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, 2020

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 Global Select Market)

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

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

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 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, 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. ☐

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

The registrant's common stock was not publicly traded as of the last business day of the registrant's most recently completed second fiscal quarter.

As of March 18, 2021, the registrant had 38,143,228 shares of common stock, $0.0001 par value per share, outstanding, comprised of 35,050,890 shares of voting common stock, $0.0001 par value per share and 3,092,338 shares of non-voting common stock, $0.0001 par value per share.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Definitive Proxy Statement relating to the 2021 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, 2020, 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, and conducting nonclinical studies and clinical trials, including our ALG-010133 and ALG-000184 Phase 1 clinical trials;
- the scope, progress, results and costs related to the research and development of our pipeline;
- 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;
- the impact of COVID-19 on our business and operations, including clinical trials, manufacturing suppliers, collaborators, use of contract research organizations and employees;
- our expectations regarding the potential market size and size of the potential patient populations for ALG-010133 and ALG-000184, our other 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;
- estimates of our expenses, future revenue, capital requirements, our needs for additional financing and our ability to obtain additional capital;
- 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 the period during which we will qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012;
- 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 and management’s beliefs and assumptions and 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 members and 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 biopharmaceutical 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, 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.
- 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.
- 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 and maintain 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 U.S. Securities and Exchange Commission. 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.

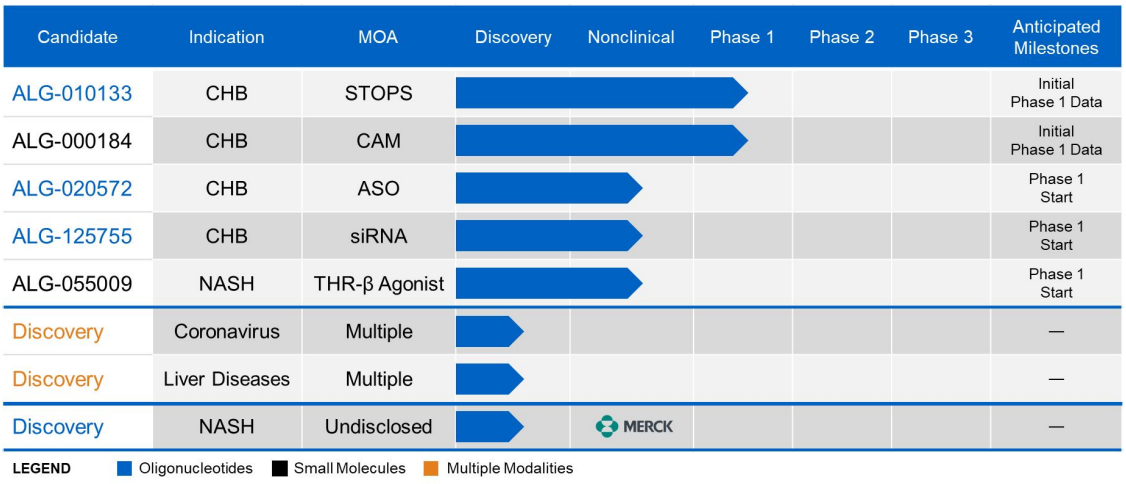
PART I

Item 1. Business.

Overview

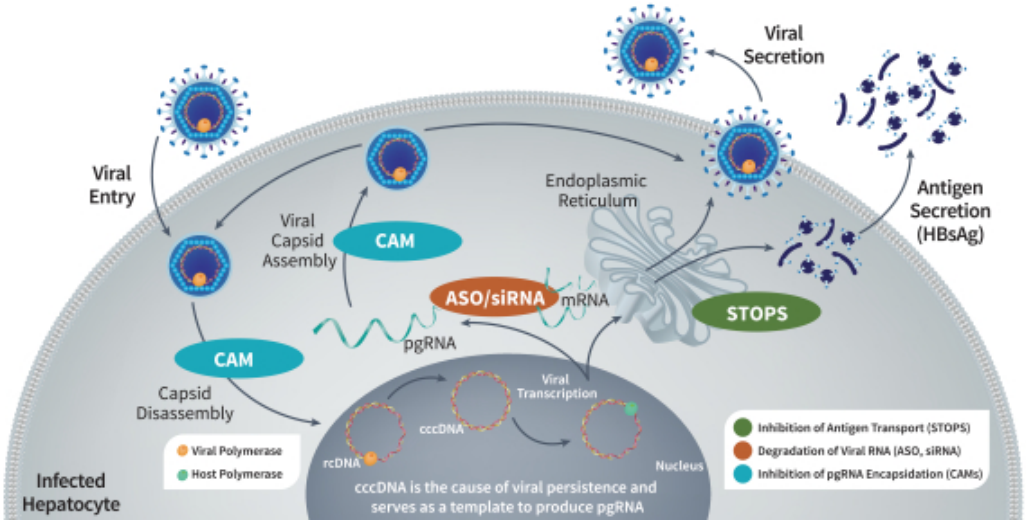
We are a clinical-stage biopharmaceutical company currently focused on developing novel therapeutics to address unmet medical needs in viral and liver diseases. We utilize our proprietary oligonucleotide and small molecule platforms to develop pharmacologically optimized drug candidates for use in combination regimens designed to achieve improved treatment outcomes. Our lead effort is to develop a functional cure for Chronic Hepatitis B (CHB), which often results in other life-threatening conditions such as cirrhosis, end-stage liver disease (ESLD) and the most common form of liver cancer, hepatocellular carcinoma (HCC). The most widely used treatment for CHB, nucleos(t)ide analogs, suppresses viral replication but only achieves low rates of functional cure and often requires long-term administration. To address this issue, we have developed a portfolio of differentiated drug candidates for CHB, including an S-antigen Transport-inhibiting Oligonucleotide Polymers (STOPS) molecule, a small molecule Capsid Assembly Modulator (CAM), and oligonucleotides (ASO and siRNA), each of which is designed against clinically validated targets in the Hepatitis B Virus (HBV) life cycle. We believe that combination regimens utilizing our portfolio of CHB drug candidates may lead to higher rates of functional cure. Phase 1 proof of concept trials evaluating the properties of our STOPS molecule and CAM are ongoing in New Zealand and each of such candidates has been approved to commence clinical trials in Hong Kong and Moldova. We may also in the future conduct clinical trials for our STOPS molecule and CAM and other drug candidates in other countries and territories, including South Korea, the United Kingdom, and China. Our second area of focus is in non-alcoholic steatohepatitis (NASH), a complex, chronic liver disease where combination regimens may likewise prove beneficial. Our most advanced drug candidate for NASH is ALG-055009, a small molecule THR-ß agonist currently in nonclinical studies to enable a first-in-human clinical trial. We believe ALG-055009 has the potential to become an integral component of future combination regimens for NASH. Our third area of focus is to develop drug candidates with pan-coronavirus activity, including Severe Acute Respiratory Syndrome coronavirus 2 (SARS-CoV-2), the virus responsible for COVID-19.

Our team's collective experience and success in discovering and developing drugs targeting viruses and liver diseases, combined with our in-house expertise in oligonucleotide and small molecule drug discovery, gives us a differentiated set of capabilities, which has enabled us to rapidly establish a robust pipeline of multiple novel drug candidates, as summarized in the pipeline chart below.



Our most advanced drug candidates are for the treatment of CHB, a disease that affects more than 290 million people worldwide with approximately 30 million people becoming newly infected every year, despite the availability of an efficacious prophylactic vaccine. Approximately 900,000 people worldwide died from complications of CHB in 2015, according to the World Health Organization, and CHB is the primary cause of liver cancer worldwide. Currently approved therapies for CHB include pegylated forms of interferon-alfa (peg-IFNα) and nucleos(t)ide analogs, which are designed to boost the body's immune response to the virus or inhibit viral replication, respectively. While these therapies have improved treatment outcomes for some patients with CHB, they have not been able to achieve meaningful rates of functional cure, which is the consensus goal of treatment and defined as a sustained loss of HBsAg with or without hepatitis B surface antibody seroconversion. Functional cure has been shown to greatly reduce the risk of developing certain other more serious downstream liver conditions, such as cirrhosis and ESLD.

Our clinical development strategy involves evaluating both Hepatitis B E-antigen (HBeAg) positive and HBeAg negative CHB patient populations. HBeAg is typically present in earlier stages of the disease and is associated with higher rates of viral replication. During the natural course of the disease, HBeAg can be cleared and antibodies develop, resulting in an HBeAg negative state where viral replication is often lower. Patients with HBeAg negative CHB are typically older and have more progressive disease-related complications (e.g., fibrosis of the liver). In addition, their immune system is likely to be more exhausted by chronic exposure to HBsAg, which makes viral clearance more difficult. Although we plan to ultimately study both populations, due to the greater availability of patients with HBeAg negative CHB at investigational sites, we intend to study this population first.



Multiple steps in the HBV life cycle, including those involving capsid assembly and production and secretion of HBsAg, are known to be essential to sustain HBV infection. We have built a portfolio of CHB drug candidates directed against clinically validated targets at several critical stages of the HBV life cycle. Our CHB portfolio includes:

- **STOPS** are protein-binding oligonucleotides that share structural similarity with nucleic acid polymers (NAPs), which have been reported in clinical trials to significantly reduce circulating HBsAg and result in high rates of functional cure when used in combination with nucleos(t)ide analogs and peg-IFNα. Our most advanced STOPS molecule is ALG-010133, which is currently being evaluated in a Phase 1 clinical trial, including in CHB patients. In nonclinical studies, ALG-010133 has demonstrated higher inhibitory activity than a reference NAP compound that is currently in clinical development.

- **CAMs** are small molecule antiviral agents that accelerate HBV capsid assembly and inhibit pregenomic RNA (pgRNA) encapsidation, which reduces production of new virions capable of infecting other cells. CAMs may also inhibit the de novo establishment of covalently closed circular DNA (cccDNA), a major factor for the persistence of HBV infection, when introduced at the onset of infection. In clinical trials, other CAM drug candidates have demonstrated significant reductions in HBV DNA and pgRNA. However, it is likely that CAMs will need to be combined with other modalities that affect HBsAg in order to achieve functional cure. Our most advanced CAM drug candidate is ALG-000184, a prodrug of ALG-001075, which is currently being evaluated in a Phase 1 clinical trial, including in CHB patients. In nonclinical studies, we have shown that ALG-001075 has significantly enhanced potency compared to other CAMs in clinical development of which we are aware
- **ASOs** are single-stranded DNA or RNA molecules that interfere with viral replication by binding to complementary messenger RNA (mRNA), allowing the combined ASO and mRNA to be degraded by the enzyme RNase H. Using our oligonucleotide discovery capabilities, we identified ALG-020572, an ASO that targets HBV mRNA and can reduce HBsAg production, which we plan to advance into clinical trials in the second half of 2021. In third-party clinical trials, ASOs targeting HBV mRNA have demonstrated significant reductions in HBsAg. Our ASO approach utilizes state of the art bioinformatics, proprietary stabilization chemistry and liver targeting technology that we believe provides a number of potential benefits compared to other ASO candidates of which we are aware, including increased potency, a higher barrier to resistance and broad genotype coverage.
- **siRNAs** are a class of double-stranded, non-coding RNA that interfere with viral replication by silencing gene expression. Multiple siRNAs have demonstrated significant reductions in HBsAg levels in clinical trials. Our oligonucleotide discovery capabilities resulted in the identification of ALG-125755, an siRNA drug candidate directed at HBV mRNA, which utilizes our proprietary liver targeting technology.

We believe that a combination of drugs capable of inhibiting HBV DNA replication and RNA packaging (e.g., using CAMs) while simultaneously suppressing HBsAg production (e.g., using our STOPS molecule, ASO, and/or siRNA) has the potential to act additively or synergistically and may lead to a higher rate of functional cure. Our clinical development strategy is designed to evaluate safety and antiviral activity as monotherapy prior to evaluating multiple combinations of our CHB assets, with or without other currently available treatment modalities such as nucleos(t)ide analogs or peg-IFNα, to identify optimized combination regimens.

Our second development effort is focused on the treatment of NASH. An estimated 1.5% to 6.5% of the global population, or up to about 450 million people, was believed to have NASH as of 2015 and this percentage is expected to increase significantly in the coming decade due to the adoption of Western dietary habits. In the absence of lifestyle modifications, the inflammation inherent in NASH persists and results in progressive fibrosis of the liver, which may lead to cirrhosis, ESLD, HCC, the need for liver transplant, and death. We believe one of the most promising pharmacologic approaches in development for NASH is a selective agonist of the beta subtype of the thyroid hormone receptor (THR-b), which, in clinical trials conducted by third parties, has demonstrated significant reduction in liver fat and inflammation, as well as the reduction in lipid levels in the serum, which may have important advantages in the NASH patient population that is at a high risk of cardiovascular co-morbidities. Utilizing our expertise in small molecule drug discovery, we identified ALG-055009, a once-daily oral THR-b agonist. In nonclinical studies, ALG-055009 has been shown to be substantially more potent compared to other THR-b agonists currently in development of which we are aware and may avoid some of their potential safety liabilities while having the potential to achieve equal or better efficacy. As a result, we believe ALG-055009 has the potential to become an integral component of combination regimens to treat NASH. We intend to advance ALG-055009 into clinical development in the second half of 2021.

Our third area of focus is to develop pan-coronavirus treatment regimens. SARS-CoV-2 is responsible for the COVID-19 pandemic, which has been identified as a cause of more than ~2.4 million deaths worldwide as of February 2021. After MERS and SARS (SARS-CoV-1), SARS-CoV-2 is the third known coronavirus to have crossed over from animal species to humans in the past 20 years and cause significant morbidity and mortality. While multiple vaccines have recently become available, it is unlikely that vaccination will be fully efficacious and widely adopted, indicating that the need for effective therapeutic treatments will remain. Many of the drugs

currently being evaluated have not been optimized for the treatment of coronavirus infections or SARS-CoV-2, specifically. There is a need for purpose-built drugs which are suitable across a broad range of coronaviruses, patient populations and clinical settings, including prophylactic and post-exposure settings. We believe that, similar to CHB, a combination of antiviral and/or immunomodulatory drugs which target multiple points in the viral replication cycle offers the best chance of success. To address this urgent, unmet medical need, we are in early stages of development for multiple drug candidates including siRNA/ASO and protease inhibitors that are specifically designed to interact with targets that are highly conserved across multiple coronaviruses. Each of these drug candidates is intended to have pan-coronavirus activity and to be used in combination regimens to maximize their antiviral activity.

Our management team consists of a group of highly collaborative, culturally diverse 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. Most 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, Olysio, Sovaldi, Hepsera, Infergen, Valtrex, Sirturo, Neupogen, Andexxa and Esbriet, 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 viral and liver diseases. Finally, we have top-tier investors, including Boxer Capital of Tavistock Group, Cormorant Asset Management, Janus Henderson Investors, Logos Capital, Novo Holdings, Pivotal bioVenture Partners, Roche Venture Fund, Versant Ventures, Vivo Capital and Wellington Management Company.

Our strategy

Our strategy is to develop pharmacologically optimized drug candidates for use in combination regimens designed to achieve improved treatment outcomes. Our initial areas of focus are viral and liver diseases where our team can leverage their in-depth knowledge and expertise to develop potentially best-in-class combination regimens addressing large areas of unmet medical need. The core elements of our business strategy include:

- ***Developing improved drug candidates against clinically validated targets.*** We leverage our oligonucleotide and small molecule platforms to identify drug candidates with pharmacologically optimized characteristics compared to other drug candidates, including the potential for improved efficacy, safety and/or route of administration. By initially focusing on clinically validated targets, we increase the likelihood of demonstrating clinical efficacy and delivering optimized combination regimens.
- ***Creating combination regimens to achieve better outcomes.*** We believe that most chronic and viral diseases require combination therapies for optimal treatment outcomes, and that combining individual drugs which can act additively or synergistically provides the greatest potential for enhanced efficacy. For each of our drug candidates, our strategy in Phase 1 is to rapidly evaluate safety and demonstrate proof of activity for each individual drug. Subsequently, we plan to combine multiple drug candidates in Phase 2 trials to identify optimized combination regimens to be advanced into pivotal trials.
- ***Developing a functional cure for CHB.*** We have a portfolio of differentiated drug candidates for CHB, including a STOPS molecule, a small molecule CAM, and other oligonucleotides (ASO and siRNA) each of which is designed to inhibit clinically validated, distinct and critical points in the HBV life cycle. Our two lead drug candidates for CHB, ALG-010133, a STOPS molecule, and ALG-000184, a CAM, are currently in Phase 1 trials. Based on nonclinical studies, we believe that each of these drug candidates has demonstrated strong potential relative to other drugs in development. In combination, we expect our drug candidates to provide greater viral suppression, potentially leading to higher rates of functional cure.
- ***Expanding our development capabilities and pipeline.*** We are utilizing our in-house discovery expertise to continually improve upon our existing drug candidates by identifying promising backup candidates and exploring novel and emerging drug targets in viral and liver diseases. We are also evaluating novel mechanisms of action with the potential to complement our current pipeline. 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 from Emory, Luxna and AM Chemicals, LLC (AM Chemicals), and have entered into collaborations with KU Leuven's Rega Institute for Medical Research, as well as its Centre for Drug Design and Discovery, and Merck Sharp & Dohme Corp., a subsidiary of Merck & Co.,

Inc. (known outside of the United States and Canada as MSD) (which Merck Sharp & Dohme Corp., or Merck & Co., Inc., individually or together, are referred to herein as "Merck").

- ***Maximizing the value of our drug candidates.*** We currently hold worldwide development and commercialization rights, including through exclusive licenses, to all of our 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.

Our approach to research and development

Our oligonucleotide and small molecule platforms allow us to discover drug candidates that can be used to develop potentially best-in-class combination regimens. Oligonucleotide approaches enable specific inhibition of the translation of viral or host genes to affect a desired outcome that would be challenging to achieve with traditional small molecules. We believe the diversity of chemical matter we can generate with these complementary modalities broadens the range of therapeutic targets we can address with our platforms and provides us with a differentiated set of in-house capabilities to use in developing novel, optimized combination regimens across all of our current areas of focus.

Our approach of combining multiple mechanisms from these distinct modalities is based on the observation that most chronic diseases, whether extrinsic (e.g., HIV and Hepatitis C) or intrinsic (e.g., metabolic syndrome conditions such as hypertension and diabetes), often require combination therapy to achieve optimal outcomes. Combination approaches have the advantage of simultaneously targeting multiple pathways and can act broadly and potentially synergistically. Particularly in the case of viral diseases, the simultaneous use of multiple drugs in combination can increase the barrier to viral resistance. As part of our drug candidate screening paradigm, we perform in vitro combination studies to ensure that none of the combinations we plan to evaluate clinically demonstrate antagonistic interactions.

Our team has extensive end-to-end drug discovery and development experience across multiple therapeutic areas and disciplines. Our clinical development strategy leverages past experience to rapidly advance drug candidates towards optimized combination 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.

Oligonucleotide platform

We have multiple distinct modalities within our oligonucleotide platform, including STOPS molecules, ASOs, and siRNAs. We have developed a portfolio of oligonucleotide drug candidates for the treatment of CHB, including: ALG-010133, a STOPS molecule drug candidate; ALG-020572, an ASO drug candidate; and ALG-125755, an siRNA drug candidate. In addition, we are leveraging our oligonucleotide platform to develop drug candidates for coronaviruses and other diseases, which includes entering into a collaboration with Merck to discover and develop oligonucleotides against an undisclosed target for the treatment of NASH.

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.

S-antigen Transport-inhibiting Oligonucleotide Polymers (STOPS) molecules

STOPS molecules are oligonucleotides which in vitro reduce the levels of key HBV viral markers, including HBsAg. They share structural similarity with NAPs such as IV-administered REP 2139 and REP 2165, which, when used in combination with nucleos(t)ides analogs and peg-IFNα in clinical trials conducted by others, have demonstrated significant declines in key HBV viral markers and increased functional cure rates over current standard of care. Our STOPS molecules, such as our lead drug candidate ALG-010133, have been highly optimized and contain several novel chemical features, leading to enhanced in vitro potency and allowing for subcutaneous dosing.

Antisense oligonucleotides (ASOs)

ASOs are single-stranded DNA or RNA molecules that interfere with viral replication by binding to and down-regulating mRNA expression, preventing subsequent protein translation. This technology has been validated across multiple indications, including CHB, where significant reductions in viral markers have been observed. We have discovered potent, liver-targeted ASOs, including ALG-020572, which has demonstrated a promising profile in nonclinical CHB models.

Small interfering RNAs (siRNAs)

siRNAs are a class of double-stranded RNA that interfere with viral replication by silencing gene expression and subsequent protein translation. siRNAs have shown efficacy across multiple indications, including CHB, where significant reductions in viral markers have been observed. Our novel and proprietary siRNA technology has resulted in the identification of molecules, including ALG-125755, that have demonstrated high potency and long-lasting durability in nonclinical CHB models.

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 viral and liver diseases.

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. CAMs are small molecules that have been shown to significantly reduce viral markers in CHB patients in clinical studies. Applying our small molecule platform, we have identified ALG-001075, which has demonstrated improved in vitro potency and increased efficacy in nonclinical animal models, as compared to other CAM candidates that have advanced into the clinic. ALG-001075 is currently being evaluated in a Phase 1 study as the prodrug ALG-000184. THR-b agonists are small molecules that have been shown to significantly reduce circulating lipid levels and improve liver histology in patients with NASH. We have discovered ALG-055009, a THR-b agonist that has demonstrated improved potency in vitro and increased efficacy in nonclinical animal models relative to other THR-b agonists in Phase 2 or later stages of development.

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). Our team has discovered multiple potential nanomolar potency drug candidates targeting the 3C-Like protease of coronaviruses. These projects are moving towards the identification of a lead drug candidate with potentially broad spectrum activity against COVID-19, SARS, MERS, and possibly other emergent coronaviruses.

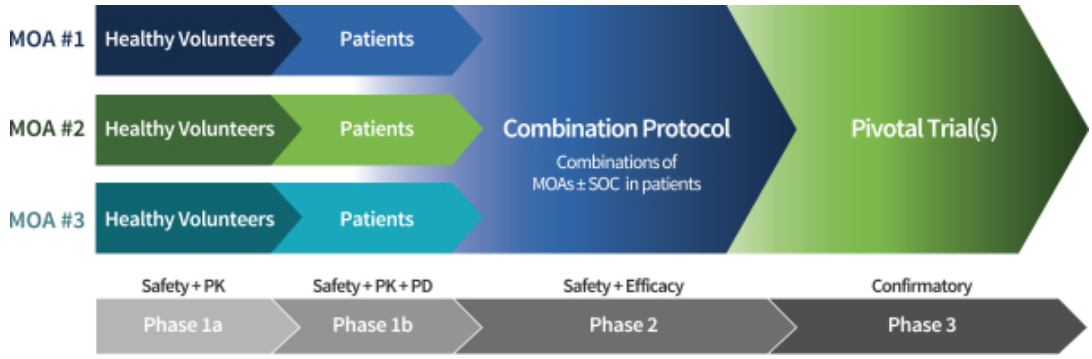
Small molecule prodrugs

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 successfully applied this approach to ALG-001075 to create ALG-000184, which is our lead CAM drug candidate, and which is currently being evaluated in the clinic for the treatment of CHB.

We are engaged in multiple other small molecule discovery efforts to identify additional potentially best-in-class drug candidates for the treatment of CHB, NASH and coronaviruses.

