, offer to sell, sell, import and export products containing certain compounds relating to Emory’s hepatitis B virus capsid assembly modulator technology, for all therapeutic and prophylactic uses. Such license is initially exclusive with respect to specified licensed patents owned by Emory and non-exclusive with respect to certain of Emory’s specified know-how. In June 2022, the license to such patents became non-exclusive with respect to all fields except for the treatment and prevention of HBV; however, we may select up to six compounds which will maintain exclusivity with respect to all therapeutic and prophylactic uses. With respect to all other compounds that are enabled by the licensed patents, those which are jointly invented by us and Emory or inventors in the Schinazi laboratory, or which are disclosed in a specified licensed patent, are licensed to us exclusively including as to Emory; whereas all other such compounds are licensed to us non-exclusively. Under the terms of the Emory License Agreement, we are obligated to use commercially reasonable efforts to bring licensed products to market in accordance with a mutually agreed upon development plan. Unless terminated earlier by either party in accordance with the provisions thereof, the Emory License Agreement shall continue until the expiration of the last–to-expire of the patents licensed to us thereunder.

Emory reserves the right for itself to practice, and have practiced by other entities solely for purposes of collaborative research with Emory, under the licensed patents for educational purposes, Emory's internal purposes, and for non-commercial research, patient care and treatment. Emory can further grant licenses to not-for-profit and governmental institutions for their internal non-commercial research and scholarly use.

Ownership of any new inventions arising out of our activities under the Emory License Agreement follows the inventorship laws of the United States. With respect to the licensed patents owned by Emory, we are required to prepare documents and filings for the prosecution and maintenance of such licensed patents, while Emory retains the option to provide final edits and approval of such documents and is responsible for the actual filing of such documents. We are responsible for the cost of the prosecution and maintenance of the licensed patents, and we have the first right, but not the obligation, to enforce such patents. We are solely responsible for the costs of any lawsuits we elect to initiate to enforce the licensed patents and cannot enter into a settlement in respect of such lawsuits without the prior written consent of Emory. Any sums recovered in such lawsuits will be shared equally between us and Emory after reimbursement of our costs for such litigation, except that for any award based on lost profits, Emory shall recover the greater of fifty percent of the award or the royalty Emory would have received had the infringing sales been made by us.

The technology claimed by the licensed patents under the Emory License Agreement may have been developed using U.S. government funding and the licenses therefore may be subject to a non-exclusive license held by the U.S. government, certain requirements that licensed products be manufactured substantially in the United States and U.S. government march-in rights. For more information on risks related to technology developed using government funding see the section titled "Risk Factors—Risks related to intellectual property."

In June 2020, we amended the license agreement with Emory. Pursuant to the amended license agreement, Emory granted us additional patent rights to certain compounds targeting the treatment or prevention of HBV. As consideration for the additional rights, we made a one-time, non-refundable payment to Emory in the amount of $0.2 million, with an additional obligation to pay up to a maximum of $35,000. On the same date, we entered into a collaboration agreement with Emory, with the initial research plan pertaining to the synthesis and evaluation of the compounds licensed through the additional patent rights granted in the amended license agreement. The research plan was set to terminate one year from the effective date of June 2020 but we exercised our option to extend it for a second year. In June 2022, the research plan terminated. In connection with the research plan, we provided Emory funding up to $0.3 million per year.

We have agreed to pay Emory up to an aggregate of $125.0 million upon the achievement of specified development, regulatory, and commercial milestones, and all ongoing patent costs. During the year ended December 31, 2025, we paid $9.0 million related to milestone payments due to the first subject dosed in a Phase 2 clinical trial. No milestone payments were made in the year ended December 31, 2024. We also agreed to pay Emory tiered single-digit royalties on worldwide annual net sales of licensed products, on a quarterly basis and calculated on a product-by-product basis. With respect to licensed products containing any of a specified subset of the licensed compounds, such royalties range from a mid-single digit to a high-single digit percentage rate. With respect to licensed products which do not contain such compounds, the royalties span a range of percentage rates within the mid-single digits if a Phase 1 clinical trial is initiated for the product within three years of the effective date of the Emory License Agreement, and range from a low-single digit to a mid-single digit rate if a Phase 1 clinical trial is initiated more than three years after the effective date.

The Emory License Agreement will expire upon expiration of the last-to-expire patent licensed to us thereunder. We may terminate the Emory License Agreement at any time in its entirety or with respect to specific patents for convenience by providing Emory with 90 days' written notice and are required to terminate the Emory License Agreement if we make a final decision to cease research, development or commercialization of any licensed products. Either party may terminate the Emory License Agreement if the other party materially breaches such agreement and fails to timely cure such breach. Emory may terminate the Emory License Agreement if we fail to reach a milestone at an agreed date and fail to timely provide commercially reasonable evidence of a reasonable, good-faith business or technical justification for such failure. Upon termination of the Emory License Agreement for our material breach, we will, upon Emory's request, grant to Emory a non-exclusive, royalty-free license to all of our rights in patents owned by, licensed or controlled by us to the extent they relate to our exercise of the licensed rights under the Emory License Agreement and include claims covering the manufacture, use or sale of any licensed products containing the licensed compounds. The Emory License Agreement will automatically terminate if we become bankrupt or insolvent or if we challenge the validity or enforceability of any patent licensed to us under the Emory License Agreement.

We have agreed to indemnify Emory and certain others under the Emory License Agreement for losses they may suffer arising out of the rights licensed thereunder or the manufacturing, testing, design, use, sale or labeling of any product containing a licensed compound, unless caused by such potential indemnitee's negligence.

Agreement with Katholieke Universiteit Leuven (KU Leuven)

On June 25, 2020, we entered into a Research, Licensing and Commercialization Agreement (KU Leuven Agreement) with KU Leuven, under which we are collaborating with KU Leuven's Rega Institute for Medical Research, as well as its CD3, to research and develop potential protease inhibitors for the treatment, diagnosis or prevention of coronaviruses, including of SARS-CoV-2. Unless terminated earlier by either party in accordance with provisions in the agreement, the collaboration period will terminate at the earlier of completion of all collaboration activities or 2.5 years. In connection with the KU Leuven Agreement, we and KU Leuven granted each other exclusive cross-licenses to use certain know-how and existing patents of the other party as well as certain joint know-how and joint patents to carry out research and development collaboration activities during the collaboration period. As of December 2022, the original collaboration period has expired. An amendment to the agreement was agreed in July 2023 to include a new collaboration plan. KU Leuven granted to us an exclusive (including as to KU Leuven), worldwide license under certain of KU Leuven's know-how, and certain joint patents and joint know-how, to manufacture and commercialize the licensed products for the treatment, diagnosis or detection of viral infections in humans. KU Leuven reserved the right to use all KU Leuven knowhow, joint patents and joint know-how for academic and non-commercial research and teaching purposes. As consideration for this license, we are obligated to make payments to KU Leuven, in aggregate, totaling up to but no more than $30.0 million upon the achievement of certain commercial sales milestones. For each licensed product developed through KU Leuven and our collaborative effort, we are obligated to make payments to KU Leuven, in aggregate, totaling up to $32.0 million upon the achievement of certain development and regulatory milestones. We are also required to pay KU Leuven a low-to-mid-single digit royalty percentage, subject to certain adjustments, on net sales of applicable products, if any. We are also required to pay a share of upfront transaction consideration received to KU Leuven should the program be partnered with an external party. Unless terminated earlier by either party, the agreement shall continue until the expiration of the last to expire royalty term, which is the later of the expiration or termination of the last valid patent claim covering the manufacture, use, sale or importation of the licensed product in a particular country or 10 years after the first commercial sale of a licensed product.

Intellectual property

One key to our success is our ability to establish and maintain protection for our drug candidates, platform technology and know-how, in order to enforce and defend our intellectual property rights. To protect our drug candidates and technologies, we file U.S., Patent Cooperation Treaty (PCT) and foreign patent applications related to our inventions, improvements, methods of use, manufacturing and analytical processes and technology. We also rely on our know-how, confidential methodologies and processes and continuing technological innovation as well as our active third-party intellectual property in-licensing program to develop and maintain our proprietary positions, in addition to trademarks, copyrights and trade secret laws, and employee disclosure and invention assignment agreements. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees, advisors and consultants, these agreements may be breached, and we may not have adequate remedies for any breach. In addition, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. As a result, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived of by the individual during the course of employment, and which relate to or are reasonably capable or being used in our current or planned business or research and development, are our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. However, such agreements and policies may be breached, and we may not have adequate remedies for such breaches. For more information regarding the risks related to our intellectual property, see the section titled "Risk Factors—Risks related to intellectual property."

We have licensed patents and patent applications from various entities, including Emory and KU Leuven, which are further described below. Regarding our owned patent portfolio, as of December 31, 2025, we own 34

issued U.S. patents, 26 U.S. non-provisional patent applications, 9 U.S. provisional patent applications (excluding any non-expired U.S. provisional applications to which priority has already been claimed), 9 PCT applications, 34 issued foreign patents and 177 foreign patent applications, including pending applications in the Arab Emirates, ARIPO, Argentina, Australia, Brazil, Canada, Chile, China, Colombia, Eurasia, Egypt, the EU, Georgia, Indonesia, Israel, India, Japan, South Korea, Malaysia, Mexico, New Zealand, OAPI, Peru, Philippines, Russian Federation, Singapore, Thailand, Taiwan, Ukraine, Uzbekistan and South Africa. The expected expiration dates of our issued patents are between 2040 and 2043, and any patents that issue from our non-provisional U.S. and foreign patent applications are expected to expire between 2040 to 2045, excluding any potentially available patent term extensions and/or patent term adjustments.

For our drug candidates, we have filed and licensed certain patent applications and we generally intend to pursue patent protection covering compositions of matter, methods of making, form and formulation, and methods of use of such drug candidates. As of December 31, 2025, we own 6 U.S. patents with claims directed to either pevifoscorvir sodium, ALG‑055009 and ALG‑097558.

Licensed intellectual property

Emory University

We have licensed exclusive rights to a patent estate from Emory in the CAM-E chemical space, consisting of 2 issued U.S. patents, one pending non-provisional U.S. patent application as well as 22 issued or allowed foreign patents and 21 foreign patent applications. The issued U.S. patents have an expected expiration date of March 2037, and any patents that issue from our non-provisional U.S. and foreign patent applications are expected to expire between 2037 and 2041, excluding any potentially available patent term extensions or adjustments.

KU Leuven

As part of our collaboration with KU Leuven, we have filed and co-own a patent estate that consists of 5 issued US patents, 4 non-provisional US patent applications, 1 provisional US patent application, 1 PCT, 2 issued foreign patents and 34 pending foreign patent applications. The issued US patents have expiration dates ranging from 2041 through 2043, not including the potential for patent term extensions or adjustments. Any patents that issue from our provisional or non-provisional US applications are expected to expire between 2043 and 2046, not including the potential for patent term extensions or adjustments.

Drug candidate intellectual property

Hepatitis B - pevifoscorvir sodium and additional potential drug candidates

We have a patent family that include 2 issued U.S. patents, 2 non-provisional U.S. patent applications, one provisional patent application and 38 applications pending across multiple jurisdictions which have claims directed to either compositions of matter, formulations or method of use for pevifoscorvir sodium, our lead CAM-E molecule for the treatment of chronic hepatitis B. Some of these applications are co-owned by Aligos and a collaborator. These patent families include claims directed to combination treatment with our lead molecule with other modes of action drugs and drug candidates directed against chronic HBV infection. Our issued U.S. Patents 11,191,747 and 11,771,680 are projected to expire in April 2040, and any patents that issue from our non-provisional U.S. and foreign patent applications are expected to expire in the 2040 - 2045 range, excluding any potentially available patent term extension or adjustment.

MASH and Obesity - ALG‑055009 and additional potential drug candidates

We own a patent family that includes 2 issued U.S. patents, 3 U.S. non-provisional applications, 4 U.S. provisional applications, 2 PCT applications, 18 issued foreign applications and 21 foreign applications which have claims directed to either composition of matter, manufacturing, formulations or methods of use for ALG‑055009, our lead drug candidate for the treatment of MASH / Obesity. These patent families also disclose combination therapies with our lead molecule. Our issued U.S. Patents 11,091,467 and 12,180,192 are expected to expire in May 2040, and any patents that issue from our non-provisional U.S. application is expected to expire between 2040 and 2045, excluding any potentially available patent term extensions or patent term adjustments.

Coronaviruses - ALG-097558 and additional potential drug candidates

We own a patent family that includes 2 issued U.S. patents, one non-provisional U.S. application, and 26 foreign patent applications all of which have claims directed to compositions of matter and method of use, including

for ALG-097558, our lead drug candidate for the treatment of coronavirus. This patent family also discloses combination therapies with our lead molecule. Our issued U.S patents 11,851,422 and 12,252,481 and any patent that issues from our non-provisional patent application expire in 2042, excluding any potentially available patent term extension or adjustment.

Discovery pipeline intellectual property

Hepatitis B

We own multiple additional patent families of applications that include claims directed to compositions of matter, pharmaceutical compositions and methods of use for the treatment of chronic HBV infection with our additional drug candidates. These families include 14 issued U.S. patents, 10 U.S. non-provisional patent applications, one U.S. provisional patent application, 2 PCT patent applications, 3 issued foreign patents and 60 foreign patent applications in the small molecule and oligonucleotide space. These patent families also disclose combination therapies with our drug candidates and other compounds for treating chronic HBV infection. Our issued patents and any patents that issue from our U.S. non-provisional or foreign patent applications in these patent families are expected to expire between 2040 to 2045, excluding any potentially available patent term extensions or patent term adjustments.

MASH and Obesity

We have 4 issued U.S. patents, 5 non-provisional U.S. patent applications, one provisional U.S. patent application, one PCT application and 14 foreign patent applications that include claims directed to compositions of matter and methods of use with our additional drug candidates, both small molecule and oligonucleotide related, for the treatment of MASH / Obesity. These applications also disclose combination therapies with our drug candidates and other compounds for treating MASH. Our issued patents are expected to expire in 2041, and any patents that issue from our non-provisional U.S. and foreign applications are projected to expire in between 2041 and 2045, excluding any potentially available patent term extensions or patent term adjustments.

Coronaviruses

We have 2 allowed U.S. patent applications, 4 U.S. non-provisional patent applications, 2 US provisional patent applications, one PCT application, two foreign patents and 6 foreign applications that include claims directed to compositions of matter, pharmaceutical compositions, and methods of use for treating coronaviruses. Some of these applications are co-owned by Aligos and a collaborator. These patent families also include disclosures relating to combination therapy strategies for treating coronaviruses. For our issued U.S. patents and any patents that issue from our U.S. non-provisional and foreign patent applications, these are expected to expire from 2041 to 2045, excluding any potentially available patent term extensions or patent term adjustments.

With respect to both our licensed and our owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any current patents or any patents that may be granted to us in the future will be commercially useful in protecting our platforms and drug candidates and the methods used to manufacture them. Moreover, the time required for development, testing and regulatory review of our drug candidates may shorten the length of effective patent protection following commercialization. If we do obtain any patents for our drug candidates, the term of such patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing of a non-provisional patent application. In the United States, the patent term of a patent that covers an FDA approved drug or biologic may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension 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 that the drug or biologic is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug or biologic may be extended. Similar provisions are available in the EU and other foreign jurisdictions to extend the term of a patent that covers an approved drug or biologic. In the future, if our drug candidates receive FDA approval and if our patent applications relating to such drug candidates issue as patents, we expect to apply for patent term extensions where applicable on patents covering those drugs. We plan to seek patent term extensions to any of our future issued patents in any jurisdiction where these are available, however there is no guarantee that the applicable authorities, including FDA in the United States, will agree with our assessment of whether these extensions should be granted, and if granted, the length of these extensions. For this and other risks

related to our proprietary technology, inventions, improvements, platforms and product candidates, see the section titled “Risk Factors—Risks related to intellectual property.”

Trademarks

Our trademark portfolio contains several trademark applications and registrations, including U.S. and foreign, as of December 31, 2025. The trademark portfolio includes the mark ALIGOS which is registered in the United States, Australia, the EU, Great Britain, Japan, and China.

Government regulation and product approval

Government regulation

The FDA and other regulatory authorities at the federal, state, and local level, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, marketing and promotion, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products, such as those we are developing. 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.

U.S. drug regulation

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (the FDCA), and its implementing regulations. FDA approval is required before any new unapproved drug can be marketed in the United States. Drugs are also subject to other federal, state and local statutes and regulations. Failure to comply with applicable FDA or other requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA clinical holds, refusal to approve pending applications, withdrawal of an approval, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

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

- completion of nonclinical laboratory tests and animal studies, where all supporting safety and toxicity studies are performed in accordance with the FDA’s Good Laboratory Practice (GLP) regulations;
- submission to the FDA of an investigational new drug application (IND), which must become effective before human clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent institutional review board (IRB), representing each clinical site before a clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice (GCP) regulations to establish the safety and efficacy of the product candidate for each proposed indication;
- preparation of and submission to the FDA of a new drug application (NDA);
- a determination by the FDA within 60 days of its receipt of an NDA to file the application for review;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility(ies) where the product is manufactured to assess compliance with current good manufacturing practice (cGMP) regulations, and of selected clinical investigation sites to assess compliance with GCP; and
- FDA review and approval of an NDA to permit commercial marketing of the product for its particular labeled uses in the United States.

Nonclinical and clinical studies

The nonclinical and clinical testing process can take many years and the actual time required to obtain approval, if any, may vary substantially based upon the type, complexity and novelty of the drug or condition being treated.

Nonclinical tests include laboratory (in vitro) evaluation of drug chemistry, formulation and toxicity, as well as animal (in vivo) studies to assess the characteristics and potential safety and efficacy of the drug candidate. The conduct of nonclinical studies that provide safety and toxicological information must comply with federal regulations and requirements, including GLPs. The results of nonclinical studies are submitted to the FDA as part of an IND along with other information, including information about drug CMC and any available human data or literature to support use of the drug in humans. Long-term nonclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

The central focus of an IND submission is on the general investigational plan and the protocol(s) for human studies. An IND must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA unless, before that time, the FDA raises concerns or questions related to the proposed clinical trials. 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 clinical trials can begin.

For each successive clinical trial conducted with the investigational drug, a separate, new protocol submission to an existing IND must be made, along with any subsequent changes to the investigational plan. Sponsors are also subject to ongoing reporting requirements, including submission of IND safety reports for any serious adverse experiences associated with use of the investigational drug or findings from nonclinical studies suggesting a significant risk for human subjects, as well as IND annual reports on the progress of the investigations conducted under the IND.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for participation in each clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety and the efficacy criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Additionally, approval must also be obtained from each clinical trial site's IRB (or a central IRB) before a trial may be initiated at the site, and the IRB must monitor the trial until completed. Sponsors of clinical trials generally must register and report ongoing clinical trials and clinical trial results to public registries, including the website maintained by the U.S. National Institutes of Health, ClinicalTrials.gov.

For purposes of NDA approval, human clinical trials are typically divided into three or four phases. Although the phases are usually conducted sequentially, they may overlap or be combined.

- ***Phase 1.*** The drug is initially introduced into healthy human subjects or into patients with the target disease or condition. These studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and if possible, to gain early evidence of effectiveness.
- ***Phase 2.*** The drug is administered to a limited patient population to evaluate tolerance and optimal dose, identify possible adverse side effects and safety risks, and preliminarily evaluate efficacy. Multiple Phase 2 trials may be conducted to obtain additional data prior to beginning Phase 3 trials.
- ***Phase 3.*** The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites to generate enough data to statistically evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational drug and to provide an adequate basis for drug approval.
- ***Phase 4.*** In some cases, the FDA may provide conditional approval of an NDA for a drug candidate on the sponsor's agreement to conduct additional clinical trials after approval. In other cases, a sponsor may voluntarily conduct additional clinical trials after approval to gain more information about the drug. Such post-approval trials are typically referred to as Phase 4 clinical trials.

The FDA, the IRB or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. The sponsor may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

Concurrent with clinical trials, companies may complete additional in vivo studies and develop additional information about the characteristics of the drug candidate. Companies must also finalize a process for manufacturing the drug in commercially applicable quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug and, among other things, must use validated methods for testing the drug against specifications to confirm its identity, strength, quality and purity. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the drug does not undergo unacceptable deterioration over its shelf life.

Submission of an NDA to the FDA

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development and testing are submitted to the FDA in the form of an NDA requesting approval to market the drug for one or more indications. The submission of an NDA requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies.

An NDA must include all relevant data available from pertinent nonclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the drug's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of the drug for a specific use, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the drug to the satisfaction of the FDA.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an application for filing. In this event, the application must be resubmitted with the additional information and is subject to payment of additional user fees. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. Under applicable Prescription Drug User Fee Act (PDUFA) performance goals, the FDA endeavors to review NDAs for drugs containing new molecular entities within ten months of the 60-day filing date under standard review or within six months of the 60-day filing date under priority review.

The FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the drug is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the drug within required specifications. Additionally, the FDA will typically inspect one or more clinical sites to assure that relevant trial data was obtained in compliance with GCP requirements.

After the FDA evaluates the NDA and conducts inspections of manufacturing facilities, it may issue an approval letter or a complete response letter. A complete response letter indicates that the review cycle of the application is complete, and the application is not ready for approval. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA may ultimately decide that an application does not satisfy the regulatory criteria for approval. If, or when, the deficiencies have been addressed to the FDA's satisfaction in a resubmission of the application, the FDA will issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

As a condition of NDA approval, the FDA may require a Risk Evaluation and Mitigation Strategy (REMS) program to help ensure that the benefits of the drug outweigh its risks. If the FDA determines a REMS program is necessary, the drug sponsor must develop and submit a REMS as part of its NDA prior to approval. A REMS program may be required to include various elements, such as a medication guide or patient package insert, a

communication plan to educate healthcare providers of the drug's risks, or other elements to assure safe use, such as limitations on who may prescribe or dispense the drug, dispensing only under certain circumstances, special monitoring and the use of patient registries. In addition, all REMS programs must include a timetable to periodically assess the strategy following implementation.

Further, the FDA may require substantial post-approval testing and surveillance as a condition of NDA approval to monitor the drug's safety and efficacy, and the FDA has the authority to prevent or limit further marketing of a product based on the results of these post-marketing programs. Once granted, product approvals may be withdrawn if compliance with regulatory requirements is not maintained or problems are identified following initial marketing. Moreover, changes to the conditions established in an approved application, including changes in indications, labeling or manufacturing processes or facilities may require submission and FDA approval of a new NDA or NDA supplement before the changes can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that supporting the original approval, and the FDA uses similar procedures in reviewing supplements as it does in reviewing original applications.

Expedited development and review programs

The FDA offers a number of expedited development and review programs for qualifying drugs, one or more of which may be available for our current or future drug candidates.

New drug candidates 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. Fast track designation applies to the combination of the drug and the specific indication for which it is being studied. The sponsor of a fast track drug candidate has opportunities for frequent interactions with the review team during drug development and, once an NDA is submitted, the drug candidate may be eligible for priority review. A fast track drug candidate may also be eligible for rolling review, where 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 drug 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 drug candidate can receive breakthrough therapy designation if preliminary clinical evidence indicates that the drug candidate 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 drug candidate, including involvement of senior managers.

After an NDA is submitted for a drug candidate, including a drug candidate with a fast track designation and/or breakthrough therapy designation, the NDA may be eligible for priority review. An NDA is eligible for priority review if it has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition compared to marketed products. Depending on whether a drug candidate contains a new molecular entity, priority review designation means the FDA's goal is to take an action on the marketing application within six to eight months of the 60-day filing date, compared with ten to twelve months under standard review.

Additionally, drug candidates studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the drug 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 accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical trials to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. In addition, the FDA currently requires, as a condition for accelerated approval, pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the drug.

Orphan drug designation

We may pursue orphan drug designation for one or more of our current or future drug candidates, as appropriate, with the potential to obtain orphan drug exclusivity for our products, if approved.

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a drug that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the drug is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the drug with orphan drug exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the application user fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the drug to meet the needs of patients with the rare disease or condition.

Under the Pediatric Research Equity Act, certain NDAs and certain supplements to an NDA must contain data to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. The Food and Drug Administration Safety and Innovation Act amended the FDCA to require that a sponsor who is planning to submit an NDA for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan (iPSP), within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of a Phase 3 or Phase 2/3 study. The iPSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the iPSP. A sponsor can submit amendments to an agreed-upon iPSP at any time if changes to the pediatric plan need to be considered based on data collected from nonclinical studies, early phase clinical trials and/or other clinical development programs.

A drug product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

Post-approval requirements

Once an NDA is approved, a drug will be subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to drug listing and registration, recordkeeping, periodic reporting, product sampling and distribution, adverse event reporting and advertising, marketing and promotion. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. While physicians may prescribe for off-label uses, manufacturers may only promote for the approved indications and in accordance with the provisions of the approved label. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. The FDA and other

agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

After approval, most changes to the approved drug, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which FDA assesses an annual program fee for each drug identified in an approved NDA. In addition, quality-control, drug manufacture, packaging and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced and announced inspections by the FDA and these state agencies, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon manufacturers and their subcontractors, if applicable. 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 of a drug if compliance with regulatory requirements is not maintained or if problems occur after the drug reaches the market. Later discovery of previously unknown problems with a drug, 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 trials 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 a drug, complete withdrawal of the drug from the market or drug recalls;
- fines, warning or untitled letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing drug approvals;
- drug seizure or detention, or refusal of the FDA to permit the import or export of drugs; or
- injunctions or the imposition of civil or criminal penalties.

The FDA may also require post-approval studies and clinical trials if the FDA finds that scientific data, including information regarding related drugs, deem it appropriate. The purpose of such studies would be to assess a known serious risk or signals of serious risk related to the drug or to identify an unexpected serious risk when available data indicate the potential for a serious risk. The FDA may also require a labeling change if it becomes aware of new safety information that it believes should be included in the labeling of a drug.

International regulation

In addition to regulations in the United States, we are subject to certain and could become subject to a variety of additional foreign regulations regarding development, approval, commercial sales and distribution of our drugs if we seek to market our drugs (if approved) in other jurisdictions. As we have ongoing clinical trials in foreign jurisdictions, we are subject to the laws of such countries in order to conduct such clinical trials. Whether or not we obtain FDA approval for a drug candidate, we must obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the drug in those countries. The approval process varies from country to country and can involve additional drug testing and additional review periods, and the time may be longer or shorter than that required to obtain FDA approval. The requirements governing, among other things, the conduct of clinical trials, drug licensing, pricing and reimbursement vary greatly from country to country. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. If we fail to comply with applicable foreign regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, drug recalls, seizure of drugs, operating restrictions and criminal prosecution.

Other U.S. healthcare laws and compliance requirements

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. In the United States, such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, price reporting, and transparency laws and regulations regarding drug pricing and payments and other transfers of value made to physicians and other healthcare providers. 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 imprisonment.

Pharmaceutical coverage, pricing and reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any drug candidates for which we or our collaborators obtain regulatory approval. In the United States and markets in other countries, sales of any drugs for which we or our collaborators receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage, and establish adequate reimbursement levels for such drug products.

In the United States, third-party payors include federal and state healthcare programs, government authorities, private managed care providers, private health insurers, and other organizations. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical drug products and medical services, in addition to questioning their safety and efficacy. Such payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the FDA-approved drugs for a particular indication. We or our collaborators may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our drugs, in addition to the costs required to obtain the FDA approvals. Nonetheless, our drug candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product.

Moreover, the process for determining whether a third-party payor will provide coverage for a drug product may be separate from the process for setting the price of a drug product or for establishing the reimbursement rate that such a payor will pay for the drug product. For drugs administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the drug itself or the treatment for which the drug is used may not be available, which may impact physician utilization. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in drug development.

Different pricing and reimbursement schemes exist in other countries. In Europe, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which drugs may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular drug candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new drugs. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any drug candidates for which we or our collaborators receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Recently, the U.S. government has increased its focus on drug pricing in the US, including through "most favored nation" pricing initiatives. Even if favorable coverage and reimbursement status is attained

for one or more drug candidates for which we or our collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare reform

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products and services, implementing reductions in Medicare and other healthcare funding and applying new payment methodologies. For example, the Affordable Care Act, or ACA was enacted in 2010, which affected existing government healthcare programs and resulted in the development of new programs.

Among the ACA's provisions of importance to our business, are provisions related to our ability to commercialize and the prices we may obtain for any drug candidates that are approved for sale, an increase of the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, an extension of manufacturer rebate liability from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations, and the establishment of an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs.

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

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. The Budget Control Act of 2011, among other things, included aggregate reductions to Medicare payments to providers, which went into effect on April 1, 2013, and will remain in effect through 2032, unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, enacted in 2013, among other things, further reduced Medicare payments to several providers. The American Rescue Plan Act of 2021, 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.

There has also been heightened governmental scrutiny recently over the manner in which pharmaceutical companies set prices for their marketed products, which has resulted in several Congressional inquiries and proposed federal legislation, as well as state efforts, designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. The Inflation Reduction Act (the IRA) was enacted in 2022. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, 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); redesigns the Medicare Part D benefit (beginning in 2024); and replaces the Part D coverage gap discount program with a new discounting program (which began in 2025). The Centers for Medicare & Medicaid Services, or CMS, has published the negotiated prices for the initial ten drugs, which went into effect in 2026, and the subsequent 15 drugs, which will first be effective in 2027. CMS has also published the next set of 15 drugs that will be subject to negotiation. The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented, although the drug price negotiated program is currently subject to legal challenges. The impact of the IRA on us and the pharmaceutical industry cannot yet be fully determined, but is likely to be significant.

The One Big Beautiful Bill Act (the OBBBA), which was enacted in July 2025, imposes significant reductions in the funding of the Medicaid program. Such reductions are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, which could adversely affect the sales of any drug candidate that we commercialize and negatively impact the pharmaceutical industry in general.

The Trump administration is pursuing a two-fold strategy to reduce drug costs in the United States. On the one hand, President Trump has threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the United States to the lowest price in a group of other countries. In response, multiple manufacturers have reportedly entered into confidential pricing agreements with the federal government. On the other hand, the Trump administration is pursuing traditional regulatory pathways to impose drug pricing policies, and published two proposed regulations in

December 2025, referred to as Globe and Guard. If finalized, these regulations would implement mandatory payment models under which manufacturers of eligible drugs would be required to pay rebates to the federal government on a portion of the units of their drugs that are reimbursed by Medicare, with the rebate amount based on most favored nation pricing. Imposing a rebate in the U.S. that is based on drug prices outside the U.S. would mark a drastic and unprecedented shift in the U.S. pharmaceutical market, and while the impact of the Globe and Guard proposed regulations, if finalized, cannot yet be determined, it is likely to be significant.

We anticipate that these new laws will result in additional downward pressure on coverage and the price that we receive for any approved drug, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs (if approved). In addition, it is possible that there will be further legislation or regulation that could harm our business, financial condition, and results of operations.

Data privacy and security

We may also be subject to federal, state and foreign data privacy and security laws and regulations. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations (e.g., Section 5 of the FTC Act), govern the collection, use, disclosure, and protection of health-related and other personal information and could apply to our operations or the operations of our partners. In addition, 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.

Employees and human capital resources

As of December 31, 2025, we had 82 full-time employees, including 64 employees engaged in research and development. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards and cash-based performance bonus awards.

Corporate information

We were founded in February 2018 as a Delaware corporation. Our principal executive offices are located at One Corporate Dr., 2nd Floor, South San Francisco, California 94080, and our telephone number is (800) 466-6059.

Our website address is www.aligos.com. We make available on or through our website certain reports and amendments to those reports that we file with or furnish to the SEC in accordance with the Securities Exchange Act of 1934, as amended, or the Exchange Act. These include our annual reports on Form 10-K, our quarterly reports on Form 10-Q, and our current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act. We make this information available on or through our website free of charge as soon as reasonably practicable after we electronically file the information with, or furnish it to, the SEC. References to our website address do not constitute incorporation by reference of the information contained on the website, and the information contained on the website is not part of this document or any other document that we file with or furnish to the SEC. The SEC maintains a site on the worldwide web that contains reports, proxy and information statements and other information regarding our filings at www.sec.gov.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks 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 the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations and the market value of our common stock.

Risks related to our limited operating history, financial position and need for additional capital

We are a clinical-stage biotechnology company with a limited operating history and no products approved for commercial sale. We have incurred significant losses since inception. We expect to incur losses for at least the next several years and may never achieve or maintain profitability for a full fiscal year, which, together with our limited operating history, makes it difficult to assess our future viability.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a clinical-stage biotechnology company, and we have only a limited operating history upon which you can evaluate our business and prospects. We currently have no products approved for commercial sale, have not generated any revenue from sales of products and have incurred losses in each year since our inception in February 2018. In addition, we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical industry.

Since inception, we have incurred significant net losses. Our net losses were $24.2 million for the year ended December 31, 2025 and $131.2 million for the year ended December 31, 2024. As of December 31, 2025, we had total stockholders' equity of $53.5 million. We have funded our operations to date primarily with proceeds from the sale of common stock, preferred stock, convertible notes and warrants, and to a lesser extent from upfront payments under our license/collaboration agreements. To date, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, acquiring and discovering development programs, securing intellectual property rights and conducting discovery, research and development activities for our programs. We have not yet demonstrated our ability to successfully complete registrational clinical trials, obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Our drug candidates will require substantial additional development time and resources before we will be able to apply for or receive regulatory approvals and, if approved, begin generating revenue from product sales. We may continue to incur significant expenses and operating losses for the foreseeable future.

We have never generated revenue from product sales and may never be profitable for a full fiscal year.

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with our collaboration partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, our drug candidates. We do not anticipate generating revenue from product sales for the next several years, if ever. Our ability to generate revenue from product sales depends heavily on our and our current and potential future collaborators' success in:

- completing clinical and nonclinical development of drug candidates and programs and identifying and developing new drug candidates;
- seeking and obtaining marketing approvals for any drug candidates that we develop;
- launching and commercializing drug candidates for which we obtain marketing approval by establishing a sales force, marketing, medical affairs and distribution infrastructure or, alternatively, collaborating with a commercialization partner;
- achieving adequate coverage and reimbursement by third-party payors for drug candidates that we develop;

- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and the market demand for drug candidates that we develop, if approved;
- obtaining market acceptance of drug candidates that we develop as viable treatment options;
- navigating technological and market developments;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations in such collaborations;
- maintaining, protecting, enforcing and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- defending against third-party interference, infringement or other intellectual property-related claims, if any; and
- attracting, hiring and retaining qualified personnel.

Even if one or more of the drug candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved drug candidate. Our expenses could increase beyond expectations if we are required by the U.S. Food and Drug Administration (the FDA), the European Medicines Agency (the EMA), or other regulatory agencies to perform clinical trials or studies in addition to those that we currently anticipate. Even if we are able to generate revenue from the sale of any approved products, we may not become profitable for a full fiscal year and may need to obtain additional funding to continue operations.

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

Our operations have consumed substantial amounts of cash since our inception. Since our inception, we have invested a significant portion of our efforts and financial resources in research and development activities for our initial nonclinical and clinical drug candidates. Nonclinical studies and clinical trials and additional research and development activities will require substantial funds to complete. In October 2023 and February 2025, we closed private investments of our securities that generated $92.1 million and $105.0 million in gross proceeds, respectively, before deducting placement agent fees and other offering expenses. As of December 31, 2025, we had cash, cash equivalents and short-term investments of $77.8 million. We expect to continue to spend substantial amounts to continue the nonclinical and clinical development of our current and future programs. If we are able to gain marketing approval for drug candidates that we develop, we will require significant additional amounts of cash in order to launch and commercialize such drug candidates. In addition, other unanticipated costs may arise. Because the design and outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any drug candidate we develop.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing our drug candidates and programs, and of conducting nonclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining marketing approvals for drug candidates we develop if clinical trials are successful;
- the cost of commercialization activities for our current drug candidates, and any future drug candidates we develop, whether alone or in collaboration, including marketing, sales and distribution costs if our current drug candidates or any future drug candidate we develop is approved for sale;
- the cost of manufacturing our current and future drug candidates for clinical trials in preparation for marketing approval and commercialization;
- our ability to establish and maintain strategic licenses or other arrangements and the financial terms of such agreements including milestone payments to our licensors;

- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- any lawsuits related to our drug candidates or commenced against us;
- the timing, receipt and amount of sales of, or profit share or royalties on, our future products, if any;
- the emergence of competing therapies for hepatological indications and viral diseases and other adverse market developments; and
- any acquisitions or in-licensing of other programs or technologies.