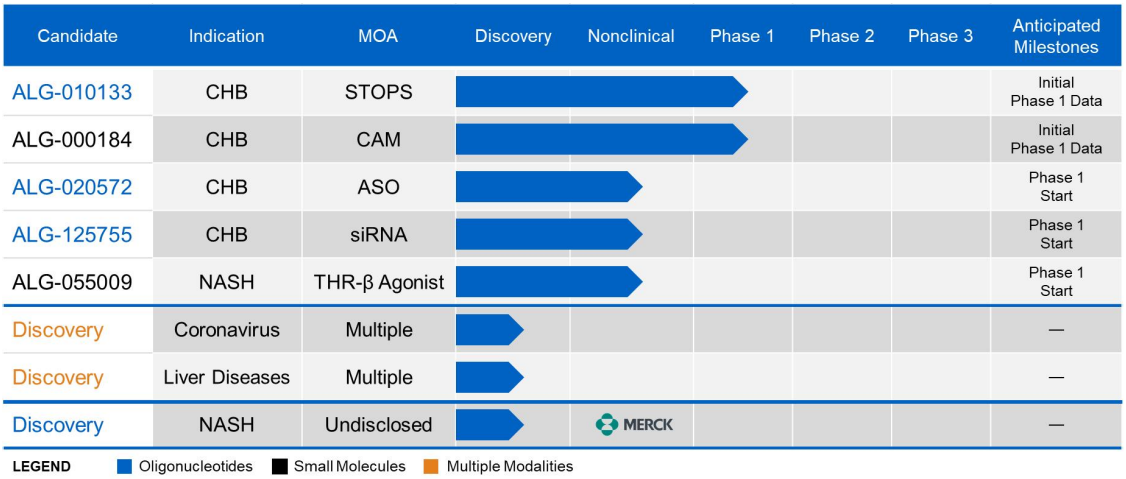
Our approach to developing potentially best-in-class therapeutic combinations

Our approach to developing potentially best-in-class regimens for our therapeutic areas of interest leverages the most promising modalities from our oligonucleotide and small molecule platforms to advance rapidly from monotherapy Phase 1 trials into Phase 2 combination trials. As a first step, we evaluate the safety and activity of each drug candidate in healthy volunteers and patients with the disease of interest. We intend to then efficiently evaluate drug candidates shown to have activity in Phase 1 in various combinations in Phase 2 platform protocols to enable us to identify optimized combination regimens that will then be evaluated in Phase 3 pivotal trials. The combinations we evaluate may include additional drug candidates or current standard of care. Throughout all phases of clinical development, pre-specified adaptive study rules allow real-time adjustment of trial conduct based on emerging clinical trial data. These practices allow us to gain a rapid understanding of the risk/benefit profile for our individual drug candidates and combination regimens, and iteratively refine our strategy based on emerging data. This approach is summarized in the figure below.



Our pipeline

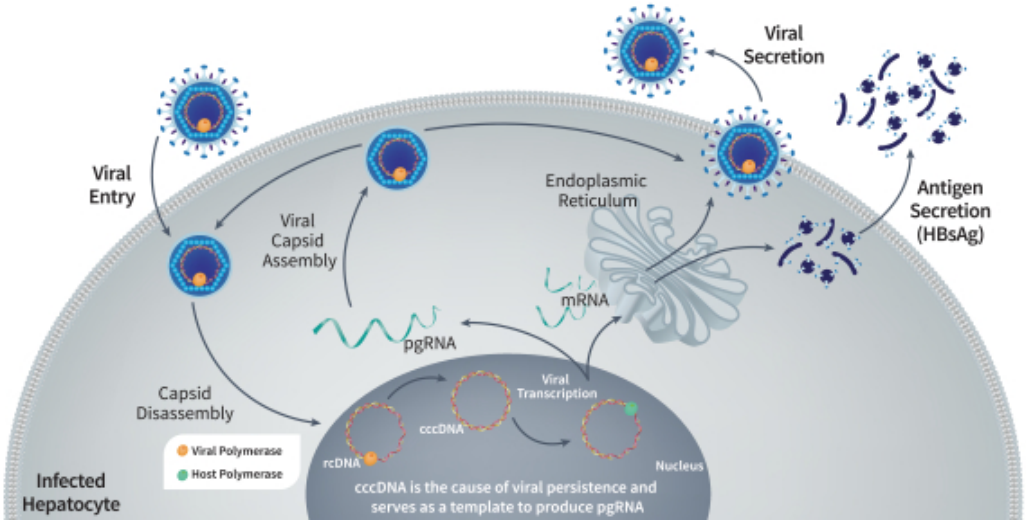
We are focused on viral and liver diseases, areas in which our employees have expertise and decades of experience. Our most advanced drug candidates are designed for use in CHB to achieve higher rates of functional cure, which we believe will require the use of a combination of drugs with complementary mechanisms of action (MOA). Each of our CHB modalities plays an important role in disrupting the HBV life cycle and, in nonclinical studies, certain combinations have been shown to act additively or synergistically. We are also advancing a THR-ß agonist for NASH and purpose-built drug candidates for coronaviruses. We also have a collaboration with Merck to discover and develop oligonucleotides against an undisclosed target for the treatment of NASH. As with CHB, we believe combination therapy will be critical for improved patient outcomes in these disease settings and intend to combine our drug candidates with others that have potentially complementary MOAs.



Functional cure for CHB

CHB is the most common viral infection in the world and an area of substantial unmet medical need. There were over 290 million chronic carriers worldwide as of July 2020 and approximately 30 million individuals become newly infected every year despite the availability of a prophylactic vaccine. In 2015, there were more than 90 million cases of CHB in China alone, while the EU, United States and Japan accounted for nearly 8 million cases. Complications from CHB include cirrhosis, end-stage liver disease, and hepatocellular carcinoma, which collectively resulted in approximately 900,000 deaths in 2015, according to the World Health Organization. CHB is the primary cause of liver cancer worldwide, and the mortality associated with HBV-related liver cancer continues to increase.

Current therapy for CHB may entail life-long treatment and does not eliminate the virus in a meaningful number of patients. In the case of nucleos(t)ide analogs, long-term treatment can lower the amount of HBV DNA in circulation, resulting in improvements in long-term disease outcomes, but virological relapse is common after treatment cessation. Our goal is to achieve meaningful rates of functional cure, which is defined as a sustained loss of HBsAg with or without hepatitis B surface antibody seroconversion. Our team's years of experience in antiviral drug development suggest that only by developing a combination regimen targeting multiple mechanisms can meaningful functional cure rates for CHB be achieved.



HBV is a small DNA virus consisting of a nucleocapsid in which the viral DNA is packaged together with the HBV polymerase by the hepatitis B core protein and a membranous envelope containing HBsAg. After infection of liver cells, HBV DNA is transformed in the nucleus into a stable viral mini-chromosome, which is composed of a cccDNA molecule, from which mRNAs encoding viral proteins are transcribed, and pgRNA, the template for the formation of new viral DNA genomes by reverse transcription. Parts of the viral genome can integrate into the host genome, which is thought to contribute to the production of HBsAg in chronically infected patients and play an important role in liver carcinogenesis, but the integrated viral genome does not produce infectious virus. HBsAg is known to prevent immune-mediated clearance of infected liver cells. HBsAg seroclearance correlates with significant decreases in cccDNA levels and implies immune control of HBV, indicating the need to reduce HBsAg to achieve functional cure.

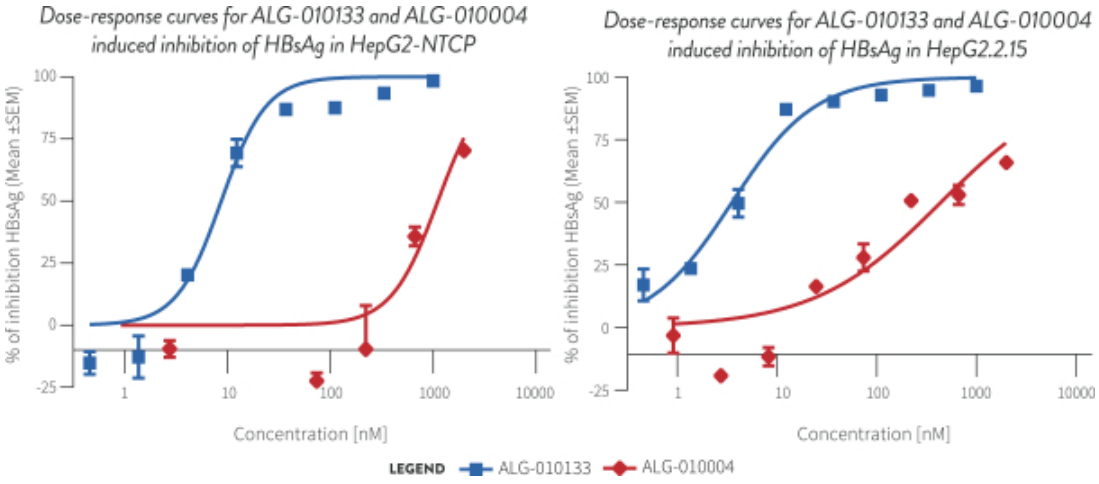
We have developed a portfolio of differentiated drug candidates for CHB, including a STOPS molecule, a small molecule CAM, and oligonucleotides (ASO and siRNA), each of which are designed to interfere with multiple clinically validated targets in the HBV life cycle and may lead to higher rates of functional cure when used in combination.

ALG-010133 (STOPS molecule) for CHB

STOPS molecules share structural similarity with NAPs but contain several novel chemical features, providing enhanced potency in several HBV-infected cell lines. NAPs such as REP 2139 and REP 2165 have been reported to significantly reduce circulating HBsAg in patients with CHB when administered either as a monotherapy or as a combination therapy, resulting in multiple $\log_{10}$ IU/mL reductions in HBsAg levels. The Replicor 401 study, a study of NAPs in combination with tenofovir and pegylated interferon, reported a 39% functional cure rate. A major drawback of NAP drug candidates is the requirement for weekly IV infusions given over two hours for 48 weeks. However, by exploring the chemistry around the STOPS structure, we have optimized STOPS molecules for activity, dose frequency and subcutaneous delivery, potentially negating the need for lengthy IV infusions. Use of our STOPS molecules given via subcutaneous injections and in combination with other convenient drug regimens may improve treatment adherence and functional cure rates. Enrollment in the Phase 1 proof of concept trial of our lead STOPS molecule, ALG-010133, is currently ongoing and we anticipate safety and antiviral data from the initial cohort(s) in the second half of 2021 and study completion in the second half 2022.

ALG-010133 is a synthetic oligonucleotide discovered by our team and that we are developing for the treatment of CHB. We originally optimized existing compounds to generate ALG-010133 by using nucleotide stabilization chemistry. Varying the length of the STOPS molecule revealed a length dependency on antiviral activity; potency was maintained at lengths of more than 34 nucleotides, and dramatically reduced at lengths of less than 30 nucleotides. Nucleotide sequence variations in STOPS molecules also had effects on activity. In addition to length and sequence, backbone and sugar chemistry were modified; activity was improved with site-specific incorporation of backbone chemistries. Collectively, these structural elements provided a framework for STOPS molecule design and were important for the progression of ALG-010133 into clinical development.

As shown in the figure and table below, transfection of STOPS molecules into multiple HBV-infected cell lines, including primary human hepatocytes, resulted in the inhibition of HBsAg release into the supernatant in a dose-dependent manner. In addition, transfection of close analogs of ALG-010133 were shown to decrease intracellular levels of HBsAg, indicating that this inhibition occurs inside the cell. This suggests that the inhibition of HBsAg release is not the result of only an inhibition of protein secretion, which would result in HBsAg accumulation within the cell, but instead could be the result of inhibition of synthesis and intracellular transport of HBsAg. The data below shows the comparison of ALG-010133 to a NAP reference compound, ALG-010004, which has an identical oligonucleotide sequence to REP 2139.



	Inhibition of HBsAg EC_{50} (nM) in Different Cell Lines		
Test Material	HepG2.2.15[a]	HepG2-NTCP[b]	HBV-Infected PHH[b]
ALG-010133 (STOPS)	3.86	3.2	5.97
ALG-010004 (NAP)	343.3	339.5	1740

EC_{50}=half-maximal effective concentration; PHH=primary human hepatocytes.
[a] A commonly used HBV model that integrates the Genotype D HBV genome.
[b] The HepG2 NTCP and PHH cell lines are live Genotype D laboratory strains of HBV-infected cells.
Data in table represents mean values.

The HepG2.2.15 cell line is a commonly used in vitro HBV cell model. The cells contain two copies of the Genotype D HBV genome that produce infectious HBV and other subviral particles. The HepG2-NTCP (Na+-taurocholate co-transporting polypeptide) cell line over-expresses the NTCP receptor and has been shown to be a robust cell culture system supporting the complete life cycle of HBV. HepG2-NTCP cells were infected with a Genotype D HBV laboratory strain. In this cell line, HBsAg and other HBV viral proteins are produced from RNA transcripts derived from HBV cccDNA. ALG-010133 and ALG-010004 were evaluated in the HepG2.2.15 cell line to assess HBsAg release in the supernatant and cell viability.

In addition, ALG-010133 demonstrated potent activity in the inhibition of HBsAg release from a variety of infected cell types with half-maximal effective concentration (EC_{50}) values ≤22.5 nM when tested against cells infected with all major HBV genotypes (A, B, C, and D), indicating that ALG-010133 may have pan-genotypic activity in CHB patients. Further, in patients with CHB, HBsAg can also be derived from an integrated HBV genome. The PLC/PRF/5 cell line, which contains an integrated partial HBV genome and produces HBsAg but not infectious virions, was used as a cell model of this condition. ALG-010133 demonstrated activity in the inhibition of HBsAg secretion from the PLC/PRF/5 cell line with an EC_{50} of 23.7 nM with a 50% cellular cytotoxic concentration (CC_{50}) of more than 1000 nM.

To assess the capability for immune activation, ALG-010133 was assayed in human peripheral blood mononuclear cells from three independent donors for cytokine induction. The results of these experiments demonstrated that no direct immune activation is mediated by ALG-010133. Nonclinical PK studies following subcutaneous dosing indicate long liver residence time that supports weekly or less frequent dosing for patients.

Our ongoing three-part Phase 1 first-in-human clinical trial comprises single and multiple ascending dose (SAD/MAD) evaluations in healthy volunteers followed by a multiple dose evaluation in patients with HBeAg negative CHB. The first two parts of this study have been completed, with ALG-010133 being administered subcutaneously once (SAD) or once weekly for three doses (MAD) in up to 104 healthy volunteers. In March 2021, we initiated the third part of this clinical trial, where we will be dosing once weekly for twelve doses in up to 60 patients with virologically suppressed HBeAg negative CHB.

ALG-000184 (CAM) for CHB

CAMs are a class of small molecule antiviral agents that accelerate HBV capsid assembly and inhibit pgRNA encapsidation, resulting in lower circulating HBV pgRNA and DNA levels. CAMs are also believed to regulate formation and transcription of cccDNA at the onset of infection, a major factor for the persistence of HBV infection. In clinical trials, CAMs have been shown to provide greater HBV DNA and RNA reduction when combined with nucleos(t)ide analogs than can be achieved with the current standard of care, nucleos(t)ide analogs alone.

In 2018, we in-licensed a lead drug candidate (GLP-26) and the associated IP for a CAM from the laboratory of Professor Raymond Schinazi at Emory. Our scientists optimized this lead drug candidate to discover the potent CAM ALG-001075, which was further optimized to the prodrug ALG-000184. ALG-000184 is currently being evaluated in a Phase 1 clinical trial. We expect safety and antiviral data from the initial cohort(s) in the second half of 2021.

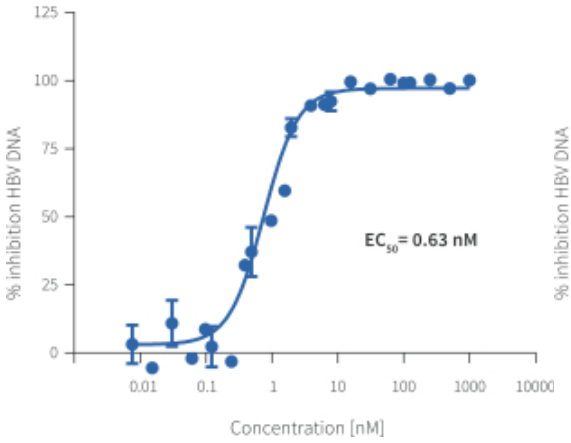
Molecular characteristics and nonclinical data

In biochemical assays, ALG-001075 was shown to induce the rapid assembly of core proteins into small, spherical capsids. Capsids assembled in the presence of ALG-001075 were highly stable with a compound residence time of more than 16 hours. In assays using genotype D HBV infected HepG2.2.15 cells, ALG-001075 demonstrated enhanced potency with an EC_{50} value of 0.53 nM compared to several CAM reference compounds. This finding was repeated in HepG2.117 cells where ALG-001075 had an EC_{50} value of 0.63 nM. This level of potency exceeds that of all other known CAMs that have entered clinical development.

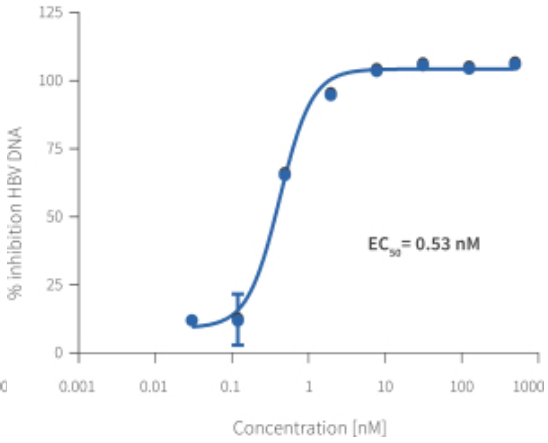
Compound	Current Status	HBV DNA reduction (EC_{50} nM)	Cell Type
Assembly ABI-H0731	Phase 2	172	AD38
Assembly ABI-H2158	Phase 2	22	AD38
Assembly ABI-H3733	Phase 1	5	AD38
Janssen JNJ-6379	Phase 2	54	HepG2.117
Janssen JNJ-0440	Completed Phase 1	12	HepG2.117
Enanta EDP-514	Phase 1	17	HepG2.2.15
Aligos ALG-000184	**Phase 1 CTA approved**	**0.63**	**HepG2.117**
		0.53	**HepG2.2.15**

With the exception of ALG-000184, data was sourced from publicly available literature, posters and presentations.
ALG-000184 data was generated by Aligos on the parent compound ALG-001075.

Dose-response curve for ALG-001075-induced inhibition of HBV DNA in HepG2.117 cells

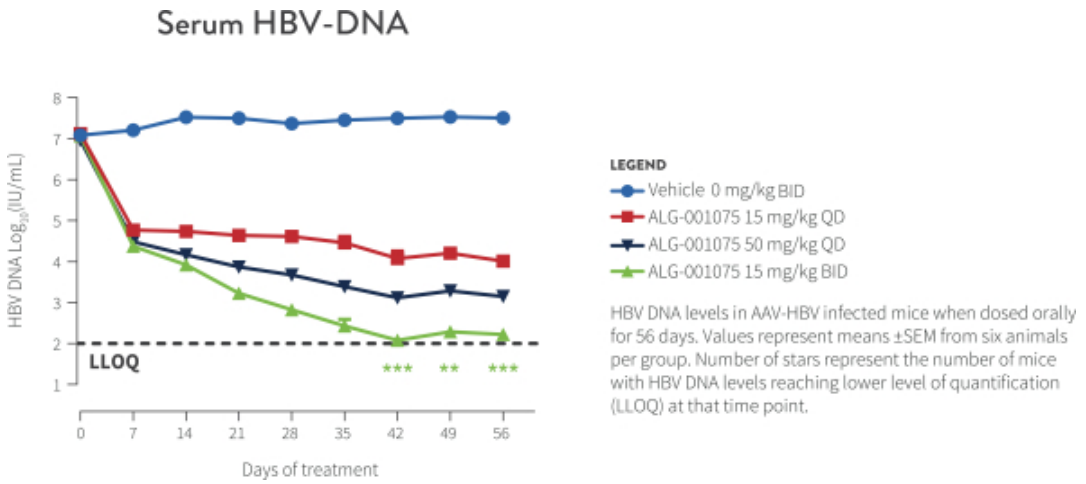


Dose-response curve for ALG-001075-induced inhibition of HBV DNA in HepG2.2.15 cells

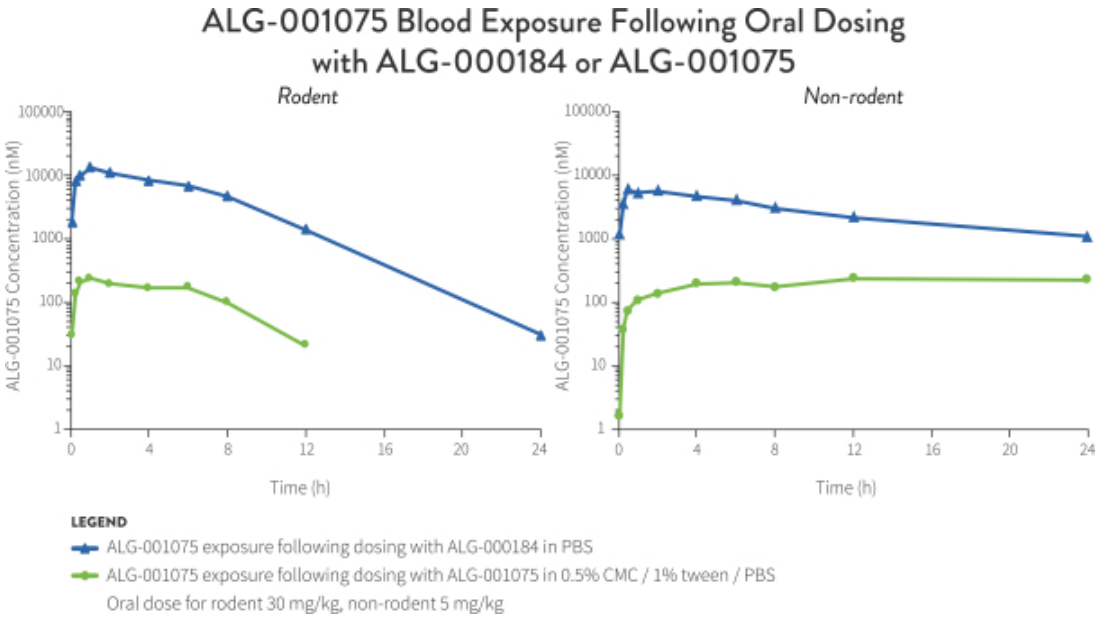


ALG-001075 was further tested in a transient HBV assay against a broad panel of HBV screens from genotypes A through J and was shown to maintain good activity against all genotypes tested except for certain genotypes with known CAM-resistant mutations.

In the adeno-associated virus (AAV)-HBV mouse efficacy model, ALG-001075 demonstrated a dose-dependent inhibition of viral replication with >5 $\log_{10}$ IU/mL reduction in HBV DNA at a dose of 15 mg/kg/dose given twice daily at 12-hour intervals (BID) as compared to a vehicle group.



We developed a highly soluble prodrug of ALG-001075, ALG-000184, to address the bioavailability limitations of ALG-001075. ALG-000184 has improved aqueous solubility, significantly better permeability and a reduced efflux ratio compared with ALG-001075. Consequently, ALG-000184 has significantly improved oral bioavailability compared to ALG-001075. When administered in vivo, as shown in the figure below, ALG-000184 was rapidly absorbed and efficiently converted to ALG-001075 in nonclinical animal models.



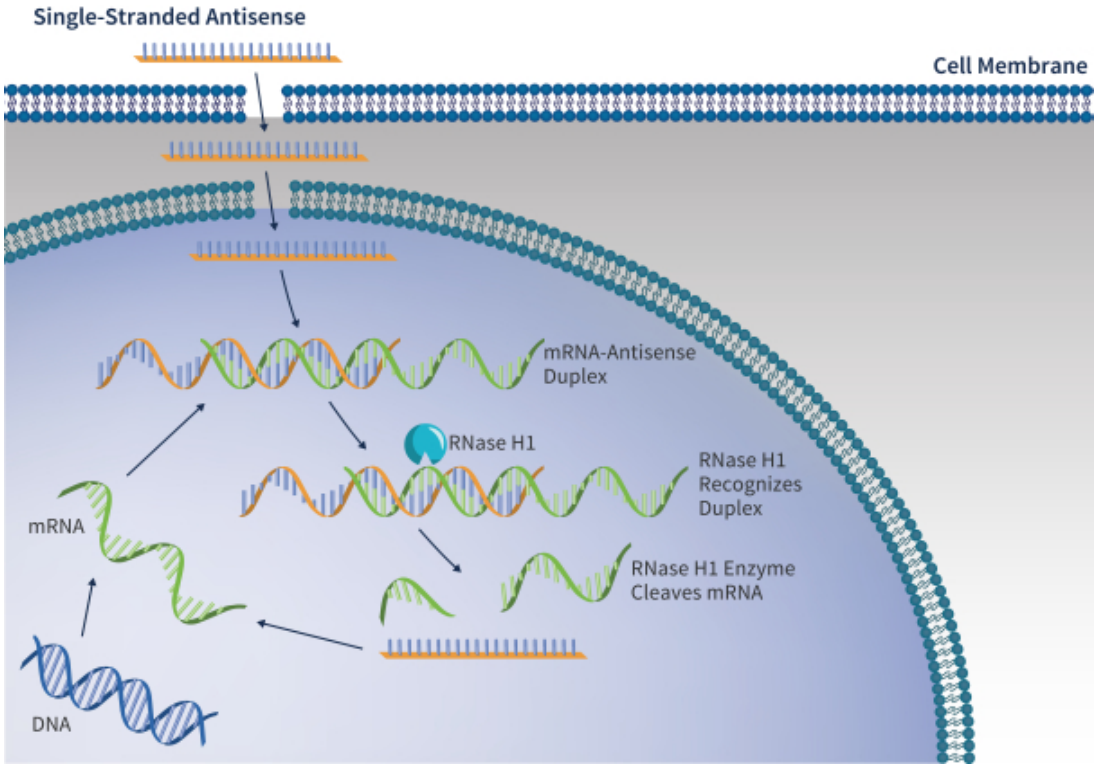
Our three-part Phase 1 first-in-human clinical trial comprises single and multiple ascending dose (SAD/MAD) evaluations in healthy volunteers followed by a multiple dose evaluation in patients with CHB.

In the healthy volunteer portion of the study, where enrollment was completed, ALG-000184 was orally administered once (SAD) or once-daily for 7 days (MAD) in healthy volunteers. Screening in CHB patients for the

third part of the study is ongoing and, upon initiation of such third part of the study, we will dose once-daily for 28 days in up to 60 patients with CHB who are not currently receiving treatment.

ALG-020572 (ASO) for HBV

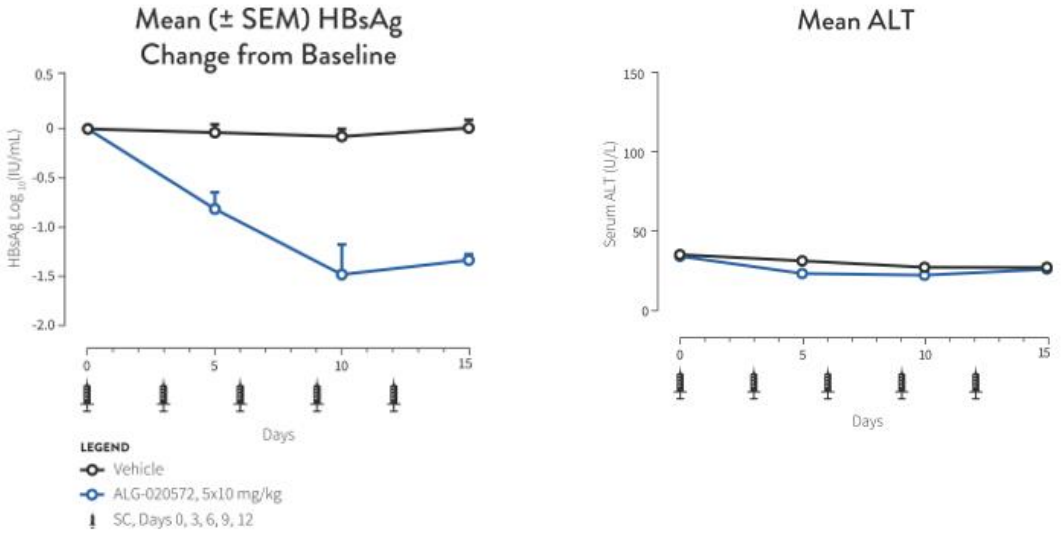
Anti-sense oligonucleotides (ASOs) are single-stranded DNA or RNA molecules that are complementary to a selected target sequence. ASO structures are typically composed of three sections, known as the wings and the gap. The wings are on each end of the oligonucleotide strand with the gap section bridging the wing sections. Wings are generally made up of BNAs, while the gap sections are typically made up of DNA or modified DNA nucleotides. ASOs interfere with viral replication by binding to complementary mRNA, a process known as hybridization. If binding occurs, this hybrid can be degraded by the enzyme RNase H resulting in significant down-regulation of mRNA expression, and, in the case of our CHB ASOs, preventing subsequent HBsAg translation and secretion. This process is shown in the figure below. ASOs have been validated across multiple indications, including CHB, where rapid and significant reductions in HBsAg have been observed.



We have exclusively licensed Luxna's intellectual property for use of next-generation nucleotide monomers in our current focus areas, including CHB and SARS-CoV-2. This chemistry forms the basis of our ASO platform and has enabled us to design highly potent, stable ASOs that have an improved toxicology profile, including a reduction of hepatotoxicity, as compared to ASOs using earlier nucleotide monomer technology. The application of this technology, combined with our proprietary liver-targeting GalNAc conjugation, has led to our discovery of ALG-020572, a potentially best-in-class HBV ASO targeting the open reading frame of HBsAg. We plan to begin a multipart Phase 1 study evaluating ALG-020572 in healthy volunteers and patients with CHB in the second half of 2021.

Molecular characteristics and nonclinical data

We explored the structure activity relationship of BNA wing and nucleobase gap modifications across a set of diverse locked nucleic acid ASOs. When conjugated to our proprietary GalNAc moiety and administered subcutaneously (5 doses total, 10mg/kg given every 3 days over 12 days) to mice previously infected with an AAV-HBV construct, ALG-020572 demonstrated a 1.5 $\log_{10}$ IU/mL mean reduction in serum HBsAg. Vehicle-treated animals did not exhibit any significant changes in their serum HBsAg. Importantly, this intensive dosing regimen was not associated with any changes in alanine aminotransferase (ALT) levels, a marker of liver cell damage.

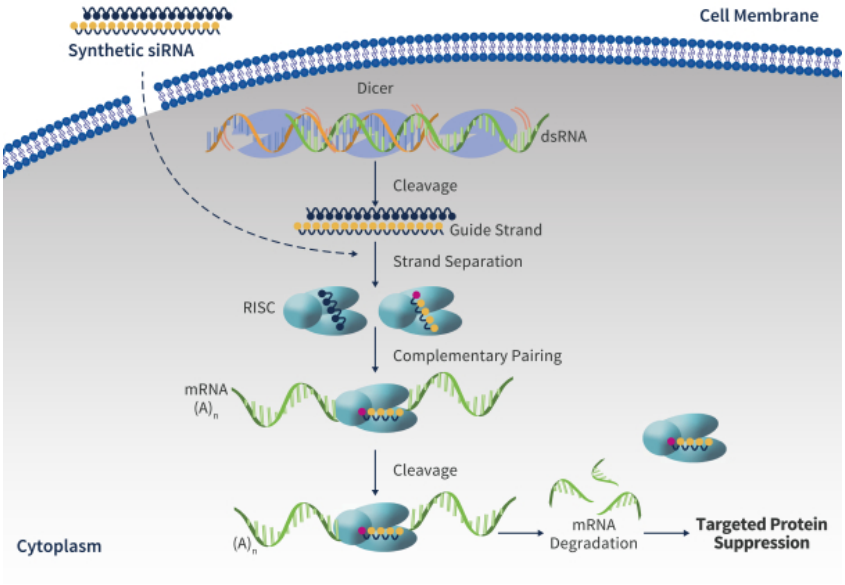


We have discovered potent, liver-targeted ASOs, including ALG-020572, which has demonstrated a promising profile in nonclinical CHB models. These ASO drug candidates may also be combined with other drug candidates against CHB.

siRNA

Small interfering RNA (siRNA), also known as short interfering RNA or silencing RNA (RNAi), are a class of double-stranded, non-coding RNA, typically 20-27 base pairs in length. siRNA interferes with viral replication by silencing gene expression and subsequent protein (e.g., HBsAg) translation and secretion. siRNAs have shown efficacy across multiple indications, including CHB, where significant, gradual and durable reductions in HBsAg have been observed in clinical trials.

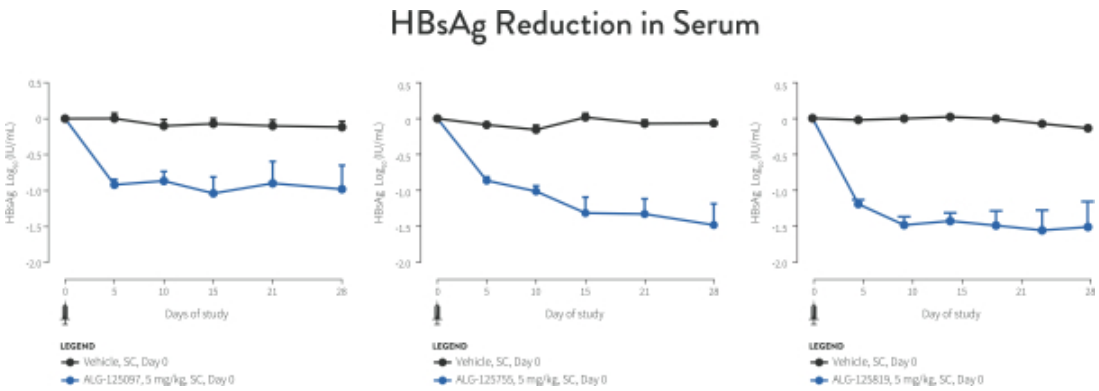
siRNA-induced gene silencing is initiated with the assembly of the RNA-induced silencing complex (RISC). One of the two siRNA strands, the guide strand or anti-sense strand, is loaded into the RISC while the other strand, the passenger strand or sense strand, is degraded. Dicer enzymes are responsible for loading the guide strand into RISC. The cleavage of the mRNA molecule is thought to be catalyzed by the Argonaute proteins of the RISC. The mRNA molecule is then cut by cleaving the phosphodiester bond between the target nucleotides which are paired to siRNA residues. This cleavage results in mRNA fragments that are further degraded by cellular exonucleases. The process of siRNA-mediated RNA degradation is shown in the figure below.



We started with our bioinformatics approach to identify regions of the HBV genome for targeting and used our proprietary technology to maximize potency and minimize the number of 2'-F nucleotides in our sequences. We applied this approach to our screening paradigm to identify our lead siRNA candidate, ALG-125755.

Molecular characteristics and nonclinical data

In cell-based assays measuring reduction in HBsAg in infected cells, our lead siRNA drug candidate, ALG-125755, as well as additional backup compounds ALG-125097 and ALG-125819, demonstrated potent inhibition of HBsAg release from HBV-infected cells. When dosed in vivo in the AAV-HBV mouse model of CHB infection, a single 5 mg/kg subcutaneous injection resulted in a sustained reduction of serum HBsAg of approximately 1-1.5 log_{10} IU/mL through the last measurement at 28 days. The results from these experiments are shown in the figure below.



Currently, we are conducting additional studies using these siRNA drug candidates in the AAV-HBV mouse model to establish the effect of doses and dosing regimens on the extent and duration of HBsAg reduction. We plan to initiate toxicology studies with ALG-125755 in the second half of 2021 to support first-in-human trials.

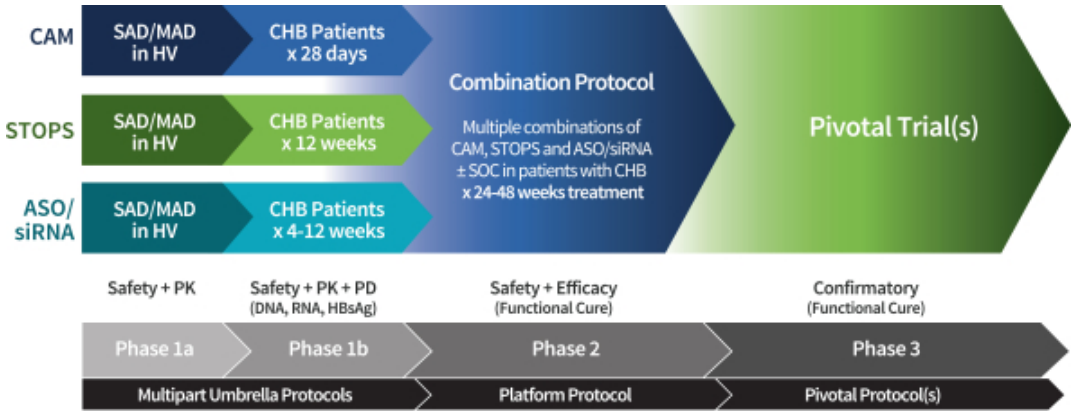
In conclusion, our proprietary siRNA technology is based on modifying chemistries and has resulted in the identification of drug candidates, including ALG-125755, that have promising profiles with long lasting durability in nonclinical CHB models.

Nonclinical combination data

We performed in vitro studies in HepG2.2.15 cells to assess the potential for drug-drug interactions on HBsAg or HBV DNA reductions when combining our drug candidates, and the degree of synergy was quantified using MacSynergy II software. Combinations of our STOPS molecule, ALG-010133, our CAM drug candidate, ALG-001075, or our ASO drug candidate, ALG-020572, with other inhibitors of HBV replication generally demonstrated either additive or synergistic interactions. We also studied in vivo combinations in the AAV-HBV mouse model with ALG-020572. These studies indicate that our drug candidates could become part of an effective combination regimen for CHB.

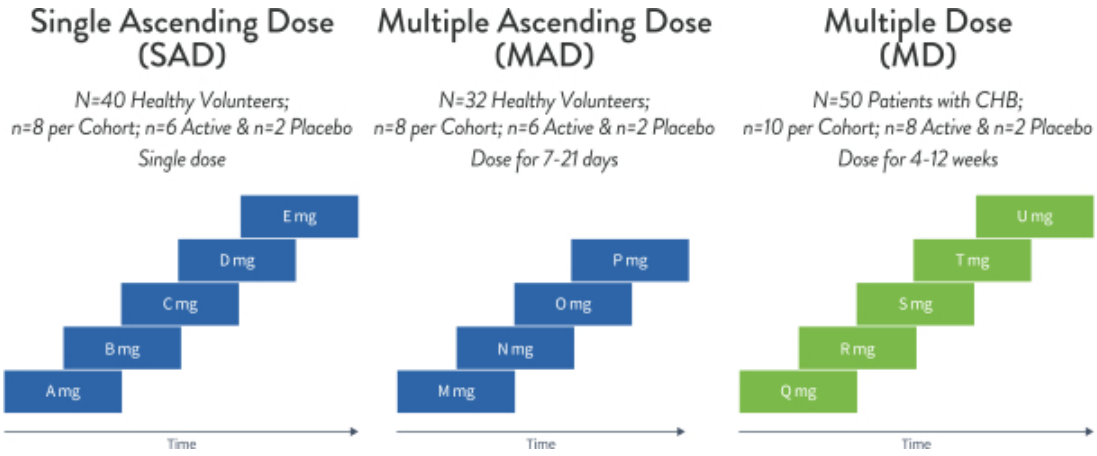
Clinical development plan for CHB

Our approach for developing a best-in-class CHB combination regimen is to discover and develop drug candidates initially targeting clinically validated MOAs, which are evaluated as monotherapy in Phase 1 and subsequently studied in Phase 2 and Phase 3 combination trials. This approach maximizes the chance of achieving higher rates of functional cure compared to current standard of care. Our CHB development strategy is depicted in the figure below.



Both our STOPS molecule (ALG-010133) and our CAM molecule (ALG-000184) Phase 1 clinical trials are ongoing.

The figure below illustrates our planned general approach to Phase 1 trial design for each of our CHB drug candidates.



Although we expect the basic Phase 1 trial design to be the same across all of our CHB drug candidates, we anticipate there will be important differences, which include routes of administration, dose and dosing frequency, patient population, and key viral markers. A summary table of the key Phase 1 design elements and how we expect them to differ across our drug candidates can be found in the table below.

Phase 1 Key Study Elements			
	STOPS (ALG-010133)	CAM (ALG-000184)	ASO (ALG-020572) siRNA (ALG-125755)
Primary Objective	Safety in healthy volunteers and CHB patients		
Key Secondary Objectives	Pharmacokinetics in healthy volunteers		
	Pharmacokinetics and antiviral activity in CHB patients		
Initial CHB Population	HBeAG-negative Virally Suppressed	HBeAG-negative Currently Not Treated	HBeAG-negative Virally Suppressed
Key HBV Biomarker Endpoint(s)	HBsAg	HBV DNA and HBV RNA	HBsAg
Route of Administration	Subcutaneous	Oral	Subcutaneous
Anticipated Dosing Frequency	Once weekly	Once daily	To be determined
Clinical Status	Enrollment Ongoing	Enrollment Ongoing	Future CTAs planned

Drug candidates that show favorable risk/benefit profiles as monotherapy in Phase 1 will be evaluated in combination in our Phase 2 platform trials. This platform approach allows us to evaluate many combinations of our drug candidates along with approved drugs and/or other drug candidates in development, as needed. This strategy allows us to identify combination regimens that could achieve a higher rate of functional cure compared to current standard of care. The optimized regimen(s) identified in Phase 2 will then be evaluated in Phase 3 registrational trials.

NASH

One of the effects of improper diet and insufficient exercise is the accumulation of fatty deposits in the liver, referred to as nonalcoholic fatty liver disease (NAFLD), which was estimated to occur in approximately 25% of the worldwide population as of 2015. At that time, an estimated 1.5% to 6.5% of the global population was estimated to have an ongoing inflammatory response to these excess fat deposits, which is referred to as NASH. Over the past several years, the prevalence of NASH has continued to rise. In the United States alone, the prevalence of NASH is projected to increase from approximately 16.5 million in 2015 to 27.0 million in 2030. In the absence of changes in diet and exercise, the inflammation inherent in NASH 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, hepatocellular carcinoma, need for liver transplant, and death.

The only widely accepted treatment for NASH is weight loss through behavioral modifications such as diet and exercise, which is difficult to achieve at the broad population level. As there are currently no approved drugs to treat NASH, many development programs are underway to identify drugs to address this epidemic. One of the promising MOAs in the NASH space appears to be drugs which preferentially target the beta subtype of the THR receptor.

THR-ß background

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-b). The distribution of the two THR subtypes varies by organ, with THR-b predominantly expressed in the liver and THR-α predominantly expressed in other tissues (e.g., heart, skeletal muscles and bone). Drug candidates like resmetirom, which preferentially binds the THR-b 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 NASH patients, lowering serum lipid levels via THR-b agonism may have favorable consequences in this population, which has a high rate of underlying cardiovascular disease.

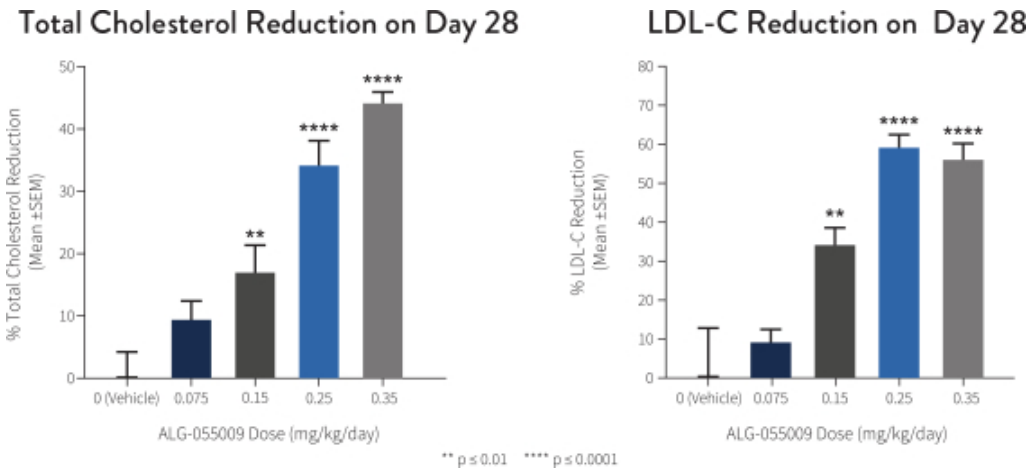
There are multiple other mechanisms being explored for the treatment of NASH, but none have yet to demonstrate a favorable risk/benefit profile and many have important limitations. In some cases, mechanisms such as Farnesoid X Receptor (FXR) agonists, Fibroblast Growth Factor-19 analogs, and Acetyl-CoA Carboxylase inhibitors have been shown to increase serum lipid profiles, which may require additional pharmacologic therapy or put patients at additional risk of cardiovascular disease. In other cases, mechanisms such as FXR agonists and drugs targeting various subtypes of the Peroxisome Proliferator Activated Receptors are associated with dose limiting toxicities such as pruritus and edema, respectively, that might limit widespread uptake even if approved. Other mechanisms in development, such as FGF19/FGF21 analogs, require subcutaneous administration, which may similarly limit widespread adoption even if approved.

Small molecule approaches

The most advanced THR-b agonists in clinical development are VK-2809 in Phase 2b and resmetirom in Phase 3. Both of these drugs have demonstrated significant reductions in lipid levels in the liver and serum and, to date, have an acceptable risk-benefit profile. In addition, resmetirom has demonstrated histologic evidence of NASH resolution in Phase 2 trials, which is one of two FDA approvable endpoints. Our lead THR-ß drug candidate ALG-055009 may have important advantages over these compounds. Side-by-side biochemical and cell-based experiments in HEK293T cells indicate that ALG-055009 is 5- to 47-fold more potent and 3- to 2-fold more selective for the b receptor compared to VK-2809 and resmetirom, respectively, which may optimize the risk-benefit profile for ALG-055009. When studied in a diet induced obesity (DIO) mouse model, these potency advantages were shown to result in greater serum lipid reductions compared to what has been previously reported for VK-2809 and resmetirom at exposures being evaluated in the clinic. Specifically, ALG-055009 achieved a 34% reduction in serum total cholesterol levels with an acceptable safety profile (e.g., no clinically relevant changes in thyroid hormone levels) in mice, as shown in the figure below. An ALG-055009 dose-related decrease in serum LDL-C was also noted in mice. Further, nonclinical pharmacokinetic studies of ALG-055009 predict low, once-daily dosing in humans with a low risk of drug-drug interactions.

Relative THR-α and THR-β Activity in Cell-Based Assays

	EC_{50} α (nM)	EC_{50} β (nM)	Relative THR-β Selectivity (α/β)
T3	14.3	11.5	1.2
MGL-3196	5927	2366	2.5
VK-2809 parent	366	269	1.4
ALG-055009	**191**	**50**	**3.8**



ALG-055009 development plans

Toxicology studies to support first-in-human trials are ongoing. In keeping with our general clinical development strategy, the first planned human trial of ALG-055009 is expected to be a Phase 1a/1b umbrella study assessing orally administered single ascending doses in healthy volunteers followed by multiple ascending doses administered orally once-daily (QD) in subjects with mild hyperlipidemia. We expect this study to commence in the second half of 2021 (with data readouts expected to begin in the first half of 2022) and the study to be complete by the second half of 2022. The data from this study will establish proof of activity and help identify doses that may be evaluated in larger studies involving patients with NASH. With this proof of activity in hand, we would have several options for further development, including continuing the development of the drug candidate into a Phase 2 clinical trial that we would sponsor. Alternatively, we may explore partnering ALG-055009 with a third-party that has an existing drug candidate for the treatment of NASH with a complementary MOA, either in a clinical collaboration or as an out-license opportunity. We believe this may be an ideal time to seek a partnership for ALG-055009, as we expect enthusiasm for the THR-β MOA to be high after the expected Phase 3 resmetirom and Phase 2b VK-2809 readouts, which are expected in 2022.

Oligonucleotide approaches

Recently, genome-wide association and large candidate gene studies have enriched our understanding of the genetic basis of NASH. Variants in multiple human genome sequences have been identified as major common genetic determinants of this disease. We are collaborating with Merck to apply our oligonucleotide platform technology to discover, research, optimize and develop oligonucleotides directed against a NASH target. In addition, we continue to evaluate additional targets for their utility in developing an oligonucleotide based treatment for NASH.