To date, we have primarily financed our operations through the sale of common stock, preferred stock, convertible notes and warrants. For example, in November 2024, we filed a Registration Statement on Form S-3 covering the offering of up to $400.0 million of common stock, preferred stock, debt securities, warrants, units and rights, which was declared effective by the SEC in November 2024 (November 2024 Shelf Registration Statement). In each of October 2023 and February 2025, we completed a private placement of common stock, warrants and pre-funded warrants.

We plan to finance our cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. In addition, we may seek additional capital to take advantage of favorable market conditions or strategic opportunities even if we believe we have sufficient funds for our current or future operating plans. Based on our research and development plans, we expect that our existing cash, cash equivalents and short-term investments will enable us to fund our operations into the third quarter of 2026, which is less than 12 months following the date of this report. Accordingly, our ability to continue as a going concern will require us to obtain additional funding for our operations or significantly curtail our operations to conserve our capital resources. Moreover, it is particularly difficult to estimate with certainty our future expenses given the dynamic nature of our business, and the macro-economic environment generally.

Our ability to raise additional funds depends on financial, economic and other factors, many of which are beyond our control. For example, if there is a disruption of global financial markets, we could be unable to access additional capital, which could negatively affect our ability to consummate certain corporate development transactions or other important, beneficial or opportunistic investments. If additional funds are not available to us when we need them, on terms that are acceptable to us, or at all, we may be required to:

- delay, limit, reduce or terminate nonclinical studies, clinical trials or other research and development activities or eliminate one or more of our development programs altogether; or
- delay, limit, reduce or terminate our efforts to establish manufacturing and sales and marketing capabilities or other activities that may be necessary to commercialize any future approved products, or reduce our flexibility in developing or maintaining our sales and marketing strategy.

We currently have a shelf registration statement effective, however, our ability to raise capital under this registration statement may be limited by, among other things, SEC rules and regulations impacting the eligibility of smaller companies to use Form S-3 for primary offerings of securities. Although alternative public and private transaction structures may be available, these may require additional time and cost, may impose operational restrictions on us, and may not be available on attractive terms.

Our recurring losses from operations and negative cash flows have raised substantial doubt regarding our ability to continue as a going concern.

Our recurring losses from operations and negative cash flows raise substantial doubt about our ability to continue as a going concern. We have devoted our resources to our research and development activities and have experienced significant operating losses since our inception. Furthermore, we expect to continue devoting substantial capital to the research and development of our drug candidates. We plan to raise additional capital to fund continued operations beyond the third quarter of 2026. We are taking steps to identify access to future capital and expect to be able to access capital in the future. However, there can be no assurance that any additional funding will be available to us on acceptable terms, if at all. If events or circumstances occur such that we do not obtain additional funding, it may be necessary to significantly reduce the scope of operations to reduce the current rate of spending, which could include reductions in staff and the need to delay, limit, reduce or terminate current or future

product development, which could have a material adverse effect on our business, results of operations and financial condition. Further, the perception of our ability to continue as a going concern may make it more difficult for us to obtain funding for the continuation of our operations, or necessitate that we obtain funding on less favorable terms, and could result in the loss of confidence by investors, our partners and employees.

The report of our independent registered public accounting firm for the year ended December 31, 2025 contains an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern.

Due to the uncertainty of our ability to meet our current operating and capital expenses, in the auditor's report on our audited annual financial statements as of and for the year ended December 31, 2025, our independent auditors included a paragraph regarding our ability to continue as going concern. Substantial doubt about our ability to continue as a going concern may materially and adversely affect the price per share of our common stock and we may have a more difficult time obtaining financing. Further, the perception that we may be unable to continue as a going concern may impede our ability to raise additional funds or operate our business due to concerns regarding our ability to discharge our contractual obligations.

Our operating results may fluctuate significantly, which will make our future results difficult to predict and could cause our results to fall below expectations.

Our quarterly and annual operating results may fluctuate significantly, which will make it difficult for us to predict our future results. These fluctuations may occur due to a variety of factors, many of which are outside of our control and may be difficult to predict, including:

- the timing and cost of, and level of investment in, research, development and commercialization activities, which may change from time to time;
- the timing and status of enrollment for our clinical trials;
- the timing of regulatory approvals, if any, in the United States and internationally;
- the timing of expanding our operational, financial and management systems and personnel, including personnel to support our clinical development, quality control, manufacturing and commercialization efforts and our operations as a public company;
- the cost of manufacturing, as well as building out our supply chain, which may vary depending on the quantity produced, and the terms of any agreements we enter into with third-party suppliers;
- the timing and amount of any milestone, royalty or other payments due under any current or future collaboration or license agreement, including our existing license agreements with Emory University (Emory) and KU Leuven;
- coverage and reimbursement policies with respect to any future approved products, and potential future drugs that compete with our products;
- the timing and cost to establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with current or future collaborators;
- expenditures that we may incur to acquire, develop or commercialize additional products and technologies;
- expenditures that we may incur in any lawsuits related to our drug candidates or commenced against us;
- the level of demand for any future approved products, which may vary significantly over time;
- future accounting pronouncements or changes in accounting principles or our accounting policies; and
- the timing and success or failure of nonclinical studies and clinical trials for our drug candidates or competing drug candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or collaboration partners.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be

meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even if we have met any previously publicly stated revenue or earnings guidance we may provide.

Our business could be materially adversely affected by the effects of health pandemics or epidemics, particularly in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations, including the San Francisco Bay Area where our headquarters are located.

Our business could be materially adversely affected by the effects of health pandemics or epidemics. For instance, the outbreak of COVID-19, which the World Health Organization had declared a global pandemic, prompted severe lifestyle and commercial restrictions aimed at reducing the spread of the disease. In March 2020, the San Francisco Bay Area counties issued a joint shelter-in-place order, which was subsequently followed by a California state-wide shelter order, and other state and local governments implemented similar orders which, among other things, directed individuals to shelter at their places of residence, directed businesses and governmental agencies to cease non-essential operations at physical locations, prohibited certain non-essential gatherings, and ordered cessation of non-essential travel. As a result of these developments, we had implemented work-from-home policies for most of our employees until March 2022 when we allowed our employees to return to work at our U.S. facility. Government-imposed quarantines and any future work-from-home policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions, the potential impact of changing government orders in response to health pandemics or epidemics and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition in the future.

Quarantines, shutdowns and shelter-in-place and similar government orders related to infectious diseases, or the perception that such events, orders or other restrictions on the conduct of business operations could occur, could impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain. Restrictions resulting from health pandemics or epidemics may at any time disrupt our supply chain and delay or limit our ability to obtain sufficient materials for our drug candidates.

In addition, our current and planned clinical trials may be affected by any future public health pandemics or epidemics. Site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the disease, and potential patients may not be able or willing to comply with clinical trial protocols, whether due to quarantines impeding patient movement or interrupting healthcare services, or due to potential patient concerns regarding interactions with medical facilities or staff. Similarly, our ability to recruit and retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to the disease, may be delayed or disrupted, which may adversely impact our clinical trial operations.

In addition, any future significant outbreak of contagious diseases in the human population could similarly adversely affect the economies and financial markets of many countries, including the United States, resulting in an economic downturn that could suppress demand for our future products. Any of these events could have a material adverse effect on our business, financial condition, results of operations or cash flows.

In addition, a continuing widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could negatively affect our liquidity and ability to progress our operations. In addition, a recession, down-turn, market correction or supply chain disruption resulting from health pandemics or epidemics could materially adversely affect the value of our common stock.

Risks related to product development and regulatory process

We are in early or mid-stages of our development efforts, and our business is dependent on the successful development of our current and future drug candidates. If we are unable to advance our current or future drug candidates through clinical trials, obtain marketing approval and ultimately commercialize any drug candidates we develop, or experience significant delays in doing so, our business will be materially harmed.

Our clinical development efforts across our drug candidates are in early or mid-stages. We have ongoing clinical trials for our most advanced drug candidates in many countries (e.g., United States, Canada, and throughout Asia and Europe). Our other programs are in the discovery or nonclinical development stage. We have invested substantially all of our efforts and financial resources in the identification of targets and nonclinical development of therapeutics to address hepatological indications and viral diseases. However, the biology of these indications and diseases is complex and not completely understood, and our current and future drug candidates may never achieve expected or functional levels of efficacy or achieve an acceptable safety profile. For example, our chronic HBV infection portfolio previously included our STOPS™ drug candidate, ALG-010133, one of our proprietary s-antigen transport-inhibiting oligonucleotide polymers that was in a Phase 1b dose range finding trial (NCT04485663) evaluating subjects with chronic HBV infection as well as our proprietary antisense oligonucleotide, ALG-020572, that was in a Phase 1a/1b umbrella study (NCT05001022) and for which dosing in chronic HBV infection patients were initiated as part of the multiple ascending dose portion of such study. However, in January 2022, we announced we halted further development of ALG-010133 based on data from such trial indicating insufficient antiviral activity to warrant further development of such drug candidate. And, in March 2022, we announced our discontinuation of further development of ALG-020572 due to an unanticipated serious adverse event involving significant increase in alanine aminotransferase (ALT) in one subject and several additional subjects experiencing ALT flares. Finally, for our siRNA drug candidate targeting HBsAg production, ALG‑125755, we conducted a Phase 1 study evaluating single doses ranging from 20-200 mg and 50-320 mg in HVs and virologically suppressed HBeAg- subjects with chronic HBV infection, respectively. In this study, we found that these single doses were well tolerated with a favorable PK profile. With respect to antiviral activity, while available data indicate evidence of HBsAg lowering at all 3 dose levels evaluated, the comparative efficacy of ALG-125755 vs. competitor siRNAs is inconclusive. Because further clinical evaluation of ALG-125755 is not prioritized with current funding, any further advancement of ALG-125755 will require additional external funding which we may not be able to obtain.

Our use of clinically validated targets to pursue treatments of these indications and diseases does not guarantee efficacy or safety or necessarily reduce the risk that our current or future drug candidates will not achieve expected or functional levels of efficacy or achieve an acceptable safety profile.

The success of our business, including our ability to finance our company and generate revenue from products in the future, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of the drug candidates we develop, which may never occur. Our current drug candidates, and any future drug candidates we develop, will require additional nonclinical and clinical development, management of clinical, nonclinical and manufacturing activities, marketing approval in the United States and other markets, demonstrating effectiveness to pricing and reimbursement authorities, obtaining sufficient manufacturing supply for both clinical development and commercial production, building of a commercial organization, and substantial investment and significant marketing efforts before we generate any revenues from product sales.

We are evaluating drug candidates in clinical trials in many countries (e.g., United States, Canada, and throughout Asia and Europe). As a company, we have limited experience in preparing, submitting and prosecuting regulatory filings. Specifically, we have not previously submitted a new drug application (NDA) to the FDA or similar approval filings to a comparable foreign regulatory authority for any drug candidate. An NDA or other relevant regulatory filing must include extensive nonclinical and clinical data and supporting information to establish that the drug candidate is safe and effective for each desired indication. The NDA or other comparable regulatory filing must also include significant information regarding the chemistry, manufacturing and controls for the product. We have had limited interactions with the FDA and cannot be certain how many clinical trials of any of our drug candidates will be required or whether the FDA will agree with the design or implementation of our clinical trials. In addition, we cannot be certain that our current or future drug candidates will be successful in clinical trials such that the information contained in an NDA or comparable regulatory filing would support approval, and thus we cannot guarantee that any of our drug candidates will receive regulatory approval. Further, even if our current or future drug candidates are successful in clinical trials, such candidates may not receive regulatory approval. If we do

not receive regulatory approvals for current or future drug candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approval to market a drug candidate, our revenue will depend, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights, as well as the availability of competitive products, third-party reimbursement and adoption by physicians.

We plan to seek regulatory approval to commercialize our drug candidates both in the United States and in select foreign countries. While the scope of regulatory approval in other countries is generally similar to that in the United States, in order to obtain separate regulatory approval in other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy. Other countries also have their own regulations governing, among other things, clinical trials and commercial sales, as well as pricing and distribution of drugs, and we may be required to expend significant resources to obtain regulatory approval and to comply with ongoing regulations in these jurisdictions.

The success of our current and future drug candidates depends on many factors, which may include the following:

- sufficiency of our financial and other resources to complete the necessary nonclinical studies and clinical trials, and our ability to raise any additional required capital on acceptable terms, or at all;
- our ability to develop and successfully utilize our drug discovery platforms;
- the timely and successful completion of our nonclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- acceptance of investigational new drug applications (INDs), clinical trial applications (CTAs) and/or similar applications in other jurisdictions for our planned and future clinical trials;
- whether we are required by the FDA or a comparable foreign regulatory agency to conduct additional clinical trials or other studies beyond those planned to support approval of our drug candidates;
- successful enrollment and completion of clinical trials;
- successful data from our clinical program that supports an acceptable risk-benefit profile of our drug candidates in the intended populations;
- receipt and maintenance of marketing approvals from applicable regulatory authorities;
- establishing agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if our drug candidates are approved;
- our ability, and the ability of any third parties with whom we contract, to remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices (cGMPs);
- entry into collaborations to further the development of our drug candidates in select indications or geographies;
- obtaining, maintaining and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- enforcing and defending our intellectual property rights and having and successfully executing an intellectual property life cycle management strategy that supports long-term product development and commercialization goals;
- obtaining and maintaining regulatory exclusivity for our drug candidates;
- successfully launching commercial sales of our drug candidates, if approved;
- acceptance of the drug candidate’s benefits and uses, if approved, by patients, the medical community and third-party payors;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our drug candidates following approval;

- effectively competing with other therapies; and
- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors.

If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully obtain approval of or commercialize the drug candidates we develop, which would materially harm our business. If we do not receive marketing approvals for our current or future drug candidates, we may not be able to continue our operations. Even if regulatory approvals are obtained, we may never be able to successfully commercialize any products. Accordingly, we cannot provide assurances that we will be able to generate sufficient revenue through the sale of products to continue our business.

Nonclinical development is uncertain. Our nonclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize our drug candidates on a timely basis or at all, which would have an adverse effect on our business.

In order to obtain approval from the FDA and other major regulatory agencies in non-U.S. countries to market a new drug candidate, we must demonstrate proof of safety and efficacy in humans. To meet these requirements, we will have to conduct adequate and well-controlled clinical trials. Before we can commence clinical trials for a drug candidate, we must complete extensive nonclinical studies that support our planned INDs or CTAs in the United States and other countries. At this time, we are evaluating drug candidates in clinical trials in many countries (e.g., United States, Canada, and throughout Asia and Europe). The rest of our programs are in nonclinical research or earlier stages of development, including our other chronic hepatitis B virus and hepatitis delta infection drug candidates and our coronavirus drug candidates. We cannot be certain of the timely completion or outcome of our nonclinical studies and cannot predict if the FDA or other regulatory authorities will accept our proposed clinical programs or if the outcome of our nonclinical studies will ultimately support further development of our programs. In addition, the FDA may decline to accept the data we obtain from foreign clinical studies in support of an IND or NDA in the United States, which may require us to repeat or conduct additional nonclinical studies or clinical trials that we did not anticipate in the United States. As a result, we cannot be sure that we will be able to submit INDs in the United States, or CTAs or similar applications in other jurisdictions, on the timelines we expect, if at all, and we cannot be sure that submission of INDs, CTAs or similar applications will result in the FDA or other regulatory authorities allowing additional clinical trials to begin.

Conducting nonclinical testing is a complex, lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity and novelty of the program, and often can take several years or more per program. Delays associated with programs for which we are directly conducting nonclinical studies may cause us to incur additional operating expenses. Moreover, we may be affected by delays associated with the studies of certain programs that are the responsibility of potential future partners, if any, over which we have no control. The commencement and rate of completion of nonclinical studies and clinical trials for a drug candidate may be delayed by many factors, including:

- inability or failure by us or third parties to comply with regulatory requirements, including the requirements of good laboratory practice (GLP);
- inability to generate sufficient nonclinical or other in vivo or in vitro data to support the initiation of clinical studies;
- delays in reaching a consensus with regulatory agencies on study design and obtaining regulatory authorization to commence clinical trials;
- obtaining sufficient quantities of our drug candidates for use in nonclinical studies and clinical trials from third-party suppliers on a timely basis; and
- delays due to global-scale potentially catastrophic events, including public health pandemics or epidemics, terrorism, war, and climate changes.

Moreover, even if candidates from our drug programs advance into clinical trials, our development efforts may not be successful, and clinical trials that we conduct or that third parties conduct on our behalf may not demonstrate sufficient safety or efficacy to obtain the requisite regulatory approvals for any drug candidates we develop. Even if we obtain positive results from nonclinical studies or initial clinical trials, we may not achieve the same success in future trials.

The regulatory approval processes of the FDA, the EMA and comparable foreign authorities are lengthy, time-consuming, complex and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our drug candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA, the EMA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a drug candidate's clinical development and may vary across jurisdictions. We have not obtained regulatory approval for any drug candidate and it is possible that none of our current or future drug candidates will ever obtain regulatory approval.

Our current and future drug candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, the EMA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, the EMA or comparable foreign regulatory authorities that a drug candidate is safe or effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, the EMA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a drug candidate's clinical and other benefits outweigh its safety risks;
- the FDA, the EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from clinical trials or nonclinical studies;
- the data collected from clinical trials of our drug candidates may not be sufficient to support the submission of an NDA to the FDA or other submission or to obtain regulatory approval in the United States, the European Union (EU) or elsewhere;
- the FDA, the EMA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, the EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of clinical trial results may result in our failing to obtain regulatory approval to market any drug candidate we develop, which would significantly harm our business, results of operations and prospects. The FDA, the EMA and other comparable foreign authorities have substantial discretion in the approval process, and in determining when or whether regulatory approval will be obtained for any drug candidate that we develop. Even if we believe the data collected from future clinical trials of our drug candidates are promising, such data may not be sufficient to support approval by the FDA, the EMA or any other regulatory authority.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our drug candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a drug candidate with a label that does not include the labeling claims that we believe are necessary or desirable for the successful commercialization of that drug candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our drug candidates.

We cannot be certain that any of our programs will be successful in clinical trials or receive regulatory approval. Further, drug candidates we develop may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our drug candidates, we may not be able to continue our operations.

Clinical product development involves a lengthy and expensive process, with uncertain outcomes. We may experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current and future drug candidates, which could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our business, financial condition, results of operations and prospects.

To obtain the requisite regulatory approvals to commercialize any of our drug candidates, we must demonstrate through extensive nonclinical studies and clinical trials that our products are safe and effective in humans. Clinical trials are expensive and can take many years to complete, and their outcomes are inherently uncertain. Failure can occur at any time during the clinical trial process and our future clinical trial results may not be successful. For example, in January 2022, we halted further development of ALG‑010133. This decision was based on emerging data from the Phase 1 Study ALG-010133-101, that indicated that at the projected efficacious dose (400 mg, estimated to achieve liver exposures >3 x EC90 for HBsAg inhibition) there was no meaningful HBsAg reduction. Furthermore, higher dose levels (maximum feasible dose is 600 mg) that were planned to be evaluated in a subsequent cohort were very unlikely to reach the 1 $\log_{10}$ IU/mL HBsAg reduction level that we had previously defined as necessary to advance the program. As another example, in March 2022, we discontinued further development of our ASO drug candidate for chronic HBV infection, ALG‑020572, due to an unanticipated serious adverse event involving significant increase in ALT in one chronic HBV infection subject and several other subjects experiencing ALT flares in the same study. Finally, for our siRNA drug candidate targeting HBsAg production, ALG‑125755, we conducted a Phase 1 study evaluating single doses ranging from 20-200 mg and 50-320 mg in HVs and virologically suppressed HBeAg negative subjects with chronic HBV infection, respectively. In this study, we found that these single doses were well tolerated with a favorable PK profile. With respect to antiviral activity, while available data indicate evidence of HBsAg lowering at all 3 dose levels evaluated, the comparative efficacy of ALG-125755 vs. competitor siRNAs is inconclusive. Because further clinical evaluation of ALG-125755 is not prioritized with current funding, any further advancement of ALG-125755 will require additional external funding which we may not be able to obtain.

We may experience delays in completing our clinical trials and initiating or completing additional clinical trials. We may also experience numerous unforeseen events prior to, during, or as a result of our nonclinical studies or clinical trials that could delay or prevent our ability to receive marketing approval or commercialize the drug candidates we develop, including:

- regulators, Institutional Review Boards (IRBs) or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations (CROs);
- the number of patients required for clinical trials may be larger than we anticipate;
- it may be difficult to enroll a sufficient number of suitable patients, or enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require us to add new clinical trial sites or investigators;
- the supply or quality of materials for drug candidates we develop or other materials necessary to conduct clinical trials may be insufficient or inadequate; and
- we may experience disruptions by man-made or natural disasters or public health pandemics or epidemics or other business interruptions.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or ethics committees of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination 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, changes in governmental regulations or administrative actions or lack of

adequate funding to continue the clinical trial. 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 marketing approval of our drug candidates.

Further, we are currently conducting clinical trials in many countries (e.g., United States, Canada, and throughout Asia and Europe). We may also in the future conduct clinical trials for these and other drug candidates in other countries and territories which presents additional risks that may delay completion of our clinical trials. These risks include the possibility that we could be required to conduct additional nonclinical studies before initiating any clinical trials, may be unable to enroll and retain patients as a result of differences in healthcare services, research guidelines or cultural customs, or may face additional administrative burdens associated with comparable foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

If we experience termination or delays in the completion of any clinical trial of our drug candidates, the commercial prospects of our drug candidates will be harmed, and our ability to generate product revenues from any of these drug candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our drug candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Significant clinical trial delays could also allow our competitors to bring products to market before we do, shorten any periods during which we may have the exclusive right to commercialize our drug candidates, impair our ability to commercialize our drug candidates and harm our business and results of operations.

Specifically, should we experience another pandemic or epidemic outbreak on a similar if not greater scale as the COVID-19 outbreak, the clinical trial sites for our current drug trials, and future planned trials may be affected due to prioritization of hospital resources toward the outbreak efforts, travel or quarantine restrictions imposed by national, federal, state or local governments, and the inability to access sites for initiation and patient monitoring and enrollment. As a result, patient screening, new patient enrollment, monitoring and data collection may be affected or delayed. Some of our third-party manufacturers we use for the supply of materials for drug candidates or other materials necessary to manufacture product to conduct clinical trials may be located in countries affected by the outbreak, and, should they experience disruptions such as temporary closures or suspension of services, we would likely experience delays in advancing these trials.

The U.S. BIOSECURE Act, which was enacted in December 2025, prohibits federal agencies from procuring or using any biotechnology equipment or services from “biotechnology companies of concern”, or entering into, extending, or renewing any contracts with entities that use such biotechnology equipment or services from “biotechnology companies of concern”. Congress has interpreted a “biotechnology company of concern” as an entity that is under the control of a foreign adversary and that poses a risk to national security based on its research or multiomic data collection (e.g., collection of genomic information). While the U.S. BIOSECURE Act has a grandfathering period of five years for existing contracts, and has carveouts for manufacture of drugs for supply under Medicaid and Medicare Part B, subject to the Secretary of Veteran Affairs’ discretion, the impact of the U.S. BIOSECURE Act on the biotechnology industry is uncertain. If the foreign CROs and CMOs we rely on become subject to trade restrictions, sanctions, increased tariffs or other regulatory requirements by the U.S. government (including designation as a “biotechnology company of concern” under the U.S. BIOSECURE Act), or if the U.S. or Chinese government take retaliatory actions due to recent or increased tensions between the U.S. and China, it may have the potential to severely restrict the ability of U.S. biopharmaceutical companies like us to purchase services or products from, or otherwise collaborate with, certain “biotechnology companies of concern” without losing the ability to contract with, or otherwise receive funding from, the U.S. government.

Imports from other countries, including China, have been made subject to new tariffs affecting our industry in multiple ways, including taxing the import of raw materials and supplies, as well as recent tariffs on pharmaceutical products. Uncertainty in scope and applicability of new tariffs, as well as the cost of the tariffs themselves, could lead to delays in drug development and commercialization, and other financial harm.

Separately, principal investigators for our clinical trials serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or a regulatory authority concludes that the financial relationship may have affected the interpretation of the clinical 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 applications we submit. Any such delay or rejection could prevent or delay us from commercializing our current or future drug candidates.

There is also uncertainty as to how measures being implemented by the new administration will impact the operations of various agencies. For example, budget cuts, layoffs, and government shut downs have and may continue to impact the work of the FDA, which may lead to delays in regulatory approvals. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or could lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our drug candidates or result in the development of our drug candidates being terminated.

Our pursuit of potential treatments for chronic HBV infection is ongoing, but we may be unable to produce a therapy that successfully treats chronic HBV infection. Even if successful, we may be unable to obtain regulatory approval for and successfully commercialize our drug candidates.

We have invested a significant portion of our time and financial resources in the pursuit of a treatment for chronic HBV infection, including pevifoscorvir sodium, a CAM-E that is currently in a Phase 2 trial. If we cannot successfully develop, obtain regulatory approval for and commercialize our drug candidates for the treatment of chronic HBV infection, our business may be harmed. The mechanism of action of our chronic HBV infection drug candidates is complex, and we do not know the degree to which it will translate into a therapeutic benefit, if any, in chronic HBV infection or any other indication, and we do not know the degree to which the complex mechanism of action may contribute to long-term safety issues or adverse events when our drug candidates are taken for prolonged periods, as is inherent in the treatment of chronic HBV infection.

In addition, the standards implemented by clinical or regulatory agencies may change at any time and we cannot be certain what efficacy endpoints the FDA or foreign clinical or regulatory agencies may require at the time we plan to conduct clinical trials with respect to chronic HBV infection or any other applicable indication. Also, if we are able to obtain accelerated approval of our drug candidates, we may be required to conduct one or more post-approval clinical outcome trials to confirm the clinical benefit of the drug candidate; if any such post-approval trial is not successful, we would not be able to continue marketing the product.

If we are successful and any of our drug candidates are approved for the treatment of chronic HBV infection, our drug candidates will likely compete with products that have already been approved or may in the future be approved for the treatment of chronic HBV infection prior to our drug candidates and/or that have greater efficacy than our drug candidates, either alone or in combination.

Our pursuit of potential treatments for MASH and obesity is ongoing, but we may be unable to produce a therapy that successfully treats MASH and/or obesity. Even if successful, we may be unable to obtain regulatory approval for and successfully commercialize our drug candidates.

We have invested a significant portion of our time and financial resources in the pursuit of a treatment for MASH, including ALG-055009, our THR-ß agonist which has completed a Phase 2a trial. In addition, we have conducted nonclinical research in obesity using our THR-ß agonist. If we cannot successfully develop, obtain regulatory approval for and commercialize our drug candidates for the treatment of MASH and/or obesity, our business may be harmed. The mechanism of action of our THR-ß agonist candidates is complex, and we do not know the degree to which it will translate into a therapeutic benefit, if any, in MASH, obesity or any other indication, and we do not know the degree to which the complex mechanism of action may contribute to long-term safety issues or adverse events when our drug candidates are taken for prolonged periods.

In addition, the standards implemented by clinical or regulatory agencies may change at any time and we cannot be certain what efficacy endpoints the FDA or foreign clinical or regulatory agencies may require at the time we plan to conduct clinical trials with respect to MASH, obesity or any other applicable indication. Also, if we are able to obtain accelerated approval of our drug candidates, we may be required to conduct one or more post-approval clinical outcome trials to confirm the clinical benefit of the drug candidate; if any such post-approval trial is not successful, we would not be able to continue marketing the product.

If we are successful and any of our drug candidates are approved for the treatment of MASH and/or obesity, our drug candidates will likely compete with products that have already been approved or may in the future be approved for the treatment of MASH and/or obesity, prior to our drug candidates and/or that have greater efficacy than our drug candidates, either alone or in combination. Behavioral modifications, such as diet and exercise, can also decrease or eliminate the demand for our THR-ß agonist candidates.

Our pursuit of potential therapies for COVID-19 is at an early stage.

In response to the outbreak of COVID-19, the disease caused by the virus SARS-CoV-2, we are pursuing various potential therapies to address the disease, including our drug candidate ALG-097558, an oral protease inhibitor which is currently in a clinical trial in COVID-19 subjects. Our development of this potential therapy is at an early stage, and we may be unable to produce in a timely manner a therapy that successfully treats the virus or that has broad clinical applicability, if at all.

For example, in June 2020, we entered into a Research, Licensing and Commercialization Agreement with KU Leuven under which we were collaborating with KU Leuven's Rega Institute for Medical Research, as well as its CD3, to research, develop, manufacture and commercialize potential protease inhibitors for the treatment of coronaviruses, including SARS-CoV-2. In July 2023, we amended our license agreement with KU Leuven (as amended, KU Leuven Agreement) to further our collaboration. While ALG-097558 has been selected as our drug candidate to move forward into development, the KU Leuven Agreement may ultimately not result in a therapy that successfully treats SARS-CoV-2. Further, if the KU Leuven Agreement does result in such a therapy, the therapy may not be developed and commercialized in a timely manner, or at all.

In the past, we have committed significant personnel to the development of ALG-097558 for COVID-19. COVID-19 may be substantially eradicated prior to our development of a successful therapy or a vaccine may be developed that is highly efficacious and widely adopted, reducing or eliminating the need for therapies to treat the disease. For instance, the Pfizer/BioNTech BNT162b2, the adenovirus type 26 (Ad26) vaccine by Janssen Pharmaceutical Companies of Johnson & Johnson, Moderna mRNA-1273 and Novavax NVX-CoV2373 COVID-19 vaccines have been approved and/or authorized for emergency use and have been widely administered in various countries throughout the world which could adversely impact the need for our potential COVID-19 therapies. Further, while we hope to develop potential therapies that are effective against other or future coronaviruses, in addition to SARS-CoV-2, we cannot be certain this will be the case. If our potential therapies are not effective against other or future coronaviruses, the value and/or sales potential of our therapies will be reduced or eliminated. Our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and could rapidly dissipate or against which our potential therapies, if developed, may not be partially or fully effective, and may ultimately prove unsuccessful or unprofitable. Furthermore, there are no assurances that our therapy will be approved for inclusion in government stockpile programs, which may be material to the commercial success of any approved coronavirus-related drug candidate, either in the United States or abroad.

We will also need to enter into manufacturing arrangements in the future in order to create a supply chain for our COVID-19 drug candidates that can adequately support demand. Even if we are successful in developing and manufacturing an effective treatment for COVID-19, the SARS-CoV-2 virus could develop resistance to our treatment, which could affect any long-term demand or sales potential for our potential therapies.

In addition, another party may be successful in producing a more efficacious therapy for COVID-19 or a therapy with a more convenient or preferred route of administration or in producing a therapy in a more timely manner, which may lead to the diversion of funding away from us and toward other companies or lead to decreased demand for our potential therapies. For instance, on May 25, 2023, Pfizer, Inc. received an approval from the FDA for Paxlovid, an orally administered SARS-CoV-2 protease inhibitor co-administered with ritonavir. Similarly, Merck (together with Ridgeback Bio), is developing the drug molnupiravir, an oral antiviral drug which was issued an emergency use authorization by the FDA on December 23, 2021. Several drugs are likely being used off-label for treatment, such as dexamethasone. There are significant efforts by other companies globally to develop both therapeutic and prophylactic drug candidates. These other entities may be more successful at developing, manufacturing or commercializing a therapy for COVID-19, especially given that several of these other organizations are much larger than we are and have access to larger pools of capital, including U.S. government funding, and broader manufacturing infrastructure. The success or failure of other entities, or perceived success or failure, may adversely impact our ability to obtain any future funding for our development and manufacturing efforts or to ultimately commercialize a therapy for COVID-19, if approved.

The results of nonclinical studies and early-stage clinical trials may not be predictive of future results.

The results of nonclinical studies may not be predictive of the results of clinical trials, and the results of any early-stage clinical trials we commence may not be predictive of the results of the later-stage clinical trials. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and initial clinical trials. There is a high failure rate for drugs proceeding through clinical

trials, and a number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies. There can be no assurance that any of our current or future clinical trials will ultimately be successful or support further clinical development of any of our drug candidates. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval of any products. Any such setbacks in our clinical development could have a material adverse effect on our business and operating results.

Interim, "topline" and preliminary data from our clinical trials may differ materially from the final data.

From time to time, we may disclose interim data from our clinical trials. Interim data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more data on existing patients become available. Adverse differences between interim data and final data could significantly harm our business, financial condition, results of operations and prospects. From time to time, we may also publicly disclose preliminary or "topline" data from our clinical trials, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same clinical trials, or different conclusions or considerations may qualify such topline results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available.

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 drug candidate or product and the value of our company in general.

In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is typically a summary of extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, drug candidate or our business. If the topline 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 drug candidates may be harmed, which could harm our business, financial condition, operating results and prospects.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study 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 drug candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents for participation in our clinical trials and, where appropriate, tissue samples for future exploratory research efforts;

- the risk that patients enrolled in clinical trials will not remain in the trial through the completion of evaluation; and
- disruption by man-made or natural disasters, reduction of government funding for health care, or public health pandemics or epidemics or other business interruptions.

In addition, our clinical trials will compete with other clinical trials for drug candidates that are in the same therapeutic areas as our current and potential future drug candidates. This competition will reduce the number and types of patients available to us, because some patients who might have enrolled in our trials may instead opt to enroll in a trial conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which would reduce the number of patients who are available for our clinical trials at such sites. Moreover, because our current and potential future drug candidates may represent a departure from more commonly used methods for treatment, potential patients and their doctors may be inclined to use conventional therapies rather than enroll patients in our clinical trials.

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

Changes in methods of drug candidate manufacturing or formulation may result in additional costs or delay.

As drug candidates proceed from nonclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered to optimize results. However, any change could entail additional cost and risk potential delay if the reformulated or otherwise altered drug candidate performs differently than expected or intended, which could require modification to the nonclinical or clinical program. Such changes may also require additional testing, including bridging or comparability testing to demonstrate the validity of clinical data obtained in clinical trials following manufacturing changes, FDA notification or FDA approval.

Moreover, we have not yet manufactured or processed on a commercial scale any of our drug candidates. We may make changes as we work to optimize our manufacturing processes, but we cannot be sure that even minor changes in our processes will result in therapies that are safe and effective or that will be approved for commercial sale.

Our current or future drug candidates may cause undesirable side effects or have other properties when used alone or in combination with other approved products or investigational new drugs that could delay or halt their clinical development, prevent their marketing approval, limit their commercial potential or result in significant negative consequences.

Undesirable or clinically unmanageable side effects from one or more of our drug candidates or potential future products could occur and cause us or regulatory authorities to interrupt, delay or terminate clinical trials, could result in a more restrictive label or could cause the delay or denial of marketing approval by the FDA or comparable foreign regulatory authorities. Further, results of our ongoing and planned clinical trials could reveal unacceptably severe and prevalent side effects or unexpected characteristics.

If unacceptable toxicities or other undesirable side effects arise in the development of any of our current or future drug candidates, we could suspend or terminate our trials, or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of the drug candidate for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial, or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. Inadequately recognizing or managing the potential side effects of our drug candidates could result in patient injury or death. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected drug candidate and may harm our business, financial condition and prospects significantly.

Although our current and future drug candidates will undergo safety testing to the extent possible and, where applicable, under such conditions discussed with regulatory authorities, not all adverse effects of drugs can be predicted or anticipated. Unforeseen side effects could arise either during clinical development or, if such side

effects are more rare, after our products have been approved by regulatory authorities and the approved product has been marketed, resulting in the exposure of additional patients. To date, we have not demonstrated that any of our drug candidates are safe in humans, and we cannot predict if ongoing or future clinical trials will do so.

Furthermore, we plan to evaluate our drug candidates in combination with approved and/or experimental therapies. These combinations may have additional or more severe side effects than caused by our drug candidates as monotherapies or may cause side effects at lower doses. The uncertainty resulting from the use of our drug candidates in combination with other therapies may make it difficult to accurately predict side effects in potential future clinical trials.

If our clinical trials result in undesirable side effects, or if any of our drug candidates receives marketing approval and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could occur, including, as applicable:

- regulatory authorities may withhold approval or may withdraw their approval of the product;
- we may be required to recall a product or change the way such product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we may be required to implement a Risk Evaluation and Mitigation Strategy (REMS) or create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of the foregoing events could prevent us from achieving or maintaining market acceptance of the particular drug candidate, if approved, and result in the loss of significant revenue to us, which would adversely affect our business, financial condition, results of operations and prospects. In addition, if one or more of our drug candidates prove to be unsafe, our entire technology platform and pipeline could be affected, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Any current or future drug candidates we may develop and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a drug candidate will prevent us from commercializing the drug candidate in a given jurisdiction. We have not received approval to market any drug candidates from regulatory authorities in any jurisdiction and it is possible that none of our current or future drug candidates will ever obtain regulatory approval. As an organization, we have no experience in filing and supporting the applications necessary to gain marketing approvals. Securing regulatory approval requires the submission of extensive nonclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the drug 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. Any drug 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.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional 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 drug 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. There is also uncertainty as to how measures being implemented by the new administration will impact the operations of various agencies including the FDA. For example, the potential loss of personnel at various agencies, reduction in funding for agencies, or government shut downs could lead to disruptions and delays in review of our drug candidates.

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 nonclinical, clinical or other studies. In addition, varying interpretations of the data obtained from nonclinical and clinical testing could delay, limit, or prevent marketing approval of a drug 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 marketing approval or if we fail to obtain marketing approval of any current or future drug candidates we may develop, the commercial prospects for those drug candidates may be harmed, and our ability to generate revenues will be materially impaired.

Even if a current or future drug 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 drug 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, or such participants may prefer existing treatment options such as, in the case of pevifoscorvir sodium, nucleos(t)ide analogs including tenofovir alafenamide, tenofovir disoproxil fumarate, and entecavir for treatment of chronic HBV infection. If the drug candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable for a full fiscal year. The degree of market acceptance of any drug candidate, if approved for commercial sale, will depend on a number of factors, including:

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

Adverse events in our therapeutic areas of focus, including hepatological indications and viral diseases, could damage public perception of our current or future drug candidates and negatively affect our business.

The commercial success of our products will depend in part on public acceptance of our therapeutic areas of focus. Adverse events in clinical trials of our drug candidates, or post-marketing activities, or in clinical trials of others developing similar products or targeting similar indications and the resulting publicity, as well as any other adverse events in our therapeutic areas of focus, including hepatological indications and viral diseases, could result in decreased demand for any product that we may develop. If public perception is influenced by claims that the use of therapies in our therapeutic areas of focus are unsafe, whether related to our therapies or those of our competitors, our products may not be accepted by the general public or the medical community.

Future adverse events in our therapeutic areas of focus or the biopharmaceutical industry could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our products. Any increased scrutiny could delay or increase the costs of obtaining marketing approval for the drug candidates we have developed, are developing and may in the future develop.

Negative developments and negative public opinion of technologies on which we rely may damage public perception of our drug candidates or adversely affect our ability to conduct our business or obtain regulatory approvals for our drug candidates.

The clinical and commercial success of our drug candidates will depend in part on public acceptance of the use of technologies for the prevention or treatment of human diseases. Adverse public attitudes may adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians specializing in our targeted diseases prescribing, and their patients being willing to receive, our drug candidates as treatments in lieu of, or in addition to, existing, more familiar, treatments for which greater clinical data may be available. Any increase in negative perceptions of the technologies that we rely on may result in fewer physicians prescribing our products (if approved) or may reduce the willingness of patients to utilize our products or participate in clinical trials for our drug candidates.

Increased negative public opinion or more restrictive government regulations in response thereto, would have a negative effect on our business, financial condition, results of operations or prospects and may delay or impair the development and commercialization of our drug candidates or demand for such drug candidates. Adverse events in our nonclinical studies or clinical trials or those of our competitors or of academic researchers utilizing similar technologies, even if not ultimately attributable to drug candidates we may discover and develop, and the resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of potential drug candidates we may identify and develop, stricter labeling requirements for those drug candidates that are approved, a decrease in demand for any such drug candidates and a suspension or withdrawal of approval by regulatory authorities of our drug candidates.

Even if we receive marketing approval of a drug candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products, if approved.

Any marketing approvals that we receive for any current or future drug candidate may be subject to limitations on the approved indicated uses for which the product may be marketed or contain requirements for potentially costly post-market testing and surveillance to monitor the safety and efficacy of the drug candidate. The FDA may also require a REMS as a condition of approval of any drug candidate, which could include requirements for a Medication Guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk-minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves a drug candidate, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import and export and record keeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, establishment registration, as well as continued compliance with cGMP, and GCP, for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with any approved candidate, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or product recalls;
- fines, untitled and warning letters, or holds on clinical trials;
- refusal by the FDA or other regulatory authorities to approve pending applications or supplements to approved applications we filed or suspension or revocation of license approvals;
- exclusion of eligibility from government contracts or refusals of government contracts;
- product seizure or detention, or refusal to permit the import or export of the product; and

- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay marketing approval of a product. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve profitability for a full fiscal year.

Even if we obtain and maintain approval for our drug candidates from the FDA, we may never obtain approval outside the United States, which would limit our market opportunities.

Approval of a drug candidate in the United States by the FDA does not ensure approval of such drug candidate by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries. Sales of our drug candidates outside the United States will be subject to foreign regulatory requirements governing clinical trials and marketing approval. Even if the FDA grants marketing approval for a drug candidate, comparable foreign regulatory authorities also must approve the manufacturing and marketing of the drug candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and more onerous than, those in the United States, including additional nonclinical studies or clinical trials. In many countries outside the United States, a drug candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for any drug candidates, if approved, is also subject to approval. Obtaining approval for our drug candidates in the European Union from the European Commission following the opinion of the EMA, if we choose to submit a marketing authorization application there, would be a lengthy and expensive process. Even if a drug candidate is approved, the EMA may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming additional clinical trials or reporting as conditions of approval. Approval of certain drug candidates outside of the United States, particularly those that target diseases that are more prevalent outside of the United States, will be particularly important to the commercial success of such drug candidates. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our drug candidates in certain countries.

Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. For example, we have or are currently conducting initial clinical trials for pevifoscorvir sodium, ALG-055009 and ALG-097558 in many countries (e.g., United States, Canada, and throughout Asia and Europe), and plan to expand into additional countries and territories and our conduct of the trials must satisfy specific requirements in order for the FDA to accept the data in support of an IND or NDA in the United States. Further, any regulatory approval for our drug candidates may be withdrawn. If we fail to comply with the applicable regulatory requirements, our target market will be reduced and our ability to realize the full market potential of our drug candidates will be harmed and our business, financial condition, results of operations and prospects could be harmed.

Risks associated with international trade policies (including with respect to tariffs) or our international operations, including seeking and obtaining approval to commercialize our drug candidates in foreign jurisdictions, could harm our business.

We engage in international operations with offices in the United States, Belgium and China as well as third-party suppliers spanning multiple countries outside the United States, and we intend to seek approval to market our drug candidates within and outside of the United States. We may also do so for future drug candidates. Due to the complex relationship among the United States and the countries in which we conduct our business, there is an inherent risk that political, diplomatic, and national security factors may lead to global trade restrictions and changes to trade policies or export and import regulations which could harm our business. The United States government has implemented tariffs affecting a wide range of products and jurisdictions and has indicated an intention to continue developing new trade policies, which may include tariffs on imported pharmaceutical products. In response, certain foreign governments have announced or implemented reciprocal or retaliatory tariffs and other protectionist measures. Additionally, some pharmaceutical companies have negotiated trade deals with the Trump Administration to address the tariffs. The United States government's tariff policy has undergone rapid shifts, creating uncertainly that may harm our business by, among other things, leading to higher import prices and negatively impacting market

conditions.

We currently rely, and expect to continue to rely, on third parties located outside of the United States for the manufacture of certain drug candidates for clinical testing, as well as for manufacture of products that we may commercialize, if approved.

We expect that we are or will be subject to additional risks related to these international business markets and relationships, including:

- different regulatory requirements for approval of drug candidates in foreign countries, including challenging processes for marketing biopharmaceutical products;
- reduced protection for and enforcement of intellectual property rights;
- heightened or different data privacy and information security laws, regulations and policies;
- unexpected changes in tariffs, proposed tariffs, implementation of new tariffs, reciprocal or retaliatory trade measures, sanctions, trade barriers and regulatory requirements;
- changes to global trade policies as a result of trade disputes or more restrictive trade policies;
- economic weakness, including inflation or political instability in particular foreign economies and markets; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing and insurance regimes;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities;
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires; and
- disruptions resulting from the impact of public health pandemics or epidemics (including, for example, the COVID-19 pandemic).

Increases in tariffs will likely result in increased research and development expenses, including with respect to increased costs associated with drug product shipments, laboratory supplies, equipment, research materials and components and information technology supplies and materials. Increases in tariffs will likely increase our supply chain complexity and could also potentially disrupt our existing supply chain. The ultimate impact of current or future tariffs and trade restrictions remains uncertain.

In addition, there are complex regulatory, tax, labor and other legal requirements imposed by many of the individual countries in which we may operate, with which we will need to comply.

Disruptions at the FDA and other government agencies caused by funding shortages, layoffs, government shutdowns, or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or could 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 to review and approve new products can be affected by a variety of factors, including government budget and funding levels, government shutdowns, statutory, regulatory, and policy changes, layoffs at the FDA and other government agencies, the FDA's hiring and retention of key personnel and receipt of user fees, changes in senior leadership at FDA and HHS, and other events that may otherwise affect the FDA's performance of routine functions. Average review times at the agency have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new products to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, on October 1, 2025, the U.S. government initiated a shutdown that lasted 43 days, and certain regulatory agencies, such as the FDA, had to

furlough employees and stop certain activities. Such shutdowns have also occurred several times in the past, with the longest prior shutdown beginning December 22, 2018 and lasting 35 days. There is no assurance that a similar shutdown will not occur in the future, causing delays at the FDA and other key agencies.

Relatedly, in response to the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations, any resurgence of the virus or emergence of new variants may lead to further inspectional or administrative delays.

If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impair 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.

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

We currently focus our product development on novel therapeutics to address unmet needs in hepatological indications and viral diseases. Our eligible patient population, pricing estimates and available coverage and reimbursement may differ significantly from the actual market addressable by our drug candidates. Our estimates of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our drug candidates, are based on our beliefs and analyses based on a variety of sources, including scientific literature, patient foundations or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of the diseases we are targeting. The number of patients may turn out to be lower than expected, and the potentially addressable patient population for each of our drug candidates may be limited or may not be receptive to treatment with our drug candidates, and new patients may become increasingly difficult to identify or access. Certain potential patients may have or develop a resistance to our potential therapies or otherwise be unable to be treated with our potential therapies for chronic HBV infection, COVID-19 or other viral diseases as a result of their genetic makeup. In addition, the route of administration for our potential therapies could be inconvenient and/or not commercially viable, which could also limit the potential market for our therapies.

If the market opportunities for our drug candidates are smaller than we estimate, it could have an adverse effect on our business, financial condition, results of operations and prospects.

For example, we believe MASH to be one of the most prevalent chronic liver diseases worldwide, however, our projections of the number of people who have MASH, as well as the subset of people with the disease who have the potential to benefit from treatment with our drug candidates, are based on our beliefs and estimates. The effort to identify patients with MASH is in early stages, and we cannot accurately predict the number of patients for whom treatment might be possible. MASH is often undiagnosed and may be left undiagnosed for a long time, partly due to the disease being largely asymptomatic. Further, if government authorities and third-party payors choose to limit coverage and reimbursement of our MASH drug candidate, such as limiting the number of patients' treatment that would be covered and reimbursable, this could result in a smaller market opportunity for our MASH drug candidate than we anticipate.

In addition, the number of people who have chronic HBV infection, as well as the subset of people with the disease who have the potential to benefit from treatment with our drug candidates, may be reduced due to factors including the genotype or variant of HBV, availability of alternative therapies, political roadblocks to approval and/or treatment in certain countries and the virus's development of resistance to our potential treatments after long-term and persistent exposure to antiviral therapy.

We intend to develop our current drug candidates, and expect to develop other future drug candidates, in combination with other therapies, which exposes us to additional risks.

We intend to develop our current drug candidates, and expect to develop other future drug candidates, in combination with one or more therapies, including therapies that we develop and those developed externally. Even if a drug candidate we develop were to receive marketing approval or be commercialized for use in combination with other therapies, we would face the risk that the FDA or similar regulatory authority outside of the United States could revoke approval of the therapy used in combination with our drug candidate or that safety, efficacy,

manufacturing or supply issues could arise with these other therapies. Combination therapies are commonly used for the treatment of viral diseases and it is generally believed they will be required for MASH, and we would be subject to similar risks if we develop any of our drug candidates for use in combination with other drugs. Our potential development of a THR-ß agonist for obesity may also rely on combination therapy, for example combinations with incretin receptor agonists. Issues with other products could result in our own products, if approved, being removed from the market or suffering commercially. In addition, we may evaluate our current drug candidates and other future drug candidates in combination with one or more other therapies that may have not yet been approved for marketing by the FDA or similar regulatory authorities outside of the United States. We will not be able to market and sell any drug candidate we develop in combination with any such unapproved therapies that do not ultimately obtain marketing approval.

If the FDA or similar regulatory authorities outside of the United States do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with, the drugs we choose to evaluate in combination with or any of our drug candidate, we may be unable to obtain approval of or market any of our combination treatments.

We face significant competition, and if our competitors develop and market products that are more effective, safer or less expensive than the drug candidates we develop, our commercial opportunities will be negatively impacted.

The life sciences industry is highly competitive. We are currently developing therapies that will compete, if approved, with other products and therapies that currently exist or are being developed. Products we may develop in the future are also likely to face competition from other products and therapies, some of which we may not currently be aware of. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities and other research institutions. Many of our competitors have significantly greater financial, manufacturing, marketing, product development, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining marketing approvals, recruiting patients and manufacturing pharmaceutical products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the drug candidates that we develop obsolete. Further, mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or marketing approval or discovering, developing and commercializing products in our field before we do.

Current FDA-approved treatments for chronic HBV infection include peg-IFNα, marketed by Roche Holding AG (Roche), and oral antiviral agents such as nucleos(t)ide analogs, marketed by Gilead Sciences, Inc. (Gilead) and Bristol-Myers Squibb Company. These treatments have not been proven to lead to either a functional or a complete cure in the vast majority of patients, and in the case of nucleos(t)ide analogs, may require life-long treatment. Several large and small pharmaceutical companies are developing programs with various mechanisms of action, to be used alone or in combination, with the goal of achieving higher rates of viral suppression or functional cure in patients with chronic HBV infection. Companies with oligonucleotide agents in clinical development include Arbutus Biopharma Corporation, Ionis Pharmaceuticals, Inc. (together with GlaxoSmithKline plc (GSK)), Arrowhead Pharmaceuticals, Inc. (together with Janssen Pharmaceuticals, Inc. (Janssen)), and Precision BioSciences, Inc. Several companies are developing CAM-Es, including Assembly Biosciences Inc. Several companies, including Janssen, are developing therapeutic vaccines for HBV, and several others have approved HBV vaccines, including Dynavax Technologies, Inc., GSK, Johnson & Johnson, and Merck. Replicor, Inc. is developing nucleic acid polymers (NAPs) for use in patients with chronic HBV infection.

Current FDA approved treatments for obesity include injectable and oral GLP-1 receptor agonists, such as Novo Nordisk’s semaglutide, as well as injectable dual agonists such as Eli Lilly and Company’s tirzepatide. Many companies are developing next-generation incretin receptor agonists, including in oral form, such as Eli Lilly and Company’s orfoglipron. Various other mechanisms are currently under development, including Pfizer’s amylin analog and Novo Nordisk’s CB1 receptor monlunabant.

There are currently two FDA-approved treatments for MASH: Madrigal Pharmaceuticals, Inc., THR-ß agonist and Novo Nordisk's GLP-1 receptor agonist semaglutide. A number of pharmaceutical companies, including AbbVie, Inc., AstraZeneca PLC/MedImmune LLC, Bristol‑Myers Squibb Company, Eli Lilly and Company, Merck, Pfizer, Inc., Novo Nordisk, Roche, as well as large and small biotechnology companies such as Gilead and Inventiva Pharma SA, are pursuing the development or marketing of pharmaceuticals that target MASH.

In addition to remdesivir, which is FDA-approved, Pfizer, Inc. has received approval from the FDA for Paxlovid, an orally administered SARS-CoV-2 protease inhibitor co‑administered with ritonavir. Similarly, Merck (together with Ridgeback Bio), is developing the drug molnupiravir, an oral antiviral drug which was issued an emergency use authorization by the FDA on December 23, 2021.

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 effects, are more convenient, have a broader label, are marketed more effectively, including gaining exclusivity for their competing products on formularies thereby excluding our products from such formularies, are reimbursed or are less expensive than any products that we may develop. Our competitors also may obtain FDA, EMA or other marketing approval for their products more rapidly than we may obtain approval for ours (if at all), which could result in our competitors establishing a strong market position before we are able to enter the market (if ever). Even if the drug candidates we develop achieve marketing approval, they may be priced at a significant premium over competitive products, resulting in reduced competitiveness of our products.

Smaller and other early-stage companies may also prove to be significant competitors. In addition, academic research departments and public and private research institutions may be conducting research on compounds that could prove to be competitive.

These third parties compete with us not only in drug candidate development, but also in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring and/or licensing technologies complementary to, or necessary for, our programs.

In addition, the biopharmaceutical industry is characterized by rapid technological change. If we fail to keep pace with technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our drug candidates obsolete, less competitive or not economical, thereby adversely affecting our business, financial condition and results of operations.

If any of our current or future drug candidates obtain regulatory approval, additional competitors could enter the market with generic versions of such products, which may result in a material decline in sales of our competing products.

Under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments to the FDCA, a pharmaceutical manufacturer may file an abbreviated new drug application (an ANDA) seeking approval of a generic version of an approved innovator product. Under the Hatch-Waxman Amendments, a manufacturer may also submit an NDA under section 505(b)(2) of the FDCA that references the FDA’s prior approval of the innovator product. A 505(b)(2) NDA product may be for a new or improved version of the original innovator product. The Hatch-Waxman Amendments also provide for certain periods of regulatory exclusivity, which preclude FDA approval (or in some circumstances, FDA filing and review) of an ANDA or 505(b)(2) NDA. In addition to the benefits of regulatory exclusivity, an innovator NDA holder may have patents claiming the active ingredient, product formulation or an approved use of the drug, which would be listed with the product in the FDA publication “Approved Drug Products with Therapeutic Equivalence Evaluations,” known as the Orange Book. If there are patents listed in the Orange Book for a product, a generic or 505(b)(2) applicant that seeks to market its product before expiration of the patents must include in their applications what is known as a “Paragraph IV” certification, challenging the validity or enforceability, or claiming non-infringement, of the listed patent or patents. Notice of the certification must be given to the patent owner and NDA holder and if, within 45 days of receiving notice, either the patent owner or NDA holder sues for patent infringement, approval of the ANDA or 505(b)(2) NDA is stayed for up to 30 months.

Accordingly, if any of our future drug candidates are approved, competitors could file ANDAs for generic versions of these products or 505(b)(2) NDAs that reference our products. If there are patents listed for such drug products in the Orange Book, those ANDAs and 505(b)(2) NDAs would be required to include a certification as to

each listed patent indicating whether the ANDA applicant does or does not intend to challenge the patent. We cannot predict which, if any, patents in our current portfolio or patents we may obtain in the future will be eligible for listing in the Orange Book, how any generic competitor would address such patents, whether we would sue on any such patents or the outcome of any such suit.

We may not be successful in securing or maintaining proprietary patent protection for products and technologies we develop or license, despite expending a significant amount of resources that could have been focused on other areas of our business. Moreover, if any of our owned or in-licensed patents that are listed in the Orange Book are successfully challenged by way of a Paragraph IV certification and subsequent litigation, the affected product could immediately face generic competition and its sales would likely decline rapidly and materially.

Even if we are able to commercialize any drug candidates, such products may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new products vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a drug candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the drug candidate, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the drug candidate in that country, potentially to the point of unviability. Adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates, even if our drug candidates obtain marketing approval.

Our ability to successfully commercialize any drug candidates, whether as a single agent or in combination, will also depend in part on the extent to which coverage and reimbursement for these drug candidates and related treatments is available from government authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. It is difficult to predict at this time what government authorities and third-party payors may decide with respect to coverage and reimbursement for our programs (if approved).

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities, particularly in the European Union, and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular products and requiring substitutions of generic products and/or biosimilars. Increasingly, third-party payors are scrutinizing the prices charged for drugs. We cannot be sure that coverage will be available for any drug candidate that we commercialize and, if coverage is available, the level of reimbursement. These government authorities and third-party payors are also examining the cost-effectiveness of drugs, in addition to their safety and efficacy. For example, in some countries, we, or any future collaborators, may be required to conduct a clinical trial that compares the cost-effectiveness of our drug to other therapies to obtain reimbursement or pricing approval. Reimbursement may impact the demand for, or the price of, any drug candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any drug candidate for which we obtain marketing approval.

Further, there may be significant delays in obtaining coverage and reimbursement for newly approved drugs, as the process is time-consuming and costly, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Additionally, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the United States, which may result in coverage and reimbursement for drug products that differ significantly from payor to payor. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may not be sufficient to cover our costs and may not be permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower-cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict or apply tariffs to imports of drugs from countries where they may be sold at lower prices than in the United States. Additionally, the Trump

administration recently published regulations that tie Medicare drug pricing to prices for the same drugs in certain reference countries. Such "most favored nation" pricing rules could limit the profitability of our drugs by affecting pricing and/or causing us to avoid commercializing our drugs in certain markets, and could have a significant impact on our commercial and financial success. For more information, see the risk factor titled "— Current and future healthcare reform legislation or regulation may increase the difficulty and cost for us to commercialize drug candidates for which we receive approval, may affect the prices we may obtain, and may have a material adverse effect on our business and results of operations."

Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved drugs that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize drugs and our overall financial condition.

We may not be successful in our efforts to identify or discover other drug candidates and may fail to capitalize on programs or drug candidates that may present a greater commercial opportunity or for which there is a greater likelihood of success.

The success of our business depends upon our ability to identify, develop and commercialize drug candidates. If we do not successfully develop and eventually commercialize products, we will face difficulty in obtaining product revenue in future periods, resulting in significant harm to our financial position and adversely affecting our share price. Research programs to identify new drug candidates require substantial technical, financial and human resources, and we may fail to identify potential drug candidates for numerous reasons.

Additionally, because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or drug candidates or for indications that later prove to have greater commercial potential. For example, we are currently focused on the development of our current drug candidates for hepatological indications, viral indications and, most recently, obesity. However, the advancement of these drug candidates may ultimately prove to be unsuccessful or less successful than another program in our pipeline that we might have chosen to pursue on a less aggressive basis. However, due to the significant resources required for the development of our drug candidates, we must focus on specific diseases and disease pathways and decide which drug candidates to pursue and the amount of resources to allocate to each. Our near-term objective is to demonstrate favorable profiles through clinical trials of our drug candidates pevifoscorvir sodium, ALG‑055009 and ALG-097558. Our estimates regarding the potential market for our drug candidates could be inaccurate and our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular drug candidates or therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities. Similarly, any potential decision to delay or terminate development of a drug candidate or program may subsequently also prove to be suboptimal and could cause us to miss valuable opportunities. Further, if we do not accurately evaluate the commercial potential for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate. Alternatively, we may allocate internal resources to a drug candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

If any of these events occur, we may be forced to abandon or delay our development efforts with respect to a particular drug candidate or we may fail to develop a potentially successful drug candidate or capitalize on profitable market opportunities, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may seek and fail to obtain fast track or breakthrough therapy designations from the FDA for our current or future drug candidates or priority review designation for any NDA we may submit to the FDA. Even if we are successful, these programs may not lead to a faster development or regulatory review process, and they do not guarantee we will receive approval for any drug candidate. We may also seek to obtain accelerated approval for one or more of our drug candidates but the FDA may disagree that we have met the requirements for such approval.

If a product is intended for the treatment of a serious or life-threatening condition and nonclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product sponsor may apply for fast track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular drug candidate is eligible for this designation, we cannot assure you that the FDA would decide

to grant it. Even if we do receive fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may rescind the fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

We may also seek breakthrough therapy designation for any drug candidate that we develop. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Like fast track designation, breakthrough therapy designation is within the discretion of the FDA. Accordingly, even if we believe a drug candidate we develop meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of breakthrough therapy designation for a drug candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if a drug candidate we develop qualifies as a breakthrough therapy, the FDA may later decide that the drug no longer meets the conditions for qualification and rescind the designation.

Drugs designated as fast track products or breakthrough therapies by the FDA are also eligible for priority review of any NDA submitted for such drug candidates, which could result in FDA action on the NDA in a shorter timeframe than under standard review. In order to grant priority review designation, the FDA must find that the product, if approved, would provide a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious disease or condition. However, priority review does not guarantee approval of the NDA and may not result in a shorter overall review timeline if the FDA has significant questions or additional requests as part of the NDA review.

In addition, the FDA may grant accelerated approval to a product if the FDA determines that it 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. For example, this is currently the case with drugs for the treatment of MASH. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. If such confirmatory studies fail to confirm the drug's clinical benefit or are not completed in a timely manner, the FDA may withdraw its approval of the drug on an expedited basis. In addition, in December 2022, President Biden signed an omnibus appropriations bill to fund the U.S. government through fiscal year 2023. Included in the omnibus bill is the Food and Drug Omnibus Reform Act of 2022, which among other things, provided the FDA with new statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval and additional oversight over confirmatory trials. Under these provisions, the FDA may, among other things, require a sponsor of a product seeking accelerated approval to have a confirmatory trial underway prior to such approval being granted.

In addition, the FDA requires pre-approval of promotional materials for accelerated approval products, once approved. We cannot guarantee that the FDA will conclude that any of our drug candidates has met the criteria to receive accelerated approval, which would require us to conduct additional clinical testing prior to seeking FDA approval. Even if any of our drug candidates received approval through this pathway, the product may fail required post-approval confirmatory clinical trials, and we may be required to remove the product from the market or amend the product label in a way that adversely impacts its marketing.

We may be required to make significant payments under our license agreements, including those with Emory University and KU Leuven.

We entered into a License Agreement with Emory in June 2018, and a Research, Licensing and Commercialization Agreement with KU Leuven in June 2020 and an amendment in July 2023. Under the Emory License Agreement and KU Leuven Agreement, we are subject to significant obligations, including milestone payments, royalty payments, and certain other agreed-to costs. For example, in August 2025, we made a $9.0 million payment to Emory University following the first subject dosed in our Phase 2 study of pevifoscorvir sodium. For more information regarding our license agreements, please see the section titled "Business—License agreements and collaborations" of our Annual Report on Form 10-K for the year ended December 31, 2025. As these payments

become due, we may not have sufficient funds available to meet our obligations and our development efforts may be materially harmed. Furthermore, if we are forced to raise additional funds, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts, or grant rights to develop and market drug candidates that we would otherwise develop and market ourselves.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of any approved products.

We face an inherent risk of product liability as a result of the clinical testing of drug candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any drug candidate we develop causes or is perceived to cause illness or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of any approved products. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for any approved product;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary payments to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- adverse effects to our results of operations and business;
- the inability to commercialize any drug candidate; and
- a decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost or at all to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with collaboration partners.

Insurance coverage is increasingly expensive. We may not be able to maintain insurance, including product liability insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise, if at all. Our product liability insurance policy contains 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 current or future collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Current and future healthcare reform legislation or regulation may increase the difficulty and cost for us to commercialize drug candidates for which we receive approval, may affect the prices we may obtain, and may have a material adverse effect on our business and results of operations.

In the United States, there have been and continue to be a number of legislative and regulatory initiatives and proposed initiatives to contain healthcare costs that could, among other things, affect our ability to profitably sell our products. Among policy makers and payors in the United States and elsewhere, there is significant interest in

promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States and elsewhere, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative and regulatory initiatives. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any drug candidates approved for sale. New and changing laws and regulations may also create uncertainty about how such laws and regulations will be interpreted and applied. If we are found to have violated laws and regulations, it could materially adversely affect our business, results of operations, and financial condition.

For example, the Affordable Care Act (the ACA) was enacted in 2010, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. Among the provisions of the ACA of importance to our business, are provisions related to our ability to commercialize and the prices we may obtain for any drug candidates that are approved for sale, an increase of the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, an extension of manufacturer rebate liability from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations, and the establishment of an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs.

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

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. The Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, enacted in 2013, among other things, further reduced Medicare payments to several types of providers. The American Rescue Plan Act of 2021 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.

The Inflation Reduction Act (the IRA), which was enacted in 2022, marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, 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); redesigns the Medicare Part D benefit (beginning in 2024); and replaces the Part D coverage gap discount program with a new discounting program (which began in 2025). CMS has published the negotiated prices for the initial ten drugs, which went into effect in 2026, and the subsequent 15 drugs, which will first be effective in 2027. CMS has also published the next set of 15 drugs that will be subject to negotiation. The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented, although the drug price negotiation program is currently subject to legal challenges. The impact of the IRA on us and the pharmaceutical industry cannot yet be fully determined, but is likely to be significant.

The One Big Beautiful Bill Act (the OBBBA), which was enacted in July 2025, imposes significant reductions in the funding of the Medicaid program. Such reductions are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, which could adversely affect the sales of any drug candidate that we commercialize and negatively impact the pharmaceutical industry in general.

The Trump administration is pursuing a two-fold strategy to reduce drug costs in the United States. While it is unclear whether and how the Trump proposals will be implemented, the Trump policies are likely to have a negative impact on the pharmaceutical industry and on our ability to receive adequate revenues for any drug candidate that we commercialize. On the one hand, President Trump has threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the United States to the lowest price in a group of other countries. In response, multiple manufacturers have reportedly entered into confidential pricing agreements with the federal government. On the other hand, the Trump administration is pursuing traditional regulatory pathways to impose drug pricing policies and published two proposed regulations in December 2025, referred to as Globe and Guard. If finalized, these regulations would implement mandatory payment models under which manufacturers of eligible drugs would be required to pay

rebates to the federal government on a portion of the units of their drugs that are reimbursed by Medicare, with the rebate amount based on most favored nation pricing. Imposing a rebate in the U.S. that is based on drug prices outside the U.S. would mark a drastic and unprecedented shift in the U.S. pharmaceutical market, and while the impact of the Globe and Guard proposed regulations, if finalized, cannot yet be determined, it is likely to be significant.

There has been and continues to be increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation and regulation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.

Some U.S. states have enacted legislation creating so-called prescription drug affordability boards, and to date one state has used its prescription drug affordability board to impose an upper payment limit. Some states are also seeking to implement general, across the board price caps for pharmaceuticals, or are seeking to regulate drug distribution. Some measures are designed to encourage importation from other countries. These types of initiatives may result in additional reductions in Medicare, Medicaid, and other healthcare funding, and may otherwise affect the prices we may obtain or the frequency with which any drug candidate that we commercialize is prescribed or used.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit prices we are able to charge for any drug candidate we develop, or could reduce the amounts that federal and state governments will pay for healthcare products and services, which could result in additional pricing pressure or reduced demand for any drug candidate we develop.

Our actual or perceived failure to comply with current or future federal, state and foreign laws and regulations and industry standards relating to data privacy and protection laws could lead to government investigations and enforcement actions, which could result in civil or criminal penalties, private litigation, and/or adverse publicity and could negatively affect our operating results, financial condition and business.

The global data protection landscape is rapidly evolving, and we and our partners may be subject to federal, state and foreign data privacy and security laws and regulations governing the collection, use, disclosure, retention, and security of personal information, such as information that we may collect in connection with clinical trials in the United States, Europe and elsewhere. Any actual or alleged failure by us or our third-party vendors, collaborators, contractors and consultants to comply with any of these laws and regulations could result in, among other things, notification obligations, government investigations or enforcement actions against us, which could result in fines and penalties, claims for damages by affected individuals and third parties, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects. These laws, rules and regulations evolve frequently and their scope may continually change, through new legislation, amendments to existing legislation and changes in enforcement practices, and may be inconsistent from one jurisdiction to another. The interpretation and application of health information-related and data protection laws in the United States, the EU and elsewhere, are often uncertain, contradictory and in flux. As a result, implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities.

In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), which govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996 as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and regulations implemented (collectively, HIPAA). Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information provided to us by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA.

Many states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. Further, we may also be subject to other state laws governing the privacy, processing and protection of personal information. For example, the California Consumer Privacy Act as amended by the California Privacy Rights Act (collectively, CCPA) requires certain businesses that process personal information of California residents to, among other things: provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information; 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 enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. It has also created a California data protection agency authorized to issue substantive regulations and 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 United States. These laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA, or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

We currently operate in countries outside of the United States, including Belgium and other parts of Europe, Australia and parts of Asia, where laws may in some cases be more stringent than the requirements in the United States. For example, in Europe, we are subject to the European Union General Data Protection Regulation (EU GDPR) and to the United Kingdom General Data Protection Regulation and Data Protection Act 2018 (collectively, the UK GDPR) (the EU GDPR and UK GDPR together referred to as the GDPR). The GDPR imposes strict requirements for the processing of the personal data of individuals within the European Economic Area (EEA) or United Kingdom (UK) in the context of our activities within the EEA or UK. The GDPR applies enhanced protections to health or sensitive personal data and other special categories of personal data, including some of the personal data we process in respect of clinical trial participants which may be subject to additional compliance obligations and to local law derogations. The GDPR also imposes additional obligations when we contract with third-party processors in connection with the processing of any personal data. Failure to comply with the requirements of the GDPR could result in fines of up to €20 million / £17.5 million or 4% of the total worldwide annual turnover of our preceding fiscal year, whichever is higher. In addition to fines, a breach of the GDPR may result in regulatory investigations, reputational damage, orders to cease/ change our data processing activities, enforcement notices, assessment notices (for a compulsory audit), civil claims (including class actions) and/or other administrative penalties.

Among other requirements, the GDPR regulates the transfer of personal data to third countries outside of the EEA or UK, such as the United States, which are not considered by the European Commission or UK government to provide an adequate level of personal data protection, and the efficacy and longevity of current transfer mechanisms between the EEA, and the United States remains uncertain. We currently rely on approved data transfer mechanisms that may include the EU standard contractual clauses (SCCs), the UK Addendum to the SCCs, the UK International Data Transfer Agreement and the new EU-U.S. Data Privacy Framework (DPF) to transfer personal data outside the EEA and the UK, including to the United States, with respect to both intragroup and third party transfers. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. 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 operate our business, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

In addition, we use artificial intelligence, including machine learning, and automated decision-making, technologies (collectively, AI Technologies) in our business. The regulatory framework for AI Technologies is rapidly evolving as many federal, state, and foreign government bodies and agencies have introduced or are currently considering additional laws and regulations. Additionally, existing laws and regulations may be interpreted in ways that would affect the operation of AI Technologies. As a result, implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future

laws, regulations, standards, or market perception of their requirements may have on our business and may not always be able to anticipate how to respond to these laws or regulations.

It is possible that new laws and regulations will be adopted in the United States and in other non-U.S. jurisdictions, or that existing laws and regulations, including competition and antitrust laws, may be interpreted in ways that would limit our ability to use AI Technologies for our business, or require us to change the way we use AI Technologies in a manner that negatively affects the performance of our products, services, and business and the way in which we use AI Technologies. We may need to expend resources to adjust our products or services in certain jurisdictions if the laws, regulations, or decisions are not consistent across jurisdictions. Further, the cost to comply with such laws, regulations, or decisions and/or guidance interpreting existing laws, could be significant and would increase our operating expenses (such as by imposing additional reporting obligations regarding our use of AI Technologies). Such an increase in operating expenses, as well as any actual or perceived failure to comply with such laws and regulations, could adversely affect our business, financial condition and results of operations.