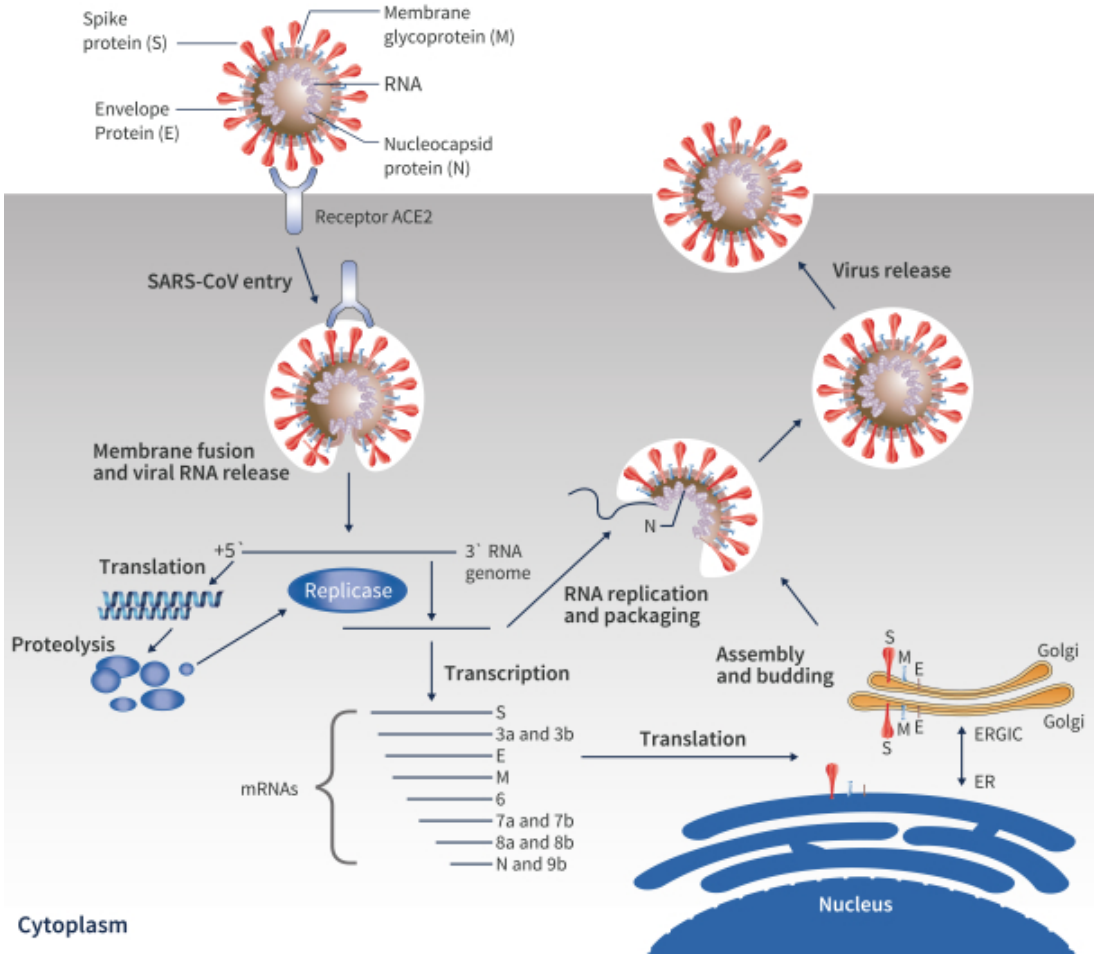
Coronaviruses

SARS-CoV-2 is responsible for the COVID-19 pandemic, which has infected more than 108 million individuals and is responsible for the death of more than 2.4 million individuals worldwide. After 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 ongoing SARS-CoV-2 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. While multiple vaccines have recently become available, it is unlikely that vaccination will be fully efficacious and widely adopted, indicating that a need for effective treatments will remain. The emergence of several SARS-CoV-2 variants in various countries may also represent an additional challenge for current vaccines.

Many of the drugs currently being evaluated have not been optimized for the treatment of coronavirus infections such as SARS-CoV-2 or have only shown efficacy in certain patient populations. Therefore, there is a need for new efficacious, purpose-built drugs which target a broad range of coronaviruses that would be suitable for use across a wide range of patient populations and clinical settings, including in pre-exposure prophylaxis and post-exposure treatment. We believe that a combination of antiviral drugs targeting multiple steps of the viral replication cycle poses the best chance of success. This approach maximizes the odds of covering a broad range of coronavirus strains and protecting against the emergence of resistance. To address this urgent unmet medical need, we are developing pan-coronavirus drug candidates including oligonucleotide and small molecule approaches that may be used in combination regimens.

Disease overview and biology

The life cycle of SARS-CoV-2 is illustrated in the figure below. The spike (S) protein binds to the angiotensin-converting enzyme 2 cellular receptor, leading to a fusion of the viral envelope with the cell membrane through the endosomal pathway. SARS-CoV-2 RNA is then released into the host cell and is subsequently translated into viral replicase polyproteins pp1a and 1ab, which are then cleaved into small products by viral protease to form the RNA replicase–transcriptase complex. The polymerase produces a series of subgenomic mRNAs by transcription, which are eventually translated into relevant viral proteins. Viral proteins and genome RNA are subsequently assembled into virions in the endoplasmic reticulum and Golgi and then transported via vesicles and released out of the infected cells through exocytosis.



Therapeutic approaches to coronaviruses

Therapeutic options for coronaviruses are currently limited and have significant drawbacks. Remdesivir, a drug originally advanced for HCV and Respiratory Syncytial Virus, but repurposed for Ebola and, now, SARS-CoV-2, is currently limited to IV administration in hospitalized patients and has been commonly associated with a high risk of ALT elevation. Dexamethasone, a corticosteroid, has been shown to lower mortality in severe SARS-CoV-2 infections, but has important safety liabilities, including immunosuppression, impaired wound healing and, rarely, anaphylaxis.

We are leveraging our expertise in virology and utilizing both our oligonucleotide and small molecule platforms to develop purpose-built pan-coronavirus drug candidates targeting key steps of the viral life cycle, which we intend to evaluate in combination. Building on the success of HIV and HCV protease inhibitors, which are integral components of existing therapies, we are exploring small molecule peptidomimetics that inhibit the 3C-like protease (3CLPro). 3CLPro is the essential enzyme that is responsible for cleaving well-defined regions of the viral polyprotein and is highly conserved across major coronaviruses including MERS, SARS-CoV-1 and SARS-CoV-2. Drug candidates inhibiting the 3CLPro have the potential to be active against a wide range of coronavirus strains and become a foundational component of future combination regimens. We have identified multiple distinct proprietary lead series with potent nanomolar activity in a SARS-CoV-2 3CLPro protease assay and in multiple coronavirus cell-based assays. Our work in this area is being performed in collaboration with KU Leuven's Rega Institute for Medical Research, as well as its Centre for Drug Design and Discovery.

We are also leveraging our oligonucleotide platform to develop broadly active coronavirus drug candidates. Using our bioinformatics capabilities, we have identified over 350 highly conserved regions across coronavirus genomes. We are currently evaluating oligonucleotides with the goal of identifying a suitable lead sequence for further optimization into a drug candidate.

Drawing on our small molecule and oligonucleotide approaches, we plan to develop a combination drug regimen that can serve in both treatment and prophylactic settings.

Clinical development plan

We plan to advance our coronavirus drug candidates individually in Phase 1 studies designed to evaluate the safety and pharmacokinetics of single and multiple ascending doses in healthy volunteers. Following this, we plan to conduct dose range finding Phase 2 studies in subjects infected with COVID-19 to evaluate proof of activity and identify a dosing regimen(s) to advance into larger confirmatory studies that could support drug registration. Following the initial Phase 2 study, we may evaluate combinations of our drug candidates, with or without the then-prevailing standard of care. We intend to assess a range of patient populations, including community and hospital-based subjects, as well as various degrees of disease severity, following the establishment of proof of activity. In addition to evaluating our drug candidates as treatment options after infection, we may also evaluate them as potential prophylactic or post-exposure therapies.

Early stage discovery efforts

For all of our drug candidates, we are pursuing backup candidates in order to create a robust portfolio of assets which we can draw upon to create an optimized combination regimen for treatment in all of our disease areas of interest. We are also targeting additional novel viral and host targets with our oligonucleotide and small molecule platforms.

Sales and marketing

All of our assets are currently pre-commercial, and as such we have not yet established a sales and marketing organization 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: oligonucleotides and small molecules. We have internal oligonucleotide and small molecule 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 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.

Oligonucleotides

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.

Small molecules

Small molecule manufacturing is a mature industry and is well supported by an extensive network of contract manufacturers. Like our approach for oligonucleotides, our internal CMC team conducts process development and optimization, and supports our contract manufacturers with technology transfer.

Competition

The biotechnology industry is intensely competitive and subject to rapid and significant technological change. Our competitors include multinational pharmaceutical companies, specialized biotechnology companies, universities and other research institutions. Many of our competitors have substantially 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 any) 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 Hepatitis B (CHB)

Current FDA-approved treatments for chronic HBV infection include peg-IFNα, marketed by Roche Holding AG (Roche), and oral antiviral agents such as nucleoside analogs, marketed by Gilead Sciences, Inc. (Gilead) and Bristol-Myers Squibb Company. These treatments do not lead to either a functional or a complete cure in the vast majority of patients, and in the case of nucleoside 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 functional or complete cure in patients with CHB. Companies with oligonucleotide agents in clinical development include Arbutus Biopharma Corporation, Dicerna Pharmaceuticals, Inc. (together with Roche), Ionis Pharmaceuticals, Inc. (together with GlaxoSmithKline plc

(GSK)), Arrowhead Pharmaceuticals, Inc. (together with Janssen Pharmaceuticals, Inc. (Janssen)), and Vir Biotechnology, Inc. (together with Alnylam Pharmaceuticals, Inc.). Several companies are developing CAMs, including Johnson & Johnson, Assembly Biosciences Inc., Arbutus Biopharma Corporation, Roche and Enanta Pharmaceuticals. Several companies, including Altimmune, Inc., GSK, Janssen and Transgene SA, 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 NAPs for use in CHB patients.

Nonalcoholic Steatohepatitis (NASH)

There currently are no FDA-approved treatments for NASH. A number of pharmaceutical companies, including AbbVie, Inc., AstraZeneca PLC/MedImmune LLC, Bristol-Myers Squibb Company, Eli Lilly and Company, Janssen, Merck, Novartis Pharmaceuticals Corporation (together with Pfizer, Inc.), Novo Nordisk A/S, Pfizer Inc., Roche, Sanofi S.A. and Takeda Pharmaceutical Company Limited (together with HemoShear Therapeutics, LLC), as well as large and small biotechnology companies such as 89bio, Inc., Akero Therapeutics, Inc., Blade Therapeutics, Inc., Cirius Therapeutics, Inc., Enanta Pharmaceuticals, Inc., FronThera US Pharmaceuticals LLC, Galectin Therapeutics Inc., Galmed Pharmaceuticals Ltd., Genfit SA, Gilead, Intercept Pharmaceuticals, Inc., Inventiva Pharma SA, Madrigal Pharmaceuticals, Inc., MediciNova, Inc., NGM Biopharmaceuticals, Inc., Pliant Therapeutics, Inc. (together with Novartis), Terns Pharmaceuticals, Inc. and Viking Therapeutics, Inc. are pursuing the development or marketing of pharmaceuticals that target NASH. It is also probable that the number of companies seeking to develop products and therapies for the treatment of serious metabolic diseases, such as NASH, will increase.

Coronaviruses

Other than Remdesivir, which is FDA-approved, there are currently no approved antiviral treatments for SARS-CoV-2. Several drugs are likely being used off-label for treatment, such as dexamethasone. Several approved drugs are being studied for their utility in reducing the severity of SARS-CoV-2 infections, including Soliris by Alexion Pharmaceuticals Inc., Jakafi by Incyte Corporation, and Kevzara by Sanofi S.A./Regeneron Pharmaceuticals, Inc. There are significant efforts globally to develop both therapeutic and prophylactic drug candidates. Several companies are focused on antibody treatments, including Amgen Inc. (together with Adaptive Biotechnologies Corporation), Abcellera Biologics, Inc. (together with Eli Lilly and Company), Regeneron Pharmaceuticals, Inc. and Vir Biotechnology, Inc. (together with GSK, Biogen Inc. and WuXi Biologics Ltd.). Numerous efforts are underway to develop vaccines against SARS-CoV-2, including by Altimmune, Inc., AstraZeneca PLC (together with Oxford University), BioNTech SE (together with Pfizer Inc.), GSK (together with Sanofi S.A.), Heat Biologics, Inc., Inovio Pharmaceuticals, Inc., Johnson & Johnson, Moderna, Inc., Novavax, Inc., and Vaxart, Inc. The recent authorization of efficacious vaccines, if widely adopted, could reduce or eliminate the market for therapies to treat COVID-19.

License agreements and collaborations

License agreement with Emory University

In June 2018, we entered into the Emory License Agreement. In June 2020, we amended the Emory License Agreement (the Emory Amendment). Under the Emory License Agreement, Emory granted us a worldwide, sublicenseable 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. Beginning in June 2022, the license to such patents will become 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 Aligos 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. We have the right to sublicense rights licensed under the Emory License Agreement, provided that the sublicense agreement must be in compliance and consistent with the terms of the Emory License Agreement.

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."

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.

Pursuant to the Emory License Agreement, we paid an upfront fee of $290,000 to Emory, reimbursed Emory for past patent expenses, and issued a convertible promissory note with a principal amount of $600,000 to Emory. In August 2018, the convertible promissory note was cancelled and converted into 64,980 shares of Series A convertible preferred stock. We paid Emory an additional $150,000 in connection with the Emory Amendment. Additionally, we agreed to pay Emory up to an aggregate of $125 million upon the achievement of specified development, regulatory, and commercial milestones, and all ongoing patent costs. 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. Our obligation to pay royalties expires on a product-by-product and country-by-country basis upon the later of ten years after the date of first commercial sale of such product in such country and the expiration of the last-to-expire licensed patent right covering such product in such country. Lastly, if we sublicense any of the licensed patent rights, we are required to pay Emory a percentage of any license issuance or upfront fees we might receive, with the percent decreasing if we sublicense after the first anniversary and third anniversary of the effective date of the Emory License Agreement from a mid-double digit to a mid-single digit percentage rate. To date we have not granted any sublicense.

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.

License agreement with Luxna Biotech Co., Ltd.

In December 2018, we entered into the Luxna Agreement. Under the Luxna Agreement, Luxna granted us an exclusive, worldwide, sublicenseable license under certain of Luxna's intellectual property rights to research, develop, make, have made, and commercialize for all therapeutic and prophylactic uses, (i) products containing oligonucleotides targeting the hepatitis B virus genome, (ii) products containing certain oligonucleotides targeting up to three genes which contribute to NASH, which we may select at any time during the first eight years of the term, to the extent not licensed to a third party, and (iii) products containing oligonucleotides targeting up to three genes which contribute to HCC, which we may select at any time during the first three years of the term. During the first three years of the term, Luxna will not grant rights to any third parties under the licensed patents to research or develop any compounds or products targeting an HCC gene target. As of June 30, 2020, we have identified two HCC gene targets and two NASH gene targets for the exclusive license. In addition, we have a right of first refusal for any additional xeno-nucleic acid (XNA) and/or gapmer modifications that are not claimed by the licensed patents that Luxna controls. If we exercise this right, we and Luxna will use good faith, diligent efforts to negotiate additional commercially reasonable financial terms for such additional modifications. We are obligated to use commercially reasonable efforts to pursue the research, development and commercialization of the licensed products throughout the term. We have the right to sublicense our licensed rights provided that the sublicense agreement must be in compliance and consistent with the terms of the Luxna Agreement.

Additionally, pursuant to an April 2020 amendment to the Luxna Agreement (the Luxna Amendment), we obtained an exclusive, worldwide license under the licensed patents to research, develop, make, have made, and commercialize products containing oligonucleotides targeting three families of viruses: orthomyxoviridae, paramyxoviridae, and coronaviridae (a family which includes SARS-CoV-2).

Pursuant to the Luxna Agreement, we paid Luxna an upfront fee of $600,000 and pursuant to the Luxna Amendment, we paid Luxna an additional $200,000. Additionally, we agreed to pay Luxna up to an aggregate of $55.5 million upon achievement of specified development, regulatory, and commercial milestones. We also agreed to pay Luxna tiered royalties on worldwide annual net sales of licensed products, on a product-by-product basis, spanning a range of rates within low-single digit percentages, on a quarterly basis. With respect to each licensed product, our obligation to pay royalties will continue until the expiration of the last-to-expire licensed patent covering such licensed product in any country.

Luxna's rights to the intellectual property subject to the Luxna Agreement stem from an exclusive license (the Luxna-Osaka Agreement) from Osaka University (Osaka) for certain rights pertaining to modifications of XNA and other gapmer technologies covered by the licensed patents. Separately, Osaka granted rights to certain third parties in connection with the licensed patents, such as rights to amido-bridged nucleic acid (AmNA) for specific indications including NASH, rights to manufacture reagents containing the modifications of AmNA and rights to use specified genes. Such rights are not included in the scope of rights granted to us under the Luxna Agreement and the Luxna Agreement does not prevent Osaka from using any of the licensed rights under the Luxna Agreement for its non-commercial research purposes relating to the modifications of XNA.

Ownership of any new inventions arising out of our activities under the Luxna Agreement will follow the inventorship laws of the United States. Luxna retains the responsibility for the prosecution and maintenance of the licensed patents, provided that Luxna consider our comments and suggestions in connection therewith. We retain step-in rights should Luxna decide to no longer prosecute or maintain any licensed patents under the Luxna Agreement. We have the first right, but not the obligation, at our sole expense to enforce the licensed patents. In connection with any infringement suit, neither party can enter into a settlement without the prior written consent of the other.

The Luxna Agreement will expire upon expiration of the last-to-expire patent licensed to us under the agreement. We may terminate the Luxna Agreement at any time for convenience by providing Luxna with 90 days' written notice. In addition, we have agreed to terminate the Luxna Agreement if we make a final decision to cease research, development or commercialization of the licensed products. Either party may terminate the Luxna Agreement if the other party materially breaches the Luxna Agreement and fails to timely cure such breach. The Luxna Agreement will automatically terminate if we become bankrupt or insolvent.

We have agreed to indemnify Luxna and certain others under the Luxna 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 product, unless caused by such potential indemnitee's negligence.

License and Research Collaboration with Merck

In December 2020, we entered into an exclusive License and Research Collaboration Agreement with Merck under which Merck and Aligos will apply our oligonucleotide platform technology to discover, research, optimize and develop oligonucleotides directed against a NASH target and up to one additional liver-targeted cardiometabolic and/or fibroses target. Under the terms of the agreement, Aligos will receive an upfront payment from Merck as well as an additional payment after designation of a research plan for such an additional target. With respect to each collaboration target, Aligos will be eligible to receive up to $458 million in development and commercialization milestones as well as tiered royalties on net sales. We will be primarily responsible for designing, preparing and evaluating the oligonucleotide molecules and delivering optimized lead molecules, and Merck will be responsible for subsequent research, clinical development and commercialization efforts.

Merck has the right to terminate the License and Research Collaboration Agreement in its entirety or on a target-by-target basis at any time by giving us 90 days' written notice. From the time Merck assumes responsibility for subsequent research until achievement of a certain regulatory event, we may terminate the License and Research Collaboration Agreement if Merck ceases all development activities for a specified period and fails to resume such activities within a reasonable time after we provide them with a resumption notice. Either party may terminate the License and Research Collaboration Agreement upon the other party's uncured material breach or insolvency. Upon termination for any reason other than our material breach, we will have the right to acquire from Merck the products and compounds being developed or commercialized by Merck under the License and Research Collaboration Agreement. Good faith negotiations between the Company and Merck would be performed to enact a transition plan.

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, 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, Luxna and AM Chemicals, which are further described below. As of December 31, 2020, we own 13 U.S. non-provisional patent applications, 35 U.S. provisional patent applications (excluding any non-expired U.S. provisional applications to which priority has already been claimed), 13 PCT applications and 14 foreign patent applications, including pending applications in Argentina and Taiwan. The projected expiration date of any patent that issues from our non-provisional U.S. and foreign applications is between 2039 to 2040, excluding any additional term from a potential patent term extension and/or patent term adjustment.

For our drug candidates, although we have filed and licensed certain patent applications and we generally intend to pursue patent protection covering compositions of matter, methods of making, and methods of use, as of December 31, 2020, we do not own or license any issued patents directed to our ALG-010133, ALG-000184, ALG-020572, ALG-125097 and ALG-055009 drug candidates.

Licensed intellectual property

Emory University

We have licensed the exclusive rights to a patent estate from Emory in the CAM chemical space, consisting of one issued U.S. patent, one pending nonprovisional U.S. patent application as well as 1 PCT patent application, 2 issued foreign patents and 21 foreign patent applications. The issued U.S. patent has an expected expiration of March 2037, excluding any potential patent term extension or adjustment.

Luxna

We have licensed the right to a patent estate from Luxna in the oligonucleotide chemical space, consisting of 3 issued U.S. patents, 2 nonprovisional U.S. patent applications and 14 issued foreign patents and 6 foreign patent applications. We have exclusive rights to use this technology in the development of drug candidates for CHB, as well as rights to certain named targets in NASH and respiratory diseases, including coronaviruses. These U.S. patents have an expected expiration between October 2030 and February 2035, excluding any potential patent term extension or adjustment.

AM Chemicals

We have licensed the exclusive right to the use of specific constructs encompassed by the patent estate from AM Chemicals, including 1 issued U.S. patent, 1 U.S. non-provisional patent application and 2 foreign patent applications. The issued U.S. patent has an expected expiration of July 2037. Any patent issuing from such non-provisional applications in this patent estate is projected to expire in July 2037, excluding any potential patent term extension or patent term adjustment.

Drug candidate intellectual property

Hepatitis B—ALG-010133 and additional potential drug candidates

We own a patent family that includes 5 applications pending across multiple jurisdictions (including the United States) and have claims directed to composition of matter, including ALG-010133 (our lead STOPS molecule), pharmaceutical composition and method of use. This patent family also includes claims directed to combination treatment with our lead molecule with other modes of action drugs and drug candidates directed against CHB. The U.S. application, if issued, is projected to expire in November 2039, excluding any potential patent term extension or adjustment.

Hepatitis B—ALG-000184 and additional potential drug candidates

We own a patent family that includes 3 applications pending across multiple jurisdictions (including the United States), and have claims directed to composition of matter, including ALG-000184 (our lead CAM molecule), pharmaceutical composition and method of use claims. This patent family also includes claims directed to combination treatment with our lead molecule with other modes of action drugs and drug candidates directed

against CHB. The U.S. application, if issued, is projected to expire in April 2040, excluding any potential patent term extension or adjustment.

Hepatitis B—ALG-020572 and additional potential drug candidates

We own a patent family that includes 3 patent applications pending across multiple jurisdictions (including the United States), and have claims to compositions of matter, including ALG-020572, our lead ASO candidate, and methods of use. This patent family also discloses combination therapies with our lead molecule. Any patent that issues from such non-provisional applications in this patent family is projected to expire in May 2040, excluding any potential patent term extension or patent term adjustment.

Hepatitis B—ALG-125755 and additional potential drug candidates

We own a patent family that includes 2 U.S. provisional application, and have claims to compositions of matter, including ALG-125755, our lead siRNA candidate, and methods of use. This patent family will also disclose combination therapies with our lead molecule. Any patent that issues from such non-provisional applications in this patent family is projected to expire in March 2041, excluding additional term from a potential patent term extension and/or patent term adjustment.

NASH—ALG-055009 and additional potential drug candidates

We own a patent family that includes 3 applications across multiple jurisdictions, and have claims to compositions of matter, including ALG-055009, our lead drug candidate for the treatment of NASH, and methods of use. This patent family also discloses combination therapies with our lead molecule. Any patent that issues from such non-provisional applications in this patent family is projected to expire in May 2040, excluding any potential patent term extension or patent term adjustment.

Discovery pipeline intellectual property

Hepatitis B

We own multiple families of applications that include claims to compositions of matter, pharmaceutical compositions and methods of use for the treatment of CHB with our additional drug candidates. This includes 4 U.S. non-provisional patent applications, 4 U.S. provisional patent applications, 5 PCT patent applications and 4 foreign patent applications in the small molecule space and 2 U.S. non-provisional patent applications, 1 U.S. provisional application, 2 PCT patent applications and 3 foreign patent applications in the oligonucleotide space. These patent families also disclose combination therapies with our drug candidates and other compounds for treating CHB. Any patent that issues from a non-provisional application in one of these patent families is projected to expire in 2040 to 2041, excluding any potential patent term extension or patent term adjustment.

NASH

We have filed 6 U.S. provisional applications that include claims to compositions of matter and methods of use with our additional drug candidates for the treatment of NASH. These U.S. provisional applications also disclose combination therapies with our drug candidates and other compounds for treating NASH. Any patent that issues from a non-provisional application claiming priority to this U.S. provisional application is projected to expire in 2041, excluding any potential patent term extension or patent term adjustment.

Coronaviruses

We have filed 13 provisional U.S. patent applications that include claims to compositions of matter, pharmaceutical compositions and methods of use for treating coronaviruses. This includes multiple applications covering both small molecule and oligonucleotide approaches. These patent families also include disclosure relating to combination therapy strategies for treating coronaviruses. Any patent that issues from a non-provisional patent application claiming priority to one or more of these U.S. provisional applications is projected to expire in 2041, excluding any potential patent term extension or patent term adjustment.

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 candidate 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, 2020. The trademark portfolio includes the marks ALIGOS and STOPS. The mark STOPS is registered in Australia and the EU and is pending in the United States and Japan. The mark ALIGOS is registered in the United States, the EU and Japan.

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 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 condition 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. 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 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. 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, in March 2010, the Affordable Care Act was enacted, which affected existing government healthcare programs and resulted in the development of new programs.

Among the Affordable Care Act's provisions of importance to the pharmaceutical industry, in addition to those otherwise described above, are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most branded and generic drugs,

respectively, and a cap on the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price (AMP);

- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals, including individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the Affordable Care Act. For example, the TCJA was enacted, which included a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the TCJA, the remaining provisions of the Affordable Care Act are invalid as well. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit ruled that that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. The U.S. Supreme Court is currently reviewing this case, although it is unclear how the Supreme Court will rule. It is also unclear how other efforts, if any, to challenge, repeal or replace the Affordable Care Act will impact the law.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013, and will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, unless additional Congressional action is taken. In addition, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives to control drug costs.

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 could apply to our operations or the operations of our partners. The Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), and regulations implemented thereunder, impose requirements relating to the privacy, security and transmission of individually identifiable health information on certain health care providers, health plans and health care clearinghouses, known as covered entities, as well as their business associates that perform certain services that involve creating, receiving, maintaining or transmitting individually identifiable health information for or on behalf of such covered entities. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, a complaint about privacy practices or an audit by U.S. Department of Health & Human Services (HHS), may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Further, entities that knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA may be subject to criminal penalties.

Even when HIPAA does not apply, according to the FTC, violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5 of the FTC Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. By way of example, California recently enacted the California Consumer Privacy Act (CCPA), which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling certain personal data of consumers or households. The CCPA requires covered companies to provide new disclosure to consumers about such companies' data collection, use and sharing practices, provide such consumers new ways to opt-out of certain sales or transfers of personal information, and provide consumers with additional causes of action. The CCPA became effective on January 1, 2020, and the California Attorney General may bring enforcement actions for violations beginning July 1, 2020. Further, the California Privacy Rights Act (CPRA) recently passed in California, which will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data privacy agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial conditions.

We also are or will become subject to privacy laws in the jurisdictions in which we sell or market our products or run clinical trials. For example, in the EU we are subject to the EU General Data Protection Regulation (GDPR) in relation to our collection, control, processing, and other use of personal data (i.e. data relating to an identifiable living individual). We process personal data in relation to participants in our clinical trials in the European Economic Area (EEA), including the health and medical information of these participants. The GDPR is directly applicable in each EU and EEA Member State, however, it provides that EU and EEA Member States may introduce further conditions, including limitations which could limit our ability to collect, use and share personal data (including health and medical information), or could cause our compliance costs to increase, ultimately having an adverse impact on our business. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and implement policies as part of its mandated privacy governance framework. It also requires data controllers to be transparent and disclose to data subjects (in a concise, intelligible and easily accessible form) how their personal information is to be used, imposes limitations on retention of personal data; defines pseudonymized (i.e., key-coded) data; introduces mandatory data breach notification

requirements; and sets higher standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities. We are also subject to EEA rules with respect to cross-border transfers of personal data out of the EEA. Recent legal developments in the EU have created complexity and uncertainty regarding transfers of personal data from the EEA to the United States. On July 16, 2020, the Court of Justice of the European Union (CJEU) invalidated the EU-US Privacy Shield Framework (the Privacy Shield) under which personal data could be transferred from the EEA to US entities who had self-certified under the Privacy Shield scheme. While the CJEU upheld the adequacy, subject to certain conditions, of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism), future regulatory guidance could result in changes to the use of standard contractual clauses. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the standard contractual clauses 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 and the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

We are subject to the supervision of local data protection authorities in those EU jurisdictions where we are subject to the GDPR, and we maintain an office in Belgium, which has its own set of stringent privacy and data protection laws and regulations. Fines for certain breaches of the GDPR are significant: up to the greater of €20 million or 4% of total global annual turnover. Further, from January 1, 2021, companies have to comply with the GDPR and also the United Kingdom GDPR (UK GDPR), which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. The relationship between the United Kingdom and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how United Kingdom data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the United Kingdom will be regulated in the long term. Currently there is a four to six-month grace period agreed in the EU and United Kingdom Trade and Cooperation Agreement, ending June 30, 2021 at the latest, whilst the parties discuss an adequacy decision. However, it is not clear whether (and when) an adequacy decision may be granted by the European Commission enabling data transfers from EU member states to the United Kingdom long term without additional measures. These changes may lead to additional compliance costs and could increase our overall risk. In addition to the foregoing, a breach of the GDPR or other applicable privacy and data protection laws and regulations could result in regulatory investigations, reputational damage, orders to cease / change our use of data, enforcement notices, or potential civil claims including class action type litigation.

Employees and human capital resources

As of December 31, 2020, we had 74 full-time employees, including 58 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 10-K, including our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. Many of the following risks and uncertainties are, and will be, exacerbated by the coronavirus pandemic (COVID-19) and any worsening of the global business and economic environment as a result. 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 biopharmaceutical 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, 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 biopharmaceutical 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 limited experience as a company and 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. Only two of our drug candidates, ALG-010133 and ALG-000184, are currently in clinical development.

Since inception, we have incurred significant net losses. Our net losses were $108.5 million for the year ended December 31, 2020 and $52.3 million for the year ended December 31, 2019. As of December 31, 2020, we had a total stockholders' equity of $220.0 million. We have funded our operations to date primarily with proceeds from the sale of common stock, preferred stock and convertible notes. 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 any clinical trials, including pivotal 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 expect to 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.

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;
- addressing any competing 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 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. As of December 31, 2020, we had cash, cash equivalents and investments of $243.5 million. In October 2020, we issued an aggregate of 3,569,630 shares of our Series B-2 redeemable convertible preferred stock in the second tranche of our Series B convertible preferred stock financing for aggregate proceeds to us of $40.0 million. In addition, we have received net proceeds of $151.4 million from the sale of an aggregate of 11,150,000 shares of our common stock on October 20, 2020 and on November 5, 2020 as part of our IPO. 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;
- 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.

We expect 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 investments will enable us to fund our operations for at least 12 months following the date of this report. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned. Moreover, it is particularly difficult to estimate with certainty our future expenses given the dynamic nature of our business, the COVID-19 pandemic and the macro-economic environment generally.

Our ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond our control. In particular, the COVID-19 pandemic continues to rapidly evolve and has already resulted in a significant disruption of global financial markets. If the disruption persists or deepens, 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.

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 Luxna Biotech Co., Ltd. (Luxna);
- 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, medical affairs 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;
- 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, including the current outbreak of COVID-19 and future coronavirus outbreaks, and in particular 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, including the current outbreak of COVID-19, which the World Health Organization declared a global pandemic and which has 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 implemented work-from-home policies for most of our employees. While modified from time to time since March 2020, the California state-wide order has no current expiration date, and Californians continue to be directed to stay at home except to go to an essential job or to shop for essential needs. The state-wide shelter order, the local shelter-in-place orders implemented by San Mateo County and any other San Francisco Bay Area counties, government-imposed quarantines and our 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 upticks in COVID-19 cases and other limitations on our ability to conduct our business in the ordinary course. Although we do not anticipate any impacts to our clinical programs, 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 COVID-19 or other 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. Although we do not anticipate any clinical supply issues or concerns for our planned clinical trials, restrictions resulting from the COVID-19 outbreak may disrupt our supply chain in the future and delay or limit our ability to obtain sufficient materials for our drug candidates.

In addition, our current clinical trial and planned clinical trials may be affected by the ongoing COVID-19 pandemic. Site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic, 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 COVID-19, may be delayed or disrupted, which may adversely impact our clinical trial operations.

In addition, the global COVID-19 pandemic has adversely affected, and 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, while the duration and severity of the effects of COVID-19 may be difficult to assess or predict, 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 or market correction resulting from the COVID-19 pandemic could materially adversely affect the value of our common stock.

Risks related to product development and regulatory process

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 clinical development efforts across our drug candidates are in an early stage. In August 2020 and October 2020, we initiated clinical trials for our most advanced drug candidates, ALG-010133 and ALG-000184, respectively, in New Zealand. 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. 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.

As an organization, we have not yet completed any clinical trials for any of our drug candidates. Each of our lead drug candidates, ALG-010133 and ALG-00184, is currently being evaluated in Phase 1 clinical trials in New Zealand and has been approved to commence Phase 1 clinical trials in Hong Kong and Moldova. 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 will depend 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), 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 have two drug candidates being evaluated in Phase 1 clinical trials in New Zealand, ALG-010133 and ALG-000184, which candidates have also been approved to commence Phase 1 clinical trials in Hong Kong and Moldova. The rest of our programs are in nonclinical research or earlier stages of development, including our other chronic hepatitis B (CHB) drug candidates, our nonalcoholic steatohepatitis (NASH) drug candidate 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;
- delays due to the COVID-19 pandemic, including due to reduced workforce productivity as a result of our implementation of a temporary work-from-home policy or illness among personnel, or due to delays at our third-party contract research organizations throughout the world for similar reasons or due to restrictions imposed by applicable governmental authorities; and
- delays due to other global-scale potentially catastrophic events, including other pandemics, 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 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.

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, including the current COVID-19 pandemic and future outbreaks of the disease.

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 a clinical trial for each of ALG-010133 and ALG-000184 in New Zealand and each of such candidates has been approved to commence clinical trials in Hong Kong and Moldova. We may also in the future conduct clinical trials for ALG-010133, ALG-00184 and other drug candidates in other countries and territories, including South Korea, the United Kingdom, and China, 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, the clinical trial sites for our current and future planned drug trials, including for ALG-010133 and ALG-000184, may be affected by the COVID-19 outbreak due to prioritization of hospital resources toward COVID-19 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 are located in countries affected by COVID-19, and, should they experience disruptions such as temporary closures or suspension of services, we would likely experience delays in advancing these trials.

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.

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 NASH is at an early stage and we may be unable to produce a therapy that successfully treats NASH. Even if successful, we may be unable to obtain regulatory approval for and successfully commercialize our drug candidates.

We have invested, and will continue to invest, a significant portion of our time and financial resources in the pursuit of a treatment for NASH. If we cannot successfully develop, obtain regulatory approval for and commercialize our drug candidates for the treatment of NASH, our business may be harmed. The mechanism of action of our NASH drug candidates is complex, and we do not know the degree to which it will translate into a therapeutic benefit, if any, in NASH 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 NASH.

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 NASH or any other applicable indication. Also, if we are able to obtain accelerated approval of our drug candidates based on a liver biopsy endpoint, we may be required to conduct a post-approval clinical outcomes trial 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 NASH, our drug candidates will likely compete with products that may be approved for the treatment of NASH 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 potential NASH treatments.

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

In response to the recent outbreak of COVID-19, the disease caused by the virus SARS-CoV-2, we are pursuing various potential therapies to address the disease, including protease inhibitors and oligonucleotides. Our identification and development of these potential therapies 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 (the KU Leuven Agreement) with Katholieke Universiteit Leuven (KU Leuven) under which we are collaborating with KU Leuven's Rega Institute for Medical Research, as well as its Centre for Drug Design and Discovery, to research, develop, manufacture and commercialize potential protease inhibitors for the treatment of coronaviruses, including SARS-CoV-2. We are in the earliest stages of our collaboration under the KU Leuven Agreement. The KU Leuven Agreement may 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.

We are also committing significant financial resources and personnel to the development of potential therapies for COVID-19, which may cause delays in or otherwise negatively impact our other development programs, despite uncertainties surrounding the longevity and extent of COVID-19 as a global health concern. 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, and Moderna mRNA-1273 COVID-19 vaccines have been authorized for

emergency use and are in the process of being widely being 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. Further, other therapies that are more affordable than our potential therapies may be used to treat COVID-19, including existing generic drugs, which could also hurt the funding of and demand for our potential therapies. In addition to BioNTech SE (together with Pfizer Inc.), Moderna, Inc. and Janssen Pharmaceutical Companies of Johnson & Johnson, there are efforts by several other public and private entities to develop a therapy or vaccine for COVID-19, including Alexion Pharmaceuticals Inc., Atea Pharmaceuticals, Inc. (together with Roche), Incyte Corporation, Sanofi S.A., Regeneron Pharmaceuticals, Inc., Amgen Inc. (together with Adaptive Biotechnologies Corporation), Abcellera Biologics, Inc. (together with Eli Lilly and Company), Vir Biotechnology, Inc. (together with Alnylam Pharmaceuticals, GSK, Biogen Inc. and WuXi Biologics Ltd.), Altimmune, Inc., AstraZeneca PLC (together with Oxford University), GlaxoSmithKline (GSK) (together with Sanofi S.A.), Heat Biologics, Inc., Inovio Pharmaceuticals, Inc., Merck (together with Ridgeback Bio), Novavax, Inc., Regeneron Pharmaceuticals Inc., Synairgen, Takeda, and Vaxart, Inc., many of which are further along in the development process than we are. 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 regulatory pathways for our drug candidates targeting SARS-CoV-2, the virus that causes COVID-19, are continually evolving, and may result in unexpected or unforeseen challenges.

Our drug candidates targeting SARS-CoV-2, the virus that causes COVID-19, are in the early discovery stages. The speed at which companies and institutions are acting to create and test many therapeutics and vaccines for COVID-19 is unusually rapid, and evolving or changing plans or priorities within the FDA, including changes based on new knowledge of COVID-19 and how the disease affects the human body, may significantly affect the regulatory timelines for our COVID-19 drug candidates. Results from our continued development and planned clinical trials may raise new questions and require us to redesign proposed nonclinical studies and clinical trials, including revising proposed endpoints or adding new clinical trial sites or cohorts of subjects, with minimal lead time.

The FDA has the authority to grant an Emergency Use Authorization (EUA) to allow unapproved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when, based on the totality of scientific evidence, there is evidence of effectiveness of the medical product, and there are no adequate, approved, and available alternatives. For instance, the FDA granted an EUR for each of the COVID-19 vaccines developed by Pfizer/BioNTech, Moderna and Janssen Pharmaceutical Companies of Johnson & Johnson. Depending on the outcomes of our planned nonclinical and initial clinical testing for our proposed COVID-19 therapies, we may seek an EUA for one or more of our drug candidates for use in the ongoing public health

emergency, which would permit us to commercialize a drug candidate prior to FDA approval of an NDA. However, commercialization under an EUA is permitted only during the underlying public health emergency (as declared by the Secretary of the Department of Health and Human Services), meaning that once the emergency declaration is terminated, we would be required to obtain NDA approval to continue marketing the product. Furthermore, the FDA may revoke an EUA based on a determination that the product no longer satisfies the criteria for issuance of an EUA—for example, if there is no longer evidence of effectiveness of the product or there are other adequate, approved alternatives. Accordingly, we cannot predict how long, if at all, an EUA for any of our drug candidates may remain in place. Any termination or revocation of an EUA (if any) for one of our drug candidates could adversely impact our business in a variety of ways, including if one of our COVID-19 drug candidates is not yet approved by the FDA and if we and our manufacturing partners have invested in the supply chain to provide one of our COVID-19 drug candidates under an EUA.

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, biopsies for future patient enrichment 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, or public health pandemics or epidemics or other business interruptions, including the current COVID-19 pandemic and future outbreaks of the virus.

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 entails additional cost and risks potential delay if the reformulated or otherwise altered drug candidate performs different 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 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 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:

- regulatory authorities 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 and expect to rely on third-party CROs or regulatory consultants to assist us in this process. 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. 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 nucleos(t)ide analogs including tenofovir and entecavir. 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. 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 current Good Manufacturing Practice, or cGMP, and Good Clinical Practice, or 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;
- 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.

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 (the EU) 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 are conducting our initial clinical trials for ALG-010133 and ALG-000184 in New Zealand and plan to conduct additional clinical trials in several other countries and territories within the Asia Pacific and/or Europe, including South Korea, Hong Kong, Moldova, the United Kingdom, and China, 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 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 and Belgium and intend to seek approval to market our drug candidates outside of the United States. We may also do so for future drug candidates. 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, trade barriers and regulatory requirements;
- 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 ongoing COVID-19 pandemic).

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 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, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform 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, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Relatedly, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020 the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission-critical inspections to resumption of all regulatory activities. The resumption of prioritized domestic inspections is dependent on the current COVID-19 data in a given state or county and the rules and guidelines established by state and local government. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to events such as the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly 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 COVID-19, HBV 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 NASH to be one of the most prevalent chronic liver diseases worldwide, however, our projections of the number of people who have NASH, 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 NASH is in early stages, and we cannot accurately predict the number of patients for whom treatment might be possible. NASH is often undiagnosed and may be left undiagnosed for a long time, partly because a definitive diagnosis of NASH is currently based on a histological assessment of a liver biopsy, which impairs the ability to easily identify patients. If improved diagnostic techniques for identifying NASH patients who will benefit from treatment are not developed, our market opportunity may be smaller than we currently anticipate. Further, if government authorities and third-party payors choose to limit coverage and reimbursement of our NASH 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 NASH drug candidate than we anticipate.

In addition, the number of people who have HBV, 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, more widespread use of vaccines or 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 NASH, and we would be subject to similar risks if we develop any of our drug candidates for use in combination with other drugs. This 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.

There are a number of companies developing or marketing treatments for CHB, including Roche Holding AG (Roche), Gilead, Bristol-Myers Squibb Company, Arbutus Biopharma Corporation, Dicerna Pharmaceuticals, Inc. (together with Roche), Ionis Pharmaceuticals, Inc. (together with GSK), Arrowhead Pharmaceuticals, Inc. (together with Janssen Pharmaceuticals Company (Janssen)), Vir Biotechnology, Inc. (together with Alnylam Pharmaceuticals, Inc.), Johnson & Johnson, Assembly Biosciences Inc., Enanta Pharmaceuticals, Altimmune, Inc., GSK, Janssen, Transgene SA, Dynavax Technologies, Inc., Merck and Replicor, Inc.

There are also companies developing or marketing treatments or vaccines for COVID-19, including Soliris by Alexion Pharmaceuticals Inc., Atea Pharmaceuticals, Inc. (together with Roche), Jakafi by Incyte Corporation, Kevzara by Sanofi S.A./Regeneron Pharmaceuticals, Inc., Amgen Inc. (together with Adaptive Biotechnologies Corporation), Abcellera Biologics, Inc. (together with Eli Lilly and Company), Vir Biotechnology, Inc. (together with GSK, Biogen Inc. and WuXi Biologics Ltd.), Altimmune, Inc., AstraZeneca PLC (together with Oxford University), BioNTech SE (together with Pfizer Inc.), GlaxoSmithKline plc (GSK) (together with Sanofi S.A.), Heat Biologics, Inc., Inovio Pharmaceuticals, Inc., Johnson & Johnson, Moderna, Inc., Novavax, Inc., Regeneron Pharmaceuticals Inc., and Vaxart, Inc. For example, BioNTech SE (together with Pfizer Inc.), Janssen Pharmaceutical Companies of Johnson & Johnson and Moderna Inc. have developed COVID-19 vaccines that have received authorization for emergency use and are being widely administered which may reduce or eliminate the need for our potential COVID therapies to treat the disease and therefore negatively impact the commercial opportunity therefor.

Furthermore, there are companies developing or marketing treatments for NASH, including AbbVie, Inc., AstraZeneca PLC/MedImmune LLC, Bristol-Myers Squibb Company, Eli Lilly and Company, FronThera US Pharmaceuticals LLC, Janssen, Merck, Novartis Pharmaceuticals Corporation (together with Pfizer, Inc.), Novo Nordisk A/S, Pfizer Inc., Roche, Sanofi S.A., Takeda Pharmaceutical Company Limited (together with HemoShear Therapeutics, LLC), 89bio, Inc., Akero Therapeutics, Inc., Blade Therapeutics, Inc., Cirius Therapeutics, Inc., Enanta Pharmaceuticals, Inc., Galectin Therapeutics Inc., Galmed Pharmaceuticals Ltd., Genfit SA, Gilead, Intercept Pharmaceuticals, Inc., Inventiva Pharma SA, Madrigal Pharmaceuticals, Inc., MediciNova, Inc., NGM Biopharmaceuticals, Inc., Pliant Therapeutics, Inc. (together with Novartis), Terns Pharmaceuticals, Inc. and Viking Therapeutics, Inc.

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 Federal Food, Drug, and Cosmetic Act (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 imports of drugs from countries where they may be sold at lower prices than in the United States. 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. In addition, we are pursuing other drug candidates for viral diseases. 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 risk/benefit profiles through Phase 1 clinical trials of our drug candidates, ALG-010133 and ALG-000184. 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 NASH. 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. 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 seek Orphan Drug Designation for drug candidates we develop, and we may be unsuccessful or may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for market exclusivity.

As part of our business strategy, we may seek Orphan Drug Designation for any drug candidates we develop, and we may be unsuccessful in obtaining such designation. Regulatory authorities in some jurisdictions, including the United States and the EU, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, Orphan Drug Designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers.

Similarly, in the EU, the European Commission grants Orphan Drug Designation after receiving the opinion of the EMA Committee for Orphan Medicinal Products on an Orphan Drug Designation application. Orphan Drug Designation is intended to promote the development of drugs that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than 5 in 10,000 persons in Europe and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for drugs intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in Europe would be sufficient to justify the necessary investment in developing the drug. In Europe, Orphan Drug Designation entitles a party to a number of incentives, such as protocol assistance and scientific advice specifically for designated orphan medicines, and potential fee reductions depending on the status of the sponsor.

Generally, if a drug with an Orphan Drug Designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same drug and indication for that time period, except in limited circumstances. The applicable period is seven years in the United States and ten years in the EU. The EU exclusivity period can be reduced to six years if a drug no longer meets the criteria for Orphan Drug Designation or if the drug is sufficiently profitable such that market exclusivity is no longer justified.

Even if we obtain orphan drug exclusivity for a drug candidate, that exclusivity may not effectively protect the drug candidate from competition because different therapies can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, 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. Moreover, orphan drug 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 quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug candidate nor gives the drug candidate any advantage in the regulatory review or approval process. While we may seek Orphan Drug Designation for applicable indications for our current and any future drug candidates, we may never receive such designations. Even if we do receive such designations, there is no guarantee that we will enjoy the benefits of those designations.

We may be required to make significant payments under our license agreements with Emory University and Luxna Biotech Co., Ltd.

We entered into a License Agreement with Emory in June 2018 (the Emory License Agreement), and a License Agreement with Luxna in December 2018 and an amendment in April 2020 (as amended, the Luxna Agreement). Under the Emory License Agreement and Luxna Agreement, we are subject to significant obligations, including milestone payments, royalty payments, and certain other agreed-to costs. For more information regarding our license agreements, please see the section titled “Business—License agreements and collaborations” of this report. If these payments become due under the terms of either the Emory University License Agreement or Luxna Agreement, 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.

Healthcare legislative reform measures 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 initiatives to contain healthcare costs. For example, in March 2010, the Affordable Care Act (the ACA) was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The ACA, among other things, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs being covered under Medicare Part D.

Since its enactment, there have been judicial, executive and Congressional challenges to the ACA. By way of example, the Tax Cuts and Jobs Act of 2017 (the TCJA) was signed into law, which included a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year, commonly referred to as the individual mandate. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the TCJA. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit ruled that that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing this case, although it is unclear how the Supreme Court will rule. It is also unclear how other efforts, if any, to challenge, repeal or replace the ACA will impact the ACA or our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, unless additional Congressional action is taken. In addition, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit 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 or complementary or companion diagnostics. For example, it is possible that additional governmental action will be taken to address the COVID-19 pandemic, which could impact our business in an as-yet unknown manner.

Additionally, there has been 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. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives to control drug costs. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payers.

Failure to comply with current or future federal, state and foreign laws and regulations and industry standards relating to privacy and data protection laws could lead to government enforcement actions, which could include civil or criminal penalties, private litigation, and/or adverse publicity and could negatively affect our operating results and business.