Further, in 2024, the National Security Division of the U.S. Department of Justice (DOJ) issued a rule—referred to as the "Data Security Program" (DSP)—to implement Executive Order 14117 aimed at preventing access to "bulk U.S. sensitive personal data" and "government-related data" by "countries of concern" (including China, Russia, Iran, North Korea, Cuba, and Venezuela) and "covered persons" (as all such terms are defined in the DSP). Effective as of April 8, 2025, and fully enforceable as of July 9, 2025, the DSP imposes stringent obligations on companies within its scope and prohibits or restricts "covered data transactions" that grant countries of concern or covered persons access to bulk U.S. sensitive personal data or any amount of government-related data. The DSP is new, complex and has yet to be enforced, and as such, there is a risk that our interpretation of its applicability, scope, and requirements is incorrect, incomplete, or misapplied. Compliance with the DSP may require us to invest heavily in data security and compliance measures, such as implementing and complying with the Cybersecurity and Infrastructure Security Agency's guidelines and other burdensome recordkeeping, reporting, and auditing requirements. It may also require us to implement new processes, stop or restrict certain data transfers, alter the geographic scope of our operations, cease doing business with certain third parties or using certain tools or vendors, or change how data flows throughout our business, any of which could materially impact our business operations or hinder our ability to grow our business. Finally, non-compliance with the DSP could result in significant civil or criminal penalties, which could materially adversely affect our business, results of operations, and financial condition.

Compliance with U.S. and foreign privacy and security laws, rules and regulations could require us to take on more onerous obligations in our contracts, require us to engage in costly compliance exercises, restrict our ability to collect, use and disclose data, or in some cases, impact our or our partners' ability to operate in certain jurisdictions. Each of these evolving laws can be subject to varying interpretations. Our actual or alleged failure by us or our employees, representatives, contractors, consultants, collaborators, or other third parties to comply with U.S. and foreign data protection laws and regulations could result in government investigations and enforcement actions (which could include civil or criminal penalties), fines and penalties, private litigation, and/or adverse publicity and could negatively affect our financial condition, operating results and business.

Our business and operations may suffer in the event that our information technology systems, or those used by our CROs or other contractors or consultants, fail or suffer security breaches.

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and the personal information of our employees, clinical trial subjects, and contractors. Despite the implementation of security measures, our information technology systems and those of our CROs and other contractors and consultants are vulnerable to attack, damage and interruption through diverse threat vectors, including natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks, computer hacks, employee theft or misuse, fraud, viruses and malware (e.g., ransomware), malicious software, phishing and other social engineering schemes, human error, denial or degradation-of-service attacks, sophisticated nation-state and nation-state-supported actors, and other unauthorized access and security breaches that could jeopardize the availability, confidentiality, integrity, and/or performance of our software, information technology systems, and data, and could expose us to legal, financial and reputational harm. There can be no assurance that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems and information.

Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. The risk is increased by recent advancements in artificial intelligence, which can be used by bad actors for harmful purposes. As such, any integration of artificial intelligence in our or any third party's operations, products or services is expected to pose new or unknown cybersecurity risks and challenges. We may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who continue to work remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques - including artificial intelligence - that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we have not to our knowledge experienced any significant system failure 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 development programs and our business operations, whether due to a loss, corruption or unauthorized disclosure of our trade secrets, personal information or other proprietary or sensitive information or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our drug candidates and to conduct clinical trials, and similar events relating to their information technology systems could also have a material adverse effect on our business. 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 confidential or proprietary information, we could be subject to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties, litigation (such as class actions), fines and significant liability and the development and commercialization of our future drug candidates could be delayed. Further, if we or our third-party vendors were to experience a significant cybersecurity breach of our or their information systems or data, the costs associated with the investigation, remediation and potential notification of the breach to counter-parties and data subjects could be material. In addition, our remediation efforts may not be successful. 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 reliance on third parties

We depend on collaborations with third parties for the development of certain of our potential drug candidates, and we may depend on additional collaborations in the future for the development and commercialization of these or other potential candidates. If our collaborations are not successful, we may not be able to capitalize on the market potential of these drug candidates.

We are currently collaborating with third parties to develop certain of our potential drug candidates. In the future, we may form or seek strategic alliances, joint ventures, or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to drug candidates we develop.

Collaborations involving our current and future drug candidates may pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations, and in some cases, may have the right to terminate the collaboration without cause;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, abandon a drug candidate, repeat or conduct new clinical trials or require a new formulation of a drug candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products (if any) or drug candidates;

- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or may otherwise not perform satisfactorily in carrying out these activities;
- collaborators may not properly prosecute, maintain, enforce or defend our intellectual property rights or may use our proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation, or other intellectual property proceedings;
- collaborators may own or co-own intellectual property covering products that result from our collaboration with them, and in such cases, we may not have the exclusive right to develop, license or commercialize such intellectual property;
- disputes may arise with respect to ownership of any intellectual property developed pursuant to our collaborations;
- disputes may arise between a collaborator or strategic partner and us that cause the delay or termination of the research, development or commercialization of the drug candidate, or that result in costly litigation or arbitration that diverts management attention and resources; and
- if a current or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated.

As a result, if we enter into additional collaboration agreements and strategic partnerships or license our intellectual property, products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to any drug candidate we develop could delay the development and commercialization of our drug candidates, which would harm our business prospects, financial condition, and results of operations.

We may seek to establish additional collaborations, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

The advancement of our drug candidates and development programs and the potential commercialization of our current and future drug candidates will require substantial additional cash to fund expenses. For some of our programs, we may decide to collaborate with other pharmaceutical and biotechnology companies with respect to development and potential commercialization. Any of these relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, divert our management's attention and disrupt our business.

We face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for any other collaborations will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the progress of our clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject drug candidate, the costs and complexities of manufacturing and delivering such drug candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative drug candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our drug candidate. Further, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our drug candidates because they may be deemed to be at too early of a stage of development for collaborative efforts and third parties may not view them as having the requisite potential to demonstrate safety and efficacy.

We may also be restricted under future collaboration agreements from entering into additional agreements on

certain terms with potential collaborators.

In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

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 drug candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our drug candidates or bring them to market and generate product revenue.

If conflicts arise between us and our collaborators or strategic partners, these parties may act in a manner adverse to us and could limit our ability to implement our strategies.

If conflicts arise between our collaborators or strategic partners and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Current or future collaborators or strategic partners may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations.

Our current or future collaborators or strategic partners may preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely, or fail to devote sufficient resources to the development and commercialization of products. Such collaborators could breach their agreements with us, or claim that we are in breach of our obligations. Furthermore, competing products, either developed by our current or future collaborators or strategic partners or to which our collaborators or strategic partners may have rights, may result in the withdrawal of partner support for our drug candidates. Any of these developments could harm our product development efforts.

We rely on third parties to conduct our ongoing and planned clinical trials and certain of our nonclinical studies for drug candidates we develop. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain marketing approval for or commercialize the drug candidates we are developing and our business could be substantially harmed.

We do not have the ability to independently conduct certain nonclinical studies and clinical trials. We rely on medical institutions, clinical investigators, contract laboratories, and other third parties, such as CROs, to conduct or otherwise support certain nonclinical studies and clinical trials for our drug candidates, including pevifoscorvir sodium, ALG‑055009, and ALG-097558, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our nonclinical studies and clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on CROs will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our nonclinical studies or clinical trials, we could be subject to untitled and warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

We and our CROs are required to comply with regulations and requirements, including GLP and GCP, for conducting, monitoring, recording and reporting the results of nonclinical studies and clinical trials, respectively, to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the Competent Authorities of the Member States of the EEA and comparable foreign regulatory authorities for any drugs in clinical development. The FDA enforces GLP and GCP requirements through periodic inspections of laboratories conducting studies, clinical trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable GLP or GCP, the data generated in our nonclinical studies or clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional nonclinical studies before allowing us to proceed with clinical trials or additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our future nonclinical studies or clinical trials will comply with GLP or GCP, as applicable. In addition, our nonclinical studies and clinical trials must be conducted with drug candidates produced under cGMP

regulations. Our failure or the failure of our CROs to comply with these regulations may require us to delay or repeat nonclinical studies or clinical trials, which would delay the marketing approval process and could also subject us to enforcement action. We also are required to register certain ongoing clinical trials and provide certain information, including information relating to the trial's protocol, on a government-sponsored database, ClinicalTrials.gov, within specific timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Although we intend to design the nonclinical studies and clinical trials for our drug candidates, CROs conduct all of the clinical trials and certain nonclinical studies. As a result, many important aspects of our nonclinical and clinical development, including their conduct and timing, will be outside of our direct control. Our reliance on third parties to conduct future nonclinical studies and clinical trials will also result in less direct control over the management of data developed through nonclinical studies or clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities;
- become financially distressed; or
- form relationships with other entities, some of which may be our competitors.

These factors may materially adversely affect the willingness or ability of third parties to conduct our nonclinical studies or clinical trials and may subject us to unexpected cost increases and/or delays that are beyond our control. If the CROs do not perform nonclinical studies or clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, marketing approval and commercialization of our drug candidates may be delayed, we may not be able to obtain marketing approval and commercialize our drug candidates, or our development program may be materially and irreversibly harmed. If we are unable to rely on nonclinical or clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of any nonclinical studies or clinical trials we conduct and this could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs on commercially reasonable terms, or at all. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the nonclinical or clinical data they obtain are compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, any nonclinical studies or clinical trials such CROs are associated with may be extended, delayed or terminated, and we may not be able to obtain marketing approval for or successfully commercialize our drug candidates. As a result, we believe that our financial results and the commercial prospects for our drug candidates in the subject indication would be harmed, our costs would increase and our ability to generate revenue would be delayed.

We rely on third parties to manufacture nonclinical and clinical drug supplies, and we intend to rely on third parties to produce commercial supplies of any approved product which increases the risk that we will not have sufficient quantities of such drug candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not own or operate manufacturing facilities for the production of nonclinical, clinical or commercial supplies of the drug candidates that we are developing or evaluating in our development programs. We lack the resources and the capabilities to manufacture any of our drug candidates on a nonclinical, clinical or commercial scale. We rely on third parties for supply of our nonclinical and clinical drug supplies (including key starting and intermediate materials), and our strategy is to outsource all manufacturing of our drug candidates and products to third parties. A disruption or termination in the supply of nonclinical or clinical drug supplies due to our reliance on third parties and/or a disruption in the supply chain generally could delay, prevent or impair our development or commercialization efforts.

In order to conduct clinical trials of drug candidates, we will need to have them manufactured in potentially large quantities. Our third-party manufacturers may be unable to successfully increase the manufacturing capacity for any of our clinical drug supplies (including key starting and intermediate materials) in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities and at any other time. For example, ongoing data on the stability of our drug candidates may shorten the expiry of our drug candidates and lead to clinical trial material supply shortages, and potentially clinical trial delays. If these third-party manufacturers are unable to successfully scale up the manufacture of our drug candidates in sufficient quality and quantity, the development, testing and clinical trials of that drug candidate may be delayed or infeasible, and regulatory approval or commercial launch of that drug candidate may be delayed or not obtained, which could significantly harm our business.

Our use of new third-party manufacturers increases the risk of delays in production or insufficient supplies of our drug candidates (and the key starting and intermediate materials for such drug candidates) as we transfer our manufacturing technology to these manufacturers and as they gain experience manufacturing our drug candidates (and the key starting and intermediate materials for such drug candidates).

Even after a third-party manufacturer has gained significant experience in manufacturing our drug candidates (or the key starting and intermediate materials for such drug candidates) or even if we believe we have succeeded in optimizing the manufacturing process, there can be no assurance that such manufacturer will produce sufficient quantities of our drug candidates (or the key starting and intermediate materials for such drug candidates) in a timely manner or continuously over time, or at all.

We may be delayed if we need to change the manufacturing process used by a third party. Further, if we change an approved manufacturing process, then we may be delayed if the FDA or a comparable foreign authority needs to review the new manufacturing process before it may be used.

We do not currently have any agreements with third-party manufacturers for long-term commercial supply. In the future, we may be unable to enter into agreements with third-party manufacturers for commercial supplies of any drug candidate that we develop, or may be unable to do so on acceptable terms. Even if we are able to establish and maintain arrangements with third-party manufacturers, reliance on third-party manufacturers entails risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how;
- the possible termination or non-renewal of the agreement by the third party at a time that is costly or inconvenient for us; and
- the lack of our ability to terminate such contracts quickly and without excessive expense, if no longer needed.

Third-party manufacturers may not be able to comply with cGMP requirements or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable requirements 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 drug candidates or products, operating restrictions and/or criminal prosecutions, any of which could significantly and adversely affect supplies of our drug candidates.

Our future drug candidates and any products that we may develop may compete with other drug candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP requirements and that might be capable of manufacturing for us.

The U.S. BIOSECURE Act, which was enacted in December 2025, prohibits federal agencies from procuring or using any biotechnology equipment or services from “biotechnology companies of concern”, or entering into, extending, or renewing any contracts with entities that use such biotechnology equipment or services from “biotechnology companies of concern”. Congress has interpreted a “biotechnology company of concern” as an entity that is under the control of a foreign adversary and that poses a risk to national security based on its research or multiomic data collection (e.g., collection of genomic information). While the U.S. BIOSECURE Act has a grandfathering period of five years for existing contracts, and has carveouts for manufacture of drugs for supply

under Medicaid and Medicare Part B, subject to the Secretary of Veteran Affairs' discretion, the impact of the U.S. BIOSECURE Act on the biotechnology industry is uncertain. If the foreign CROs and CMOs we rely on become subject to trade restrictions, sanctions, increased tariffs or other regulatory requirements by the U.S. government (including designation as a "biotechnology company of concern" under the U.S. BIOSECURE Act), or if the U.S. or Chinese government take retaliatory actions due to recent or increased tensions between the U.S. and China, it may have the potential to severely restrict the ability of U.S. biopharmaceutical companies like us to purchase services or products from, or otherwise collaborate with, certain "biotechnology companies of concern" without losing the ability to contract with, or otherwise receive funding from, the U.S. government.

Imports from other countries, including China, have been made subject to new tariffs affecting our industry in multiple ways, including taxing the import of raw materials and supplies, as well as recent tariffs on pharmaceutical products. Uncertainty in scope and applicability of new tariffs, as well as the cost of the tariffs themselves, could lead to delays in drug development and commercialization, and other financial harm.

If the third parties that we engage to supply any materials or manufacture product for our nonclinical studies and clinical trials should cease to continue to do so for any reason, we likely would experience delays in advancing these studies and trials while we identify and qualify replacement suppliers or manufacturers and we may be unable to obtain replacement supplies on terms that are favorable to us or at all. In addition, if we are not able to obtain adequate supplies of our drug candidates or the substances used to manufacture them, it will be more difficult for us to develop our drug candidates and compete effectively.

Some of our third-party manufacturers which we use for the supply of materials for drug candidates or other materials necessary to manufacture product to conduct clinical trials could experience unexpected disruptions from man-made or natural disasters or public health pandemics or epidemics or other business interruptions which, if they occurred, might result in delays in advancing our clinical development.

Our current and anticipated future dependence upon others for the manufacture of our drug candidates (or the key starting and intermediate materials for such drug candidates) may adversely affect our future profit margins and our ability to develop drug candidates and commercialize any products that receive marketing approval on a timely and competitive basis.

Our relationships with customers and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any drug candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers, and current arrangements and interactions with healthcare practitioners and institutions, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act (the FCA), which may constrain the business or financial arrangements and relationships through which we develop, sell, market and distribute any products for which we seek and/or obtain marketing approval. In addition, we may be subject to transparency laws by the U.S. federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, 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 the Medicare and Medicaid programs or other federal healthcare programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, clinical investigators (particularly if elements of the applicable clinical protocol are federally reimbursed), purchasers, and formulary managers on the other;

- the federal civil and criminal false claims laws, including the FCA, which prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. 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, or may assert that alleged pre-approval or off-label promotion of a drug can lead to a false claim;
- HIPAA, which created 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 federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statutes or specific intent to violate them;
- the Physician Payments Sunshine Act, created under the ACA, and its implementing regulations, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (including physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants and certified nurse-midwives) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- The PhRMA Code on interactions with healthcare practitioners, and state laws that codify the PhRMA Code;
- FDA rules, regulations and guidance regarding pre-approval and off-label promotion of pharmaceutical products;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and healthcare items or services reimbursed by non-governmental third-party payors, 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 federal government or otherwise restrict payments that may be made to healthcare providers; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and healthcare laws in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities could be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring that our business arrangements and interactions with third parties comply with applicable healthcare laws, as well as responding to investigations by government authorities, can be time- and resource-consuming and can divert management's attention from the business.

If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil, criminal and administrative penalties,

damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal- and state-funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, which could lead to delays in product approvals, any of which could harm our ability to operate our business and our financial results. Further, if the physicians or other providers or entities with whom we interact are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. In addition, the approval and commercialization of any drug candidate we develop outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Risks related to intellectual property

If we and our collaborators are unable to obtain, maintain, protect and enforce sufficient patent and other intellectual property protection for our drug candidates and technology, our competitors could develop and commercialize products and technology similar or identical to ours, and we may not be able to compete effectively in our market or successfully commercialize any drug candidates we may develop.

Our success depends in significant part on our ability and the ability of our current or future collaborators and licensors to obtain, maintain, enforce and defend patents and other intellectual property rights with respect to our drug candidates and technology and to operate our business without infringing, misappropriating, or otherwise violating the intellectual property rights of others. If we and our current or future collaborators and licensors are unable to obtain and maintain sufficient intellectual property protection for our drug candidates or other drug candidates that we may identify, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors and other third parties could develop and commercialize drug candidates similar or identical to ours, and our ability to successfully commercialize our drug candidates and other drug candidates that we may pursue may be impaired. While we own some issued or allowed patents with respect to our programs, including our chronic HBV infection, and MASH programs, we can provide no assurance that any of our other current or future patent applications will result in issued patents or that any issued patents will provide us with any competitive advantage. We cannot be certain that there is no invalidating prior art of which we and the patent examiner are unaware or that our interpretation of the relevance of prior art is correct. If a patent or patent application is determined to have an earlier priority date, it may prevent our patent applications from issuing at all or issuing in a form that provides any competitive advantage for our drug candidates. Failure to obtain additional issued patents could have a material adverse effect on our ability to develop and commercialize our drug candidates. Even if our patent applications do issue as patents, third parties may be able to challenge the validity and enforceability of our patents on a variety of grounds, including that such third party's patents and patent applications have an earlier priority date, and if such challenges are successful, we may be required to obtain one or more licenses from such third parties, or be prohibited from commercializing our drug candidates.

We seek to protect our proprietary positions by, among other things, filing patent applications in the United States and abroad related to our current drug candidates and other drug candidates that we may identify. Obtaining, maintaining, defending and enforcing pharmaceutical patents is costly, time consuming and complex, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain, enforce and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner. Additionally, the patenting rules and processes vary throughout the world, and may in some countries require a lengthy process of filings and appeals, and may never be successful. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, under certain of our license or collaboration agreements, we may not have the right to control the preparation, filing, prosecution and maintenance of patent applications, or to maintain the rights to patents licensed to or from third parties.

We currently are the assignee of a number of U.S. provisional patent applications. U.S. provisional patent applications are not eligible to become issued patents until, among other things, we file a non-provisional patent application within 12 months of filing one or more of our related provisional patent applications. With regard to such U.S. provisional patent applications, if we do not timely file any non-provisional patent applications, we may lose our priority dates with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. Further, in the event that we do timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents or if such issued patents will provide us with any competitive advantage.

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, collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Further, we may not be aware of all third-party intellectual property rights potentially relating to our drug candidates. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

The patent position of pharmaceutical companies generally is highly uncertain, involves complex legal, technological and factual questions and has, in recent years, been the subject of much debate and litigation throughout the world. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. The subject matter claimed in a patent application can be significantly reduced or eliminated before the patent issues, if at all, and its scope can be reinterpreted or narrowed after issuance. Therefore, our pending and future patent applications may not result in patents being issued in relevant jurisdictions that protect our drug candidates, in whole or in part, or that effectively prevent others from commercializing competitive drug candidates, and even if our patent applications issue as patents in relevant jurisdictions, they may not issue in a form that will provide us with any meaningful protection for our drug candidates or technology, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Additionally, our competitors may be able to circumvent our patents by challenging their validity or by developing similar or alternative drug candidates or technologies in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party pre-issuance submission of prior art to the United States Patent and Trademark Office (the USPTO), or become involved in opposition, derivation, revocation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others, or other proceedings in the USPTO or applicable foreign offices that challenge priority of invention or other features of patentability. An adverse determination in any such submission, proceeding or litigation could result in loss of exclusivity or ability to sell our products free from infringing the patents of third parties, patent claims being narrowed, invalidated or held unenforceable, in whole or in part, and limitation of the scope or duration of the patents directed to our drug candidates, all of which could limit our ability to stop others from using or commercializing similar or identical drug candidates or technology to compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drug candidates or approved products (if any) without infringing third-party patent rights. In addition, if the breadth or strength of the claims of our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future drug candidates, or could have a material adverse effect on our ability to raise funds necessary to continue our research programs or clinical trials. 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.

In addition, given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products or technology similar or identical to ours for a meaningful amount of time, or at all. Moreover, some of our licensed patents and owned or licensed patent applications may in the future be co-owned with third parties. If we are unable to obtain exclusive licenses to any such co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

The steps we take to protect our sensitive intellectual property, including trade secrets, may be inadequate to prevent such information from being compromised through inadvertent disclosure, theft, or other means. Loss of valuable trade secrets could harm our competitive position, business, financial condition, results of operations and

prospects.

We have entered into licensing and collaboration agreements with third parties. If we fail to comply with our obligations in the agreements under which we license intellectual property rights to or from third parties, or these agreements are terminated, or we otherwise experience disruptions to our business relationships with our licensors or licensees, our competitive position, business, financial condition, results of operations and prospects could be harmed.

In addition to patent and other intellectual property rights we own or co-own, we have licensed, and may in the future license, patent and other intellectual property rights to and from other parties. For example, we have in-licensed significant intellectual property rights from Emory and KU Leuven. Licenses may not provide us with exclusive rights to use the applicable intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our drug candidates, products (if approved) and technology in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products or technologies.

In addition, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications or to maintain, defend and enforce the patents that we license to or from third parties, and we may have to rely on our partners to fulfill these responsibilities. For example, under the Emory License Agreement, we obtained a license from Emory University under patents relevant to certain aspects of our small molecule chronic HBV infection program. Although we direct prosecution of patents licensed under the Emory License Agreement, we are obligated to consult with Emory University with respect to prosecution of these patents and Emory and its counsel are responsible for making all filings related to such prosecution. Similarly, although we will control the prosecution of jointly developed patents resulting from our collaboration with the Rega Institute for Medical Research and the CD3 under the KU Leuven Agreement, we are obligated to consult with such parties with respect to prosecution of these patents. Consequently, any such licensed patents and applications may not be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our current or future licensors, licensees or collaborators fail to prepare, file, prosecute, maintain, enforce, and defend licensed patents and other intellectual property rights, such rights may be reduced or eliminated, and our right to develop and commercialize any of our drug candidates or technology that are the subject of such licensed rights could be adversely affected. In addition, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights.

If we fail to comply with our obligations, including the obligation to make various milestone payments and royalty payments, under any of the agreements under which we license intellectual property rights from third parties, the licensor may have the right to terminate the license.

If any of our license agreements are terminated, the underlying licensed patents fail to provide the intended exclusivity or we otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business or be prevented from developing and commercializing our drug candidates, and competitors could have the freedom to seek regulatory approval of, and to market, products identical to ours. Termination of these agreements or reduction or elimination of our rights under these agreements may also 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, delay or prohibit the further development or commercialization of one or more drug candidates that rely on such agreements. It is possible that we may be unable to obtain any additional licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our drug 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.

In addition, the research resulting in certain of our owned and in-licensed patent rights and technology may have been funded in part by the U.S. federal or state governments. As a result, the government may have certain rights, including march-in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention for noncommercial purposes. These rights may permit the government to disclose our confidential information to third parties or allow third parties to use our licensed technology. The government can exercise its march-in rights if it determines that action is necessary

because we fail to achieve practical application of the government-funded technology, or because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues and certain provisions in intellectual property license agreements may be susceptible to multiple interpretations. Disputes may arise between us and our licensing partners regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which technology and processes of one party infringe intellectual property of the other party that are not subject to the licensing agreement;
- rights to sublicense patent and other rights to third parties;
- any diligence obligations with respect to the use of the licensed technology in relation to development and commercialization of our drug candidates, and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property;
- rights to transfer or assign the license; and
- the effects of termination.

The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could harm our business, financial condition, results of operations and prospects. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms or at all, we may be unable to successfully develop and commercialize the affected drug candidates. Moreover, any dispute or disagreement with our licensing partners may result in the delay or termination of the research, development or commercialization of our drug candidates or any future drug candidates, and may result in costly litigation or arbitration that diverts management attention and resources away from our day-to-day activities, which may adversely affect our business, financial conditions, results of operations and prospects.

Furthermore, current and future collaborators or strategic partners may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations. Competing products, either developed by our collaborators or strategic partners or to which the collaborators or strategic partners have rights, may result in the withdrawal of partner support for our drug candidates. Any of these developments could harm our product development efforts.

In addition, if our licensors fail to abide by the terms of the license, if the licensors fail to prevent infringement by third parties or if the licensed patents or other rights are found to be invalid or unenforceable, our business, competitive position, financial condition, results of operations and prospects could be materially harmed. For more information regarding our license agreements, see the section titled “Business—License agreements and collaborations” of our Annual Report on Form 10-K for the year ended December 31, 2025.

If we are unable to obtain licenses from third parties on commercially reasonable terms or at all, our business could be harmed.

It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products (if approved), in which case we would be required to obtain a license from these third parties. The licensing of third-party intellectual property rights is a competitive area, and more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. More 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. We also may be unable to license or acquire third party

intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. 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 drug candidates, which could materially harm our business, and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, 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, or become, non-exclusive, thereby giving our competitors access to the same technologies licensed to us. For example, under the Emory License Agreement we currently have an exclusive license with respect to certain patents and a non-exclusive license with respect to certain of Emory's specified know-how. In June 2022, the license to such patents became non-exclusive with respect to all fields except for the treatment and prevention of HBV. For more information regarding our license agreements, see the section titled "Business—License agreements and collaborations" of our Annual Report on Form 10-K for the year ended December 31, 2025. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might subject us to infringement claims or adversely affect our ability to develop and market our drug candidates.

We cannot guarantee that any of our or our licensors' patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending patent application in the United States and abroad that is relevant to or necessary for the commercialization of our drug candidates in any jurisdiction. For example, U.S. patent applications filed before November 29, 2000 and certain U.S. patent applications filed after that date that will not be filed outside the United States remain confidential until patents issue. As mentioned above, patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our drug candidates could have been filed by third parties without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our drug candidates or the use of our drug candidates. The scope of a patent claim is 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 drug candidates. We may incorrectly determine that our drug candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our drug candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our drug candidates.

We are aware of certain third-party issued patents and/or pending patent applications, including those of our competitors, that, if issued with their current claim scope, may be construed to cover our drug candidates, including ALG-055009. In the event that any of these patents were asserted against us, we believe that we would have defenses against any such action, which may include that such patents are not valid. However, if any such patents were to be asserted against us and our defenses to such assertion were unsuccessful and alternative technology was not available or technologically or commercially practical, unless we obtain a license to such patents, we could be liable for damages, which could be significant and include treble damages and attorneys' fees if we are found to willfully infringe such patents, and we could be precluded from commercializing any drug candidates that were ultimately held to infringe such patents.

In addition, if we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, which may be significant, we may be temporarily or permanently prohibited from commercializing any of our drug candidates that are held to be infringing. We might, if possible, also be forced to redesign drug candidates so that they no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business and could adversely affect our business, financial condition, results of operations and prospects.

Patent terms may be inadequate to establish our competitive position on our drug candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our drug candidates are obtained, once the patent life has expired for a drug candidate, we may be open to competition from competitive medications, including generic versions. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents directed towards such drug candidates might expire before or shortly after such drug candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing drug candidates similar or identical to ours for a meaningful amount of time, or at all.

Depending upon the timing, duration and conditions of any FDA marketing approval of our drug candidates, one or more of our owned or licensed U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act, and similar legislation in the EU and certain other countries. The Hatch-Waxman Act permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. In the U.S., only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval and only those claims for the approved drug, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable drug candidate will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and nonclinical data and launch their product earlier than might otherwise be the case, and our competitive position, business, financial condition, results of operations and prospects could be materially harmed.

Further, there are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the Orange Book. We may be unable to obtain patents covering our drug candidates that contain one or more claims that satisfy the requirements for listing in the Orange Book. Even if we submit a patent for listing in the Orange Book, the FDA may decline to list the patent, or a manufacturer of generic drugs may challenge the listing. If one of our drug candidates is approved and a patent covering that drug candidate is not listed in the Orange Book, a manufacturer of generic drugs would not have to provide advance notice to us of any abbreviated new drug application filed with the FDA to obtain permission to sell a generic version of such drug candidate. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

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

Filing, prosecuting, maintaining, defending and enforcing patents on our drug candidates in all countries throughout the world would be prohibitively expensive, and consequently our intellectual property rights in some countries outside the United States may be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patents to develop their own products and may export otherwise infringing products to territories where we have patents, but enforcement rights are not as strong as those in the United States. These products may compete with our drug candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries do not favor the enforcement or protection of patents, trade secrets and other intellectual property, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights

generally. For example, some companies in our industry have experienced theft or breach of their intellectual property rights, including trade secrets, in China, a country where we have operations and do business. Proceedings to enforce our intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

Many foreign countries, including some EU countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of the applicable patents and limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license, which could adversely affect our business, financial condition, results of operations and prospects.

In addition, on June 1, 2023, the European Patent Package, or EU Patent Package, regulations were implemented with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court, or UPC, for litigation involving European patents. Under the UPC, all European patents, including those issued prior to ratification of the European Patent Package, will by default automatically fall under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents, and allow for the possibility of a competitor to obtain pan-European injunctions. 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. Under the EU Patent Package as currently proposed, we have the right to opt our patents out of the UPC over the first seven years of the court's existence, but doing so may preclude us from realizing the benefits of the new unified court.

Moreover, geo-political actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, the U.S. and foreign government actions related to Russia's conflict in Ukraine may limit or prevent filing, prosecution, and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees from the United States without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our drug candidates.

Obtaining and enforcing patents in the pharmaceutical industry is inherently uncertain, due in part to ongoing changes in the patent laws. For example, in the United States, depending on decisions by Congress, the federal courts, and the USPTO, the laws and regulations governing patents, and interpretation thereof, could change in unpredictable ways that could weaken our and our collaborators' or licensors' ability to obtain new patents or to enforce existing or future patents. For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Therefore, there is increased uncertainty with regard to our and our collaborators' or licensors' ability to obtain patents in the future, as well as uncertainty with respect to the value of patents once obtained.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and our collaborators' or licensors' patent applications and the enforcement or defense of our or our collaborators' or licensors' issued patents. For example, assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the

United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act (the Leahy-Smith Act), enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications filed after March 2013 are prosecuted and may also affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to challenge the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. The USPTO has developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, particularly the first inventor-to-file provisions. Similarly, statutory or judicial changes to the patent laws of other countries may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. All of the foregoing could harm our business, financial condition, results of operations and prospects.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful, and issued patents directed towards our technology and drug candidates could be found invalid or unenforceable if challenged.

Competitors and other third parties may infringe or otherwise violate our issued patents or other intellectual property or the patents or other intellectual property of our licensors and collaborators. In addition, our patents or the patents of our licensors and collaborators may become involved in inventorship or priority disputes. To counter infringement or other unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Significantly, our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Our ability to enforce patent rights also depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their products and services. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product or service. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents or that our patents are invalid or unenforceable. In a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the 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. An adverse result in any litigation proceeding could put one or more of our owned or licensed patents at risk of being invalidated, held unenforceable or interpreted narrowly. We may find it impractical or undesirable to enforce our intellectual property against some third parties.

If we were to initiate legal proceedings against a third party to enforce a patent directed to our drug candidates, or one of our future drug candidates, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or insufficient written description. 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 also raise similar claims before the USPTO or an equivalent foreign body, even outside the context of litigation. Potential proceedings include reexamination, post-grant review, inter partes review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our technology or any drug candidates that we may develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent rights directed towards the applicable drug candidates or technology related to the patent rendered invalid or unenforceable. Such a loss of patent rights would materially harm our business, financial condition, results of operations and prospects.

Interference proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable

outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be materially harmed if the prevailing party does not offer us a license on commercially reasonable terms.

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.

Some of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating or otherwise violating our intellectual property. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims could result in substantial costs and diversion of management resources, which could harm our business. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, or in-license needed technology or other drug candidates. There could also be public announcements of the results of the hearing, motions, or other interim proceedings or developments. If securities analysts or investors perceive those results to be negative, it could cause the price of shares of our common stock to decline. Any of the foregoing events could harm our business, financial condition, results of operation and prospects.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could negatively impact the success of our business.

Our commercial success depends upon our ability to develop, manufacture, market and sell our drug candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. There is considerable intellectual property litigation in the pharmaceutical industry. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our drug candidates and their manufacture and our other technology, including reexamination, interference, post-grant review, inter partes review or derivation proceedings before the USPTO or an equivalent foreign body. Numerous U.S.- and foreign-issued patents and pending patent applications owned by third parties exist in the fields in which we are developing our drug candidates. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit.

Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of claim scope, infringement, validity, enforceability or priority. A court of competent jurisdiction could hold that third-party patents asserted against us are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize any drug candidates we may develop and any other drug candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If we are found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, and we are unsuccessful in demonstrating that such rights are invalid or unenforceable, we could be required to obtain a license from such a third party in order to continue developing and marketing our products and technology. However, 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 or may become non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. A finding of infringement could prevent us from commercializing our drug candidates or force us to cease some of our business operations. 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 and other fees, redesign our infringing drug candidate or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. Any of the foregoing events would harm our business, financial condition, results of operations and prospects.

We may be subject to claims by third parties asserting that we or our employees have infringed, misappropriated or otherwise violated their intellectual property rights, or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at other biotechnology or pharmaceutical companies. Although we try to ensure that our employees, consultants and advisors 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 these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer. We may also be subject to claims that patents and applications we have filed to protect inventions made on our behalf by our employees, consultants and advisors, even those related to one or more of our drug candidates, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs, delay development of our drug candidates and be a distraction to management. Any of the foregoing events would harm our business, financial condition, results of operations and prospects.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we or our licensors or collaborators may have inventorship disputes arising from conflicting obligations of employees, consultants or others who are involved in developing our drug candidates. While it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' or collaborators' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we or our licensors or collaborators fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our drug candidates. 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. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection, if any, 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. For example:

- others may be able to make products that are similar to any drug candidates we may develop or utilize similar technology but that are not covered by the claims of the patents that we license or may own in the future;
- we, or our current or future licensors or collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;
- we, or our current or future licensors or collaborators might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our pending owned or licensed patent applications or those that we may own or license in the future will not lead to issued patents;

- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the intellectual property rights of others may harm our business; and
- 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 directed to such intellectual property.

Should any of these events occur, they could harm our business, financial condition, results of operations and prospects.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent rights, if any, could be reduced or eliminated if we fail to comply with these requirements.

Periodic maintenance fees, renewal fees, annuity fees, and various other fees are required to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of a patent. In certain circumstances, we rely on our collaborators or licensors to pay these fees. The USPTO and various foreign patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar requirements during the patent application and prosecution process. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official communications within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. While an inadvertent lapse can in some cases 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 irrevocable abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we or our licensors fail to maintain the patents and patent applications covering our drug candidates, our competitors might be able to enter the market with similar or identical products or technology, which would harm our business, financial condition, results of operations and prospects.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. 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. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. As noted above, some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace, including compromising our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development collaborations that would help us commercialize our drug candidates, if approved. Any of the foregoing events would harm our business, financial condition, results of operations and prospects.

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

We rely on confidential methodologies and processes and confidentiality agreements to protect our unpatented know-how, technology and other proprietary information and to maintain our competitive position. Trade secrets and know-how can be difficult to protect. We seek to protect these trade secrets and other proprietary technology, in

part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, licensors, collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our drug candidates that we consider proprietary. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary information will be effective.

We also seek to preserve the integrity and confidentiality of our confidential proprietary information by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets, and we may need to share our trade secrets and proprietary know-how with current or future partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Further, we may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

Risks related to employee matters, managing our growth and other risks related to our business

We are highly dependent on our key personnel, and if we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

We are highly dependent on our management, scientific and medical personnel. The loss of the services of any of them may adversely impact the achievement of our objectives. Any of our executive officers could leave our employment at any time, as all of our employees are “at-will” employees. We currently do not have “key person” insurance on any of our employees.

Recruiting and retaining qualified employees, consultants and advisors for our business, including scientific and technical personnel, also will be critical to our success. Competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies and academic institutions for skilled individuals. In addition, failure to succeed in nonclinical studies, clinical trials or applications for marketing approval may make it more challenging to recruit and retain qualified personnel. The inability to recruit, or the loss

of services of certain executives, significant employees, consultants or advisors, may impede the progress of our research, development and commercialization objectives and have a material adverse effect on our business, financial condition, results of operations and prospects.

We currently have no sales organization. If we are unable to establish sales capabilities on our own or through third parties, we may not be able to market and sell any products effectively, if approved, or generate product revenue.

We currently do not have a marketing or sales organization, other than at the senior management level. In order to commercialize any product, if approved, in the United States and foreign jurisdictions, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. In advance of any of our drug candidates receiving regulatory approval, we expect to establish a sales organization with technical expertise and supporting distribution capabilities to commercialize each such drug candidate, which will be expensive and time-consuming. We, as a company, have no prior experience in the marketing, sale and distribution of pharmaceutical products, and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain, and 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 would adversely impact the commercialization of our drug candidates. We may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our drug candidates. If we are not successful in commercializing products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for our current drug candidates and any other drug candidate we develop, while complying with our contractual obligations to contractors and other third parties; and
- expanding and enhancing our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to advance development of and, if approved, commercialize our current drug candidates and any other drug candidate we develop will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including many aspects of marketing, clinical management, and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed or at a reasonable cost, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our nonclinical studies and clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of any current or future drug candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups

of consultants and contractors, we may experience delays or may not be able to successfully implement the tasks necessary to further develop and commercialize our current drug candidates and any future drug candidates we develop and, accordingly, may not achieve our research, development and commercialization goals.

If we are not able to successfully manage any dispute with an employee or contractor, a resulting settlement or judgment could be expensive, time-consuming and distracting, and could affect our ability to focus on and fund our core activities.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. We cannot eliminate the risk of contamination or injury from these materials, and we generally contract with third parties for the disposal of these materials and wastes. In the event of contamination or injury resulting from our use or third-party disposal of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials, and as such we would have to pay the full amount of any resultant liability out of pocket, which could significantly impair our financial condition.

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

Our corporate headquarters and other facilities are located in the San Francisco Bay Area, which in the past has experienced both severe earthquakes and wildfires. We are also conducting clinical trials in many other countries and regions, which may be subject to natural disaster risks. We do not carry earthquake insurance, and as such we would have to pay the full amount of any resultant liability out of pocket, which could significantly impair our financial condition. In addition, earthquakes, wildfires or other natural disasters could severely disrupt our operations. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our enterprise financial systems or manufacturing resource planning and enterprise quality systems, that delayed our clinical trials, 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 currently are limited and are unlikely to prove adequate 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, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business, results of operations, financial condition and prospects. Furthermore, integral parties in our supply chain are similarly vulnerable to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our business.

Our employees, independent contractors, vendors, principal investigators, CROs, consultants and collaborators may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, independent contractors, vendors, principal investigators, CROs, consultants and collaborators may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and comparable foreign regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the United States and abroad; or laws that require the reporting of financial information or data

accurately. In particular, 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 also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our nonclinical studies or clinical trials, 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 these laws or regulations. Additionally, we are subject to the risk that a person 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, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Risks related to our common stock

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for investors.

Our stock price is likely to be volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:

- the success of our and competitive products or technologies;
- results of clinical trials and nonclinical studies or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to our drug candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license drug candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- 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, political, and market conditions and overall fluctuations in the financial markets in the United States and abroad;
- future public health pandemics or epidemics; and
- investors' general perception of us and our business.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from selling their shares at or above the price paid for the shares and may otherwise negatively affect the liquidity of our common stock.

Some companies that have experienced volatility in the trading price of their shares have been the subject of securities class action litigation. Any lawsuit to which we are a party, with or without merit, may result in an

unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Defending against litigation is costly and time consuming, and could divert our management's attention and our resources. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a further negative effect on the market price of our common stock.

An active trading market for our common stock may not be sustained.

An active trading market for our shares may not be sustained. In the absence of an active trading market common stock, investors may not be able to sell their common stock at a price or at the time that they would like to sell.

An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other drug candidates, businesses, or technologies using our shares as consideration.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We do not currently intend to pay any cash dividends on our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, investors are not likely to receive any dividends on common stock owned by them for the foreseeable future. Since we do not intend to pay dividends, an investor's ability to receive a return on its investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our holders purchased it.

We are a "smaller reporting company," and as a result of the reduced disclosure and governance requirements applicable to smaller reporting companies, our common stock may be less attractive to investors.

We are a smaller reporting company and may therefore choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and are eligible to take advantage of certain of the reduced disclosure obligations regarding compensation disclosures. In addition, as a smaller reporting company with less than $100 million in annual revenue, we are exempt from the requirement to obtain an auditor attestation on the effectiveness of our internal control over financial reporting provided in Section 404(b) of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act. These exemptions and reduced disclosures in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze our results of operations and financial prospects.

Our executive officers, directors and their affiliates have significant influence over our company, which will limit an investor's ability to influence corporate matters and could delay or prevent a change in corporate control.

As of December 31, 2025, our executive officers, directors and their affiliates beneficially own, in the aggregate, approximately 64% of our outstanding common stock (assuming all shares of non-voting common stock are converted into voting common stock in accordance with the terms of our amended and restated certificate of incorporation), and 34% of our outstanding common stock (assuming all shares of non-voting common stock are converted to voting common stock and all pre-funded warrants are exercised in full on a cash exercise basis). In addition, in our October 2023 and February 2025 private placements, certain of the holders of 5% or more of our capital stock acquired pre-funded warrants to purchase shares of our common stock (which are immediately exercisable and have an exercise price of $0.0025 and $0.0001 per share, respectively) and common warrants to purchase shares of our common stock (which are immediately exercisable and have an exercise price of $18.92 and $26.02 per share, respectively). Until exercised, the shares issuable upon the exercise of the pre-funded warrants and the common warrants are not included in the number of our outstanding shares of common stock. If such holders exercise their warrants, then the shares of our capital stock beneficially owned by our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates would increase significantly. As a result, these stockholders, if they act together, will be able to influence our management and affairs and the outcome of matters submitted to our stockholders for approval, including the election of directors and any sale, merger, consolidation or sale of all or substantially all of our assets. In addition, this concentration of ownership might adversely affect the market price of our common stock by:

- delaying, deferring or preventing a change of control of us;

- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

The dual class structure of our common stock may limit the ability to influence corporate matters and may limit the visibility with respect to certain transactions.

The dual class structure of our common stock may limit an investor's ability to influence corporate matters. Holders of our common stock are entitled to one vote per share, while holders of our non-voting common stock are not entitled to any votes. Nonetheless, each share of our non-voting common stock may be converted at any time into one share of our common stock at the option of its holder by providing written notice to us, subject to the limitations provided for in our amended and restated certificate of incorporation. Consequently, the exercise by holders of our non-voting common stock of their option to make this conversion will have the effect of increasing the relative voting power of such holders, and correspondingly decreasing the voting power of the holders of our common stock, which may limit an investor's ability to influence corporate matters. As of December 31, 2025, we had 800,000 shares of non-voting common stock outstanding. Additionally, stockholders who hold, in the aggregate, more than 10% of our common stock and non-voting common stock, but 10% or less of our common stock, and are not otherwise a company insider, may not be required to report changes in their ownership due to transactions in our non-voting common stock pursuant to Section 16(a) of the Securities Exchange Act of 1934, as amended (the Exchange Act), and may not be subject to the short-swing profit provisions of Section 16(b) of the Exchange Act.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline.

As of December 31, 2025, approximately 2.6 million shares of common stock that are either subject to outstanding options or RSUs or reserved for future issuance under our equity incentive plans, and excluding all outstanding pre-funded warrants, are eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

In addition, the holders of approximately 6.2 million of our total common stock and non-voting common stock are entitled to rights with respect to the registration of their shares under the Securities Act described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders could have a material adverse effect on the market price of our common stock.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code), and corresponding provisions of state law, if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percentage point change (by value) in its equity ownership over a rolling three-year period), the corporation's ability to use its pre-change net operating loss (NOL) carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We performed a Code Section 382 analysis in February 2025 but determined there was no ownership change at that time that resulted in any limitations. We may have experienced additional ownership changes in the past and may in the future experience ownership changes as a result of changes in our stock ownership (some of which are not in our control). In addition, under current tax law, federal NOL carryforwards generated in periods after December 31, 2017, may be carried forward indefinitely but may only be used to offset 80% of our taxable income. For these reasons, our ability to utilize our NOL carryforwards and other tax attributes to reduce future tax liabilities may be limited.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock relies, in part, on the research and reports that industry or financial

analysts publish about us or our business. If no or few analysts commence coverage of us, the trading price of our stock would likely decrease. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which, in turn, could cause our stock price to decline.

If we fail to implement and maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

Pursuant to Section 404 of Sarbanes-Oxley, our management is required to report upon the effectiveness of our internal control over financial reporting for our fiscal year ended December 31, 2025. If we become an accelerated or large accelerated filer, we will be subject to the independent auditor attestation requirement under Section 404(b) of the Sarbanes-Oxley Act. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation.

We cannot assure you that there will not be material weaknesses in our internal control over financial reporting in the future. Any failure to implement and maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent changes in control or changes in our management without the consent of our board of directors. These provisions include the following:

- 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 being able to fill 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 price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval;
- the required approval of at least 66 2/3% of the shares entitled to vote at an election of directors to adopt, amend or repeal our amended and restated bylaws or repeal the provisions of our amended and 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 our chief executive officer or, in the absence of a chief executive officer, president or by 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 acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- we will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful;
- we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law;
- we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;
- we will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors;
- the rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter and have entered into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and
- we may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

Our amended and restated certificate of incorporation provides for an exclusive forum in the Court of Chancery of the State of Delaware for certain disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and 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 is the sole and exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation, our amended and restated bylaws or any action as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; or any action asserting a claim against us that is governed by the internal affairs doctrine. Our amended and restated certificate of incorporation also provides that the federal district courts of the United States of America is the exclusive forum for the resolution of any complaint asserting a cause of action against us or any of our directors, officers, employees or

agents and arising under the Securities Act. We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, these provisions may have the effect of discouraging lawsuits against our directors and officers. The choice of forum provision requiring that the Court of Chancery of the State of Delaware or the federal district courts of the United States of America be the exclusive forum for certain actions does not apply to suits brought to enforce any liability or duty created by the Exchange Act. Our exclusive forum provision does not relieve us of our duties to comply with the federal securities laws and the rules and regulations thereunder, and our stockholders will not be deemed to have waived our compliance with these laws, rules and regulations. Although our amended and restated certificate of incorporation contains the choice of forum provisions described above, it is possible that a court could find that such a provision is inapplicable for a particular claim or action or that such provision is unenforceable.

General risk factors

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies.

To date, we have primarily financed our operations through the sale of common stock, preferred stock, convertible notes, revenue from license/collaboration agreements, and warrants. We will be required to seek additional funding in the future and may do so through public or private equity offerings or debt financings, credit or loan facilities, collaborations or a combination of one or more of these funding sources. If we raise additional funds by issuing equity securities, our stockholders may suffer dilution and the terms of any equity financing may adversely affect the rights of our stockholders. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. Debt financing, if available, is likely to involve restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities received any distribution of our corporate assets. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our drug candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. Attempting to secure additional financing may also divert our management's attention from our day-to-day activities, which may adversely affect our ability to develop our drug candidates.

Unfavorable global or domestic economic or political conditions could adversely affect our business, financial condition, stock price and results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The applicability of, and lack of clarity around, trade tariffs imposed by the U.S. government and retaliatory tariffs imposed by other governments may have a significant impact on the financial condition of companies. Adverse developments that affect financial institutions, transactional counterparties, or other third parties, or concerns or rumors about these events, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank (SVB) was closed by the California Department of Financial Protection and Innovation, which appointed the U.S. Federal Deposit Insurance Corporation (FDIC) as receiver. Similarly, other institutions have been and may continue to be swept into receivership. We have no borrowing or deposit exposure to directly impacted institutions and have not experienced an adverse impact to our liquidity or to our business operations, financial condition, or results of operations as a result of these recent events. However, uncertainty may remain over liquidity concerns in the broader financial services industry, and there may be unpredictable impacts to our business and our industry.

While the situation involving the conflict between Russia and Ukraine and the conflicts in the Middle East remain highly fluid, the ongoing conflict and any associated sanctions may have a severe impact on the global economy, or on the economy and stability of the United States. A severe or prolonged economic downturn, such as the 2008 global financial crisis, and one that could be caused by the war in Ukraine or conflicts in the Middle East, or by U.S. government shutdowns or other domestic issues, including political unrest, could result in a variety of risks to our business, including, weakened demand for any drug candidates we may develop and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or disruptions in the

supply chain generally could also strain our suppliers, possibly resulting in supply disruption. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers or other partners may not survive such difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current political and economic climate and financial market conditions could adversely impact our business. Furthermore, our stock price may decline due in part to the volatility of the stock market and any general economic downturn.

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

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, property, umbrella, clinical trials and directors' and officers' insurance. Any additional 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. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

We also expect that operating as a public company will make it more difficult and more expensive for us to obtain directors' and officers' 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 are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, violations of which can have serious negative consequences for our business.

U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations (collectively, Trade Laws), prohibit, among other matters, companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, and reputational harm, among other consequences. We routinely have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations, and we expect our non-U.S. activities to increase in time. We plan to engage third parties for clinical trials and/or obtain necessary permits, licenses, patent registrations, and other regulatory approvals from such officials, employees and government agencies and affiliates and we may be held liable for any corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

We may in the future engage in strategic transactions; such transactions could affect our liquidity, dilute our existing stockholders, increase our expenses and present significant challenges in focus and energy to our management or prove not to be successful.

From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of intellectual property, products or technologies.

Such potential transactions that we may consider in the future include a variety of business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations, investments and licensings. Any future transactions could result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or

acquired in-process research and development expenses, any of which could affect our financial condition, liquidity and results of operations. Future acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits of the acquisition.

Public health pandemics or epidemics, political instability, terrorist attacks, other acts of violence or war, or other unexpected events could materially and adversely impact us.

Public health pandemics or epidemics, political instability, terrorist attacks, other acts of violence or war or other unexpected events could materially interrupt our business operations (or those of the third parties upon whom we depend), cause consumer confidence and spending to decrease or result in increased volatility in the United States and worldwide financial markets and economy. They also could result in or prolong an economic recession in the United States. Any of these occurrences could materially and adversely affect us.

Litigation or administrative proceedings could have a material adverse effect on our business, our financial condition and our results of operations.

We may be involved in legal proceedings, administrative proceedings, claims, and other litigation that arise in the ordinary course of business. Unfavorable outcomes or developments relating to proceedings to which we are a party or transactions involving our current or future drug candidates, such as judgments for monetary damages, injunctions, or denial or revocation of permits, could have a material adverse effect on our business, our financial condition, and our results of operations. In addition, settlement of claims could adversely affect our financial condition and our results of operations.

We incur significantly increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, we incur significant legal, accounting and other expenses that we did not previously incur as a private company. We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, results of operations and prospects. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services (if approved). For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

We may experience fluctuations in our tax obligations and effective tax rate, which could materially and adversely affect our results of operations.

We are subject to U.S. federal and state income taxes and taxes in certain other non-U.S. jurisdictions. Tax laws, regulations and administrative practices in various jurisdictions may be subject to significant change, with or without advance notice, due to economic, political and other conditions, and significant judgment is required in

evaluating and estimating our provision and accruals for these taxes. For example, the OBBBA was signed into law in July 2025. The OBBBA contains numerous tax provisions that we are currently in the process of evaluating, and which may affect our business or financial condition. Regulatory guidance under the OBBBA, and other tax-related legislation is and continues to be forthcoming, and such guidance could ultimately increase or lessen the impact of these laws on our business and financial condition. In addition, it is uncertain if and to what extent various states will conform to changes to federal tax legislation. There are many transactions that occur during the ordinary course of business for which the ultimate tax determination is uncertain. Our effective tax rates could be affected by numerous factors, such as changes in tax, accounting and other laws, regulations, administrative practices, principles and interpretations, the outcome of current and future tax audits, examinations, or administrative appeals, changes in the mix and level of earnings in a given taxing jurisdiction or changes in our ownership or capital structures.

Our current shares outstanding and resulting market valuation do not reflect shares of our common stock issuable upon the exercise of pre-funded warrants and common warrants that are exercisable at the discretion of the holders of such warrants. If we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline.

We may from time to time issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. For example, in October 2023 and February 2025, we closed private placements which included the sale of pre-funded warrants and common warrants to purchase shares of our common stock. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution, such dilutive impact may be difficult to compute, and our stock price may decline.

If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our operating results could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. If our assumptions change or if actual circumstances differ from our assumptions, our operating results may be adversely affected and could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

Item 1B. Unresolved Staff Comments.

None.

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.

Our cybersecurity risk management program is integrated into our overall 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 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, suppliers, and vendors based on our assessment of their criticality to our operations and respective risk profile.

The Audit Committee oversees the Company's enterprise risk management process. This includes programs designed to identify, manage, respond to and mitigate risks related to cybersecurity, artificial intelligence, privacy, critical infrastructure and disaster recovery.

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—Risks related to product development and regulatory process—Our business and operations may suffer in the event that our information technology systems, or those used by our CROs or other contractors or consultants, fail or suffer security breaches.”

Cybersecurity Governance

Our Board considers cybersecurity risk as part of its risk oversight function and has delegated to the Audit Committee (Committee) oversight of cybersecurity risks, including oversight of management’s implementation of our cybersecurity risk management program. The Committee receives reports from management on our cybersecurity risks, at a minimum annually and as needed. In addition, management updates the Committee, where it deems appropriate, regarding any cybersecurity incidents it considers to be significant or potentially significant. The Committee reports to the full Board regarding its activities, including those related to cybersecurity. The Board also periodically receives briefings from management on our cyber risk management program. Board members receive presentations on cybersecurity topics from our Vice President, Information Technology, internal security staff or external experts as part of the Board’s continuing education on topics that impact public companies.

Our management team, led by our Vice President, Information Technology, is responsible for assessing and managing our material risks from cybersecurity threats. The team has primary responsibility for our overall cybersecurity risk management program and supervises our retained external cybersecurity consultants. Our Vice President, Information Technology's experience includes 25 years of experience in managing IT environments including assessing the overall risk management program and material risks, as well as building our cybersecurity framework over the past seven years.

Our management 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 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 our IT environment.

Item 2. Properties.

Our corporate headquarters are located in South San Francisco, California, where we lease and occupy space in two separate buildings. The total amount of space leased across both buildings equals approximately 45,200 square feet of office and laboratory space. The current term of each of our two South San Francisco leases expires in March 2027 and July 2027, with options to extend the terms through March 2035 and July 2032, respectively.

We also have an office in Leuven, Belgium, where we lease and occupy approximately 8,100 square feet of office and laboratory space. The current term of our Leuven, Belgium lease expires in August 2028.

We also have an office in Shanghai, China, where we lease and occupy 800 square feet of office space. The current term of this lease expires in May 2026.

We lease all of our facilities and do not own any real property. We believe our existing facilities are sufficient for our needs for the foreseeable future. To meet the future needs of our business, we may lease additional or alternate space, and we believe suitable additional or alternative space will be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings.

From time to time, we may become involved in litigation or other legal proceedings. While the outcome of any such proceedings cannot be predicted with certainty, we are not currently involved in any legal proceedings that we believe are, individually or in the aggregate, material to our business, results of operations or financial condition. However, regardless of the outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of associated costs and diversion of management time.

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.

Market Information

Our common stock was listed on The Nasdaq Global Select Market under the symbol “ALGS” from October 20, 2020 to March 5, 2024 and has been listed on The Nasdaq Capital Market since March 6, 2024. Prior to October 20, 2020, there was no public trading market for our common stock.

Holders of Record

As of March 2, 2026, there were 24 holders of record of our common stock, which consist of 22 holders of record of our voting common stock and 2 holders of record of our non-voting common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees.

Dividend Policy

We have never declared or paid any cash dividend on our common stock. We do not expect to declare or pay any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors might deem relevant.

Securities Authorized for Issuance under Equity Compensation Plans

The information required by this item is incorporated by reference to the definitive Proxy Statement for our 2026 Annual Meeting of Stockholders, which will be filed with the SEC no later than 120 days after December 31, 2025.

Recent Sales of Unregistered Securities

In December 2025, the Company issued 911 shares of common stock to employees who reside in Belgium that were not registered under the Securities Act of 1933, as amended (the "Securities Act"). These shares were issued at a purchase price of $4.964 per share, for aggregate consideration of approximately $5 thousand. The Company relied on the exemption from registration provided by Section 4(a)(2) of the Securities Act and/or Rule 506(b) of Regulation D promulgated thereunder, based on the fact that the shares were sold to a limited number of employees who qualified as accredited investors, there was no general solicitation, and the purchasers had access to information about the Company as both employees and through the Company's public filings with the Securities and Exchange Commission.

Use of Proceeds.

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers.

None.

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 consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. In addition to historical financial information, this discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Special Note Regarding Forward-Looking Statements" and "Risk Factors" and elsewhere in this Annual Report on Form 10-K. Our fiscal year ends on December 31 each year.

Overview

We are a clinical-stage biotechnology company focused on developing novel therapeutics to address unmet medical needs in liver diseases and viral infections, including in the areas of chronic hepatitis B virus (HBV) infection, metabolic dysfunction-associated steatohepatitis (MASH), and coronavirus infections (e.g., SARS-CoV-2, SARS-CoV, MERS-CoV, and other related infections) as well as obesity. The Aligos team has a demonstrated track record of success in drug development and medicinal chemistry in liver and viral diseases, resulting in three potential best-in-class drug candidates currently in clinical development.

Our pipeline of drug candidates includes pevifoscorvir sodium (previously known as ALG-000184) for chronic HBV infection, ALG-055009 for MASH and obesity, ALG-097558 for coronavirus infections, and a portfolio of preclinical programs. Pevifoscorvir sodium is our potential best-/first-in-class Capsid Assembly Modulator (CAM-E) for chronic HBV infection which has shown in pre-clinical testing to have enhanced pharmacologic properties vs. competitor CAM-E drugs and greater HBV DNA suppression compared to the standard of care, nucleos(t)ide analogs (NAs), and has shown multi-$\log_{10}$ reductions in viral antigens in Phase 1 clinical studies conducted to date. ALG-055009 is our potential best-in-class thyroid hormone receptor beta (THR-β) agonist for obesity and MASH with pharmacologic properties that appear to be enhanced based on data to date vs. competitor THR-β agonists. Phase 2a topline data in MASH demonstrated that ALG-055009 dose groups met the primary endpoint with statistically significant reductions in liver fat at Week 12 as measured by MRI-PDFF in subjects with presumed MASH. Recently presented nonclinical data suggests synergistic fat mass loss in combination with incretin receptor agonists in diet induced obese (DIO) mice. ALG-097558 is our potential best-in-class small molecule pan-coronavirus 3CL protease inhibitor (PI), which has been at least 3-fold more potent in cell-based assays of coronavirus infection than other approved CoV PIs and we believe can be dosed twice daily without the requirement for ritonavir co-dosing based on Phase 1 clinical studies conducted to date.

Pevifoscorvir sodium: Potential best-in-class small molecule CAM-E for chronic hepatitis B virus infection

Our primary area of focus seeks to enhance the viral suppression and rate of functional cure for chronic HBV infection, which often results in life-threatening conditions such as cirrhosis, end-stage liver disease, and the most common form of liver cancer, hepatocellular carcinoma (HCC). To achieve this, we are developing a portfolio of differentiated chronic HBV infection drug candidates, including a small molecule CAM that results in the production of empty viral capsids.

In 2018, we in-licensed a lead drug candidate (GLP-26) and the associated IP for a CAM-E from the laboratory of Professor Raymond Schinazi at Emory University. Our scientists optimized this lead drug candidate to discover the highly potent CAM-E, ALG-001075, which was further optimized to the prodrug pevifoscorvir sodium. Based on pre-clinical data to date, pevifoscorvir sodium has superior DMPK properties with enhanced absorption and high liver uptake, with a ~2-300-fold improvement in in vitro potency compared to other known CAMs. CAM-Es are a class of small molecule antiviral agents that accelerate HBV capsid assembly and inhibit pgRNA encapsidation (1st MOA), resulting in empty viral capsids and lower circulating HBV DNA and RNA levels. CAM-Es are also believed to prevent the establishment of cccDNA (2nd MOA), a major factor for the persistence of HBV infection which can be assessed by circulating HBV antigen levels (HBsAg, HBcrAg, and HBeAg). In clinical trials, competitor CAM-Es have shown reductions in HBV DNA and RNA (1st MOA), but have rarely or inconsistently shown reductions in HBV antigens (2nd MOA). There have also been observations of the emergence of viral CAM-E drug resistance with competitor compounds.

A multi-part Phase 1 study is complete, with evaluation of the safety, tolerability, and pharmacokinetic

profile of pevifoscorvir sodium in HVs. Additionally, a dose-ranging phase assessing the safety, pharmacokinetics (PK), and antiviral activity of 10‑300 mg doses of pevifoscorvir sodium administered over 28 days in untreated HBeAg+/- subjects with chronic HBV infection has also been completed. In these study phases, pevifoscorvir sodium was found to be well tolerated with a favorable PK profile and demonstrated potentially best-in-class multi-log_{10} HBV DNA and RNA reductions at all doses tested, as well as HBV surface antigen (HBsAg) reductions in a subset of HBeAg+ subjects receiving 100 mg or 300 mg of pevifoscorvir sodium (Hou et al, AASLD 2022). Based on the favorable profile observed with dosing up to 300 mg of pevifoscorvir sodium for 28 days, additional Phase 1 studies evaluated the risk-benefit profile of pevifoscorvir sodium at doses of 300 mg, with or without entecavir (ETV) therapy, for up to 96 weeks in HBeAg+ and HBeAg- subjects with chronic HBV infection. Data from these cohorts (Yuen et al., AASLD 2025) have been presented, showing that pevifoscorvir sodium, administered for up to 96 weeks, was well tolerated, exhibited a favorable PK profile, and suggested potentially best-in-class potent and durable antiviral activity.

Data from this study following an oral daily dose of 300 mg pevifoscorvir sodium monotherapy in HBeAg+ subjects demonstrated sustained HBV DNA suppression (<LLOQ (10 IU/mL, target detected (TD) or target not detected (TND)) in 6/10 (60%) subjects with chronic HBV infection at Week 48 and 9/9 (100%) at Week 96. Additionally, HBV DNA level continuously declined to < LLOQ (10 IU/mL, TND) in 5 of 10 subjects at Week 96. Data from the 300 mg pevifoscorvir sodium HBeAg- monotherapy cohort demonstrated HBV DNA suppression in all 11/11 (100%) subjects by Week 24 with the HBV DNA suppression level maintained for up to 96 weeks, with further decline in HBV DNA to < LLOQ (10 IU/mL, TND) observed in 8/9 subjects (89%) at Week 96. Importantly, no viral breakthrough was observed in any subject, and no known CAM resistant mutations were identified.

Additionally, HBV RNA level achieved < LLOQ (10 copies/mL) in all HBeAg+ and HBeAg- subjects by Week 52 and Week 6, respectively. Furthermore, concurrent multi-log_{10} reductions in HBV antigens (HBsAg, HBeAg, and HBcrAg) in HBeAg+ subjects and HBcrAg decline in HBeAg- subjects were observed, suggesting the potential inhibition of cccDNA establishment by CAM-E 2nd mechanism of action of pevifoscorvir sodium.

Further, data presented at AASLD's The Liver Meeting® 2025 highlighted outcomes for treatment-naïve or currently not treated HBeAg+ and HBeAg- subjects who completed 96 weeks of 300 mg pevifoscorvir sodium monotherapy, followed by 8 weeks of nucleos(t)ide analog (NA) monotherapy. Reductions in HBV DNA, HBV antigens, and HBV RNA were largely maintained during the NA-only 8-week follow-up period. Notably, viral biomarkers such as HBV antigens and HBV RNA are typically unaffected by NA therapy, suggesting that pevifoscorvir sodium may reduce the cccDNA pool through engagement of its secondary mechanism of action (Yuen et al., AASLD 2025).

Additionally, preclinical in vitro data demonstrated that ALG-001075, the active parent moiety of pevifoscorvir sodium, can prevent cccDNA formation and HBV DNA integration. This finding is further supported by cell-based studies, which showed prevention of cccDNA establishment and HBV DNA integration following treatment with ALG-001075 (Verheyen, et. al. AASLD 2025).

With the completion of the 96 week Phase 1 study, we initiated the Phase 2 B-SUPREME study (NCT06963710), which is designed as a randomized, double-blind, active-controlled multicenter study evaluating the safety and efficacy of pevifoscorvir sodium monotherapy compared with tenofovir disoproxil fumarate for 48 weeks in approximately 200 currently untreated HBeAg+ and HBeAg- adult subjects with chronic HBV infection. The primary endpoint in the HBeAg+ arm is HBV DNA <LLOQ (10 IU/mL, TD or TND) and the primary endpoint in the HBeAg- arm is HBV DNA <LLOQ (10 IU/mL, TND). The study is also evaluating safety, PK, and other secondary and exploratory HBV biomarkers, including reductions in HBV antigens and other markers of HBV infection. The Phase 2 study has obtained regulatory approvals to move forward in every country included in the study, has reached the planned number of subjects enrolled in the HBeAg- cohort, and is currently enrolling subjects in the HBeAg+ cohort.

The first interim analysis is expected to occur in the first half of 2026. The first protocol defined interim analysis includes approximately 60% (or 36) HBeAg- participants that complete 12 weeks of the treatment period. This enrollment milestone occurred in Q4 2025.

A second protocol defined interim analysis is planned when approximately 50% (or 55) HBeAg+ participants complete 24 weeks of the treatment period. This enrollment milestone occurred in January 2026. This interim analysis is expected to occur in the second half of 2026.

To preserve study integrity and comply with FDA regulatory requirements, we will remain blinded to

subject-level data and will receive insights from the Data Safety Monitoring Board on protocol-specified assessments, including the potential for sample size re-estimation at each interim analysis.

Topline data for the Phase 2 B-SUPREME study are expected in 2027.

Compared to Phase 3 studies with the current standard of care nucleos(t)ide analogs (NAs), tenofovir disoproxil fumarate (TDF) and tenofovir alafenamide (TAF) (Buti et al., Lancet Gastro, 2016; Chen et al., Lancet Gastro 2016), these Phase 1 data to date suggest, subject to confirmation via further study, that pevifoscorvir sodium treatment may be superior to NAs in HBeAg+/- subjects in achieving HBV DNA levels < LLOQ (10 IU/mL) after 48 weeks on treatment. Chronic suppressive therapy of HBV DNA levels is a validated approval pathway in chronic HBV infection (Food and Drug Administration (FDA) Guidance, Chronic Hepatitis B Virus Infection: Developing Drugs for Treatment Guidance for Industry, April 2022 – Section III.B.1.a). We have received affirmative feedback from the FDA, the Committee for Medicinal Products for Human Use (CHMP: EU) and the National Medical Products Administration (NMPA: China) supporting subsequent studies utilizing the chronic suppressive therapy pathway for pevifoscorvir sodium. Our ongoing Phase 2 B-SUPREME study is being conducted to test superiority to standard of care NA treatment (HBV DNA levels <LLOQ (10 IU/ml, TD or TND) in HBeAg+ subjects and HBV DNA levels < LLOQ (10 IU/ml, TND) in HBeAg- subjects) after 48 weeks of monotherapy treatment. Furthermore, when combined with other mechanisms of action, including other candidates in our chronic HBV infection portfolio, pevifoscorvir sodium dosing regimens have the potential to contribute to achieving higher rates of functional cure, subject to testing such endpoint, as compared with currently approved agents.

We are also exploring additional ways to potentially treat patients with chronic HBV infection, including our antisense oligonucleotide (ASO) platform which utilizes novel monomers that could potentially reduce ASO toxicity and improve ASO liver to kidney ratios. Along with our partner Xiamen Amoytop Biotech Co., Ltd. (Amoytop), ALG-170675 was recently selected to proceed into IND-enabling studies. Current costs for development in China are being funded by Amoytop, who maintain rights in China, Taiwan, Hong Kong and Macau. This next-generation ASO works via two mechanisms of action. It targets and destroys HBsAg mRNA and activates the immune response through TLR-8 agonism.

Additionally, we are pursuing a novel strategy for a potential cure for hepatitis delta virus (HDV) coinfection by utilizing a proprietary ASO approach targeting the destruction of the viral genome. Ongoing work is aimed at the selection of a clinical development candidate.

ALG‑055009: Potential best-in-class small molecule THR-β agonist for metabolic dysfunction-associated steatohepatitis and obesity

Obesity is a complex disease caused by an overabundance of body fat that increases the risk of other comorbidities, such as MASH. MASH is a complex, chronic liver disease which is a leading cause of liver-related morbidity including cirrhosis, hepatocellular carcinoma, liver transplant, and end-stage liver disease. In 2014, the first GLP-1 receptor agonist, liraglutide, was approved for weight loss and in 2024, the FDA approved resmetirom, a THR-β agonist, as the first drug for the treatment of MASH. However, additional agents in these classes are needed to address remaining unmet needs, including the potential for improved efficacy and a more favorable risk-benefit profile. To achieve this, ALG-055009 has been purposefully designed to exhibit significantly greater potency (approximately 50-fold higher compared to resmetirom in head-to-head in vitro studies) and enhanced β selectivity, along with optimized pharmacologic properties to deliver a potentially improved PK profile compared to other THR-β agonists. We believe these advantages position ALG‑055009 as a strong candidate to become a best-in-class THR-β agonist.

A first-in-human Phase 1 study of ALG‑055009 in MASH in HVs (oral single ascending doses (SAD)) and in subjects with hyperlipidemia (14 oral daily multiple ascending doses (MAD)) has been completed. Clinical data after single doses up to 4 mg and multiple doses up to 1 mg showed that ALG‑055009 was well tolerated, had dose proportional PK with low intersubject variability, and demonstrated expected thyromimetic effects (i.e., generally dose proportional increases in sex hormone binding globulin and decreases in various atherogenic lipids and thyroid hormones without any clinical evidence of thyroid dysfunction). We also evaluated relative bioavailability where we showed the soft gelatin capsules used in the Phase 2a study described below delivered similar exposures compared to the solution formulation used in the SAD/MAD parts of the Phase 1 study; we observed low intersubject PK variability and there was no evidence of a meaningful food effect.

Based on these promising Phase 1 data, we conducted the Phase 2a HERALD study (NCT06342947) at

sites across the United States. The study was a 12-week randomized, double-blind, placebo-controlled trial evaluating 4 doses (0.3 mg, 0.5 mg, 0.7 mg, and 0.9 mg) of ALG-055009 vs. placebo in 102 subjects with presumed MASH and liver fibrosis at stages 1-3 (F1-F3). The primary endpoint of this study was percent relative change in liver fat content by MRI-PDFF at Week 12. This study also evaluated the safety and PK of ALG-055009 treatment and its effect on multiple other efficacy biomarkers, including other non-invasive tests previously shown to be impacted by treatment with THR-β agonists. We announced positive topline data from this study in 2024, demonstrating that ALG-055009 dose groups were well-tolerated and met the primary endpoint. Specifically, doses of 0.5 mg to 0.9 mg ALG-055009 demonstrated statistically significant reductions in liver fat at Week 12, with placebo-adjusted median relative reductions up to 46.2% as measured by MRI-PDFF. Up to 70% of subjects achieved ≥30% relative reduction in liver fat compared to baseline. Eighteen subjects who were on stable GLP-1 agonist therapy qualified for enrollment in the study, with liver fat content meeting the inclusion criteria of ≥10% at baseline as measured by MRI-PDFF. Notably, 11 of 14 subjects on stable GLP-1 agonists treated with ALG-055009 had liver fat decreases, whereas 4 of 4 subjects on stable GLP-1 agonists treated with placebo had increases in liver fat over the 12-week dosing period (Loomba et al, AASLD 2024).