We and our partners may be subject to federal, state and foreign data privacy and security laws and regulations. Failure by us or our third-party vendors, collaborators, contractors and consultants to comply with any of these laws and regulations could result in notification obligations or enforcement actions against us, which could result in, among other things, fines, claims for damages by affected individuals, 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, and may be inconsistent from one jurisdiction to another. The interpretation and application of consumer, health-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 HIPAA, as amended by HITECH. 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. In addition, California recently enacted the CCPA, which became effective on January 1, 2020. The CCPA, among other things, requires new disclosures to California consumers and affords such consumers new abilities to access and delete their personal information, opt-out of certain sales of personal information and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase the frequency of data breach litigation. Further, the CPRA recently passed in California, which will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. In the event that we are subject to or affected by HIPAA, 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 Australia, where laws may in some cases be more stringent than the requirements in the United States. For example, in Europe, the GDPR went into effect in May 2018 and imposes strict requirements for the collection, storage, use, disclosure, transfer and other processing of the personal data of individuals within the EEA. The GDPR applies extra-territorially under certain circumstances and imposes stringent requirements on controllers and processors of personal data, including, for example, requirements to obtain consent or other legal bases from individuals to process their personal data, provide robust disclosures to individuals, accommodate a set of individual data rights, provide data security breach notifications within 72 hours after discovering the breach, limit retention of personal information and apply enhanced protections to health data and other special categories of personal data. The GDPR also applies to pseudonymized data, which is defined as "the processing of personal data in such a way that the data can no longer be attributed to a specific data subject without the use of additional information," and imposes additional obligations when we contract with third-party processors in connection with the processing of any personal data. The GDPR provides that EU and EEA member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data, which could limit our ability to use and share personal data, could cause our costs to increase and could harm our financial condition. Failure to comply with the requirements of the GDPR and the applicable national data protection laws of the EU and EEA member states may result in fines of up to €20 million or up to 4% of the total worldwide annual turnover of our preceding fiscal year, whichever is higher, and other administrative penalties. Further, from January 1, 2021, we have to comply with the GDPR and the UK GDPR, which, together, with the amended Data Protection Act 2018, retains the GDPR in UK national law, the latter regime having the ability to separately fine up to the greater of £17.5 million or 4% of global turnover. The relationship between the United Kingdom and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how United Kingdom data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the United Kingdom will be regulated in the long term. Currently there is a four to six-month grace period agreed in the EU and United Kingdom Trade and Cooperation Agreement, ending June 30, 2021 at the latest, whilst the parties discuss an adequacy decision. However, it is not clear whether (and when) an adequacy decision may be granted by the European Commission enabling data transfers from EU member states to the United Kingdom long term without additional measures. These changes may lead to additional costs and increase our overall risk exposure. Failure to comply with the GDPR and other countries' privacy or data security-related laws, rules or regulations could result in material penalties imposed by regulators, affect our compliance with contracts entered into with our collaborators and other third-party payors, and have an adverse effect on our business and financial condition.

The GDPR further prohibits, without an appropriate legal basis, the transfer of personal data to countries outside of the EEA, such as the United States, which are not considered by the European Commission to provide an adequate level of data protection. Recent legal developments in Europe have created complexity and uncertainty regarding transfers of personal data from the EEA to the United States. For example, on July 16, 2020, the Court of Justice of the European Union (CJEU) invalidated the EU-US Privacy Shield Framework (the Privacy Shield) under which personal data could be transferred from the EEA to United States entities that had self-certified under the Privacy Shield scheme. While the CJEU upheld the adequacy, subject to certain conditions, of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism), future regulatory guidance could result in changes to the use of standard contractual clauses.

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. Failure 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, private litigation, and/or adverse publicity and could negatively affect our operating results and business.

Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from cyber-attacks, computer hacks, theft, viruses, malicious software, phishing, employee error, denial-of-service attacks, unauthorized access and other security breaches that could jeopardize the performance of our software and computer systems, and could expose us to financial and reputational harm. 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. As a result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. 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. While we have not to our knowledge experienced any such material 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. 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 computer 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 incur liability and the development and commercialization of our future drug candidates could be delayed.

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. For example, we are collaborating with the Rega Institute and Centre for Drug Design and Discovery at KU Leuven with respect to potential protease inhibitors for the treatment of coronaviruses, including SARS-CoV-2, with Emory University with respect to certain aspects of our small molecule CHB program and with Merck with respect to the discovery, research and development of oligonucleotides against a NASH target. 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;
- 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 future 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 academic 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. 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 ALG-010133 and ALG-000184, 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, 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, or if they are negatively impacted by the COVID-19 pandemic, 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 have limited personnel with experience in drug manufacturing and 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.

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; and

- the possible termination or non-renewal of the agreement by the third party at a time that is costly or inconvenient for us.

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.

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 are located in countries affected by COVID-19, and should they experience disruptions, such as temporary closures or suspension of services, we would likely experience 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 future 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 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 sell, market and distribute any products for which we 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, 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;
- 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) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, such obligations will include payments and other transfers of value provided in the previous year to certain other healthcare professionals, including physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants and certified nurse-midwives;
- 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 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, 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 expect to do business 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 and maintain 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. We do not own any issued patents with respect to our programs, including our CHB and NASH programs, and we do not own or in-license any issued patents with claims that specifically recite our ALG-010133, ALG-000184, ALG-020572, ALG-125097 and ALG-055009 drug candidates, and we can provide no assurance that any of our 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. For example, there are certain patents and patent applications (and there may be other patents and patent applications) that are owned by third parties, including our competitors, that have (or may have) an earlier filing date, and could be determined to have an earlier priority date, than our patent applications relating to our STOPS candidate, ALG-010133. 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 product candidates. Failure to obtain 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 product candidates. We may not be able to obtain these licenses on acceptable or commercially reasonable terms, if at all, or these licenses may be non-exclusive, which could result in our competitors using the same intellectual property.

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. 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 of 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 preissuance 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.

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. In particular, we have in-licensed significant intellectual property rights from Emory and Luxna. 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 Luxna Agreement, we obtained a license from Luxna under patents relevant to certain aspects of our HBV programs as well as to various potential therapies, which we are pursuing to address SARS-CoV-2. Although we have review and comment rights regarding prosecution of patents that we license under the Luxna Agreement, Luxna retains ultimate decision-making control with respect to the prosecution of these patents. Additionally, under the Emory License Agreement, we obtained a license from Emory University under patents relevant to certain aspects of our small molecule CHB 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 Centre for Drug Design and Discovery 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, such as the Emory License Agreement or Luxna Agreement, the licensor may have the right to terminate the license. Under some of our in-license agreements, as a sublicensee, we may be obligated to comply with applicable requirements, limitations or obligations of our sublicensors to other third parties. For example, the Luxna Agreement includes rights that Luxna in-licensed from Osaka University (Osaka), which are in turn sublicensed to us. Prior to granting such rights to Luxna, Osaka granted certain rights to third parties and therefore the rights we in-license from Luxna are subject to such third-party rights. Although we understand that these rights granted to such third parties are for uses outside the scope of our business, license agreements are complex, subject to multiple interpretations and disputes may arise regarding scope of such licensed rights. Further, under the Luxna Agreement and other in-licenses under which we sublicense certain rights, we rely on Luxna and our other sublicensors to comply with their obligations under their upstream license agreements, where we may have no relationship with the original licensor of such rights. If our sublicensors fail to comply with their obligations under their upstream license agreements, and the upstream license agreements are consequently terminated, such termination may result in the termination of our sublicenses.

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 this report.

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. Beginning in June 2022, the license to such patents will become 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 this report. 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 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, ALG-125097 and ALG-010133. In the event that any of these patents were asserted against us, we believe that we would have defenses against any such action, including 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. 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. 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.

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 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. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents. 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.

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, including our Chief Executive Officer, Dr. Blatt, and our President, Dr. Beigelman. 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. 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 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 of December 31, 2020, we had 74 full-time employees, including 58 employees engaged in research and development. 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 substantially all 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 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 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 our initial clinical trials for ALG-010133 and ALG-000184 in New Zealand, an area also known for earthquakes. 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 ongoing COVID-19 pandemic, for example, has negatively affected the

stock market and investor sentiment and has resulted in significant volatility. 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;
- the COVID-19 pandemic; 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.

Prior to our initial public offering in October 2020, there was no public market for shares of our common stock and an active trading market for our shares may not be sustained. In the absence of an active trading market for our 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 an emerging growth company and a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the JOBS Act). For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, certain disclosure obligations regarding executive compensation and the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following the year of our IPO, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700.0 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to use the extended transition period for any other new or revised accounting standards during the period in which we remain an emerging growth company; however, we may adopt certain new or revised accounting standards early. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

Even after we no longer qualify as an emerging growth company, we may continue to qualify as a smaller reporting company, which would allow us to rely on certain reduced disclosure requirements, such as an exemption from providing selected financial data and executive compensation information. We are also exempt from the requirement to obtain an external audit on the effectiveness of internal control over financial reporting provided in Section 404(b) of the Sarbanes-Oxley Act. These exemptions and reduced disclosures due to our status as a smaller reporting company mean that our auditors do not review our internal controls over financial reporting and may make it harder for investors to analyze our results of operations and financial prospects.

We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions as an emerging growth company and a smaller reporting company. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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, 2020, our executive officers, directors and their affiliates beneficially own, in the aggregate, approximately 45.3% 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). 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. Entities affiliated with or managed by Baker Brothers Life Sciences, L.P. hold an aggregate of 3,092,338 shares of our non-voting common stock (in addition to any shares of voting common stock acquired by such entities). Upon written notice, these entities could convert a portion of their shares of non-voting common stock into up to an aggregate of 4.99% of our shares of common stock. Upon 61 days' prior written notice, these entities could convert all of their respective shares of non-voting common stock into shares of common stock, representing approximately 8.1% of the voting power of our outstanding common stock. 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. 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 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 after the lock-up and other legal restrictions on resale lapse, the market price of our common stock could decline.

As of the completion of our initial public offering (including the partial exercise by the underwriters of their option to purchase additional shares), we had outstanding a total of 38,117,910 shares of common stock. Of these shares, substantially all of the shares of our common stock sold in the initial public offering are freely tradable, without restriction, in the public market.

The lock-up agreements entered into in connection with our IPO will expire at the close of business on April 13, 2021. J.P. Morgan Securities LLC, Jefferies LLC and Piper Sandler & Co., in their sole discretion, may permit our equity holders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements. After the lock-up agreements expire, the shares of common stock will be eligible for sale in the public market. Approximately 14.5% of these additional shares are owned by directors, executive officers and other affiliates and will be subject to certain limitations of Rule 144 under the Securities Act.

In addition, approximately 6,932,561 shares of common stock that are either subject to outstanding options or reserved for future issuance under our equity incentive plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements 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 24.2 million of our total common stock and non-voting common stock (including 3,092,338 shares of non-voting common stock), are entitled to rights with respect to the registration of their shares under the Securities Act, subject to the lock-up agreements 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 an IRC Section 382 analysis in 2020 and determined there was an ownership change that resulted in Section 382 limitations. The ownership change limited our ability to utilize net operating losses against future taxable income but will not result in the expiration of any NOLs. We 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, in taxable years beginning after December 31, 2020, 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 will be required to report upon the effectiveness of our internal control over financial reporting beginning with the annual report for our fiscal year ending December 31, 2021. When we lose our status as an "emerging growth company," our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. 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. To comply with the requirements of being a reporting company under the Exchange Act, we will need to implement additional financial and management controls, reporting systems and procedures and hire additional accounting and finance staff, all of which will entail additional expense.

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 and convertible notes. We will be required to seek additional funding in the future and may to 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 economic 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. For example, the 2008 global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as the 2008 global financial crisis, 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 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 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.

The United Kingdom's withdrawal from the European Union may have a negative effect on global economic conditions, financial markets and our business.

Following a national referendum and enactment of legislation by the government of the United Kingdom, the United Kingdom formally withdrew from the European Union and ratified a trade and cooperation agreement governing its future relationship with the European Union. The agreement, which is being applied provisionally from January 1, 2021 until it is ratified by the European Parliament and the Council of the European Union, addresses trade, economic arrangements, law enforcement, judicial cooperation and a governance framework

including procedures for dispute resolution, among other things. Because the agreement merely sets forth a framework in many respects and will require complex additional bilateral negotiations between the United Kingdom and the European Union as both parties continue to work on the rules for implementation, significant political and economic uncertainty remains about how the precise terms of the relationship between the parties will differ from the terms before withdrawal.

These developments, or the perception that any related developments could occur, have had and may continue to have a material adverse effect on global economic conditions and financial markets, and may significantly reduce global market liquidity, restrict the ability of key market participants to operate in certain financial markets or restrict our access to capital. Any of these factors could have a material adverse effect on our business, financial condition and results of operations and reduce the price of our common stock.

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.

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. 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.

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.

Current or future 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 are incurring 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. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the Dodd-Frank Act) was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas, such as “say on pay” and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the pricing of

the IPO. We intend to take advantage of this legislation, but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. 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. 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 mix and level of earnings in a given taxing jurisdiction or our ownership or capital structures.

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. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution and, as a result, 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 2. Properties.

Our corporate headquarters are located in South San Francisco, California, where we lease and occupy approximately 39,000 square feet of office and laboratory space. The current term of our South San Francisco lease expires in March 2027, with an option to extend the term through March 2035.

We also have an office in Leuven, Belgium, where we lease and occupy approximately 5,400 square feet of office and laboratory space. The current term of our Leuven, Belgium lease expires in August 2023, with an option to extend the term through August 2028.

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, as of December 31, 2020, we were not a party to any litigation or legal proceedings that, in the opinion of our management, are probable to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources and other factors.

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 has been listed on The Nasdaq Global Select Market under the symbol "ALGS" since October 20, 2020. Prior to that date, there was no public trading market for our common stock.

Holders of Record

As of February 28, 2021, there were 99 holders of record of our common stock, which consist of 97 holders of record of our voting common stock and 2 holdings 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 2021 Annual Meeting of Stockholders, which will be filed with the SEC no later than 120 days after December 31, 2020.

Recent Sales of Unregistered Securities

From January 1, 2020 through December 31, 2020, we sold and issued the following unregistered securities:

1. In October 2020, we issued an aggregate of 3,569,630 shares of Series B-2 redeemable convertible preferred stock to 38 accredited investors at a price per share of $11.20563 for aggregate proceeds to us of $40 million.

2. We issued an aggregate of 120,702 shares of Series A redeemable convertible preferred stock common stock, at an exercise price of $9.3197 per share upon the exercise of warrants.

3. We granted stock options and stock awards to employees, directors and consultants covering an aggregate of 5,382,362 shares of common stock, at a weighted-average exercise price of $11.42 per share. Of these, options covering an aggregate of 6,472 shares were cancelled or forfeited without being exercised.

4. We sold an aggregate of 188,675 shares of common stock to employees, directors and consultants for cash consideration in the aggregate amount of $0.3 million pursuant to stock options and restricted stock awards.

No underwriters were involved in the foregoing sales of securities. The issuance described in paragraph (1) above was undertaken in reliance upon the exemption from registration requirements of Section 4(a)(2) of the Securities Act of 1933, as amended, including Rule 506 of the Securities Act. The recipients of these shares of common stock represented their intentions to acquire the shares for investment only and not with a view to or for sale in connection

with any distribution, and appropriate restrictions were set out in the applicable agreements issued in these transactions. All recipients had adequate access, through their relationships with us, to information about us. The issuances described in paragraphs (2)-(3) were undertaken in reliance upon the exemption from registration requirements Section 4(a)(2) of the Securities Act in that such sales and issuances did not involve a public offering or under Rule 701 promulgated under the Securities Act, in that they were offered and sold either pursuant to written compensatory plans or pursuant to a written contract relating to compensation, as provided by Rule 701.

Use of Proceeds.

On October 15, 2020, our registration statement on Form S-1 (File No. 333-249077) relating to our IPO of Common Stock became effective. The IPO closed on October 20, 2020, at which time we issued 10 million shares of common stock at a price to the public of $15.00 per share. We received net proceeds from the IPO of approximately $135.4 million, after deducting the underwriting discounts and commissions of $10.5 million and expenses of $4.1 million. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to our affiliates. On November 5, 2020, the underwriters of the IPO partially exercised their overallotment option by purchasing an additional 1,150,000 shares from the Company at the IPO price, resulting in an additional $16.0 million in net proceeds after deducting the underwriting discounts and commissions. J.P. Morgan Securities LLC, Jefferies LLC, Piper Sandler & Co. acted as joint book-running managers for the offering.

There has been no material change in the planned use of our net IPO proceeds as described in our Prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on October 19, 2020.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers.

None.

Item 6. Selected Financial Data.

You should read the selected historical consolidated financial data below in conjunction with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the audited consolidated financial statements included elsewhere in this report. The selected consolidated financial data included in this section are not intended to replace the consolidated financial statements included elsewhere in this Annual Report on Form 10-K. We derived the selected consolidated statements of operations data for the years ended December 31, 2020, and 2019 and the selected consolidated balance sheet data at December 31, 2020 and 2019 from our audited consolidated financial statements included elsewhere in this report on Form 10-K. Our historical results are not necessarily indicative of the results that may be expected in the future. We refer to the year ended December 31, 2020 as "Fiscal 2020" and the year ended December 31, 2019 as "Fiscal 2019."

(in thousands, except share and per share data)	Fiscal 2020	Fiscal 2019
Consolidated Statements of Operations Data:		
Operating expenses:(1)		
Research and development	$ 79,890	$ 44,038
General and administrative	17,944	10,005
Total operating expenses	97,834	54,043
Loss from operations	(97,834)	(54,043)
Interest and other income (expense), net:		
Interest income, net	1,256	1,562
Other (loss) income, net	(11,804)	302
Total interest and other income (expense), net	(10,548)	1,864
Loss before provision for income taxes	(108,382)	(52,179)
Income tax expense	(161)	(85)
Net loss	$ (108,543)	$ (52,264)
Net loss per share:(2)(3)		
Basic and diluted	$ (10.87)	$ (26.04)
Weighted-average number of shares used in computing net loss per share:(2)(3)		
Weighted-average number of shares	9,988,191	2,007,173

(1) Includes stock-based compensation as follows (in thousands):

Research and development	$ 1,041	$ 462
General and administrative	1,934	290
Total	$ 2,975	$ 752

(2) See Note 15 to our audited consolidated financial statements for an explanation of the calculations of our basic and diluted net loss per share, respectively.

(3) All share and per share amounts set forth in the table above have been adjusted to give retrospective effect to the 1-for-9.3197 reverse stock split effected on October 9, 2020.

(in thousands)	Fiscal 2020	Fiscal 2019
Consolidated Balance Sheet Data:		
Cash, cash equivalents and investments	$ 243,513	$ 127,682
Working capital	219,743	106,408
Total assets	265,302	146,520
Current liabilities	30,274	13,818
Derivative liabilities	0	461
Convertible preferred stock liabilities	0	3,174
Operating lease liabilities, net of current portion	10,371	11,701
Redeemable convertible preferred stock	0	182,079
Accumulated deficit	(174,740)	(66,197)
Total stockholders' equity (deficit)	220,039	(64,891)

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 biopharmaceutical company currently focused on developing novel therapeutics to address unmet medical needs in viral and liver diseases. We utilize our proprietary oligonucleotide and small molecule platforms to develop pharmacologically optimized drug candidates for use in combination regimens designed to achieve improved treatment outcomes. Our lead effort is to develop a functional cure for Chronic Hepatitis B (CHB), which often results in other life-threatening conditions such as cirrhosis, end-stage liver disease (ESLD) and the most common form of liver cancer, hepatocellular carcinoma (HCC). The most widely used treatment for CHB, nucleos(t)ide analogs, suppresses viral replication but only achieves low rates of functional cure and often requires long-term administration. To address this issue, we have developed a portfolio of differentiated drug candidates for CHB, including an S-antigen Transport-inhibiting Oligonucleotide Polymers (STOPS) molecule, a small molecule Capsid Assembly Modulator (CAM), and oligonucleotides (ASO and siRNA), each of which is designed against clinically validated targets in the Hepatitis B Virus (HBV) life cycle. We believe that combination regimens utilizing our portfolio of CHB drug candidates may lead to higher rates of functional cure. Phase 1 proof of concept trials evaluating the properties of our STOPS molecule and CAM are ongoing in New Zealand and each of such candidates has been approved to commence clinical trials in Hong Kong and Moldova. We may also in the future conduct clinical trials for our STOPS molecule and CAM and other drug candidates in other countries and territories, including South Korea, the United Kingdom, and China. Our second area of focus is in non-alcoholic steatohepatitis (NASH), a complex, chronic liver disease where combination regimens may likewise prove beneficial. Our most advanced drug candidate for NASH is ALG-055009, a small molecule THR-ß agonist currently in nonclinical studies to enable a first-in-human clinical trial. We believe ALG-055009 has the potential to become an integral component of future combination regimens for NASH. Our third area of focus is to develop drug candidates with pan-coronavirus activity, including SARS-CoV-2, the virus responsible for COVID-19.

In October 2020, we completed our initial public offering (IPO) and issued 10,000,000 shares of our common stock at a price to the public of $15.00 per share for net proceeds of $135.4 million, after deducting underwriting discounts and commissions of $10.5 million and estimated expenses of $4.1 million. In connection with the IPO, all shares of Series A, Series B-1 and Series B-2 redeemable convertible preferred stock converted into 19,761,870 shares of voting common stock and 3,092,338 shares of non-voting common stock. On November 5, 2020, the underwriters of the IPO partially exercised their overallotment option by purchasing an additional 1,150,000 shares from the Company, resulting in an additional $16.0 million, after deducting underwriting discounts and commissions of $1.2 million. Prior to our IPO, we had received gross proceeds of approximately $186.9 million from sales of our preferred stock and our issuance of convertible debt.

We have incurred net losses and negative cash flows from operations in each year since our formation in February 2018. Our net losses were $108.5 million and $52.3 million for the years ended December 31, 2020 and December 31, 2019, respectively. We have had no revenue from product sales. As of December 31, 2020, we had an accumulated deficit of $174.7 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 salesforce and outsource a substantial portion of our clinical trial work to third parties.

Components of our results of operations

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 rely substantially on third parties to conduct our discovery activities, nonclinical studies, clinical trials and manufacturing. We primarily 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 with no alternative use;
- 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.

We expect our research and development costs to 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 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.

We expect that our general and administrative expenses will 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 also expect to 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 (expense) income, net

Interest and other (expense) income, net comprises interest (expense) income, net and other income (expense), net. Interest income (expense), net primarily consists of interest earned on our cash, cash equivalents, and short-term investments and interest expense related to our convertible preferred stock liability and warrants. Other (expense) income, net consists primarily of the change in fair value of our derivative liabilities.

We classified our warrants and the commitment to sell redeemable convertible preferred stock as liabilities on our consolidated balance sheets and recorded changes in fair value at each balance sheet date with the corresponding change recorded as other income (expense), net. Prior to our IPO, all outstanding warrants were exercised for the issuance of shares of common stock and, upon that exercise, such warrants were no longer outstanding. Similarly, the redeemable convertible preferred stock liability was converted to common stock.

We do not anticipate other (expense) income, net to fluctuate in the future due to the conversion of the redeemable convertible preferred stock liability prior to our IPO.

Provision for income taxes

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, 2020, we had federal net operating loss (NOL) carryforwards of $149.5 million available to reduce taxable income and these NOLs can be carried forward indefinitely. We have state NOL carryforwards of $153.0 million as of December 31, 2020, available to reduce future state taxable income, which expire at various dates beginning in 2038. As of December 31, 2020, we also had federal and state research and development tax credit carryforwards of $4.1 million and $2.1 million, respectively. The federal development tax credit carryforwards begin to expire in 2038, while the state development tax credit carryforwards can be carried forward indefinitely. 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 corporation’s ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We performed an IRC Section 382 analysis in 2020 and determined there was an ownership change that resulted in Section 382 limitations. The ownership change limited our ability to utilize net operating losses against future taxable income but will not result in the expiration of any NOLs. We 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, in taxable years beginning after December 31, 2020, 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.

Results of operations

Comparison of the years ended December 31, 2020 and 2019

The following table summarizes our operating expenses for the years ended December 31, 2020 and 2019:

Consolidated Statements of Operations Data: (in thousands)	Fiscal 2020	Fiscal 2019	Change $	Change %
Operating expenses:				
Research and development	$ 79,890	$ 44,038	$ 35,852	81%
General and administrative	17,944	10,005	7,939	79%
Total operating expenses	97,834	54,043	43,791	81%
Loss from operations	(97,834)	(54,043)	(43,791)	81%
Interest and other income (expense), net				
Interest income, net	1,256	1,562	(306)	(20)%
Other (loss) income, net	(11,804)	302	(12,106)	(4,009)%
Total interest and other income (expense), net	(10,548)	1,864	(12,412)	(666)%
Loss before provision for income taxes	(108,382)	(52,179)	(56,203)	108%
Income tax expense	(161)	(85)	(76)	89%
Net loss	$ (108,543)	$ (52,264)	$ (56,279)	108%

Research and development expenses

Research and development expenses were $79.9 million for the year ended December 31, 2020, compared to $44.0 million for the year ended December 31, 2019, an increase of $35.9 million. The increase was primarily due to an increase of $25.2 million in third-party expenses for our preclinical programs related to research activities as well as development costs associated with our STOPs molecule and CAM candidate. The increase also includes $8.4 million of additional employee-related costs, including a $0.6 million increase in stock-based compensation. Additionally, there is a $0.7 million of increased laboratory supplies and an increase of $0.5 million in depreciation and other expenses.