In the Phase 2a HERALD study, ALG-055009 demonstrated a favorable tolerability profile with no evidence of clinical hyper/hypothyroidism. Incidence of gastrointestinal-related treatment emergent adverse events were similar in ALG-055009 dose groups compared to placebo. Specifically, similar rates of diarrhea were observed in ALG-055009 dose groups compared to placebo, with no dose-response. Significant reductions in atherogenic lipids, including LDL-C, lipoprotein (a), and apolipoprotein B, were also observed (Loomba et al, AASLD 2024).

Preclinical and clinical findings reported by other companies have suggested that THR-β agonists can significantly enhance weight loss when administered in combination with incretin receptor agonists (RAs) for the treatment of obesity.

Recently presented in vivo data in diet induced obese (DIO) mice treated with SEMA, TIRZEP, or a combination of ALG-055009 and SEMA or TIRZEP for 28 days demonstrated synergistic weight loss in the combination groups compared to monotherapy groups. SEMA monotherapy resulted in a maximum of 23.9 ±2.6% body weight loss, while the combination of SEMA and ALG-055009 had an additional 8.6% decrease for a maximum 33% body weight loss. The low and high doses of TIRZEP led to maximum of 27.1 ±2.7% and 34.4 ±1.6% body weight loss, respectively. Combination of TIRZEP (low) or TIRZEP (high) with ALG-055009 induced an additional 11.7% and 5.8% decrease for a maximum of 39% and 40% body weight loss, respectively.

Furthermore, the additional weight loss in the combination therapy of either incretin receptor agonist and ALG-055009 was mainly due to additional loss of fat mass, with no significant effect on lean mass or food consumption as compared to incretin receptor agonist monotherapy. These preclinical data suggest a potentially significant benefit of adding ALG-055009 to an incretin receptor agonist therapy for weight loss, especially in combination with a low-dose of a potent molecule, such as tirzepatide.

We believe ALG-055009 warrants further development as a potential treatment for both obesity and MASH. We are continuing to evaluate a variety of options to fund continued development, including potential out-licensing.

ALG-097558: Potential best-in-class small molecule ritonavir-free protease inhibitor for pan-coronavirus

Another area of focus is to develop drug candidates with pan-coronavirus antiviral activity, including against Severe Acute Respiratory Syndrome coronavirus 2 (SARS-CoV-2), the virus responsible for COVID-19. In this area of focus, we are exploring small molecule coronavirus 3CL protease inhibitors (PIs) in collaboration with the Rega Institute at Katholieke Universiteit Leuven (KU Leuven), the Center for Innovation and Stimulation of Drug Discovery (CISTIM) and the Centre for Drug Design and Discovery (CD3). This collaboration led to the discovery of ALG-097558 which has completed a Phase 1 first-in-human evaluation in HVs and advanced into a clinical trial evaluating the compound in high-risk COVID-19 patients.

ALG-097558 has been shown in preclinical studies to be at least 3-fold more potent than nirmatrelvir and other PIs in clinical development against a panel of SARS-CoV-2 variants (including Omicron). It also has demonstrated broad pan-coronavirus activity, including against SARS-CoV-1 and MERS-CoV in preclinical studies. In the first-in-human Phase 1 clinical study, single doses up to 2000 mg and multiple doses up to 800 mg Q12H for 7 days were well tolerated with an acceptable PK profile that suggests ritonavir boosting may not be

required. Furthermore, the absence of a clinically relevant DDI with midazolam suggests that ALG‑097558 may be shown to be appropriate for co-administration with CYP3A4 substrates (NCT05840952). Based on these Phase 1 data (Wilkes et al., RespiDart, 2024), the projected efficacious dose range to treat SARS-CoV-2 is 200-600 mg ALG‑097558 Q12 x 5 days, without the need for ritonavir coadministration.

A Phase 2 study of ALG‑097558 began in 2024. The AGILE trial, a United Kingdom government-supported platform trial (MRC and Wellcome Trust funding), is sponsoring and performing a study in standard and high‑risk COVID‑19 patients evaluating ALG‑097558 as monotherapy or in combination with remdesivir (NCT04746183). We expect that future development of ALG‑097558 will be funded by external sources, including public funding sources as described below.

Preclinical activities for our coronavirus program were partially funded through a grant from the National Institutes of Health (NIH) and the National Institute of Allergy and Infectious Diseases (NIAID) Antiviral Drug Discovery (AViDD) Centers for Pathogens of Pandemic Concern program through the Metropolitan AntiViral Drug Accelerator (MAVDA) consortium. Specific clinical and nonclinical studies for the ALG-097558 program and the follow up compound, are now also being funded with federal funds from the NIAID, NIH, Department of Health and Human Services, under Contract No. 75N93023C00052. We filed an IND in the third quarter of 2024. We expect to receive approximately $15.3 million in funds across these two NIH awards and contracts to support these activities. To date, these funds have not been impacted by any changes at the NIH or NIAID. We are also seeking additional external funding (e.g., from governmental agencies) and/or collaborations (e.g., platform trials) to support future studies as we advance ALG‑097558 for the treatment of COVID‑19 and future coronavirus pandemics.

Components of our results of operations

Revenue

Our revenues consist of the following:

Collaboration revenue included recognition of our upfront payments pursuant to an agreement and amendment with Merck Sharp & Dohme Corp, that were terminated in prior years. In order to record collaboration revenue, we utilized an input method to recognize revenue over time as costs were incurred.

Customer revenue includes recognition of revenue generated from research and development services under third-party contracts with customers. In order to record customer revenue, we utilize an input method to recognize revenue over time as costs are incurred.

Operating expenses

Our operating expenses since inception have consisted solely of research and development costs and general and administrative costs.

Research and development expenses

We expect our expenses to increase substantially in connection with our ongoing clinical development activities related to our chronic HBV infection drug candidate pevifoscorvir sodium. We rely substantially on third parties to conduct our discovery activities, nonclinical studies, clinical trials and manufacturing. We estimate research and development expenses based on estimates of services performed, and rely on third party contractors and vendors to provide us with timely and accurate estimates of expenses of services performed to assist us in these estimates. A portion of our research and development expenses are based on contractual milestones. Research and development costs consist primarily of costs incurred for the identification and development of our drug candidates through our technology platforms, which include:

- salaries, benefits and other employee-related costs, including stock-based compensation expense, for personnel engaged in research and development functions;
- costs of outside consultants, including their fees, and related travel expenses;
- costs associated with in-process research and development, including license fees and milestones paid to third-party collaborators for technologies;
- costs related to production of clinical materials, including fees paid to contract manufacturers;

- expenses incurred under agreements with collaborators that perform nonclinical activities;
- costs related to compliance with regulatory requirements; and
- facility costs, depreciation, and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance, and other supplies.

We expense research and development costs as the services are performed or the goods are received. Non-refundable payments for goods or services that will be used for future research and development activities are deferred and capitalized. Such amounts are recognized as an expense as the goods are delivered or the related services are performed until it is no longer expected that the goods will be delivered or the services will be rendered.

Our research and development costs may increase in future periods as we continue to invest in research and development activities and advance our nonclinical and clinical programs through clinical development. The process of conducting nonclinical studies and, eventually, clinical trials necessary to obtain regulatory approval is costly and time consuming, and the successful development of our drug candidates is highly uncertain. As a result, we are unable to determine the duration and completion costs of our research and development projects or clinical trials or if and to what extent we will generate revenue from the commercialization and sale of any of our drug candidates.

General and administrative expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive, finance, corporate, legal and business development and administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters; professional fees for accounting, auditing, tax and consulting services; insurance costs; travel expenses; and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs not otherwise classified as research and development costs.

Our general and administrative expenses may increase in the future as we increase our general and administrative personnel headcount to support personnel in research and development and to support our operations generally as we increase our research and development activities and activities related to the potential commercialization of our drug candidates. We may also incur increased expenses associated with operating as a public company, including costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing rules and requirements of the Securities and Exchange Commission (the SEC), director and officer insurance costs, and investor and public relations costs.

Interest and other income, net

Interest and other income, net comprises interest income, net and other income, net. Interest income, net primarily consists of interest earned on our cash, cash equivalents, and investments. Other income, net includes investments and foreign currency gains/losses.

Change in fair value of 2023 Common Warrants

The change in fair value of 2023 Common Warrants includes the remeasurement of the 2023 Common Warrants using the Black Scholes option pricing model at each reporting period.

Income tax provision

Since our inception in 2018, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in any year or for our earned research and development tax credits, due to our uncertainty of realizing a benefit from those items. As of December 31, 2025, we had federal net operating loss (NOL) carryforwards of $92.5 million available to reduce taxable income and these NOLs can be carried forward indefinitely. We have state NOL carryforwards of $105.7 million as of December 31, 2025, available to reduce future state taxable income, which expire at various dates beginning in 2043. As of December 31, 2025, we also had federal and state research and development tax credit carryforwards of $3.5 million and $2.2 million, respectively. The federal research and development tax credit carryforwards begin to expire in 2043, while the state research and development tax credit carryforwards can be carried forward indefinitely. As of December 31, 2025, the Company had $3.2 million of Australian NOL carryforwards and $0.7 million of Australian research and development tax credit carryforwards available. The Australian NOL carryforwards and research and development tax credits have no expiration date.

On July 4, 2025, the One Big Beautiful Bill Act (OBBBA) was signed into law. The effects of this legislation include extending and modifying certain key provisions of the Tax Cuts and Jobs Act enacted in December 2017

(both domestic and international). The corporate tax rate remains unchanged but bonus, depreciation and an adjustment to the interest limitation were retroactive to January 1, 2025. The OBBBA makes additional changes to international tax provisions, including substantive changes to existing Global Intangible Low Tax Income, foreign-derived intangible income, and base erosion and anti-abuse tax provisions. These changes are effective for taxable years after 2025. The impact of this legislation does not materially impact the current period nor do we expect it to have a material impact on our tax positions for future years.

Under Sections 382 and 383 of the Internal Revenue Code (Code), and corresponding provisions of state law, if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percentage point change (by value) in its equity ownership over a rolling three-year period), our ability to use our pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We performed a Code Section 382 analysis in 2025 and determined no further ownership change.

We may experience additional ownership changes as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. In the future, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards or other tax attributes to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us and could adversely affect our business, results of operations, and cash flows. In addition, under current tax law, federal NOL carryforwards generated in periods after December 31, 2017, may be carried forward indefinitely but, may only be used to offset 80% of our taxable income.

Results of operations

Comparison of the years ended December 31, 2025 and 2024

The following table summarizes our operating expenses for the years ended December 31, 2025 and 2024:

	Twelve Months Ended December 31,		Change	
	2025	2024	($)	%
Revenue from collaborations	$ -	$ 334	$ (334)	-100%
Revenue from customers	2,186	3,611	(1,425)	-39%
Operating expenses:				
Research and development	69,453	70,269	(816)	-1%
General and administrative	20,718	22,830	(2,112)	-9%
Total operating expenses	90,171	93,099	(2,928)	-3%
Loss from operations	(87,985)	(89,154)	1,169	-1%
Interest and other income, net:				
Interest income, net	2,164	1,670	494	30%
Other income, net	1,758	2,736	(978)	-36%
Change in fair value of 2023 Common Warrants	60,184	(46,132)	106,316	-230%
Loss before income tax	(23,879)	(130,880)	107,001	-82%
Income tax provision	(314)	(331)	17	-5%
Net loss	(24,193)	(131,211)	107,018	-82%

Revenue from collaborations

Revenue from collaborations was $0.3 million for the year ended December 31, 2024. There was no collaboration revenue for the year ended December 31, 2025. This is due to the completion of the amended collaboration agreement with Merck ended in May 2024.

Revenue from customers

Revenue from customers was $2.2 million for the year ended December 31, 2025, compared to $3.6 million for the year ended December 31, 2024, a decrease of $1.4 million, primarily due to the collaboration and license

agreement with Amoytop, the collaboration portion of which ended in November 2025. Refer to Note 10, Revenue from Contracts with Customers for further information.

Research and development expenses

We track direct external research and development expenses on a program-specific basis (chronic HBV infection, MASH, coronaviruses and early-stage programs). The following table summarizes these research and development costs (in thousands):

	Year ended December 31,	
	2025	2024
Direct research and development expenses by development program:		
Chronic Hepatitis B virus infection program	$ 30,559	$ 8,270
Metabolic dysfunction-associated steatohepatitis program	1,323	19,171
Coronaviruses program	(1,218)	4,511
Other early-stage programs	3,147	3,507
Total direct research and development expenses	$ 33,811	$ 35,459
Total indirect research and development expenses	35,642	34,810
Total research and development expense	$ 69,453	$ 70,269

Research and development expenses were $69.5 million for the year ended December 31, 2025, compared to $70.3 million for the year ended December 31, 2024, a decrease of $0.8 million. This is primarily due to a decrease of $1.8 million in third-party expenses due to increased government funds received for the coronavirus program which offset related costs. There was also a decrease of $0.2 million in depreciation. Offsetting this were increases of $0.4 million in employee-related costs, $0.4 million in facility expenses, and $0.4 million in travel and recruiting expenses.

We expect research and development expenses will increase in future periods as we continue to focus on advancing our clinical trials for pevifoscorvir sodium.

General and administrative expenses

General and administrative expenses were $20.7 million for the year ended December 31, 2025, compared to $22.8 million for the year ended December 31, 2024, a decrease of $2.1 million. This is due to a decrease of $2.1 million of third-party expenses primarily due to reduced legal and IP spend, and a decrease of $0.3 million in facility expenses. This was partially offset by an increase of $0.1 million in depreciation and $0.2 million in travel and recruiting costs.

We expect general and administrative expenses will increase in future periods due to increased activity in our research and development group, which will require more resources and additional activities in our general and administration group.

Interest income, net

Interest income, net was $2.2 million for the year ended December 31, 2025 compared to $1.7 million for the year ended December 31, 2024, an increase of approximately $0.5 million, primarily due to a higher average investment balance.

Other income, net

Other income, net was an income of $1.8 million for the year ended December 31, 2025 compared to income of $2.7 million for the year ended December 31, 2024, a decrease of $1.0 million. The difference was due to a decrease in the accretion of short-term investments.

Change in fair value of 2023 Common Warrants

The change in fair value of 2023 Common Warrants was an income of $60.2 million for the year ended December 31, 2025 compared to an expense of $46.1 million for the year ended December 31, 2024, a difference of $106.3 million. The increase was due to a change in the fair value of the 2023 Common Warrants measured using the Black Scholes option pricing model remeasured at each reporting period.

Liquidity and capital resources

Liquidity

We have incurred net losses and negative cash flows from operations in each year since our formation in February 2018. Our net losses were $24.2 million and $131.2 million for the years ended December 31, 2025 and 2024, respectively. We have had no revenue from product sales. We have not yet commercialized any products and we do not expect to generate revenue from sales of any drug candidates for at least several years, if ever.

Our operations have been financed primarily by net proceeds from the sale and issuance of our convertible preferred stock, net proceeds from our IPO, and the issuance of convertible debt.

In October 2023, we completed a PIPE offering and entered into a securities purchase agreement (the 2023 Securities Purchase Agreement) pursuant to which we issued 1,257,168 shares of our common stock, par value $0.0001 per share, pre-funded warrants to purchase an aggregate of 3,242,018 shares of our common stock (the 2023 Pre-Funded Warrants), and common warrants to purchase an aggregate of 2,249,680 shares of our common stock (the 2023 Common Warrants, and together with the 2023 Pre-Funded Warrants, the 2023 Warrants). Each 2023 Warrant is exercisable for one share of common stock. We received gross proceeds of $92.1 million, and after deducting the placement agent fees and expenses and offering costs, net proceeds were $86.2 million.

In February 2025, we entered into a securities purchase agreement (the 2025 Securities Purchase Agreement) with certain investors named therein (the Purchasers) pursuant to which we issued (i) 2,103,307 shares of common stock, consisting of 1,427,000 shares of voting common stock and 676,307 shares of non-voting common stock, (ii) pre‑funded warrants (the 2025 Pre-Funded Warrants) to purchase up to an aggregate of 1,922,511 shares of voting common stock, and (iii) accompanying common warrants (the 2025 Common Warrants and, together with the 2025 Pre-Funded Warrants, the 2025 Warrants) to purchase up to an aggregate of 2,012,909 shares of voting common stock. Each Warrant is exercisable for one share of common stock (the 2025 Private Placement). We received gross proceeds of approximately $105.0 million. In connection to the 2025 Private Placement, we also entered into a registration rights agreement with the Purchasers, pursuant to which we agreed to register for resale the shares of common stock sold to the Purchasers, as well as the shares of common stock underlying the 2025 Warrants sold to the Purchasers, on the terms set forth therein. We also entered into a registration rights agreement with Baker Brothers Life Sciences, L.P. (together with its affiliates, the Lead Investor), pursuant to which we agreed to file a resale registration statement with the SEC following demand by the Lead Investor to register the resale of shares of common stock and any common stock issued or issuable upon the exercise or conversion of non-voting common stock and any of our other securities held by the Lead Investor.

As of December 31, 2025, we had cash, cash equivalents and investments of $77.8 million. As of December 31, 2025, we had an accumulated deficit of $642.2 million. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating losses over at least the next several years. Our net operating losses may fluctuate from quarter to quarter and year to year depending primarily on the timing of our clinical trials and nonclinical studies and our other research and development expenses. We have no internal manufacturing capabilities or sales force and outsource a substantial portion of our clinical trial work to third parties.

Going concern

As of December 31, 2025 and December 31, 2024, we had an accumulated deficit of $642.2 million and $618.0 million, respectively, and cash, cash equivalents and short-term investments of $77.8 million and $56.9 million, respectively. Our current operating plan and projected cash outflows for the upcoming periods raise doubt about our ability to continue as a going concern for at least 12 months from the issuance of the financial statements included elsewhere in this Annual Report. We plan to raise additional capital to fund continued operations beyond the third quarter of 2026. We are taking steps to identify access to future capital and expect to be able to access capital in the future. However, there can be no assurance that any additional funding will be available to us on acceptable terms, if at all. If events or circumstances occur such that we do not obtain additional funding, it may be necessary to significantly reduce the scope of operations to reduce the current rate of spending, which could include reductions in staff and the need to delay, limit, reduce or terminate current or future product development, which could have a material adverse effect on our business, results of operations and financial condition. Moreover, even if financing efforts are successful and additional capital is obtained, available liquidity may still be insufficient to eliminate the aforementioned substantial doubt regarding our ability to continue as a going concern. Accordingly, the report from our independent registered public accounting firm for the year ended December 31, 2025 includes an explanatory paragraph stating that our recurring losses since inception raise substantial doubt about our ability to

continue as a going concern. See Part I, Item 1A. Risk Factors under the header “Risks related to our limited operating history, financial position and need for additional capital” for additional information.

Capital resources

Our primary use of cash is to fund operating expenses, which consist primarily of research and development costs related to our drug candidates and our discovery programs, and to a lesser extent, general and administrative expenditures. Our current operating plan and projected cash outflows for the upcoming periods raise doubt about our ability to continue as a going concern for at least 12 months from the issuance of the financial statements. We expect our expenses to increase substantially in connection with our ongoing clinical development activities related to our chronic hepatitis B drug candidate pevifoscorvir sodium, which has an ongoing Phase 2 clinical trial, as well as our research and development of our other drug candidates within our MASH and coronavirus programs.

We expect that our expenses will increase substantially to the extent we:

- conduct our current and future clinical trials, and additional nonclinical studies;
- initiate and continue research and nonclinical and clinical development of other drug candidates;
- seek to identify additional drug candidates;
- pursue marketing approvals for any of our drug candidates that successfully complete clinical trials, if any;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- require the manufacture of larger quantities of our drug candidates for clinical development and potentially commercialization;
- obtain, maintain, expand, protect and enforce our intellectual property portfolio;
- acquire or in-license other drug candidates and technologies;
- hire and retain additional clinical, quality control, manufacturing, medical affairs and scientific personnel;
- achieve milestones triggering payments by us under our current and potential future licensing and/or collaboration agreements;
- build out or expand existing facilities to support our ongoing development activity; and
- add operational, financial and management information systems and personnel, including personnel to support our drug development, any future commercialization efforts and any additional requirement of being a public company.

We expect that our existing cash, cash equivalents and short-term investments will enable us to fund our operations into the third quarter of 2026, which is less than 12 months following the date of this report. Accordingly, our ability to continue as a going concern will require us to obtain additional funding for our operations or significantly curtail our operations to conserve our capital resources. Moreover, it is particularly difficult to estimate with certainty our future expenses given the dynamic nature of our business, and the macro-economic environment generally.

Because of the numerous risks and uncertainties associated with our research and development programs and because the extent to which we may enter into collaborations with third parties for development of our drug candidates is unknown, we are unable to estimate the timing and amounts of increased capital outlays and operating expenses associated with completing the research and development of our drug candidates. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of researching and developing our drug candidates and programs, and of conducting nonclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining marketing approvals for drug candidates we develop if clinical trials are successful;

- the cost of commercialization activities for our current drug candidates, and any future drug candidates we develop, whether alone or in collaboration, including marketing, sales and distribution costs if our current drug candidates or any future drug candidate we develop is approved for sale;
- the cost of manufacturing our current and future drug candidates for clinical trials in preparation for marketing approval and commercialization;
- our ability to establish and maintain strategic licenses or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the timing, receipt and amount of sales of, or profit share or royalties on, our future products, if any;
- the emergence of competing therapies for hepatological indications and viral diseases and other adverse market developments; and
- any acquisitions or in-licensing of other programs or technologies.

Developing pharmaceutical products, including conducting nonclinical studies and clinical trials, is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval for any drug candidates or generate revenue from the sale of any drug candidate for which we may obtain marketing approval. In addition, our drug candidates, if approved, may not achieve commercial success. Our commercial product revenues, if any, will be derived from sales of drugs that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

Adequate additional funds may not be available to us on acceptable terms, or at all. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interest may be diluted, and the terms of these securities may include liquidation or other preferences and anti-dilution protections that could adversely affect the rights of a common stockholder. Additional debt or preferred equity financing, if available, may involve agreements that include restrictive covenants that may limit our ability to take specific actions, such as incurring debt, making capital expenditures or declaring dividends, which could adversely constrain our ability to conduct our business, and may require the issuance of warrants, which could potentially dilute ownership interest.

If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technology, future revenue streams, research programs, or drug 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 or collaborations, strategic alliances or licensing arrangements with third parties when needed, we may be required to delay, limit, reduce and/or terminate our product development programs or any future commercialization efforts or grant rights to develop and market drug candidates that we would otherwise prefer to develop and market ourselves.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented (in thousands):

	Year Ended December 31,	
	2025	2024
Net cash and cash equivalents used in operating activities	$ (82,503)	$ (80,743)
Net cash and cash equivalents used in investing activities	(37,826)	(18,279)
Net cash and cash equivalents provided by financing activities	101,635	355
Net decrease in cash, cash equivalents, and restricted cash	$ (18,694)	$ (98,667)

Operating activities

During Fiscal 2025, operating activities used $82.5 million of cash, primarily resulting from our net loss of $24.2 million, which was largely due to ongoing research and development activities and general and administrative expenses to support those activities. Cash used as a result of changes in our operating assets and liabilities of $3.8

million consisted of a decrease of $3.1 million in operating lease liabilities, a decrease of $0.2 million in deferred revenue, a decrease in accrued liabilities of $2.0 million, offset by an increase of $1.4 million in accounts payable and an increase of $0.1 million in other assets. Additionally, there were non-cash charges of $54.5 million, primarily driven by the non-cash change in fair value of the 2023 Common Warrants.

During Fiscal 2024, operating activities used $80.7 million of cash, primarily resulting from our net loss of $131.2 million, which was largely due to ongoing research and development activities and general and administrative expenses to support those activities. Cash used as a result of changes in our operating assets and liabilities of $5.0 million, consisted of a decrease of $2.7 million in operating lease liabilities, a decrease of $1.2 million in deferred revenue, a decrease in accrued liabilities of $1.4 million, partially offset by an increase in other current assets of $0.2 million, and an increase of $0.1 million in accounts payable. Offsetting this, there were non-cash charges of $55.4 million, primarily driven by the non-cash change in fair value of the 2023 Common Warrants.

Investing activities

During Fiscal 2025, investing activities used $37.8 million of cash, consisting primarily of investment purchases of $164.9 million partially offset by investment maturities of $127.5 million.

During Fiscal 2024, investing activities used $18.3 million of cash, consisting primarily of investment purchases of $108.1 million partially offset by investment maturities of $90.0 million.

Financing activities

During Fiscal 2025, net cash provided by financing activities was $101.6 million, primarily from proceeds from issuance of common stock, common warrants and pre-funded warrants in connection with PIPE offering.

During Fiscal 2024, net cash provided by financing activities was not material.

Contractual obligations and commitments

Our principal commitments consist of obligations under license agreements, for example with Emory and KU Leuven, where we may be required to make significant milestone or royalty payments. Additionally we have additional obligations under our operating leases for office space in South San Francisco, California, Belgium, and Shanghai, China and finance lease commitments representing obligations related to vehicle leases for employees and a lease for lab equipment. All of our finance leases are for assets in Belgium. We do not have any material purchase commitments for contracts with fixed or minimum service requirements. We also enter into contracts in the normal course of business with various vendors that generally provide for contract termination following a certain notice period. The Company enters into contracts in the normal course of business that includes arrangements with clinical research organizations, vendors for preclinical research and vendors for manufacturing. These agreements generally allow for cancellation with notice. As of December 31, 2025, we had no material non-cancellable purchase commitments.

Off-balance sheet arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

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, 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.

Critical accounting estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles (GAAP). The preparation of these consolidated financial statements requires us to make estimates and

assumptions that affect the reported amounts and the disclosure of assets and liabilities at the date of the consolidated financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on relevant assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in the notes to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K, we believe that the following critical accounting policies are most important to understanding and evaluating our reported financial results and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Accrued research and development expenses

We record accrued expenses for estimated costs of our research and development activities conducted by third-party service providers, which include the conduct of clinical trials and nonclinical studies. We record the estimated expenses of research and development activities based upon the estimated amount of services provided but not yet invoiced. We record accrued expenses for these costs based on factors such as estimates of the work completed and in accordance with agreements established with these third-party service providers and discussions with internal personnel and external service providers as to the progress or stage of completion of these services. Any payments made in advance of services provided are recorded as prepaid expenses and other assets, which are expensed as the contracted services are performed.

As actual costs become known, we adjust our accrued estimates. 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 could vary from actuals and result in us reporting amounts that are too high or too low in any particular period. Our accrued expenses are dependent, in part, upon the receipt of timely and accurate reporting from clinical research organizations and other third-party service providers. For the periods presented, we have experienced no material differences between our accrued expenses and actual expenses.

Emerging growth company status

In April 2012, the Jumpstart Our Business Startups Act of 2012 (the JOBS Act), was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" (an EGC) can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an EGC can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We elected to use the extended transition period for any new or revised accounting standards during the period in which we remained an EGC. Our status as an EGC ended on the last day of the fiscal year ending after the fifth anniversary of our initial public offering, i.e., December 31, 2025.

Recently issued and adopted accounting pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our consolidated financial statements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Interest rate risk

Our cash, cash equivalents and investments of $77.8 million as of December 31, 2025, consist of bank deposits, money market funds, and US Treasury available-for-sale securities. We are exposed to market risk related to changes in interest rates applicable to our investment portfolio of cash equivalents and short-term investments. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. Should U.S. interest rates decline, interest income would be reduced in future periods for short-term investments which mature and the proceeds of which are reinvested in similar instruments at lower interest rates. Additionally, the fair value of our short-term investments is subject to change as a result of potential changes in market interest rates. As of December 31, 2025, we estimate that a hypothetical 100 basis point adverse movement would not result in a material impact on our financial position or results of operations or cash flows.

Foreign currency exchange risk

We have employees and operations, including contracts with third-party vendors, in Europe through our subsidiary Aligos Belgium BVBA. We have employees and operations in China through our subsidiary Aligos Therapeutics (Shanghai) Co., Ltd., and similar, but more limited, operations in Australia. Though the functional currency in these locations is the U.S. dollar, we remeasure transactions initially recorded in local currencies in these locations, the Euro, Australian dollar and Chinese Yuan, respectively, to the U.S. dollars periodically. As such, we are exposed to foreign currency exchange risk as the underlying contracts to pay employees or vendors in these locations are generally denominated in the local currencies. A decline in the value of the U.S. dollar relative to these currencies would increase our cost of doing business in these locations. We are subject to foreign currency transaction gains or losses on our contracts denominated in foreign currencies. To date, foreign currency transaction gains and losses have not been material to our financial statements, and we have not had a formal hedging program with respect to foreign currency. A 10% increase or decrease in current exchange rates would not have a material effect on our financial position or results of operations or cash flows.

Item 8. Financial Statements and Supplementary Data.

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Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors of Aligos Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Aligos Therapeutics, Inc. (the Company) as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity (deficit) and cash flows for each of the two years in the period ended December 31, 2025, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred recurring losses from operations, negative cash flows from operating activities, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 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 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

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

Accrued research and development expenses – clinical trials

Description of the Matter	The Company recorded accrued research and development expenses of $1.6 million as of December 31, 2025. As described in Note 2, the Company records accruals for estimated clinical trial expenses based on the services performed pursuant to contracts with contract research organizations that conduct and manage clinical trials on the Company's behalf. Auditing management's accounting for clinical trial accruals was challenging as evaluating the progress of the activities under the Company's clinical trial agreements is dependent upon information from internal clinical operations personnel and third-party service providers and involves a high volume of data.
How We Addressed the Matter in Our Audit	To test the completeness and accuracy of information used to estimate clinical trial expenses, our audit procedures included, among others, confirming with a sample of vendors the progress of activities under research and development contracts at period end, testing a sample of cash disbursements after period end to assess the completeness of accrued expenses, and making inquiries of individuals outside the finance function who oversee the clinical operations process.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2019.

San Francisco, California
March 5, 2026

Consolidated Balance Sheets
(In thousands, except share and per share data)

	December 31, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 18,303	$ 36,997
Restricted cash	110	110
Short-term investments	59,541	19,942
Other current assets	4,908	5,092
Total current assets	82,862	62,141
Operating lease right-of-use assets	3,089	4,964
Property and equipment, net	1,867	2,362
Other assets	715	627
Total assets	$ 88,533	$ 70,094
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 3,982	$ 2,571
Accrued liabilities	13,526	15,557
Operating lease liabilities, current	3,580	3,422
Finance lease liabilities, current	145	36
Deferred revenue, current	-	151
Total current liabilities	21,233	21,737
Operating lease liabilities, net of current portion	1,525	4,795
Finance lease liabilities, net of current portion	-	122
2023 Common Warrants liability	12,183	72,367
Long term liability	47	46
Total liabilities	34,988	99,067
Commitments and contingencies (Note 12)		
Stockholders' equity (deficit):		
Preferred Stock, $0.0001 par value; 10,000,000 shares authorized as of December 31, 2025 and December 31, 2024, respectively; no shares issued and outstanding as of December 31, 2025 and December 31, 2024, respectively.	-	-
Common stock, $0.0001 par value; 115,800,000 shares and 20,800,000 shares authorized as of December 31, 2025 and December 31, 2024, respectively; 6,178,230 and 3,864,436 shares issued and outstanding as of December 31, 2025 and December 31, 2024, respectively.	9	8
Additional paid-in capital	695,269	588,576
Accumulated deficit	(642,201)	(618,008)
Accumulated other comprehensive income	468	451
Total stockholders' equity (deficit)	53,545	(28,973)
Total liabilities and stockholders' equity (deficit)	$ 88,533	$ 70,094

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

Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)

	Year Ended December 31,	
	2025	2024
Revenue from collaborations	$ —	$ 334
Revenue from customers	2,186	3,611
Operating expenses:		
Research and development	69,453	70,269
General and administrative	20,718	22,830
Total operating expenses	90,171	93,099
Loss from operations	(87,985)	(89,154)
Interest and other income, net	3,922	4,406
Change in fair value of 2023 Common Warrants	60,184	(46,132)
Loss before income tax	(23,879)	(130,880)
Income tax provision	(314)	(331)
Net loss	(24,193)	(131,211)
Other comprehensive income (loss):		
Unrealized gain on available-for-sale securities	22	9
Unrealized loss on pension plans	(5)	(103)
Other comprehensive income (loss)	17	(94)
Comprehensive loss	$ (24,176)	$ (131,305)
Net loss per share, basic and diluted	$ (2.45)	$ (20.94)
Weighted average shares of common stock, basic and diluted	9,884,955	6,264,612

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

Consolidated Statements of Changes in Stockholders' Equity (Deficit)
(In thousands, except share and per share data)

	Year Ended December 31, 2025					
	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	Income	Equity (Deficit)
Balance as of December 31, 2023	3,003,855	$ 7	$ 578,325	$ (486,797)	$ 545	$ 92,080
Issuance of common stock related to ESPP purchase	32,958	-	436	-	-	436
Issuance of common stock upon exercise of pre-funded warrants	800,613	1	2	-	-	3
Issuance of common stock upon exercise of common warrants	22,024	-	1,361	-	-	1,361
Issuance of common stock from RSU vesting	4,986	-	-	-	-	-
Stock-based compensation expense related to employee stock awards	-	-	7,948	-	-	7,948
Stock-based compensation expense related to employee stock purchases	-	-	504	-	-	504
Other comprehensive loss	-	-	-	-	(94)	(94)
Net loss	-	-	-	(131,211)	-	(131,211)
Balance as of December 31, 2024	3,864,436	$ 8	$ 588,576	$ (618,008)	$ 451	$ (28,973)
Issuance of common stock related to ESPP purchase	61,121	-	304	-	-	304
Issuance of common stock upon exercise of pre-funded warrants	146,468	-	-	-	-	-
Issuance of common stock upon exercise of common warrants	-	-	-	-	-	-
Issuance of common stock from RSU vesting	2,898	-	-	-	-	-
Issuance of common stock upon PIPE	2,103,307	1	105,003	-	-	105,004
Issuance costs	-	-	(3,658)	-	-	(3,658)
Stock-based compensation expense related to employee stock awards	-	-	4,541	-	-	4,541
Stock-based compensation expense related to employee stock purchases	-	-	503	-	-	503
Other comprehensive income	-	-	-	-	17	17
Net loss	-	-	-	(24,193)	-	(24,193)
Balance as of December 31, 2025	6,178,230	9	695,269	(642,201)	468	53,545

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

Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,	
	2025	2024
Cash flows from operating activities:		
Net loss	$ (24,193)	$ (131,211)
Adjustments to reconcile net loss to net cash used in operating activities:		
Accretion of discount on investments	(2,188)	(1,783)
Non cash lease expense	1,875	1,595
Change in fair value of 2023 Common Warrants	(60,184)	46,132
Depreciation expense	930	1,027
Stock-based compensation including ESPP	5,044	8,452
Changes in operating assets and liabilities:		
Accounts payable	1,411	54
Accrued liabilities	(2,031)	(1,388)
Operating lease liabilities	(3,112)	(2,680)
Deferred revenue	(151)	(1,157)
Other assets	96	216
Net cash and cash equivalents used in operating activities	(82,503)	(80,743)
Cash flows from investing activities:		
Maturities of short-term investments	127,500	90,000
Purchase of short-term investments	(164,889)	(108,149)
Purchases of property and equipment	(437)	(130)
Net cash and cash equivalents used in investing activities	(37,826)	(18,279)
Cash flows from financing activities:		
Proceeds from issuance of common stock upon exercise of pre-funded warrants	-	2
Proceeds from issuance of common stock, common warrants and pre-funded warrants in connection with PIPE offering, net of costs	101,345	-
Payments on finance lease	(14)	(83)
Proceeds from the ESPP purchase	304	436
Net cash and cash equivalents provided by financing activities	101,635	355
Net decrease in cash, cash equivalents, and restricted cash	(18,694)	(98,667)
Cash, cash equivalents, and restricted cash, beginning of period	37,107	135,774
Cash, cash equivalents, and restricted cash, end of period	$ 18,413	$ 37,107

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

Aligos Therapeutics, Inc.
Notes to consolidated financial statements

1. Organization and basis of presentation

Description of business

Aligos Therapeutics, Inc. (Aligos-US) was incorporated in the state of Delaware on February 5, 2018 (inception). On September 10, 2018, the Company formed Aligos Belgium BVBA (the Subsidiary or Aligos-Belgium). On March 30, 2020, the Company formed as a wholly owned subsidiary, Aligos Australia Pty LTD (Aligos-Australia), a proprietary limited company. On May 18, 2021, the Company formed as a wholly owned subsidiary, Aligos Therapeutics (Shanghai) Co. Ltd. (Aligos-Shanghai) and together with Aligos-US, Aligos-Belgium, and Aligos-Australia being the Company or Aligos.