General and administrative expenses

General and administrative expenses were $17.9 million for the year ended December 31, 2020, compared to $10.0 million for the year ended December 31, 2019, an increase of $7.9 million. The increase was primarily due to $2.5 million increase in third party costs and a $2.6 million in increased personnel-related costs primarily due to general and administrative headcount to support the growth of our research and development organization, including an increase of $1.6 million of additional stock-based compensation expense. Additionally, there was a $1.0 million increase in consulting services due to our IPO, a $0.9 million increase in depreciation, and a $1.0 million increase in general costs due to D&O insurance and other public company expenses.

Interest income, net

Interest income, net decreased to $1.3 million for the year ended December 31, 2020 from $1.6 million for the year ended December 31, 2019, a decrease in $0.3 million, primarily due to the change in our portfolio of cash equivalents, short-term investments and long-term investments as well as general decrease in interest rates during the year ended December 31, 2020.

Other (loss) income, net

Other (loss) income, net decreased to a loss of $11.8 million for the year ended December 31, 2020 from income of $0.3 million for the year ended December 31, 2019, a decrease of $12.1 million, primarily due to the loss recognized on the net increase in fair value of both our redeemable convertible preferred stock liability and warrant liabilities prior to the IPO.

Liquidity and capital resources

Liquidity

We have incurred net losses since inception. We have not generated any revenue from product sales or any other sources and have incurred significant operating losses. 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 2020, we issued an aggregate of 3,569,630 shares of our Series B-2 redeemable convertible preferred stock in the second tranche of our Series B convertible preferred stock financing for aggregate proceeds of $40.0 million. On October 20, 2020, we closed our IPO and issued 10,000,000 shares of our common stock at a price to the public of $15.00 per share for net proceeds of $135.4 million, after deducting underwriting discounts and commissions of $10.5 million and expenses of $4.1 million. On November 5, 2020, the underwriters of the IPO partially exercised their overallotment option by purchasing an additional 1,150,000 shares from the Company, resulting in an additional $16.0 million, after deducting underwriting discounts and commissions of $1.2 million.

As of December 31, 2020, we had cash, cash equivalents and investments of $243.5 million.

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. We expect our expenses to increase substantially in connection with our ongoing clinical development activities related to our most advanced drug candidates, ALG-010133 and ALG-000184, which are still in the early stages of development, as well as our research and development of our other drug candidates within our CHB, NASH and coronavirus programs.

In addition, we are incurring additional costs associated with operating as a public company following our IPO in October 2020. 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 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 our transition to becoming a public company.

We believe that our existing cash, cash equivalents and investments will enable us to fund our planned operating expenses and capital expenditure requirements through at least the twelve months from the date of issuing

our financial statements. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. Furthermore, we may elect to raise additional capital on an opportunistic basis to fund operations.

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 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)	Fiscal 2020	Fiscal 2019
Net cash (used in) operating activities	$ (74,263)	$ (46,767)
Net cash provided by investing activities	32,755	6,791
Net cash provided by financing activities	192,348	85,532
Net increase in cash, cash equivalents, and restricted cash	$ 150,840	$ 45,556

Operating activities

During Fiscal 2020, operating activities used $74.3 million of cash, primarily resulting from our net loss of $108.5 million, partially offset by non-cash charges of $18.2 million and cash provided by changes in our operating assets and liabilities of $16.1 million. Net cash provided by changes in our operating assets and liabilities of $16.1 million consisted of an increase of $9.4 million in accounts payable and accrued liabilities, an increase of $12.0 million in deferred revenue, partially offset by an increase of $4.1 million in other current assets, and a decrease of $1.3 million in operating lease liability. The increase in accounts payable and accrued liabilities was largely due to an increase in external research and development costs. The increase in other assets was largely due to an increase in prepayments for services. The decrease in the operating lease liability was a result of payments made on outstanding lease obligations.

During Fiscal 2019, operating activities used $46.8 million of cash, primarily resulting from our net loss of $52.3 million, partially offset by non-cash charges of $1.8 million and cash provided by changes in our operating assets and liabilities of $3.7 million. Net cash provided by changes in our operating assets and liabilities of $3.7 million consisted of an increase of $4.6 million in accounts payable and accrued liabilities, an increase of $1.3 million in other current assets and a decrease of $0.3 million in other receivables. The increase in accounts payable and accrued liabilities was largely due to an increase in external research and development costs. The increase in other assets was largely due to an increase in prepayments for services. The decrease in other receivables was due to receipt of tax credits associated with income taxes paid by us on behalf of employees due to the exercise of restricted stock purchase rights.

Investing activities

During Fiscal 2020, investing activities provided $32.8 million of cash, consisting primarily of $80.1 million of investment maturities, offset by $45.3 million of investment purchases and $2.0 million of purchases of property and equipment.

During Fiscal 2019, investing activities provided $6.8 million of cash, consisting primarily of $80.0 million of short-term investment maturities, offset by $70.4 million of short-term and long-term investment purchases and $2.8 million of purchases of property and equipment.

Financing activities

During Fiscal 2020, net cash provided by financing activities was $192.3 million, consisting primarily of $155.5 million in net proceeds from the initial public offering and underwriters exercise of the overallotment option and $41.1 million in proceeds from the issuance of redeemable convertible preferred stock, partially offset by $4.1 million in payments of deferred offering costs.

During Fiscal 2019, net cash provided by financing activities was $85.5 million, consisting primarily of net proceeds of $85.0 million from our sales of shares of our Series B-1 convertible preferred stock, proceeds from the exercise of stock options of $0.5 million, and proceeds from the exercise of warrants to purchase shares of Series A convertible preferred stock of $0.1 million, partially offset by the payment of finance leases of $0.1 million.

Contractual obligations and commitments

The following table summarizes our commitments and contractual obligations as of December 31, 2020:

(in thousands)	Payments due by period				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating lease commitments	$ 17,103	$ 2,616	$ 5,396	$ 5,450	$ 3,642
Finance lease commitments	202	80	121	1	—
Total	17,305	$ 2,695	$ 5,517	$ 5,451	$ 3,642

The operating lease commitments noted in the table above represent operating lease obligations related to our currently occupied premises in South San Francisco, California, and Belgium. The finance lease commitments represent obligations related to vehicle leases for employees 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. These contracts do not contain any minimum purchase commitments, and as a result, are not included in the table of contractual obligations above. Payments due upon cancelation consist only of payments for services provided, expenses incurred up to the date of cancelation and de minimis termination penalties. Accordingly, we believe that our non-cancelable obligations under such agreements are not material and therefore have excluded these from the table above.

This table also does not include any milestone or royalty payments to third parties as the amounts, timing and likelihood of such payments are not known at this time. For a summary of certain milestone and royalty payment obligations under our agreements with Emory and Luxna, see the section titled “Business—License agreements and collaborations”.

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 policies and use of 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 costs

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 costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and include these costs in accrued liabilities in the consolidated balance sheets and within research and development expense in the consolidated statements of operations and comprehensive loss. These expenses are a significant component of our research and development costs. 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. 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.

We estimate the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. We make significant judgments and estimates in determining the accrued balance in each reporting period. 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.

Research and development expenses

We expense research and development costs as incurred. Acquired intangible assets are expensed as research and development if, at the time of payment, the technology is under development; is not approved by the U.S. Food and Drug Administration or other regulatory agencies for marketing; has not reached technical feasibility; or otherwise has no foreseeable alternative future use.

Research and development expenses also include costs incurred for internal and sponsored and collaborative research and development activities. Research and development expenses consist of salaries and benefits, including associated stock-based compensation, and laboratory supplies and facility costs, as well as fees paid to other entities that conduct certain research and development activities on our behalf. Costs associated with co-development activities performed under the various license and collaboration agreements are included in research and development expense as incurred.

Stock-based compensation

We measure stock options and other stock-based awards granted to employees, directors and other service providers based on their fair value on the date of grant and recognize compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. We recognize the impact of forfeitures on stock-based compensation expense as forfeitures occur. We apply the straight-line method of expense recognition to all awards with only service-based vesting conditions. During the year ended December 31, 2019, we did not grant any stock-based awards with performance-based vesting conditions. During the year ended December 31, 2020, we granted stock-based awards with performance-based vesting conditions. We recognize compensation expense related to these awards when it is determined that satisfying the performance conditions is probable using the accelerated attribution method over the requisite service period.

We estimate the fair value of each stock option grant on the date of grant using the Black-Scholes option-pricing model, which requires the use of highly subjective assumptions including:

- Expected term—We have opted to use the "simplified method" for estimating the expected term of plain-vanilla options, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option (generally 10 years). We estimated the expected term of

performance-based vesting options based on the expected life of the options to remain outstanding, which is estimated to be materially consistent with time-vesting options.

- Risk-free interest rate—The risk-free rate assumption is based on the U.S. Treasury instruments with maturities similar to the expected term of our stock options.
- Expected dividend—We have not issued any dividends and do not anticipate to issue dividends on our common stock. As a result, we have estimated the dividend yield to be zero.
- Expected volatility—Due to our limited operating history and a lack of company-specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The historical volatility data was computed using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards.

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 have elected to use the extended transition period for any new or revised accounting standards during the period in which we remain an EGC; however, we may adopt certain new or revised accounting standards early.

We will remain an EGC until the earliest to occur of: (1) the last day of the fiscal year in which we have more than $1.07 billion in annual revenue; (2) the date we qualify as a "large accelerated filer," with at least $700.0 million of equity securities held by non-affiliates; (3) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (4) the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

In addition, we intend to rely on the other exemptions and reduced reporting requirements provided to EGCs by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, as an EGC, we are not required to, among other things, (i) provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis) or (iv) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the Chief Executive Officer's compensation to median employee compensation.

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 $243.5 million as of December 31, 2020, 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 and long-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- and long-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 and long-term investments is subject to change as a result of potential changes in market interest rates, including changes resulting from the impact of the COVID-19 pandemic. As of December 31, 2020, 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 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 and Australian dollar, 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.

Index to Financial Statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and the 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, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, changes in redeemable convertible preferred stock and stockholders' equity (deficit) and cash flows for the years then ended, 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, 2020 and 2019, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These 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.

/s/ Ernst & Young LLP

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

Redwood City, California
March 23, 2021

Consolidated balance sheets
(In thousands, except share and per share data)

	December 31, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 220,383	$ 69,565
Restricted cash	560	538
Short-term investments	23,130	48,098
Other current assets	5,944	2,025
Total current assets	250,017	120,226
Operating lease right-of-use assets	6,901	7,570
Property and equipment, net	8,007	8,517
Other assets	377	188
Long-term investments	—	10,019
Total assets	$ 265,302	$ 146,520
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 3,313	$ 3,767
Accrued liabilities	16,564	7,599
Operating lease liabilities, current	2,442	2,378
Finance lease liabilities, current	64	74
Deferred Revenue from collaborations, current	7,891	—
Total current liabilities	30,274	13,818
Derivative liabilities	—	461
Convertible preferred stock liabilities	—	3,174
Operating lease liabilities, net of current portion	10,371	11,701
Finance lease liabilities, net of current portion	130	178
Long term liabilities	379	—
Deferred revenue from collaborations	4,109	—
Total liabilities	$ 45,263	$ 29,332
Commitments and contingencies (Note 13)		
Series A Redeemable Convertible Preferred Stock, $0.0001 par value; no shares and 101,962,864 shares authorized as of December 31, 2020 and 2019, respectively; no shares and 10,819,843 shares issued and outstanding as of December 31, 2020 and 2019, respectively; aggregate minimum liquidation preference of $100,838 at December 31, 2019	—	100,695
Series B-1 Redeemable Convertible Preferred Stock, $0.0001 par value; no shares and 77,764,055 shares authorized as of December 31, 2020 and 2019, respectively; no shares and 8,344,034 issued and outstanding as of December 31, 2020 and 2019, respectively; aggregate minimum liquidation preference of $85,005 at December 31, 2019	—	81,384
Preferred Stock, $0.0001 par value; 10,000,000 and no shares authorized as of December 31, 2020 and 2019, respectively; no shares and no shares issued and outstanding as of December 31, 2020 and 2019, respectively.	—	—
Stockholders' equity (deficit):		
Common stock, $0.0001 par value; 320,000,000 and 278,000,000 shares authorized as of December 31, 2020 and 2019, respectively; 36,606,247 and 3,927,803 shares issued and outstanding as of December 31, 2020 and 2019, respectively	4	—
Additional paid-in capital	394,963	1,421
Accumulated deficit	(174,740)	(66,197)
Accumulated other comprehensive income (loss)	(188)	(115)
Total stockholders' equity (deficit)	220,039	(64,891)
Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)	$ 265,302	$ 146,520

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, 2020	Year ended December 31, 2019
Operating expenses:		
Research and development	$ 79,890	$ 44,038
General and administrative	17,944	10,005
Total operating expenses	97,834	54,043
Loss from operations	(97,834)	(54,043)
Interest and other (expense) income, net	(10,548)	1,864
Loss before income tax expense	(108,382)	(52,179)
Income tax expense	(161)	(85)
Net loss	(108,543)	(52,264)
Other comprehensive (loss) and income:		
Loss on pension plans	(141)	(118)
Gain on available for sale investments	68	—
Comprehensive loss	$ (108,616)	$ (52,382)
Net loss per share, basic and diluted	$ (10.87)	$ (26.04)
Weighted average shares of common stock, basic and diluted	9,988,191	2,007,173

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

Consolidated statements of changes in redeemable convertible preferred stock and stockholders' equity (deficit)
(In thousands, except share and per share data)

	Series A Redeemable Convertible Preferred Stock		Series B-1 Redeemable Convertible Preferred Stock		Series B-2 Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Income (Loss)	(Deficit)
Balance as of December 31, 2018	10,806,432	100,519	—	—	—	—	3,036,574	—	182	(13,933)	3	(13,748)
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—	891,229	—	461	—	—	461
Vesting of early exercised common stock	—	—	—	—	—	—	—	—	26	—	—	26
Issuance of redeemable convertible Series B-1 preferred stock, net of $442 issuance costs and $3,174 of convertible preferred stock liabilities	—	—	8,344,034	81,384	—	—	—	—	—	—	—	—
Issuance of redeemable convertible Series A preferred stock upon exercise of warrants	13,411	176	—	—	—	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	752	—	—	752
Other comprehensive loss	—	—	—	—	—	—	—	—	—	—	(118)	(118)
Net loss	—	—	—	—	—	—	—	—	—	(52,264)	—	(52,264)
Balance as of December 31, 2019	10,819,843	$ 100,695	8,344,034	$ 81,384	—	$ —	3,927,803	$ —	$ 1,421	$ (66,197)	$ (115)	$ (64,891)
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—	188,594	0	261	—	—	261
Vesting of early exercised common stock	—	—	—	—	—	—	—	—	363	—	—	363
Issuance of Series A redeemable convertible stock upon exercise of Series A warrants	120,702	1,262	—	—	—	—	—	—	—	—	—	—
Issuance of redeemable convertible Series B-2 preferred stock	—	—	—	—	3,569,630	40,000	—	—	—	—	—	—
Reclassification of Series A warrant and convertible preferred stock liabilities to equity	—	620	—	—	—	14,560	—	—	—	—	—	—
Conversion of redeemable convertible preferred stock to common stock in connection with initial public offering	(10,940,545)	(102,577)	(8,344,034)	(81,384)	(3,569,630)	(54,560)	22,854,209	3	238,520	—	—	238,523
Issuance of common stock in connection with initial public offering, net of offering costs	—	—	—	—	—	—	10,000,000	1	139,499	—	—	139,500
Issuance of common stock in connection with Greenshoe initial public offering, net of offering costs	—	—	—	—	—	—	1,150,000	0	16,042	—	—	16,043
Costs related to the IPO and Greenshoe	—	—	—	—	—	—	—	—	(4,116)	—	—	(4,116)
Stock-based compensation	—	—	—	—	—	—	—	—	2,975	—	—	2,975
Other comprehensive loss	—	—	—	—	—	—	—	—	—	—	(73)	(73)
Net loss	—	—	—	—	—	—	—	—	—	(108,543)	—	(108,543)
Balance as of December 31, 2020	(0)	$ (0)	-	$ (0)	-	$ —	38,120,606	$ 4	$ 394,963	$ (174,740)	$ (188)	$ 220,039

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

Consolidated statements of cash flows
(In thousands)

(in thousands)	Year ended December 31, 2020	Year ended December 31, 2019
Cash flows from operating activities:		
Net loss	$ (108,543)	$ (52,264)
Adjustments to reconcile net loss to net cash used in operating activities:		
Accretion of discount on short term investments	234	(877)
Amortization of right of use assets	590	903
Depreciation expense	2,735	1,396
Stock-based compensation	2,975	752
Change in fair value of derivative liability	296	(348)
Change in fair value of convertible preferred stock liabilities	11,387	—
Changes in operating assets and liabilities:		
Other assets	(4,107)	(1,030)
Right of use assets	—	95
Accounts payable	(130)	385
Accrued liabilities	9,566	4,222
Operating lease liabilities	(1,266)	(1)
Deferred revenue	12,000	—
Net cash and cash equivalents used in operating activities	$ (74,263)	$ (46,767)
Cash flows from investing activities:		
Purchases of short-term investments	(32,097)	(60,404)
Purchases of long-term investments	(13,184)	(10,019)
Maturities of short-term investments	80,100	80,000
Purchases of property and equipment	(2,064)	(2,786)
Net cash and cash equivalents provided by investing activities	$ 32,755	$ 6,791
Cash flows from financing activities:		
Payments on finance lease	(58)	(43)
Payments on deferred offering costs	(4,116)	—
Payments of series B-1 issuance cost	(405)	—
Proceeds from exercise of warrants for series A redeemable convertible preferred stock	1,125	125
Proceeds from issuance of redeemable convertible preferred stock Series B-1, net of $37 issuance costs paid	40,000	84,963
Proceeds from exercise of stock options	260	487
Proceeds from issuance of common stock in initial public offering, net of underwriting commissions	139,500	—
Proceeds from issuance of common stock in connection with the overallotment option, net of costs	16,042	—
Net cash and cash equivalents provided by financing activities	$ 192,348	$ 85,532
Net increase in cash, cash equivalents, and restricted cash	$ 150,840	$ 45,556
Cash, cash equivalents, and restricted cash, beginning of period	70,103	24,547
Cash, cash equivalents, and restricted cash, end of period	$ 220,943	$ 70,103

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

Consolidated statements of cash flows
(In thousands)

	Year ended December 31, 2020	Year ended December 31, 2019
Reconciliation to amounts on the consolidated balance sheet:		
Cash and cash equivalents	$ 220,383	$ 69,565
Restricted cash	560	538
Total cash, cash equivalents, and restricted cash	$ 220,943	$ 70,103
Supplemental disclosures of cash flow information:		
Interest paid	$ —	6
Income taxes paid	$ —	$ 1
Supplemental disclosures of noncash financing and investing activities:		
Leasehold improvement directly paid by landlord	$ 79	$ 3,990
Liability in connection to the issuance of redeemable convertible preferred stock series B-1	$ 14,560	$ 3,174
Mark to market adjustments for available-for-sale investments	$ 68	$ —
Unpaid issuance cost in connection to the issuance of redeemable convertible preferred stock series B-1	$ —	$ 405
Equipment acquired through finance lease	$ —	$ 259
Vesting of early exercised options	$ 363	$ —
Acquisition of right-of-use asset through operating lease obligation	$ —	$ 252
PP&E Purchase still in Accounts Payable	$ 82	$ —
Change in pension obligation	$ (142)	$ —
Conversion of redeemable convertible preferred stock to common stock in connection with initial public offering	$ 238,522	$ —
Change in fair value of derivative liability upon exercise of warrants	$ 757	$ 51

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

Unless otherwise indicated, financial information except share and per share data, including dollar values stated in the text of the notes to financial statements, is expressed in dollars.

1. Organization

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, and together with Aligos-US and Aligos-Belgium being the Company or Aligos.

Aligos is a clinical-stage biopharmaceutical company developing novel therapeutics to address unmet medical needs in viral and liver diseases, including chronic hepatitis B and coronaviruses and therapeutics for nonalcoholic steatohepatitis (NASH).

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 preclinical 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.

Reverse stock split

On October 8, 2020, the Company's board of directors approved a 1-for-9.3197 reverse stock split (the Reverse Stock Split) of the Company's common stock and redeemable convertible preferred stock to be consummated prior to the effectiveness of the Company's planned initial public offering (IPO). The par value and authorized shares of the common stock and redeemable convertible preferred stock were not adjusted as a result of the reverse stock split. All issued and outstanding common stock, options to purchase common stock and per share amounts contained in the financial statements have been retroactively adjusted to give effect to the reverse stock split for all periods presented. The Company filed an amended and restated certificate of incorporation in Delaware on October 9, 2020 that automatically effectuated the Reverse Stock Split without any further action required.

Initial public offering

On October 20, 2020, the Company closed its IPO and issued 10,000,000 shares of its common stock at a public offering price of $15.00 per share for net proceeds of $135.4 million, after deducting underwriting discounts and commissions of $10.5 million and expenses of $4.1 million. In connection with the IPO, all shares of Series A redeemable convertible preferred stock (Series A), Series B-1 redeemable convertible preferred stock (Series B-1) and Series B-2 redeemable convertible preferred stock (Series B-2) converted into 19,761,870 shares of voting common stock and 3,092,338 shares of non-voting common stock. On November 5, 2020, the underwriters of the IPO partially exercised their overallotment option by purchasing an additional 1,150,000 shares from the Company, resulting in an additional $16.0 million in net proceeds, after deducting underwriting discounts and commissions of $1.2 million.

Liquidity and going concern assessment

The Company has incurred losses and negative cash flows from operations since its inception. As of December 31, 2020 and 2019, the Company has an accumulated deficit of approximately $174.7 million and $66.2 million, respectively. Management expects to continue to incur additional substantial losses in the foreseeable future as a result of expanded research and development activities.

As of December 31, 2020, the Company has unrestricted cash, cash equivalent and short-term investments of approximately $243.5 million, which is available to fund future operations. The Company expects to continue to spend substantial amounts to continue the nonclinical and clinical development of its current and future programs. If the Company is able to gain marketing approval for drug candidates that are being developed, it 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 the Company's planned and anticipated clinical trials is highly uncertain, the Company cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any drug candidate the Company may develop.

The Company expects to finance its 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, the Company may seek additional capital to take advantage of favorable market conditions or strategic opportunities even if the Company believes it has sufficient funds for its current or future operating plans. Based on the Company's research and development plans, it is expected that the Company's existing cash, cash equivalents and investments, will enable the Company to fund its operations for at least 12 months following the date the consolidated financial statements are issued. However, the Company's operating plan may change as a result of many factors currently unknown, and the Company may need to seek additional funds sooner than planned. Moreover, it is particularly difficult to estimate with certainty the Company's future expenses given the dynamic nature of its business, the COVID-19 pandemic and the macro-economic environment generally.

The Company's ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond its control. In particular, the COVID-19 pandemic continues to rapidly evolve and has already resulted in a significant disruption of global financial markets. If the disruption persists or deepens, the Company could be unable to access additional capital, which could negatively affect its ability to consummate certain corporate development transactions or other important, beneficial or opportunistic investments. If additional funds are not available to the Company when needed, on terms that are acceptable to the Company, or at all, the Company 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 its development programs altogether; or delay, limit, reduce or terminate its efforts to establish manufacturing and sales and marketing capabilities or other activities that may be necessary to commercialize any future approved products, or reduce the Company's flexibility in developing or maintaining its sales and marketing strategy.

2. Summary of significant accounting policies

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

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 (FASB).

Principles of consolidation

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

Use of estimates

The preparation of the consolidated financial statements in conformity with U.S. GAAP generally requires management to make certain estimates and assumptions that affect the reported amounts in the consolidated financial statements and accompanying notes. The Company regularly evaluates estimates and assumptions related to assets and liabilities, at the dates of the consolidated financial statements and the reported amounts of expenses during the reporting period. Areas where management uses subjective judgments include, but are not limited to, right-of-use assets, lease obligations, impairment of long-lived assets, stock-based compensation, accrued research and development costs, pension liabilities, derivative liabilities and redeemable convertible preferred stock liability in the accompanying consolidated financial statements. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

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 gain was recognized during the year ended December 31, 2020 of $121,000 and a re-measurement loss was recognized during the year ended December 31, 2019 of $47,000 and are reflected within interest and other income (expense), net on the consolidated statements of operations and comprehensive loss.