Aligos is a clinical-stage biotechnology company developing novel therapeutics to address unmet medical needs in liver and viral diseases, including for chronic hepatitis B virus (HBV) infection, obesity, metabolic dysfunction associated steatohepatitis (MASH), and coronaviruses.

The Company is devoting substantially all of its efforts to the research and development of its drug candidates. The Company has not generated any product revenue to date. The Company is also subject to a number of risks similar to other companies in the biotechnology industry, including the uncertainty of success of its nonclinical studies and clinical trials, regulatory approval of drug candidates, uncertainty of market acceptance of products, competition from substitute products and larger companies, the need to obtain additional financing, compliance with government regulations, protection of proprietary technology, dependence on third-parties, product liability, and dependence on key individuals.

Basis of presentation

The accompanying consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP) and include all adjustments necessary for the fair presentation of the Company's financial position for the periods presented. Any reference in these notes to applicable accounting guidance is meant to refer to the authoritative U.S. GAAP included in the Accounting Standards Codification (ASC), and Accounting Standards Update (ASU) issued by the Financial Accounting Standards Board (the FASB).

Liquidity and Going Concern

As of December 31, 2025, the Company has cash, cash equivalent and short-term investments of $77.8 million, and as of December 31, 2025 and 2024, the Company had an accumulated deficit of approximately $642.2 million and $618.0 million, respectively. The Company has incurred losses and negative cash flows from operations since its inception. The Company expects that its cash, cash equivalents and short-term investments will be sufficient to fund current planned operations into the third quarter of 2026, which is less than one year from the date of filing this Annual Report on Form 10-K. The Company plans to raise substantial additional capital to continue as a going concern, including through a combination of public or private equity offerings, third-party funding, collaborations, strategic alliances, and licensing arrangements. In addition, the Company is evaluating future financing opportunities, and intends to secure additional funding.

However, there can be no assurance that any additional financing will be available to the Company on acceptable terms, if at all. If events or circumstances occur such that the Company does not obtain additional funding, it may be necessary to significantly reduce its scope of operations to reduce the current rate of spending, which could include reductions in staff and the need to delay, limit, reduce or terminate current or future product development, which could have a material adverse effect on the Company's business, results of operations and financial condition. Moreover, even if financing efforts are successful and additional capital is obtained, available liquidity may still be insufficient to eliminate the aforementioned substantial doubt regarding the Company's ability to continue as a going concern.

The accompanying financial statements have been prepared assuming the Company will continue to operate as a going concern, which contemplates the realization of assets and the settlement of liabilities in the normal course of business. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts of liabilities that may result from uncertainty related to the

Company's ability to continue as a going concern.

Periodically, the Company maintains deposits in accredited financial institutions in excess of federally insured limits. The Company deposits its cash in financial institutions that it believes have high credit quality and has not experienced any losses on such accounts and does not believe it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships. The Company maintains a dual banking system to limit its credit and liquidity risk.

2. Summary of significant accounting policies

The accompanying consolidated financial statements have been prepared on a basis that contemplates the continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the normal course of business.

Risks and uncertainties

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the need to obtain additional financing. As a result, the Company is unable to predict the timing or amount of increased expenses or when or if the Company will be able to achieve or maintain profitability. Drug candidates currently under development will require significant additional research and development efforts, including extensive nonclinical and clinical testing and regulatory approval.

Moreover, it is particularly difficult to estimate with certainty the Company's future expenses given the dynamic nature of its business, and the macro-economic environment generally.

Principles of consolidation

The accompanying consolidated financial statements include Aligos-US and its wholly owned subsidiaries Aligos-Belgium, Aligos-Australia and Aligos-Shanghai. All intercompany balances and transactions have been eliminated.

Use of estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make judgments, estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosures. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. These estimates form the basis for making judgments about the carrying values of assets and liabilities when these values are not readily apparent from other sources. Accounting estimates and judgments are inherently uncertain, and the actual results could differ from these estimates.

Foreign currency

The Company's foreign subsidiaries use the U.S. dollar as their functional currency, and they initially measure the foreign currency denominated assets and liabilities at the transaction date. Monetary assets and liabilities are then re-measured at exchange rates in effect at the end of each period, and non-monetary assets and liabilities are converted at historical rates. A re-measurement loss of $0.2 million was recognized during the year ended December 31, 2025 and an immaterial re-measurement loss was recognized during the year ended December 31, 2024, and are reflected within interest and other income, net on the Consolidated Statements of Operations and Comprehensive Loss.

Segment information

The Company has one reportable segment which is focused on discovering and developing drug candidates in both liver and viral diseases. The Company's Chairman, President and Chief Executive Officer, who is the chief operating decision maker (CODM), assesses segment performance and decides how to allocate resources based on net loss that is also reported on the Consolidated Statements of Operations and Comprehensive Loss. See Note 15, Segment disclosure, for additional information.

Cash equivalents

The Company considers all highly liquid investments purchased with original maturities of 90 days or less at acquisition to be cash equivalents.

Restricted cash

For each of the years ended December 31, 2025 and 2024, the restricted cash balance was $0.1 million, and was used primarily to secure letters of credit in relation to the Company's operating leases and deposits on rental assets (Note 5), as well as employee withholdings for the employee stock purchase plan.

Short-term investments

The Company generally invests its excess cash in money market funds and investment grade short-to-intermediate-term fixed income securities. Such investments are included in cash, cash equivalents and short-term investments on the Consolidated Balance Sheets.

The Company determines the appropriate classification of securities at the time of purchase and re-evaluates such designation as of each balance sheet date. Available-for-sale debt securities are measured and reported at fair value using quoted prices in active markets for similar securities. Unrealized gains and losses on available-for-sale securities are reported as a separate component of stockholders' equity (deficit). Premiums or discounts from par value are amortized to investment income over the life of the underlying investment. The cost of securities sold is determined on a specific identification basis, and realized gains and losses are included in interest and other income, net within the Consolidated Statements of Operations and Comprehensive Loss.

The Company assesses available-for-sale debt securities on a quarterly basis to see whether any unrealized loss is due to credit-related factors. Factors considered in determining whether an impairment is credit-related include the extent to which the investment's fair value is less than its cost basis, declines in published credit ratings, changes in interest rates, and any other adverse factors related to the security. If it is determined that a credit-related impairment exists, the Company will measure the credit loss based on a discounted cash flow model. Credit-related impairments on available-for-sale debt securities are recognized as an allowance for credit losses with a corresponding adjustment to other income, net in the Company's consolidated statement of operations. The unrealized loss position that is not credit-related is recorded, net of any related tax effects, in other comprehensive income until realized. There were no credit-related losses recognized for the periods presented.

Accrued Interest Receivable

Accrued interest receivable related to the Company's available-for-sale debt securities is presented within other current assets on the Company's consolidated balance sheets. The Company has elected to exclude accrued interest receivable from both the fair value and the amortized cost basis of available-for-sale debt securities for the purposes of identifying and measuring any impairment. The Company writes off accrued interest receivable once it has determined that the asset is not realizable. Any write offs of accrued interest receivable are recorded by reversing interest income, recognizing credit loss expense, or a combination of both. To date, the Company has not written off any accrued interest receivables associated with its available-for-sale debt securities.

Concentrations of credit risk and significant suppliers

The Company has no significant off-balance sheet risk, such as foreign exchange contracts, option contracts, or other foreign hedging arrangements. Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, restricted cash and investments. Periodically, the Company maintains deposits in accredited financial institutions in excess of federally insured limits. The Company deposits its cash in financial institutions that it believes have high credit quality and has not experienced any losses on such accounts and does not believe it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships. The Company generally invests its excess capital in money market funds, U.S. treasury bonds, U.S. treasury bills and certificates of deposit that are subject to minimal credit and market risks.

The Company is dependent on various third parties to manufacture compounds for the Company to conduct research and studies for its programs. These programs would be adversely delayed by a significant interruption in the supply of active pharmaceutical ingredients.

Accounting for Government Grants

In 2022, the Company was awarded a grant of $1.1 million by the National Institutes of Health (NIH) for research to target coronaviruses. The grant is for multiple years with the amount updated after each year of progress through 2025, subject to the annual reapplication and approval by the NIH. In 2023, the approved grant awarded was an additional $1.4 million. In 2024, the approved grant awarded was an additional $1.5 million. The contract ended in 2025.

In 2023, the Company was awarded a contract of $8.5 million by the National Institute of Allergies and Infectious Diseases (NIAID) for research to target coronaviruses. In March 2024, the Company entered into an amendment to the above contract and was awarded an additional $1.3 million, making the total contract value $9.8 million. In April 2025, the Company entered into an amendment to the above contract and was awarded an additional $1.5 million, for a total of $11.3 million. The contract completion is expected in 2026.

U.S. GAAP does not contain authoritative accounting standards for grants or contracts provided by governmental entities to a for-profit entity. Absent authoritative accounting standards, interpretative guidance issued and commonly applied by financial statement preparers allows for the selection of accounting policies amongst acceptable alternatives. The Company determined it most appropriate to account for grants by analogy to International Accounting Standards 20 ("IAS 20"), Accounting for Government Grants and Disclosure of Government Assistance. Under this model, reimbursements the Company receives from the U.S. government for qualifying expenditures under the NIH grant will be recognized in earnings as a reduction to research and development expense when there is reasonable assurance that the Company will receive the grant. IAS 20 does not define "reasonable assurance"; however, the Company analogized this to "probable" as defined in FASB ASC 450-20-20 under U.S. GAAP, which is the definition the Company has applied. The grants and contracts will be recognized in earnings as a reduction of the related research and development (R&D) expenses.

During the year ended December 31, 2025, $5.4 million was recognized as a reduction to R&D expenses. During the year ended December 31, 2024, $2.8 million was recognized as a reduction to R&D expenses.

Common Warrants liability

The Company accounts for certain warrants as liabilities at fair value and adjusts the instruments to fair value at each reporting period. The Company determined that its outstanding warrants are freestanding derivative instruments. The warrants are subject to remeasurement at each balance sheet date until exercised, and any change in fair value is recognized in the Consolidated Statements of Operations and Comprehensive Loss. The fair value of the warrants issued by the Company has been estimated and is remeasured at the end of each reporting period using a Black-Scholes option pricing model.

Leases

The Company determines at the inception of the lease if an arrangement is a lease. Operating leases are included in operating lease right-of-use (ROU) assets and operating lease liabilities in the Consolidated Balance Sheets. Finance leases are included in property and equipment and finance lease liabilities in the Consolidated Balance Sheets.

ROU assets represent the right to use an underlying asset for the lease term and lease liabilities represent the obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. When the Company's leases do not provide an implicit rate, an incremental borrowing rate is used based on the information available at the commencement dates in determining the present value of lease payments. The Company uses the implicit rate when readily determinable. The operating lease ROU assets also include any lease payments made and excludes lease incentives when paid by the Company or on the Company's behalf. The Company's lease terms may include the period covered by options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for operating leases is recognized on a straight-line basis over the lease term.

The Company has lease agreements with lease and non-lease components. The Company elected to not separate lease and non-lease components for all of its building leases. For vehicle leases, lease and non-lease components are accounted for separately. The Company also made an accounting policy election to recognize lease expense for leases with a term of 12 months or less on a straight-line basis over the lease term and not recognize ROU assets or lease liabilities for such leases.

Property and equipment

Property and equipment is stated at cost less accumulated depreciation, and is depreciated using the straight-line method over the estimated useful life of the asset, which are as follows:

Lab equipment	3 years
Computer equipment	3 years
Furniture and office equipment	3-8 years
Vehicles	4 years
Leasehold improvements	Shorter of the useful life or remaining lease term

Expenditures for repairs and maintenance of assets are charged to expense as incurred. Upon retirement or sale, the cost and related accumulated depreciation of assets disposed of are removed from the accounts and any resulting gain or loss is included in loss from operations.

Impairment of long-lived assets

The Company regularly reviews the carrying amount of its property, equipment, other long-lived assets and intangible assets to determine whether indicators of impairment may exist which warrant adjustments to carrying values or estimated useful lives. If indications of impairment exist, projected future undiscounted cash flows associated with the asset are compared to the carrying amount to determine whether the asset's value is recoverable. If the carrying value of the asset exceeds such projected undiscounted cash flows, the asset will be written down to its estimated fair value. No impairment charges were recorded during the years ended December 31, 2025 or 2024.

Research and development expenses

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including salaries, stock-based compensation and benefits, facilities costs, depreciation, and third-party license fees. Non-refundable prepayments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized.

In-process research and development (IPR&D) expense represents the costs to acquire technologies to be used in research and development that have not reached technological feasibility or have no alternative future uses and thus are expensed as incurred. IPR&D expense also includes upfront license fees and milestones paid to collaborators for technologies with no alternative use.

Collaborative arrangements

The Company enters into collaboration arrangements with pharmaceutical and other partners, under which the Company may grant licenses to its collaboration partners to research and develop potential drug candidates. Consideration under these contracts may include an upfront payment, development, regulatory, sales and other milestone payments. Contractual payments received for research and development activities performed are recognized on a gross basis in revenue from collaboration arrangements.

The Company may also perform research and development activities under the collaboration agreements where the Company may be granted licenses from its collaboration partners. Contractual payments to the other party in collaboration agreements and costs incurred by the Company are recognized on a gross basis in research and development expenses. Development and regulatory milestones payments to collaboration partners are recorded as

research and development costs when such payments become probable. Royalties and sales-based milestone payments are recorded when the related sales occur.

When the Company enters into collaboration arrangements, the Company assesses whether the arrangement falls within the scope of ASC 808, *Collaborative Arrangements* (ASC 808) based on whether the arrangement involves joint operating activities and whether both parties would be active participants and would be exposed to significant risks and rewards of the arrangement. To the extent that the arrangement falls within the scope of ASC 808, the Company assesses whether the payments between the parties fall within the scope of other accounting literature such as ASC 606, *Revenue from Contracts with Customers* (ASC 606).

Revenue from contracts with customers

The Company enters into revenue arrangements with certain partners. Consideration under these contracts may include an upfront payment, development, regulatory, sales and other milestone payments. Contractual payments received for research and development activities performed are recognized on a gross basis in Revenue from Customers.

The Company may also perform research and development activities under the revenue agreements where the Company may be granted licenses from its partners. Contractual payments to the other party in revenue agreements and costs incurred by the Company are recognized on a gross basis in research and development expenses. For arrangements that include royalties and sales-based milestone payments, the license is deemed to be the predominant item to which such payments relate and the Company recognizes revenue at the later of when the related sales occur or when the performance obligation to which the royalty has been allocated has been satisfied.

When the Company enters into revenue arrangements, the Company assesses whether the arrangement first falls within the scope of ASC 808 based on whether the arrangement involves joint operating activities and whether both parties would be active participants and would be exposed to significant risks and rewards of the arrangement. If the arrangement does not fall into this literature, the Company then looks to ASC 606 to see whether the partner is considered a customer.

Fair value measurements

Certain assets and liabilities of the Company are carried at fair value under U.S. GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

Level 1—Quoted prices in active markets for identical assets or liabilities.

Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

Level 3—Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

Stock-based compensation

The Company's stock-based awards consist of restricted stock awards and stock options. For stock-based awards issued to employees and nonemployees, the Company measures the estimated fair value of the stock-based awards on the date of grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective awards. The Company records expense for awards with service-based vesting using the straight-line method. The Company accounts for forfeitures as they occur.

The Company classifies stock-based compensation expense in its Consolidated Statements of Operations and Comprehensive Loss in the same manner in which the award recipient's cash compensation costs are classified.

The fair value of each restricted stock award is the closing price of the Company's common stock on the date of grant. The fair value of each stock option award is estimated on the date of grant using the Black-Scholes option pricing model. The Black-Scholes option-pricing model requires the use of a number of assumptions including the fair value of the common stock, expected volatility, risk-free interest rate, expected dividends, and expected term of the option.

The Company determined the expected stock volatility using a weighted-average of the historical volatility of a group of guideline companies that issued options with substantially similar terms, and expects to continue to do so until such time as the Company has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options has been determined utilizing the simplified method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. The Company has not paid, and does not anticipate paying, cash dividends on its common stock; therefore, the expected dividend yield is assumed to be zero.

The fair value of the Company's 2020 Employee Stock Purchase Plan (the ESPP) is determined on the date the offering period begins using a Black-Scholes option-pricing model and similar assumptions for stock options as described above.

Income taxes

Deferred tax assets and liabilities are determined on the basis of the differences between the consolidated financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established.

The Company accounts for uncertain tax positions recognized in the consolidated financial statements by prescribing a more-likely-than-not threshold for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related interest and penalties.

Comprehensive Loss

Comprehensive loss comprises net loss and other comprehensive income (loss). Other comprehensive income (loss) income consists of foreign currency translation adjustments, unrealized gain on marketable securities and unrealized loss on pension plans.

Net loss per share

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, without consideration for potentially dilutive securities. The weighted-average number of shares of common stock outstanding includes the shares subject to the pre-funded warrants as per ASC 260, shares issuable for little or no cash consideration upon the satisfaction of certain conditions, shall be considered outstanding common shares.

Diluted net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, stock options, common stock subject to repurchase related to early exercise of stock options, unvested restricted stock subject to repurchase, common stock warrants and convertible notes are considered to be potentially dilutive securities.

Accordingly, in periods in which the Company reports a net loss, diluted net loss per share is the same as basic net loss per share, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

Benefit plans

The Company has established a defined contribution savings plan for its employees in Aligos-US under Section 401(k) of the Internal Revenue Code, and a defined benefits plan for its employees in Aligos-Belgium.

The Company uses the standard method for the recognition of the actuarial results as described in ASC 715. This means application of a 10% corridor and amortization over the expected average remaining working lives of

the employees. The plan contains benefits to the plan participant on the normal plan retirement date and benefits to the partner after death of the plan participant. This plan is recognized under ASC 715.

Reverse Stock Split

In June 2024, the Company's stockholders approved a reverse stock split of its authorized, issued and outstanding voting and non-voting common stock at a range of ratios between 1-for-5 to 1-for-30, and the Company's board of directors subsequently approved the implementation of the reverse stock split at a ratio of 1-for-25 (the Reverse Stock Split). The Reverse Stock Split was effective as of August 19, 2024.

As of the effective time of the Reverse Stock Split, every 25 issued and outstanding shares of the Company's common stock was automatically reclassified into one issued and outstanding share of the Company's common stock. This reduced the number of shares outstanding from 79.9 million shares to 3.3 million shares. The Reverse Stock Split did not affect the par value of the common stock. No fractional shares of common stock were issued in connection with the Reverse Stock Split and all fractional shares were rounded down to the nearest whole share with respect to outstanding shares of common stock. Any holders of common stock who would have otherwise received a fractional share of common stock pursuant to the Reverse Stock Split, received cash in lieu of the fractional share. All prior period share and per share amounts of the Company's common stock presented have been retroactively adjusted to reflect the 1-for-25 Reverse Stock Split.

Recent accounting pronouncements

In November 2024, the FASB issued ASU 2024-03 Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses. The standard is effective for fiscal years beginning after December 15, 2026, and interim periods beginning after December 15, 2027. Early adoption is permitted. The Company is evaluating the potential impact of this standard on its consolidated financial statements.

In November 2025, the FASB issued ASU 2025-10 Government Grants (Topics 832) - Accounting for Government Grants Received by Business Entities. The standard is effective for fiscal years beginning after December 15, 2028, and interim periods within those annual reporting periods. Early adoption is permitted. The Company is evaluating the potential impact of this standard on its consolidated financial statements.

The Company adopted ASU 2023-09, Income Taxes (Topic 740) in the year ended December 31, 2025, and reflected the amendments on a prospective basis. See Note 11 for the income tax disclosures as amended by this ASU.

3. Balance sheet components

Property and equipment

The components of property and equipment were as follows as of December 31, 2025 and 2024:

	December 31, 2025	December 31, 2024
Leasehold improvements	$ 6,264	$ 6,101
Lab equipment	6,209	5,975
Computer equipment	1,075	1,051
Furniture and office equipment	751	732
Vehicles and equipment	280	281
Asset under construction	-	4
Total, at cost	14,579	14,144
Accumulated depreciation	(12,712)	(11,782)
Total, net	$ 1,867	$ 2,362

During the years ended December 31, 2025 and 2024, depreciation expense was $0.9 million and $1.0 million, respectively. Finance leases for vehicles and lab equipment are also included in property and equipment on the Consolidated Balance Sheets (Note 5).

Accrued Liabilities

Accrued liabilities consisted of the following as of December 31:

	December 31, 2025	December 31, 2024
Accrued R&D expenses	$ 1,204	$ 2,042
Accrued clinical expenses	1,609	1,749
Accrued compensation	7,464	6,387
Other accrued expenses	3,249	5,379
Total	$ 13,526	$ 15,557

4. Investments

As of December 31, 2025 and 2024, amortized cost, gross unrealized gains and losses, and estimated fair values of total fixed-maturity securities, classified as Level 1 and Level 2 in the fair value hierarchy, were as follows:

		December 31, 2025			
		Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
Available-for-sale securities:					
U.S. Treasury bonds	Level 2	$ 59,519	$ 22	$ -	$ 59,541
Money market funds	Level 1	$ 9,992	$ -	$ -	$ 9,992

		December 31, 2024			
		Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
Available-for-sale securities:					
U.S. Treasury bonds	Level 2	$ 19,933	$ 9	$ -	$ 19,942
Money market funds	Level 1	$ 25,411	$ -	$ -	$ 25,411

No short-term investments are in an unrealized loss position. Changes in fair value are related to changes in market interest rates. The Company expects to collect all contractual principal and interest payments and does not intend to sell the investments before recovery of their amortized cost bases. As of December 31, 2025, all investments had a remaining maturity of less than one year.

The Company recorded interest income of $2.2 million and $1.7 million, respectively, during the years ended December 31, 2025 and 2024, as a component of interest and other income, net on the Company's Consolidated Statement of Operations and Comprehensive Loss. Accrued interest receivable was not material at each year ended December 31, 2025 and 2024.

5. Leases

The Company has operating and finance leases for corporate offices, research and development facilities, and certain vehicles and lab equipment. These leases have remaining lease terms of three to five years, some of which include options to extend the leases for five to eight years. The Company has determined that it is not reasonably certain to exercise the options under any leases. The lease of research and development facilities includes costs for utilities and common area maintenance which have been included in the calculation of lease payments. Differences between lease payments as measured at lease inception and variations in monthly payments will be recognized as operating expenses in the period in which the obligation is incurred.

Maturities of lease liabilities as of December 31, 2025, were as follows:

	Operating Lease	Finance Lease
Year ending December 31:		
2026	$ 3,827	144
2027	1,415	-
2028	174	-
2029	-	-
2030	-	-
Thereafter	-	-
	5,416	144
Less: imputed interest	(311)	1
Present value of lease liabilities	5,105	145
Less: current portion	(3,580)	(145)
Lease liabilities, net of current portion	$ 1,525	$ -

The components of lease expense were as follows for the years ended December 31, 2025 and 2024:

	2025	2024
Operating lease cost	$ 2,462	$ 1,931
Finance lease cost:		
Amortization of right-of-use assets	$ 63	$ 56
Interest on lease liabilities	5	7
Total finance lease cost	$ 68	$ 63

The Company made payments of $3.8 million and $3.6 million during the years ended December 31, 2025 and 2024, respectively, net of immaterial sublease income.

As of December 31, 2025 and 2024, $0.7 million and $0.6 million of finance lease ROU assets, respectively, were presented as part of property and equipment on the Consolidated Balance Sheets with accumulated amortization of $0.5 million and $0.5 million, respectively.

Additional information related to the Company's leases was as follows as of December 31:

	December 31, 2025	December 31, 2024
Operating Lease:		
Weighted-average remaining lease term (years)	1.43	1.78
Weighted-average discount rate	8.83%	8.90%
Finance Lease:		
Weighted-average remaining lease term (years)	0.67	1.67
Weighted-average discount rate	5.57%	3.59%

6. Capital stock

Common stock

On October 20, 2020, the Company amended its certificate of incorporation to increase the total shares of common stock authorized for issuance to 12,800,000 and decrease the total shares of preferred stock authorized for issuance to 10,000,000 with a par value of $0.0001 per share. 12,000,000 shares of the common stock were designated as "Voting Common Stock" and 800,000 shares of the common stock were designated as "Non-Voting Common Stock".

On June 27, 2024, the Company amended its certificate of incorporation to increase the total shares of voting common stock authorized for issuance from 12,000,000 to 20,000,000.

On June 25, 2025, the Company's stockholders approved an amendment to the Company's Amended and Restated Certificate of Incorporation to increase the number of authorized shares of voting common stock from 20,000,000 shares to 100,000,000 shares and to increase the number of authorized shares of non-voting common stock from 800,000 shares to 15,800,000 shares.

The holders of shares of voting common stock are entitled to one vote for each share of common stock at all meetings of stockholders.

Preferred stock

As of December 31, 2025 and 2024, there were 10,000,000 shares of preferred stock authorized and no preferred stock issued.

7. Common Warrants and Pre-Funded Warrants

2025 PIPE

In February 2025, the Company closed its private investment in public equity (PIPE) offering (the 2025 Private Placement) and entered into a securities purchase agreement with certain investors (the 2025 Securities Purchase Agreement) that resulted in gross proceeds of $105.0 million. In the 2025 Private Placement, the Company issued (i) 2,103,307 shares of the Company’s common stock, par value $0.0001 per share (the Common Stock), consisting of 1,427,000 shares of voting common stock and 676,307 shares of non-voting common stock, (ii) pre‑funded warrants (the 2025 Pre-Funded Warrants) to purchase up to 1,922,511 shares of Common Stock and (iii) accompanying common warrants (the 2025 Common Warrants) to purchase up to 2,012,909 shares of Common Stock. The purchase price per share was $26.0825, or $26.0824 per 2025 Pre-Funded Warrant, which represents the purchase price per share less the $0.0001 per share exercise price of each Pre-Funded Warrant. Each 2025 Pre-Funded Warrant is immediately exercisable and does not expire. Each 2025 Common Warrant has an exercise price of $26.02, is immediately exercisable and will expire in February 2032. The Company received net proceeds of $101.4 million, after deducting the placement agent fees and expenses and offering costs.

The Company accounts for the 2025 Common Warrants and 2025 Pre-Funded Warrants in Stockholders Equity (Deficit) on the Consolidated Balance Sheet and determined the outstanding 2025 Common Warrants and 2025 Pre-Funded Warrants are freestanding derivative instruments. The Company classified the 2025 Common Warrants and 2025 Pre-Funded Warrants as equity because they met the equity scope exception under ASC 815, Derivatives and Hedging, based on the terms in the 2025 Securities Purchase Agreement.

2023 PIPE

In October 2023, the Company completed a PIPE offering and entered into a securities purchase agreement (the 2023 Securities Purchase Agreement) with certain institutional and accredited investors, pursuant to which the Company agreed to offer, issue and sell to these investors 1,257,168 shares of Common Stock, par value $0.0001 per share, pre-funded warrants to purchase an aggregate of 3,242,018 shares of Common Stock (the 2023 Pre-Funded Warrants), and warrants to purchase an aggregate of 2,249,680 shares of Common Stock (the 2023 Common Warrants). Each 2023 Pre-Funded Warrant has an exercise price of $0.0001 per share of common stock, was immediately exercisable and is exercisable until exercised in full. Each 2023 Common Warrant has an exercise price of $18.92 per share of common stock, is immediately exercisable and will expire on October 25, 2030. The closing of the offering occurred on October 25, 2023. The Company received gross proceeds of $92.1 million, and after deducting the placement agent fees and expenses and offering costs, net proceeds were $86.2 million.

The following table summarizes information about shares issuable under the 2023 and 2025 Pre-Funded Warrants outstanding at December 31, 2025 and December 31, 2024:

Pre-funded warrant shares outstanding	December 31, 2025	December 31, 2024
Outstanding at the beginning of the year	2,441,405	3,242,018
Issued	1,922,511	-
Exercised	(146,484)	(800,613)
Outstanding at the end of the period	4,217,432	2,441,405
Exercisable at the end of the period	4,217,432	2,441,405

The following table sets forth a summary of the activities of the Company's 2023 Common Warrant liability, which represents a recurring measurement that is classified with Level 3 of the fair value hierarchy wherein the fair value is estimated using significant unobservable inputs (in thousands):

	December 31, 2025	December 31, 2024
Beginning liability	$ 72,367	$ 27,596
Common warrants issued	-	-
Common warrants exercised	-	(1,361)
Change in fair value	(60,184)	46,132
Ending liability	$ 12,183	$ 72,367

The fair value of the 2023 Common Warrants is determined at each reporting date utilizing the Black Scholes option pricing model. Changes in the fair value are recognized in earnings. The valuation of 2023 Common Warrants is inherently sensitive to fluctuations of the inputs used, primarily driven by the Company's stock price. The inputs used to determine the fair value at the reporting date were as follows:

	December 31, 2025	December 31, 2024
Expected term (in years)	4.83	5.83
Risk-free interest rate	3.72%	4.43%
Dividend yield	-	-
Volatility	90.98%	84.62%

The following table summarizes information about shares issuable under the 2023 and 2025 Common Warrants outstanding at December 31, 2025 and 2024:

Common warrant shares outstanding	December 31, 2025	December 31, 2024
Outstanding at the beginning of the year	2,200,858	2,249,680
Issued	2,012,909	-
Exercised	-	(48,822)
Outstanding at the end of the period	4,213,767	2,200,858
Exercisable at the end of the period	4,213,767	2,200,858

8. Stock-based compensation

2018 Equity incentive plan

Following the Company's IPO in October 2020, the remaining shares from the 2018 Equity Incentive Plan (the 2018 Plan) were made available for issuance under the 2020 Incentive Award Plan (the 2020 Plan). As of December 31, 2025, there are 55,234 options outstanding and exercisable under the 2018 Plan.

2020 Incentive award plan

The Company adopted the 2020 Plan effective October 15, 2020. The 2020 Plan provides for a variety of stock-based compensation awards, including stock options, stock appreciation rights, or SARs, restricted stock awards, restricted stock unit awards, performance bonus awards, performance stock unit awards, dividend equivalents, or other stock or cash-based awards. The Company has granted 1,771,959 shares subject to awards as of December 31, 2025 with 465,915 remaining available for future grant.

Following the effectiveness of the 2020 Plan, the Company will not make any further grants under the 2018 Plan. However, the 2018 Plan will continue to govern the terms and conditions of the outstanding awards granted under this plan. Shares of common stock subject to awards granted under the 2018 Plan that are forfeited or lapse unexercised and which following the effective date of the 2020 Plan are not issued under the 2018 Plan will be available for issuance under the 2020 Plan.

2024 Employment inducement award plan

The Company adopted the 2024 Employment Inducement Award Plan (the 2024 Plan) in September 2024 as an inducement material to entering employment in accordance with Nasdaq Listing Rule 5635(c)(4). The 2024 Plan is used exclusively for the grant of equity awards to individuals who were not previously employed by the Company. The 2024 Plan provides for issuance of non-qualified stock options only. The Company has granted 269,500 shares subject to awards as of December 31, 2025 with 348,584 remaining available for future grant.

2020 Employee stock purchase plan

The Company adopted the 2020 Employee Stock Purchase Plan (the 2020 ESPP) effective on October 15, 2020. The 2020 ESPP enables eligible employees of the Company to purchase shares of common stock at a discount to fair market value. The Company has initially reserved for issuance 14,756 shares of common stock pursuant to the 2020 ESPP. As of December 31, 2025, 133,682 grants of awards under this plan have been made.

During each of the years ended December 31, 2025 and 2024, the Company's 2020 ESPP compensation expense was $0.5 million. The assumptions that the Company used to determine the grant-date fair value of shares granted to participants were as follows, disclosed on a grant date basis:

	2025	2024
Expected term (in years)	0.5 - 2.0 years	0.5 - 2.0 years
Risk-free interest rate	4.83% - 5.38%	2.58% - 5.38%
Dividend yield	-	-
Volatility	53.24% - 82.71%	50.36% - 73.67%
Weighted-average estimated fair value of purchase rights	$2.26 - $7.56	$4.00 - $15.14

Stock options

The exercise price for incentive stock options is at least 100% of the fair market value on the date of grant for stockholders owning less than 10% of the voting power of all classes of stock, or at least 110% of the fair market value for stockholders owning more than 10% of the voting power of all classes of stock. Options generally expire in 10 years and vest over periods determined by the Board, generally 48 months. Certain stock options referred to as “early exercise stock options” permit the holders to exercise the option in whole or in part prior to the full vesting of the option in exchange for unvested shares of Restricted Stock with respect to any unvested portion of the option so exercised.

During the years ended December 31, 2025 and December 31, 2024, the Company’s stock option compensation expense was approximately $4.4 million and $7.9 million, respectively, and there was no recognized

tax benefit in either year. As of December 31, 2025, unrecognized stock-based compensation expense related to stock options was $11.4 million, to be recognized over a weighted-average period of 3.02 years.

The assumptions that the Company used to determine the grant-date fair value of stock options granted to Participants were as follows, presented on a weighted-average basis:

	2025	2024
Expected term (in years)	6.01	5.94
Risk-free interest rate	4.07%	3.98%
Dividend yield	-	-
Volatility	96.99%	87.35%

Stock option activity during the year ended December 31, 2025 and 2024 was as follows:

	Shares subject to options	Weighted-average exercise price	Weighted-average remaining contractual term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2024	627,685	$ 35.93	8.50	$ 10,611
Granted	1,159,434	11.42	—	—
Exercised	—	—	—	—
Forfeited or Expired	(58,382)	61.79	—	—
Outstanding as of December 31, 2025	1,728,737	18.62	8.82	$ 859
Options vested and expected to vest as of December 31, 2025	1,728,737	18.62	8.82	$ 859
Options vested and exercisable as of December 31, 2025	488,305	34.67	7.74	$ 95

The weighted-average grant date fair value of stock options granted was $8.83 per share during the year ended December 31, 2025. The weighted-average grant date fair value of stock options granted was $12.88 per share during the year ended December 31, 2024. The total intrinsic value of stock options exercised during the years ended December 31, 2025 and 2024 were not material.

During the years ended December 31, 2025 and 2024 the Company did not issue shares for unvested stock options. As of December 31, 2025 and 2024, there were no shares of Common Stock held by employees subject to repurchase.

Restricted stock awards

The Company may grant restricted stock purchase awards to the Participants to purchase restricted stock under the Company's Plan, which are subject to vesting conditions. The purchase prices of the restricted stock are determined by the Board. The Company has a right to repurchase the shares if the Participant's service period is not fulfilled or upon termination of service at the original per share issuance price. The right of repurchase lapses over a service period which is typically four years with 25% vesting on the first anniversary of the vesting commencement date and 1/48 each month thereafter.

Before the adoption of the Company's Plan, the Company granted 20,118 restricted stock awards to employees and founders. These restricted stock awards have similar characteristics to the restricted stock awards granted under the Company's Plan, other than the right of repurchase, which typically lapses over three years with 33% vesting on the first anniversary of the vesting commencement date and 1/36 each month thereafter.

During each of the years ended December 31, 2025 and 2024, the Company recorded a total stock-based compensation expense of $0.1 million, related to the restricted stock awards. The number of restricted stock awards vested includes shares of common stock that the Company withheld on behalf of employees or sold to cover to

satisfy the minimum statutory tax withholding requirements. As of December 31, 2025, there was $0.7 million unrecognized stock-based compensation costs related to outstanding unvested restricted stock awards that are expected to vest over 3.37 years.

The following table summarizes the Company's restricted common stock activity for years ended December 31, 2025 and 2024:

	Number of Awards	Weighted-Average Grant Date Fair Value	Aggregate Fair Value (in thousands)
Issued and unvested as of December 31, 2024	4,729	$ 15.44	$ 74
Granted	74,955	10.11	758
Vested and released	(2,898)	16.47	(48)
Issued and unvested as of December 31, 2025	76,786	$ 10.20	$ 784

Stock-based compensation expense was allocated as follows for the years ended December 31, 2025 and December 31, 2024:

	Year Ended December 31,	
	2025	2024
Research and development	$ 2,712	$ 4,842
General and administrative	2,332	3,610
Total	$ 5,044	$ 8,452

9. In-licensing agreements

Agreement with Emory University (Emory)

In June 2018, the Company entered into a license agreement with Emory (the Emory License Agreement), pursuant to which Emory granted the Company a worldwide, sublicensable license under certain of its intellectual property rights to make, have made, develop, use, offer to sell, sell, import and export products containing certain compounds relating to Emory's hepatitis B virus capsid assembly modulator technology, for all therapeutic and prophylactic uses. Such license is initially exclusive with respect to specified licensed patents owned by Emory and non-exclusive with respect to certain of Emory's specified know-how. In June 2022, the license to such patents became non-exclusive with respect to all fields except for the treatment and prevention of HBV; however, the Company may select up to six compounds which will maintain exclusivity with respect to all therapeutic and prophylactic uses. With respect to all other compounds that are enabled by the licensed patents, those which are jointly invented by the Company and Emory or inventors in the Schinazi laboratory, or which are disclosed in a specified licensed patent, are licensed to the Company exclusively including as to Emory; whereas all other such compounds are licensed to the Company non-exclusively. Under the terms of the Emory License Agreement, the Company is obligated to use commercially reasonable efforts to bring licensed products to market in accordance with a mutually agreed upon development plan. Unless terminated earlier by either party in accordance with the provisions thereof, the Emory License Agreement shall continue until the expiration of the last–to-expire of the patents licensed to the Company thereunder.

In June 2020, the Company amended the license agreement with Emory. Pursuant to the amended license agreement, Emory granted the Company additional patent rights to certain compounds targeting the treatment or prevention of HBV. As consideration for the additional rights, the Company made a one-time, non-refundable payment to Emory in the amount of $0.2 million, with an additional obligation to pay up to a maximum of $35,000. On the same date, the Company entered into a collaboration agreement with Emory, with the initial research plan pertaining to the synthesis and evaluation of the compounds licensed through the additional patent rights granted in

the amended license agreement. The research plan was set to terminate one year from the effective date of June 2020 but the Company exercised its option to extend it for a second year. In June 2022, the research plan terminated.

The Company has agreed to pay Emory up to an aggregate of $125.0 million upon the achievement of specified development, regulatory, and commercial milestones, and all ongoing patent costs. During the year ended December 31, 2025 and 2024, the Company paid $9.0 million related to milestone payments due to the first subject dosed in a Phase 2 clinical trial. The Company also agreed to pay Emory tiered single-digit royalties on worldwide annual net sales of licensed products, on a quarterly basis and calculated on a product-by-product basis. With respect to licensed products containing any of a specified subset of the licensed compounds, such royalties range from a mid-single digit to a high-single digit percentage rate. With respect to licensed products which do not contain such compounds, the royalties range from a low-single digit to a mid-single digit rate.

During the twelve months ended December 31, 2025 and 2024, the Company made no payments associated with royalties and recognized no expense or accruals.

Agreement with Katholieke Universiteit Leuven (KU Leuven)

On June 25, 2020, the Company entered into a Research, Licensing and Commercialization Agreement (KU Leuven Agreement) with KU Leuven, under which the Company is collaborating with KU Leuven's Rega Institute for Medical Research, as well as its CD3, to research and develop potential protease inhibitors for the treatment, diagnosis or prevention of coronaviruses, including of SARS-CoV-2. Unless terminated earlier by either party in accordance with provisions in the agreement, the collaboration period will terminate at the earlier of completion of all collaboration activities or 2.5 years. In connection with the KU Leuven Agreement, KU Leuven and the Company granted each other exclusive cross-licenses to use certain know-how and existing patents of the other party as well as certain joint know-how and joint patents to carry out research and development collaboration activities during the collaboration period. As of December 2022, the original collaboration period has expired. An amendment to the agreement was agreed in July 2023 to include a new collaboration plan. KU Leuven granted to the Company an exclusive (including as to KU Leuven), worldwide license under certain of KU Leuven's know-how, and certain joint patents and joint know-how, to manufacture and commercialize the licensed products for the treatment, diagnosis or detection of viral infections in humans. KU Leuven reserved the right to use all KU Leuven knowhow, joint patents and joint know-how for academic and non-commercial research and teaching purposes. As consideration for this license, the Company is obligated to make payments to KU Leuven, in aggregate, totaling up to but no more than $30.0 million upon the achievement of certain commercial sales milestones. For each licensed product developed through KU Leuven and the Company's collaborative effort, the Company is obligated to make payments to KU Leuven, in aggregate, totaling up to $32.0 million upon the achievement of certain development and regulatory milestones. The Company is also required to pay KU Leuven a low-to-mid-single digit royalty percentage, subject to certain adjustments, on net sales of applicable products, if any. The Company is also required to pay a share of upfront transaction consideration received to KU Leuven should the program be partnered with an external party. Unless terminated earlier by either party, the agreement shall continue until the expiration of the last to expire royalty term, which is the later of the expiration or termination of the last valid patent claim covering the manufacture, use, sale or importation of the licensed product in a particular country or 10 years after the first commercial sale of a licensed product.

During the years ended December 31, 2025 and 2024, we did not recognize any milestone payments.

10. Revenue from contracts with customers

Agreement with Amoytop

In May 2023, the Company and Amoytop Biotech Co., Ltd (Amoytop) entered into a Research Collaboration and Development Agreement (the Amoytop Agreement) with a focus on nucleic acid technology for HBV treatment, with the Company granting to Amoytop an exclusive, time-limited option to enter into an exclusive, territory-limited license to develop and commercialize such compounds. Under the terms of the agreement, the Company received an upfront payment of $7.0 million, less withholding taxes of $1.1 million from Amoytop. With respect to the agreement, the Company is eligible for up to $109.0 million in development and commercialization milestones as well as tiered royalties on net sales. These potential payments consist of (i) potential development milestones (such as for the commencement of a Good Laboratory Practice toxicology study for a collaboration compound, approval of IND by regulatory authority, initiation of Phase 2 and 3 clinical trials, and regulatory

approval of a licensed product), and (ii) sales-based milestones.

In May 2024, the Company and Amoytop entered into an extension to the Amoytop Agreement, covering work performed through January 2025. Under the terms of the agreement, the Company received an upfront payment of $1.5 million, which was recognized from the second quarter of 2024 through the first quarter of 2025.

In May 2025, the Company and Amoytop entered into an additional extension to the Amoytop Agreement, covering work performed through approximately November 2025. Under the terms of the agreement, the Company received an upfront payment of $1.0 million, which was recognized from the second quarter of 2025 through the fourth quarter of 2025.

In September 2025, Amoytop exercised its option to obtain an exclusive, territory-limited license to one compound developed under the Amoytop Agreement, with the right to choose such compound among four identified candidates following the completion of the work outlined in the May 2025 extension. IND-enabling studies began on its chosen compound in January 2026, which earned the Company a milestone payment of $3.0 million.

The Company determined that the Amoytop agreement falls within the scope of ASC 606. The agreement did not fall under the ASC 808 guidance due to Amoytop and the Company not being joint active participants, and both parties not having significant risks and rewards. Management of the Company determined that there were three performance obligations for the agreement given the deliverables are distinct. The Company evaluated the standalone selling price for each obligation based on available data for similar arrangements. The Company evaluated the performance obligations and determined the provision of R&D services for the collaboration compound performance obligation will be satisfied over time, the research license including data and know-how has been satisfied, and the provision of materials will be satisfied upon delivery. Given the nature of the arrangement, the Company believes that the satisfaction of its performance obligations is best measured by the progress of its efforts as it relates to the performance of the R&D services. As such, the Company has used an input method based on costs incurred to recognize revenue associated with the upfront payments, and the Company recognizes revenue over time based on the costs incurred. The effect of any updates to the estimated overall costs are recorded as a change in estimate. In addition, variable consideration (e.g., milestone payments) were evaluated based on the Company's analysis that the probability of achieving any of the milestone payments is remote, and therefore determined to be constrained and excluded from the transaction price.

During the years ended December 31, 2025 and 2024, the Company recognized $2.2 million and $3.6 million, respectively, in revenue from customers related to upfront payments. During the years ended December 31, 2025 and 2024, the Company recognized no revenue from customers related to milestone payments. The unrecognized portion of the upfront payments received during the twelve months ended December 31, 2025 and 2024 is recorded on the Consolidated Balance Sheets as "Deferred revenue, current".

Changes in deferred revenue balances arose as a result of the Company recognizing the following revenue from customers during the periods below (in thousands):

	As of December 31,	
	2025	2024
Deferred revenue as of January 1	$ 151	$ 1,224
Consideration received in the period	2,035	2,538
Revenue recognized in the period	(2,186)	(3,611)
Deferred revenue as of December 31	$ —	$ 151

Agreement with ADCT

The Company determined that the ADC Therapeutics (ADCT) agreement falls within the scope of ASC 606. The agreement did not fall under the ASC 808 guidance due to ADCT and the Company not being joint active participants, nor both parties having significant risks and rewards. Management of the Company determined that there was one performance obligation for the agreement given the deliverables are not distinct. The Company evaluated the performance obligation and determined the performance obligations are satisfied over time. Given the nature of the arrangement, the Company believes that the satisfaction of its performance obligations is best measured by the progress of its efforts. As such, the Company has used an input method based on costs incurred to recognize revenue associated with the upfront payments, and the Company recognizes revenue over time based on

the costs incurred. The effect of any updates to the estimated overall costs are recorded as a change in estimate. In addition, variable consideration (e.g., milestone payments) were evaluated based on the Company's analysis that the possibility of achieving any of the milestone payments is remote, and therefore determined to be constrained and excluded from the transaction price. Similarly, the Company accounts for the future royalties under the sales-based royalty exception in ASC 606-10-55-65 through 55-65B therefore they are not considered in the transaction price and expected to be recognized when future sales occur since that is expected to occur after the performance obligation has been fully satisfied.

11. Income taxes

The components of the Company's loss before income taxes were as follows for the years ended December 31, 2025 and 2024 (in thousands):

	2025	2024
United States	$ (20,765)	$ (128,077)
Foreign	(3,114)	(2,803)
Total loss before income taxes	$ (23,879)	$ (130,880)

The components of the Company's income tax provision were as follows for the years ended December 31, 2025 and 2024:

	2025	2024
Current:		
Federal	$ -	$ -
State	-	-
Foreign	314	331
Total current provision for income taxes	$ 314	$ 331
Deferred:		
Federal	$ -	$ -
State	-	-
Foreign	-	-
Total deferred provision for income taxes	$ -	$ -

A reconciliation of the expected income tax computed at the federal statutory income tax rate to the Company's effective income tax expense and rate is as follows for the year ended December 31, 2025:

	$	%
Income tax computed at federal statutory tax rate	$ (5,015)	21.00%
State and local taxes, net of federal income tax effect	-	0.00%
Research tax credits	(1,253)	5.25%
Change in valuation allowance	17,724	-74.22%
Nondeductible items:		
Stock based compensation	896	-3.76%
Warrant marked to market	(12,638)	52.93%
Other	1	-0.01%
Foreign tax effects:		
Australia:		
Other	(260)	1.09%
Change in Valuation Allowance	693	-2.90%
Foreign Withholding Tax and Other	166	-0.69%
Income tax expense and effective income tax rate	$ 314	-1.31%

As previously disclosed for the year ended December 31, 2024, a reconciliation of the expected income tax computed at the federal statutory income tax rate to the Company's effective income tax rate as follows:

	%
Income tax computed at federal statutory tax rate	21.00%
State taxes, net of federal income tax effect	4.49%
Research tax credits	0.79%
Change in valuation allowance	-17.04%
Nondeductible items:	
Stock based compensation	-1.92%
Warrant marked to market	-7.41%
Other	0.10%
Foreign tax	-0.27%
Effective income tax rate	-0.26%

Income taxes paid (net of refunds) for the year ended December 31, 2025 is disaggregated as follows (in thousands):

Federal income taxes paid (net of refunds)	$ -
State income taxes paid (net of refunds)	-
Foreign income taxes paid (net of refunds):	
China	199
Belgium	116
Total income taxes paid (net of refunds)	$ 315

The components of the deferred tax assets and liabilities were as follows at December 31:

	2025	2024
Deferred tax assets:		
Net operating loss carryforward	$ 29,976	$ 17,625
Operating lease liabilities	1,457	2,418
Tax credits	4,656	2,745
Other accruals and reserves	1,624	1,457
Stock-based compensation	1,703	1,555
Capitalized R&D costs	42,111	31,848
Other	806	626
	82,333	58,274
Valuation allowance	(81,284)	(56,517)
Net deferred tax assets	$ 1,049	$ 1,757
Deferred tax liabilities:		
Right of use assets	(907)	(1,520)
Property and equipment	(142)	(237)
Total deferred tax liabilities	$ (1,049)	$ (1,757)
Total deferred income taxes	$ -	$ -

Management believes that, based on a number of factors, including the Company's historical operating performance and accumulated deficit, it is more likely than not that the deferred tax assets will not be utilized, such that a full valuation allowance has been recorded against the Company's deferred tax assets. In assessing the reliability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized on a jurisdiction-by-jurisdiction basis. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. The valuation allowance increased by $24.8 million during the year ended December 31, 2025, and decreased by $22.3 million during the year ended December 31, 2024.

As of December 31, 2025, the Company had $92.5 million of federal and $105.7 million of state net operating loss (NOL) carryforwards available to offset future taxable income. The Company's federal NOL carryforwards can be carried forward indefinitely while state NOL carryforwards, if not utilized, will begin expiring in 2043. As of December 31, 2025, the Company had research and development credit carryforwards of $3.5 million and $2.2 million available to reduce future taxable income, if any, for federal and state income tax purposes, respectively. If not utilized, the federal credit carryforwards will begin expiring in 2043. The California credit carryforwards have no expiration date. The Company had $3.2 million of Australian NOL carryforwards and $0.7 million of Australian research and development tax credit carryforwards.

On July 4, 2025, the OBBBA was enacted in the United States. The OBBBA includes several significant tax provisions, such as the permanent extension of certain expiring provisions of the Tax Cuts and Jobs Act, modifications to the international tax framework and the restoration of certain business provisions. The legislation has multiple effective dates, with certain provisions effective in 2025 and others implemented through 2027. The Company will no longer be required to capitalize its domestic research and experimental costs under Section 174 of the Internal Revenue Code beginning with the tax year ending December 31, 2025. The Company evaluated the impact of the OBBBA and determined that it did not have a material impact on the Company's consolidated financial statements for the year ended December 31, 2025.

Under Sections 382 and 383 of the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percentage point change (by value) in its equity ownership over a rolling three-year period), the Company's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income may be limited. The Company performed a Code Section 382 analysis in 2025, which resulted in no further ownership changes.

We may experience additional ownership changes as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. In the future, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards or other tax attributes to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us and could adversely affect our business, results of operations, and cash flows. In addition, under current tax law, federal NOL carryforwards generated in periods after December 31, 2017, may be carried forward indefinitely but, may only be used to offset 80% of our taxable income.

ASC 740-10 prescribes a comprehensive model for the recognition, measurement, presentation and disclosure in financial statements of any uncertain tax positions that have been taken or expected to be taken on a tax return. It is the Company's policy to include penalties and interest expense related to income taxes as a component of other expense and interest expense, respectively, as necessary. During the years ended December 31, 2025 and 2024, the Company had not recognized any tax-related penalties or interest. No liability related to uncertain tax positions is recorded on the financial statements related to uncertain tax positions.

	2025	2024
Balance, beginning of the period	$ 771	$ 99
(Decrease) increase related to prior year positions	(34)	17
Increase related to current year positions	709	655
Balance, end of the period	$ 1,446	$ 771

The reversal of the uncertain tax benefits would not impact the Company's effective tax rate as the Company continues to maintain a full valuation allowance against its deferred tax assets.

The Company files income tax returns in the United States, including California and Texas, Australia, Belgium, and China. The Company is not currently under examination by income tax authorities in federal, state or other jurisdictions. All income tax returns will remain open for examination by the federal, state and foreign authorities for three or four years, from the date of utilization of any NOLs or credits.

12. Commitments and contingencies

From time to time, the Company may have certain contingent liabilities, including legal matters that arise in the ordinary course of its business activities. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. Contingent liabilities requiring accrual were appropriately accrued as of December 31, 2025 and December 31, 2024. The Company enters into contracts in the normal course of business that includes arrangements with clinical research organizations, vendors for preclinical research and vendors for manufacturing. These agreements generally allow for cancellation with notice. As of December 31, 2025, the Company had no material non-cancelable purchase commitments.

13. Benefit plans

Defined contribution plans

The Company established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan covers substantially all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. The Company made matching contributions of $0.7 million each to the plan during the years ended December 31, 2025 and 2024, respectively.

Defined benefit plans—regular pension plan

ASC Topic 715, *Compensation—Retirement Benefits*, requires an employer to: (a) recognize in its statement of financial position an asset for a plan's overfunded status or a liability for a plan's under-funded status; (b) measure a plan's assets and its obligations that determine its funded status as of the end of the employer's fiscal year; and (c) recognize changes in the funded status of a defined benefit post retirement plan in the year in which the changes occur. Accordingly, the Company is required to report changes in its funded status on its Consolidated Statement of Changes in Stockholders' Equity (Deficit) and Consolidated Statement of Operations and Comprehensive Loss.

Aligos-Belgium offers its employees a regular pension plan in the form of a defined contribution plan (the Regular Pension Plan), which contains a 2.50% legally required minimum rate of return for the participants. The Regular Pension Plan does not meet all the requirements that are needed for recognition of the plans as a defined contribution plan. The Company therefore recognizes the Regular Pension Plan as a defined benefit plan.

The Company measures the fair value of the Regular Plan assets by using Level 3 inputs, unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of assets, including pricing models, discounted cash flow methodologies and similar techniques.

As of December 31, 2025, the projected benefit obligation was $1.7 million, the plan assets were $1.6 million and the net pension liability was $0.1 million. As of December 31, 2024, the projected benefit obligation was $1.3 million, the plan assets were $1.3 million, and the net pension liability was $0.1 million. The Company has recorded the unfunded amount as a liability in its Consolidated Balance Sheets at December 31, 2025 and 2024, under the accrued liabilities caption.

Defined benefit plans—Top Hat Plan

In Aligos-Belgium, the Company established a pension bonus complementary plan (the Top Hat Plan), where the bonus payments to each participant are added to the Top Hat Plan. The annual contributions to this plan are based on performance and determined on a discretionary basis by the Company. The Top Hat Plan contains a legal yield guarantee of 2.5%. The Top Hat Plan became effective as of January 1, 2019.

In 2019, the Company accounted for the Top Hat Plan in accordance with ASC 715, *Compensation—Retirement Benefits*, once it became effective. The Top Hat Plan does not meet all the requirements that are needed for recognition as a defined contribution plan. The Company therefore recognizes the Top Hat Plan as a defined benefit plan.

As of December 31, 2025, the projected benefit obligation was $2.7 million, the plan assets were $2.5 million and the net pension liability was $0.3 million. As of December 31, 2024, the projected benefit obligation was $2.1 million, the plan assets were $1.9 million, and the net pension liability was $0.2 million. The Company has recorded the unfunded amount as a liability in its Consolidated Balance Sheets at December 31, 2025 and 2024, under the accrued liabilities caption.

14. Net loss per share

The following table summarizes the computation of basic and diluted net loss per share of the Company:

	Year Ended December 31,	
	2025	**2024**
Net loss, as reported	$ (24,193)	$ (131,211)
Less: increase in available income	-	-
Diluted net loss	$ (24,193)	$ (131,211)
Weighted average shares outstanding, basic	9,884,955	6,264,612
Add: Weighted average shares issuable	-	-
Weighted average shares outstanding, diluted	9,884,955	6,264,612
Net loss per share - basic	$ (2.45)	$ (20.94)
Net loss per share - diluted	$ (2.45)	$ (20.94)

The Company's potentially dilutive securities, which include options to purchase common stock, unvested restricted stock and warrants to purchase common stock, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of shares of Common Stock outstanding used to calculate both basic and diluted net loss per share is the same. The Company excluded the following potential shares of Common Stock, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect:

	Year Ended December 31,	
	2025	2024
Options to purchase common stock	1,728,737	441,113
Unvested restricted stock	76,786	1,379
Warrants to purchase common stock	4,213,767	2,200,858
	6,019,290	2,643,350

15. Segment information

The CODM assesses performance for the Company's single reportable segment and decides how to allocate resources based on the Company's total operating expenses as reported on the Consolidated Statements of Operations and Comprehensive Loss. The CODM's review of total operating expenses at the consolidated level is used to monitor the Company's spending as well as budget versus actual results. As part of the CODM's review of the segment's performance, the CODM reviews the Company's operating expense information. This includes research and development costs as well as general and administrative expenses. Based upon the operating expense information, the CODM can reconcile to net loss as reported on the Consolidated Statements of Operations and Comprehensive Loss, shown in the table below. The significant expense categories are consistent with those presented on the face of the consolidated financial statements, except for the breakout of the early-stage research and development from the late-stage research and development. The CODM does not receive or use any other segmented or disaggregated financial or any significant expense information for decision making purposes.

The following table provides segment revenues, significant segment expenses and reported segment net income for the years ended December 31, 2025 and 2024:

	Year ended December 31,	
	2025	2024
Revenue from collaborations	$ -	$ 334
Revenue from customers	2,186	3,611
Less:		
Early-stage research and development[(1)]	(3,147)	(3,506)
Late-stage research and development[(2)]	(66,306)	(66,763)
General & Administrative	(20,718)	(22,830)
Total operating expenses	(90,171)	(93,099)
Interest and other income, net	3,922	4,406
Change in fair value of 2023 Common Warrants	60,184	(46,132)
Loss before income tax	(23,879)	(130,880)
Income tax provision	(314)	(331)
Segment and consolidated net loss	$ (24,193)	$ (131,211)

(1) Early-stage research and development includes costs incurred from Discovery programs.

(2) Late-stage research and development includes costs incurred from Phase 1 clinical trial programs.

The Company's reportable segment primarily generates revenue through its license and collaboration agreements (see Notes 9 and 10). The measure of segment assets is reported on the Consolidated Balance Sheets as total assets. The Company has $1.7 million and $0.2 million of fixed assets in Aligos-US and Aligos-Belgium,

respectively, as of December 31, 2025, and $2.1 million and $0.2 million of fixed assets in Aligos‑US and Aligos-Belgium, respectively as of December 31, 2024.

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

None.

Item 9A. Controls and Procedures.

Evaluation of disclosure controls and procedures

Our management has evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, our principal executive officer and principal financial officer, respectively, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this Annual Report on Form 10‑K. 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 and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures have been designed to provide reasonable assurance of achieving their objectives. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2025, our disclosure controls and procedures were effective at the reasonable assurance level.

Management’s annual report on internal control over financial reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management has assessed the effectiveness of our internal control over financial reporting based on the framework set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013 framework). Based on our evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2025.

Changes in internal control over financial reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended December 31, 2025 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent limitation on the effectiveness over financial reporting

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute assurances. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business but cannot assure you that such improvements will be sufficient to provide us with effective internal control over financial reporting.

Item 9B. Other Information.

During the three months ended December 31, 2025, none of our directors or officers (as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, as amended) adopted, terminated or modified a “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” as each term is defined in Item 408(a) of Regulation S-K.

On March 3, 2026, the Company’s Board of Directors adopted resolutions approving the ratification, pursuant to Section 204 of the Delaware General Corporation Law (the "DGCL"), of the issuance of 911 shares of the

Company's common stock in excess of the share reserve under the Company's 2020 Employee Stock Purchase Plan (the “ESPP”). The shares were issued on December 8, 2025 in connection with an offering period that ended in November 2025. The failure of authorization was that such shares were issued in excess of the number of shares available for issuance under the ESPP’s share reserve at the time of issuance. The public filing of this Annual Report on Form 10-K with the Securities and Exchange Commission constitutes the notice required to be given under Section 204(g) of the DGCL. Any claim that any defective corporate act or putative stock ratified pursuant to the ratification is void or voidable due to the failure of authorization, or that the Delaware Court of Chancery should declare in its discretion that the ratification in accordance with Section 204 of the DGCL not be effective or be effective only on certain conditions, must be brought within 120 days from the giving of this notice (which is deemed given on the date that this Annual Report on Form 10-K is filed with the Securities and Exchange Commission).

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

We have adopted a code of ethics for directors, officers (including our principal executive officer, principal financial officer and principal accounting officer) and employees, known as the Code of Business Conduct and Ethics. This code is publicly available on our website at investor.aligos.com under the Governance section. If we make any amendments to this code other than technical, administrative or other non-substantive amendments, or grant any waivers, including implicit waivers, from a provision of this code we will disclose the nature of the amendment or waiver, its effective date and to whom it applies on our website at aligos.com or in a Current Report on Form 8-K filed with the SEC.

We have an insider trading policy (the Trading Policy), governing the purchase, sale and other dispositions of our securities that applies to all of our personnel, including directors, officers, employees and other covered persons. We believe that our Trading Policy is reasonably designed to promote compliance with insider trading laws, rules and regulations, and listing standards applicable to us. A copy of our Trading Policy is filed as Exhibit 19.1 to this Form 10-K.

The remaining information required by this item, including information about our Directors, Executive Officers and Audit Committee, is incorporated by reference to the definitive Proxy Statement for our 2026 Annual Meeting of Stockholders, which will be filed with the SEC no later than 120 days after December 31, 2025.

Item 11. Executive Compensation.

The information required by this Item will be set forth in the section headed “Executive Compensation” in our Proxy Statement and is incorporated in this Annual Report by reference.

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

The information required by this Item will be set forth in the section headed “Security Ownership of Certain Beneficial Owners and Management” in our Proxy Statement and is incorporated in this Annual Report by reference.

Information regarding our equity compensation plans will be set forth in the section headed “Executive Compensation” in our Proxy Statement and is incorporated in this Annual Report by reference.

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

The information required by this Item will be set forth in the section headed “Transactions with Related Persons” in our Proxy Statement and is incorporated in this Annual Report by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this Item will be set forth in the section headed “—Ratification of Selection of Independent Registered Public Accounting Firm” in our Proxy Statement and is incorporated in this Annual Report by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) Documents filed as a part of this Annual Report on Form 10-K:

1. Financial Statements

The following financial statements are included in Part II, Item 8 of this Annual Report on Form 10-K.

2. All other schedules have been omitted because they are not required, not applicable, or the required information is otherwise included.

3. The exhibits listed in the Exhibit Index below are filed or incorporated by reference as part of this Annual Report.

Item 16. Form 10-K Summary.

None.

Exhibit Index

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1(a)	Amended and Restated Certificate of Incorporation.	8-K	10/20/2020	3.1	
3.1(b)	Certificate of Amendment, dated June 27, 2024, to Amended and Restated Certificate of Incorporation.	8-K	6/28/2024	3.1	
3.1(c)	Certificate of Amendment, dated August 14, 2024, to Amended and Restated Certificate of Incorporation.	8-K	8/19/2024	3.1	
3.1(d)	Certificate of Amendment to Amended and Restated Certificate of Incorporation.	8-K	6/25/2025	3.1	
3.2	Amended and Restated Bylaws.	8-K	10/20/2020	3.2	
4.1	Reference is made to Exhibits 3.1(a), 3.1(b), 3.1(c), 3.1(d) and 3.2				
4.2	Form of Common Stock Certificate.	10-Q	11/6/2024	4.2	
4.3	Description of Securities.				X
4.4	Form of 2023 Pre-Funded Warrant	8-K	10/25/2023	4.1	
4.5	Form of 2023 Common Warrant	8-K	10/25/2023	4.2	
4.6	Form of 2025 Pre-Funded Warrant	8-K	2/12/2025	4.1	
4.7	Form of 2025 Common Warrant	8-K	2/12/2025	4.2	
10.1(a)†	Aligos Therapeutics/Emory University License Agreement by and between Aligos Therapeutics, Inc. and Emory University, dated June 26, 2018.	S-1	9/25/2020	10.1(a)	
10.1(b)†	First Amendment to License Agreement by and between Aligos Therapeutics, Inc. and Emory University, dated June 18, 2020.	S-1	9/25/2020	10.1(b)	
10.3	Lease between Aligos Therapeutics, Inc. and Britannia Biotech Gateway Limited Partnership, dated June 21, 2018.	S-1	9/25/2020	10.3	
10.4(a)#	2018 Equity Incentive Plan, as amended.	S-1	9/25/2020	10.5(a)	
10.4(b)#	Form of Stock Option Grant Notice and Stock Option Agreement under 2018 Equity Incentive Plan, as amended.	S-1	9/25/2020	10.5(b)	
10.4(c)#	Form of Early Exercise Stock Option Grant Notice and Stock Option Agreement under 2018 Equity Incentive Plan, as amended.	S-1	9/25/2020	10.5(c)	
10.4(d)#	Form of International Stock Option Grant Notice and Stock Option Agreement under 2018 Equity Incentive Plan, as amended.	S-1	9/25/2020	10.5(d)	
10.5(a)#	2020 Incentive Award Plan.	S-1/A	10/9/2020	10.6(a)	
10.5(b)#	Amendment to the Aligos Therapeutics, Inc. 2020 Incentive Award Plan.	8-K	6/28/2024	10.1	
10.5(c)#	Amendment to the Aligos Therapeutics, Inc. 2020 Incentive Award Plan.	8-K	6/26/2025	10.1	
10.5(d)#	Form of Stock Option Grant Notice and Stock Option Agreement under the 2020 Incentive Award Plan.	S-1/A	10/9/2020	10.6(b)	
10.5(e)#	Form of Restricted Stock Award Agreement under the 2020 Incentive Award Plan.	S-1/A	10/9/2020	10.6(c)	
10.5(f)#	Form of Restricted Stock Unit Award Grant Notice under the 2020 Incentive Award Plan.	S-1/A	10/9/2020	10.6(d)	
10.6#	2020 Employee Stock Purchase Plan.	S-1/A	10/9/2020	10.7	

10.7(a)#	2024 Employment Inducement Award Plan	10-Q	11/6/2024	10.1(a)	
10.7(b)#	Form of Stock Option Grant Notice and Stock Option Agreement	10-Q	11/6/2024	10.1(b)	
10.7(c)#	Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement.	10-Q	11/6/2024	10.1(c)	
10.8#	Form of Indemnification Agreement for Directors and Officers.	S-1/A	10/9/2020	10.12	
10.9#	Amended and Restated Employment Agreement, effective as of February 10, 2021, by and between the Company and Lawrence M. Blatt, Ph.D.	10-Q	5/10/2021	10.2	
10.10#	Employment Agreement by and between Aligos Therapeutics, Inc. and Julian Symons, D.Phil., effective as of May 14, 2019.	10-Q	5/10/2021	10.3	
10.11#	Form of Change in Control and Severance Agreement.	10-Q	8/6/2025	10.3	
10.12#	Lease Agreement between 601 & 651 Gateway Center LP and Aligos Therapeutics, Inc., dated December 9, 2021	10-K	3/10/2022	10.16	
10.13#	Non-Employee Director Compensation Policy	10-Q	5/6/2025	10.1	
10.14#	Form of Securities Purchase Agreement, dated October 23, 2023, by and among the Company and the Purchasers.	8-K	10/25/2023	10.1	
10.15#	Amended and Restated Employment Agreement, effective as of December 1, 2020, by and between the Company and Lesley Calhoun	10-K	3/12/2024	10.17	
10.16#	Employment Agreement by and between Aligos Therapeutics, Inc. and Hardean Achneck, M.D., effective as of September 4, 2024.	10-Q	11/6/2024	10.2	
10.17	Securities Purchase Agreement, dated February 11, 2025, by and among the Company and the investors party thereto.	8-K	2/12/2025	10.1	
10.18	Registration Rights Agreement, dated February 13, 2025, by and among the Company and the investors party thereto.	10-K	3/10/2025	10.18	
10.19	Lead Investor Registration Rights Agreement, by and among the Company and the investors party thereto.	10-K	3/10/2025	10.19	
10.20	Letter Agreement, by and among the Company and the investors party thereto.	10-K	3/10/2025	10.20	
19.1	Insider Trading Policy	10-K	3/10/2025	19.1	
21.1	Subsidiaries of Registrant.	10-K	3/9/2023	21.1	
23.1	Consent of Independent Registered Public Accounting Firm.				X
24.1	Power of Attorney (included on signature page to this Form 10-K).				X
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X

32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
97.1	Policy relating to Recovery of Erroneously Awarded Compensation	10-K	3/12/2024	97.1	
101.INS	Inline XBRL Instance Document.				X
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents				X
104	The cover page from the Company's Annual Report on Form 10-K for the year ended December 31, 2025 has been formatted in Inline XBRL.				X

† Portions of the exhibit, marked by brackets, have been omitted because the omitted information (i) is not material and (ii) is the type of information that the registrant both customarily and actually treats as private and confidential.
# Indicates management contract or compensatory plan.
* The certifications attached as Exhibits 32.1 and 32.2 that accompany this Annual Report on Form 10-K, are deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Aligos Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

SIGNATURES

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

Aligos Therapeutics, Inc.

Date: March 5, 2026

By: /s/ Lawrence M. Blatt
Lawrence M. Blatt, Ph.D.
President, Chairman, and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Lawrence M. Blatt, Ph.D. and Lesley Ann Calhoun, and each of them acting individually, as his or her true and lawful attorneys-in-fact and agents, each with full power of substitution, for him in any and all capacities, to sign any and all amendments to this annual report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

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/ Lawrence M. Blatt Lawrence M. Blatt, Ph.D.	Chairman, President, and Chief Executive Officer *(Principal Executive Officer)*	March 5, 2026
/s/ Lesley Ann Calhoun Lesley Ann Calhoun	Executive Vice President, Chief Operating Officer & Chief Financial Officer *(Principal Financial Officer)*	March 5, 2026
/s/ Nikhil Aneja Nikhil Aneja	VP Finance *(Principal Accounting Officer)*	March 5, 2026
/s/ K. Peter Hirth K. Peter Hirth, Ph.D.	Director	March 5, 2026
/s/ Carole Nuechterlein Carole Nuechterlein	Director	March 5, 2026
/s/ James Scopa James Scopa	Director	March 5, 2026
/s/ Bridget Martell Bridget Martell, M.D.	Director	March 5, 2026
/s/ Margarita Chavez Margarita Chavez	Director	March 5, 2026
/s/ Heather Preston Heather Preston, M.D.	Director	March 5, 2026

ALIGOS CORPORATE INFORMATION

BOARD OF DIRECTORS
LAWRENCE M. BLATT, PH.D., M.B.A.
Chair of the Board of Directors, President and Chief Executive Officer

MARGARITA CHAVEZ, J.D.
Venture Partner at Wellington Partners

K. PETER HIRTH, PH.D.
Former Chief Executive Officer of Plexxikon, Inc.

HEATHER PRESTON, M.D.
Senior Advisor at TPG Biotech

BRIDGET MARTELL, M.A., M.D.
Senior Advisor for Two Bear Capital

CAROLE NUECHTERLEIN, J.D.
Former Head of the Roche Venture Fund

JAMES SCOPA, J.D., M.B.A.
Former Managing Director at MPM Capital

EXECUTIVE OFFICERS
LAWRENCE M. BLATT, PH.D., M.B.A.
Chair of the Board of Directors, President and Chief Executive Officer

LESLEY ANN CALHOUN
Executive Vice President, Chief Operating Officer and Chief Financial Officer

JULIAN A. SYMONS, D.PHIL.
Executive Vice President, Chief Scientific Officer

STOCKHOLDER ACCOUNT ASSISTANCE

Registered stockholder records are maintained by our transfer agent:

Continental Stock Transfer & Trust Company
1 State Street, 30th Floor
New York, NY 10004
Website: www.continentalstock.com
Telephone: (212) 509-4000 or (800) 509-5586
Email: cstmail@continentalstock.com

FINANCIAL INFORMATION

Copies of Aligos's annual reports, Forms 10-K and 10-Q and annual proxy statements are available on the Company's website.

ANNUAL STOCKHOLDERS MEETING

Our annual meeting will be held on June 25, 2026 at 8:00 a.m. Pacific Time, via live webcast at www.proxydocs.com/ALGS.

STOCK LISTING

The Nasdaq Capital Market
Nasdaq Ticker: ALGS