Segment information

The Company has determined that the Chief Executive Officer is its Chief Operating Decision Maker. The Company's Chief Executive Officer reviews financial information presented on a consolidated basis for the purposes of assessing the performance and making decisions on how to allocate resources. Accordingly, the Company has determined that it operates in a single reportable segment. No revenue has been generated since inception.

The Company has $6.6 million and $1.4 million of fixed assets in Aligos-US and Aligos-Belgium, respectively, as of December 31, 2020 and $7.3 million and $1.2 million of fixed assets in Aligos-US and Aligos-Belgium, respectively as of December 31, 2019.

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

As of December 31, 2020 and 2019, the restricted cash balance was $560,000 and $538,000, respectively, and was used to secure the letters of credit in relation to the Company's operating leases and deposits on rental assets (Note 6).

Investments

The Company determines the appropriate classification of debt securities at the time of purchase and re-evaluates such designation as of each balance sheet date. Debt securities are classified as held-to-maturity when the Company has the positive intent and ability to hold the securities to maturity, otherwise debt securities are classified as available-for sale. Held-to-maturity securities are carried at amortized cost. 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 debt securities are reported as a separate component of stockholders' 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 (expense) income, net within the condensed consolidated statements of operations and comprehensive loss.

For both held-to-maturity and available-for-sale investments, the Company periodically reviews each individual security position that has an unrealized loss, or impairment, to determine if that impairment is other-than-temporary. If the Company believes an impairment of a security position is other than temporary, based on available quantitative and qualitative information as of the report date, the loss will be recognized as other income (expense) in the Company's condensed consolidated statements of operations and a new cost basis in the investment is established. No impairment charges were recorded during the years ended December 31, 2020 and 2019.

As of December 31, 2020 and 2019, short-term investments consisted of U.S. Treasury securities with original maturities of less than one year. As of December 31, 2019, long-term investments consisted of U.S. Treasury securities with original maturities of more than one year.

Deferred offering costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the financing, these costs are recorded as a reduction of the proceeds received from the equity financing. If a planned equity financing is abandoned, the deferred offering costs are expensed immediately as a charge to operating expenses in the consolidated statement of operations and comprehensive loss. There were no deferred offering costs on the Company's consolidated balance sheets at December 31, 2020 and 2019.

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 and U.S. treasury bills 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.

Leases

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

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 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, 2020 or 2019.

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. Royalties and license payments are recorded as due.

When the Company enters into collaboration arrangements, the Company assesses whether the arrangement fall 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).

During the year ended December 31, 2019, no milestones were met and no royalties were due; therefore, the Company did not pay or expense any milestone or royalties. In the year ended December 31, 2020, a development milestone was met as the first patient dosing occurred and so the Company made a payment of $4.5 million, which is included in research and development in the consolidated statement of operations. The upfront payment received during the year ended December 31, 2020 was recorded on the consolidated balance sheet as deferred revenue from collaborations.

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 determined based on the number of shares granted and the value 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.

See Note 9 for the assumptions used by the Company in determining the grant date fair value of stock-based awards granted, as well as a summary of the stock-based award activity under the Company's stock-based compensation plan for years ended December 31, 2020 and 2019.

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.

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.

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, redeemable convertible preferred stock, stock options, common stock subject to repurchase related to early exercise of stock options, unvested restricted stock subject to repurchase, warrants and convertible notes are considered to be potentially dilutive securities.

The Company applies the two-class method to calculate its basic and diluted net loss per share as the Company has issued shares that meet the definition of participating securities. The two-class method is an earnings allocation formula that treats a participating security as having rights to earnings that otherwise would have been available to common stockholders. The Company's participating securities contractually entitle the holders of such

shares to participate in dividends, but do not contractually require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss, such losses are not allocated to such participating 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.

Recently adopted accounting pronouncements

In June 2018, the FASB issued ASU No. 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* (ASU 2018-07). ASU 2018-07 amends the FASB ASC to expand the scope of FASB ASC Topic 718, *Compensation-Stock Compensation*, to include accounting for share-based payment transactions for acquiring goods and services from non-employees. The amendments in ASU 2018-07 are effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2018. Early adoption was permitted. The Company early adopted this guidance at inception.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)* (ASU 2014-09), which supersedes existing revenue recognition guidance under U.S. GAAP. The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. The standard defines a five-step process to achieve this principle and requires companies to use more judgment and make more estimates than under the current guidance. These judgments and estimates include identifying performance obligations in the customer contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts. The Company early adopted ASU 2014-09 at inception. The adoption of ASU 2014-09 did not have an impact on the Company's consolidated financial statements as the Company does not currently have any revenue-generating arrangements.

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements (Topic 808)—Clarifying the Interaction between Topic 808 and Topic 606* (ASU 2018-18). The amendments in ASU 2018-18 clarify that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606 when the collaborative arrangement participant is a customer in the context of a unit of account. The amendments under ASU 2018-18 are effective for interim and annual fiscal periods beginning after December 15, 2019, with early adoption permitted. The amendments in ASU 2018-18 should be applied retrospectively to the date of initial application of ASC 606. The Company early adopted ASU 2018-18 at inception.

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business* (ASU 2017-01). ASU 2017-01 provides guidance to evaluate whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. If substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single asset or a group of similar assets, the assets acquired (or disposed of) are not considered a business. The Company adopted this standard at inception.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* (ASU 2016-02), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e.,

lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification determines whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less may be accounted for similar to existing guidance for operating leases. The standard is effective for all entities for fiscal years beginning after December 15, 2019. Early adoption is permitted. The Company adopted this standard at inception.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230) Restricted Cash* (ASU 2016-18), which requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents and restricted cash. Therefore, amounts described as restricted cash should be included with cash and cash equivalents when reconciling the beginning of period and end of period amounts shown on the statement of cash flows. The standard is effective for all entities for fiscal years beginning after December 15, 2018. The Company early adopted this guidance at inception. The cash, cash equivalent and restricted cash balances as of December 31, 2019 and 2020 are presented in the Company's consolidated statements of cash flows.

In March 2017, the FASB issued ASU No. 2017-07, *Compensation-Retirement Benefits (ASC Topic 715)* (ASU 2017-07), which requires employers to disaggregate the service cost component from other components of net periodic benefit costs and to disclose the amounts of net periodic benefit costs that are included in each income statement line item. The standard requires employers to report the service cost component in the same line item as other compensation costs and to report the other components of net periodic benefit costs separately and outside a subtotal of operating income. The Company adopted this standard at inception and has recognized its net periodic benefit costs, excluding service costs, in interest and other income (expense), net on its consolidated statements of operations and comprehensive loss.

In August 2018, the FASB issued ASU No. 2018-14, *Compensation—Retirement Benefits—Defined Benefit Plans—General (Subtopic 715-20)* (ASU 2018-14). The guidance eliminates requirements for certain disclosures that are no longer considered cost beneficial and requires new ones that the FASB considers pertinent. The standard is effective for fiscal years ending after December 15, 2021 for all entities. Early adoption is permitted. The Company adopted this standard at inception.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework— Changes to the Disclosure Requirements for Fair Value Measurement* (ASU 2018-13). The amendments eliminate, add, and modify certain disclosure requirements for fair value measurements. The amendments are effective for interim and annual reporting periods beginning after December 15, 2019, with early adoption permitted for either the entire ASU or only the provisions that eliminate or modify requirements. The amendments with respect to changes in unrealized gains and losses, the range and weighted-average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty are to be applied prospectively. All other amendments are to be applied retrospectively to all periods presented. The Company adopted this standard in the year ended December 31, 2020.

Recently issued accounting standards

In June 2016, the FASB issued ASU No. 2016-13. *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* (ASU 2016-13), which requires that financial assets measured at amortized cost be presented at the net amount expected to be collected. Currently, U.S. GAAP delays recognition of the full amount of credit losses until the loss is probable of occurring. Under this ASU, the income statement will reflect an entity's current estimate of all expected credit losses. The measurement of expected credit losses will be based upon historical experience, current conditions, and reasonable and supportable forecasts that affect the collectability of the reported amount. In November 2018, the FASB issued ASU No. 2018-19, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses* (ASU 2018-19), which clarifies that receivables from operating leases are accounted for using the lease guidance and not as financial instruments. In April 2019, the FASB issued ASU No. 2019-04, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses* (ASU 2019-04), which clarifies the new expected credit loss methodology for loans, receivables and other financial assets, including recoveries and accrued interest on receivables. In November 2019, the FASB issued

ASU No. 2019-11, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses* (ASU 2019-11), which clarifies guidance around how to report expected recoveries. The standard is effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. Early adoption is permitted. The Company is evaluating the potential impact of this standard on its consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* (ASU 2019-12). The guidance removes specific exceptions to the general principles in ASC 740, improves application of income tax-related guidance and reduces complexity related to the accounting for income taxes. The standard is effective for fiscal years beginning after December 15, 2021, and interim periods with fiscal years beginning after December 15, 2022. Early adoption is permitted. The Company is evaluating the potential impact of this standard on its consolidated financial statements.

From time to time, new accounting pronouncements are issued by FASB that the Company adopts as of the specified effective date. The Company qualifies as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 and has the option to not "opt out" of the extended transition related to complying with new or revised accounting standards. This means that when a standard is issued or revised and it has different application dates for public and nonpublic companies, the Company has the option to adopt the new or revised standard at the time nonpublic companies adopt the new or revised standard and can do so until such time that the Company either (i) irrevocably elects to "opt out" of such extended transition period or (ii) no longer qualifies as an emerging growth company.

3. Property and equipment

The components of property and equipment were as follows as of December 31, 2020 and 2019:

(in thousands)	2020	2019
Leasehold improvements	$ 5,655	$ 5,100
Lab equipment	4,833	3,204
Computer equipment	942	890
Furniture and office equipment	459	425
Vehicles	296	296
Asset under construction	65	110
Total, at cost	12,250	10,025
Accumulated depreciation	(4,243)	(1,508)
Total, net	$ 8,007	$ 8,517

During the years ended December 31, 2020 and December 31, 2019, depreciation expense was $2.7 million and $1.4 million, respectively. Finance leases for vehicles are also included in property and equipment on the consolidated balance sheets (Note 6).

4. Investments

As of December 31, 2020 and 2019, amortized cost, gross unrealized gains and losses, and estimated fair values of total fixed-maturity securities were as follows:

	2019			
(in thousands)	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
Held-to-maturity securities:				
U.S. Treasury bonds	$ 58,117	$ 31	$ (1)	$ 58,147

(in thousands)	2020 Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
Held-to-maturity securities:				
U.S. Treasury bonds	$ 10,002	$ 14	$ —	$ 10,016
Available-for-sale securities:				
U.S. Treasury bonds	$ 13,060	$ 68	$ —	$ 13,128
	$ 23,062	$ 82	$ —	$ 23,144

Changes in fair value are related to changes in market interest rates. The Company expects to collect all contractual principal and interest payments.

Amortized cost and estimated fair value of fixed-maturity securities at December 31, 2020 by contractual maturity were as follows:

(in thousands)	2020 Amortized Cost	Estimated Fair Value
Amounts maturing in:		
One year or less	$ 23,062	$ 23,144
More than one year	—	—
Total investments	$ 23,062	$ 23,144

The Company recorded interest income of $1.2 million and $1.6 million, respectively, during the years ended December 31, 2020 and 2019, as a component of interest and other income (expense), net on the Company's consolidated statement of operations and comprehensive loss.

5. Accrued liabilities

Accrued liabilities consisted of the following as of December 31:

(in thousands)	2020	2019
Accrued compensation	$ 7,274	$ 3,211
Accrued payables	8,554	3,113
Liability with early exercised stock options	569	753
Other	167	522
Total	$ 16,564	$ 7,599

6. Leases

The Company has operating and finance leases for corporate offices, research and development facilities, and certain vehicles. These leases have remaining lease terms of four to eight and a half 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.

Leases with an initial term of 12 months or less are not recorded on the balance sheet, and the Company recognizes lease expense for these leases on a straight-line basis over the lease terms. Leases with terms greater than

12 months are included in operating lease ROU assets and operating lease liabilities in the Company's consolidated balance sheets as of December 31, 2020 and 2019. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

Maturities of lease liabilities as of December 31, 2020, were as follows:

(in thousands)	Operating Lease	Finance Lease
Year ending December 31:		
2021	$ 2,616	$ 80
2022	2,700	79
2023	2,696	42
2024	2,678	1
2025	2,772	—
Thereafter	3,642	—
	17,104	202
Less: imputed interest	(4,291)	(8)
Present value of lease liabilities	12,813	194
Less: current portion	(2,442)	(64)
Lease liabilities net of current portion	$ 10,371	$ 130

The components of lease expense were as follows for the years ended December 31, 2020 and 2019:

(in thousands)	2020	2019
Operating lease cost	$ 1,847	$ 2,228
Finance lease cost:		
Amortization of right-of-use assets	60	46
Interest on lease liabilities	9	6
Total finance lease cost	$ 69	$ 52
Short-term lease cost	$ 15	$ 11

The Company made payments of $2.5 million and $1.2 million during the years ended December 31, 2020 and 2019, respectively, which are included as cash flow from operations on the consolidated statements of cash flows.

As of December 31, 2020 and 2019, $296,000 and $296,000 of finance lease ROU assets, respectively, were presented as part of property and equipment on the consolidated balance sheet with accumulated amortization of $107,000 and $47,000, respectively.

Additional information related to the Company's leases was as follows as of December 31:

	2020	2019
Operating Lease:		
Weighted-average remaining lease term (years)	5.97	7.10
Weighted-average discount rate	9.35%	9.34%
Finance Lease:		
Weighted-average remaining lease term (years)	2.68	3.66
Weighted-average discount rate	3.15%	3.18%

7. Derivative liabilities and redeemable convertible preferred stock liability

Warrants

In connection with the issuance of the Notes, Lenders were issued Warrants to purchase 134,112 shares of the Company's capital stock. The Warrants have a coverage percentage of 25% of the principal amount of the Notes and have a ten-year expiration date from the applicable closing date of April 20, 2018 or June 6, 2018.

The underlying shares issuable upon the exercise of the Warrants were eligible to be converted into the next round of equity financing. The Warrants became exercisable into shares of Series A for an exercise price of $9.32 per share.

The Company recorded the Warrants initially at fair value (Note 10) as derivative liabilities on the consolidated balance sheet with the remaining value being allocated to the Notes as a debt discount. The fair value of the Warrants upon issuance on April 20, 2018 and June 6, 2018, was $0.7 million and $238,000, respectively. The fair value of the Warrants was $0 and $461,000 as of December 31, 2020 and 2019, respectively.

In December 2019, Warrants were exercised into 13,411 shares of Series A. As a result, there were Warrants to purchase 120,701 shares of Series A outstanding as of December 31, 2019. Following completion of an IPO or change of control, any then outstanding warrants will automatically be exercised, on net share basis, for the issuance of shares of Common Stock and, upon that exercise, such warrants will no longer be outstanding. As Series A contains a conditional obligation for the Company to repurchase the shares for cash consideration, the Warrants remain outstanding as derivative liabilities with changes in fair value being recorded on the consolidated statements of operations and comprehensive loss. For the years ended December 31, 2020 and 2019, the Company recorded a change in fair value of derivative liabilities of $296,000 and $348,000, respectively.

Redeemable convertible preferred stock liability

In connection with the issuance of Series B-1 Redeemable Convertible Preferred Stock (the Series B-1) (Note 8), the Series B-1 preferred stockholders committed to purchase and the Company committed to sell 3,569,630 shares of Series B-2 Redeemable Convertible Preferred Stock (the Series B-2) at a price of $11.20563 per share in a subsequent closing, contingent upon the achievement of certain developmental milestones or a receipt of a waiver of achievement of the milestones. The Redeemable Convertible Preferred Stock Liability is considered a freestanding instrument that qualifies as a liability under ASC Topic 480, *Distinguishing Liabilities from Equity* (ASC 480) as the Company is committed to issue an instrument that ultimately may require a transfer of assets. The liability is accounted for at fair value and re-measured at each reporting date (Note 10). On the date of the initial closing, the Company recorded the Redeemable Convertible Preferred Stock Liability at a fair value of $3.2 million.

As of December 31, 2020, all Series B-2 shares were issued and then, as a result of the IPO, converted to shares of common stock. The Company recorded a change in fair value of the liability of $11.4 million for the year ended December 31, 2020 included in other expense, net. The convertible preferred stock liability was retired as of December 31, 2020.

As of December 31, 2019, none of the Series B-2 shares were issued and the fair value of the liability related to this freestanding instrument remained unchanged.

8. Capital stock

Common stock

On February 5, 2018, the date of incorporation, the Company was authorized to issue 20,000,000 shares of common stock with a par value of $0.0001 per share (the Common Stock).

On March 19, 2018, the Company granted two founders the right to purchase 1,508,900 shares of the Company's Common Stock at a purchase price of $0.001 per share upon the terms and subject to the conditions set forth in a restricted stock purchase agreement. The shares were purchased for $2 on the grant date and the shares vested immediately upon grant.

On March 19, 2018, the Company granted two founders and one employee the right to purchase 425,585 shares of the Company's Common Stock at a purchase price of $0.001 per share upon the terms and subject to the conditions set forth in a restricted stock purchase agreement. The shares were purchased for a de-minimis amount on the grant date and the shares vest monthly over a three-year period after a one-year cliff. If the purchasers no longer provide services to the Company, any portion of the shares that have not vested pursuant to the vesting schedule shall, on the date that is 61 days following such termination of service, automatically be forfeited by purchaser without any additional consideration therefore and without any further action by the Company and such shares shall immediately be canceled by the Company and shall no longer be outstanding.

On July 23, 2018, the certificate of incorporation was amended to increase the number of shares authorized for issuance to 25,000,000 shares of Common Stock. On that same date, the Company issued for purchase by employees and founders an additional 77,379 shares for a de-minimis amount subject to the same terms and conditions as the shares issued on March 19, 2018.

The Common Stock issuances with vesting conditions were issued outside of the equity incentive plan and are described in more detail in Note 9—Stock-based compensation.

On August 15, 2018, the certificate of incorporation was amended to increase the total shares of Common Stock authorized for issuance to 149,000,000 and additionally 102,500,000 shares of preferred stock with a par value of $0.0001 per share. Effective immediately on filing date, the Company converted all shares of Common Stock into 0.90144231 shares of Common Stock (the 2018 Reverse Stock Split). All share and data shown in the accompanying consolidated financial statements and related notes have been retroactively revised to reflect the 2018 Reverse Stock Split. Shares of Common Stock underlying outstanding stock options and other equity instruments were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the agreements governing such securities.

On December 23, 2019, the certificate of incorporation was amended to increase the total shares of Common Stock authorized for issuance to 278,000,000 and the total shares of preferred stock authorized for issuance to 212,994,964 with a par value of $0.0001 per share. The total shares of preferred stock authorized comprised 101,962,864 shares of Series A, 77,764,055 shares of Series B-1, and 33,268,045 shares of Series B-2.

On October 20, 2020, the certificate of incorporation was amended to increase the total shares of Common Stock authorized for issuance to 320,000,000 and decrease the total shares of preferred stock authorized for issuance to 10,000,000 with a par value of $0.0001 per share. 300,000,000 shares of the Common Stock were designated as "Voting Common Stock" and 20,000,000 shares of the Common Stock were designated as "Non-Voting Common Stock".

The holders of shares of Common Stock are entitled to one vote for each share of Common Stock at all meetings of stockholders.

Redeemable convertible preferred stock

On August 16, 2018, the Company entered into the Series A Preferred Stock Purchase Agreement for the purchase and sale of Series A preferred stock for $9.32 per share. The Company received $75.0 million in cash proceeds from the initial purchasers. On September 19, 2018, the Company received an additional $20.0 million in cash proceeds from subsequent purchasers. Additionally, on the initial closing date, $5.6 million in convertible notes plus accrued interest converted into shares of Series A and the notes were subsequently cancelled. The Warrants associated with the convertible notes became exercisable into Series A. Each share of Series A is convertible into Common Stock on a one-for-one basis. In connection with the issuance of Series A, the Company incurred $194,000

in issuance costs which have offset amounts reported as temporary equity as of December 31, 2019. As of December 31, 2020, in connection with the Company's IPO, all shares of Series A converted into Common Stock.

On December 23, 2019, the Company entered into the Series B-1 and Series B-2 Preferred Stock Purchase Agreement, pursuant to which the investors committed to invest an aggregate amount of up to $125.0 million for the issuance and sale of shares of Series B-1 and Series B-2 (collectively, the Series B), at a price of $10.18690 and $11.20563 per share, respectively. The Company issued 8,344,034 shares of Series B-1 for cash proceeds of $85.0 million at the initial closing on December 23, 2019. The investors also committed to purchase and the Company committed to sell 3,569,630 shares of Series B-2 in a subsequent closing (the Second Closing), contingent upon achievement by the Company of certain development milestones or a receipt of a waiver of achievement of the milestones. No shares of Series B-2 were issued as of December 31, 2019. In connection with the issuance of Series B-1, the Company incurred $442,000 in issuance costs which have offset amounts reported as temporary equity as of December 31, 2019.

Prior to the IPO, the Company issued 3,569,630 shares of Series B-2, which upon the closing of the IPO converted into common stock. In connection with the Company's IPO, all shares of Series B-1 converted into common stock. As of December 31, 2020, there was 10,000,000 shares of preferred stock authorized and no preferred stock issued.

9. Stock-based compensation

2018 Equity incentive plan

The Company's 2018 Equity Incentive Plan (the 2018 Plan) allows the Company to issue restricted stock awards and restricted stock units, and to grant incentive stock options or non-qualified stock options. Incentive stock options may be granted only to the Company's employees including officers and members of the Board who are also employees. Restricted stock awards, restricted stock units and non-qualified stock options may be granted to employees, members of the Board, outside advisors, and consultants of the Company (the Participants). The Company is authorized to issue awards for 4,913,665 shares of Common Stock under the 2018 Plan. The Company has granted awards of common stock in the form of 4,279,693 shares as of December 31, 2020 with none remaining available for future grant. Following the Company's IPO in October 2020, all future grants will be made under the 2020 Plan (as defined below).

2020 Incentive award plan

The Company adopted the 2020 Incentive Award Plan (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 3,374,466 shares subject to awards as of December 31, 2020 with 1,068,965 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.

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 will enable 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 368,901 shares of common stock pursuant to the 2020 ESPP. As of December 31, 2020, no grants of awards under this plan have been made.

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, 2020 and December 31, 2019, the Company’s stock option compensation expense was approximately $2.6 million and $261,000, respectively, and there was no recognized tax benefit in either year. As of December 31, 2020, unamortized expense balance was $38.8 million, to be amortized over a weighted-average period of 3.43 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:

	2020	2019
Expected term (in years)	5.79	6.06
Risk-free interest rate	0.93%	1.94%
Dividend yield	—	—
Volatility	77.14%	60.24%

Stock option activity during the year ended December 31, 2020 and 2019 was as follows:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2018	1,062,457	$ 1.30	9.88	$ —
Granted	178,863	$ 1.30		
Exercised	(891,229)	$ 1.30		37
Forfeited	(3,219)	$ 1.30		
Outstanding as of December 31, 2019	346,872	$ 1.30	9.01	$ 744
Granted	5,382,362	$ 11.42		
Exercised	(188,990)	$ 2.33		810
Forfeited	(52,096)	$ 1.76		
Outstanding as of December 31, 2020	5,488,148	$ 11.19	9.57	$ 90,335
Options vested and expected to vest as of December 31, 2020	5,427,891	$ 11.28	9.58	$ 88,881
Options vested and exercisable as of December 31, 2020	464,567	$ 3.20	8.95	$ 11,360
Options vested and expected to vest as of December 31, 2019	884,623	$ 1.30	9.01	$ 1,896
Options vested and exercisable as of December 31, 2019	31,330	$ 1.30	8.88	$ 67

The weighted-average grant date fair value of stock options granted was $7.50 per share during the year ended December 31, 2020. The weighted-average grant date fair value of stock options granted was $0.08 per share during the year ended December 31, 2019.

During the years ended December 31, 2020 and December 31, 2019, the Company issued 371,939 and 537,781 and shares of Common Stock, respectively, upon exercise of unvested stock options or purchases for unvested restricted stock awards. As of December 31, 2020 and 2019, there were 396,522 and 577,124 shares of Common Stock, respectively, held by employees subject to repurchase at an aggregate price of $0.6 million and $0.7 million, respectively. A corresponding liability was recorded and included in accrued expenses on the consolidated balance sheet as of December 31, 2020 and 2019.

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 502,964 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 the years ended December 31, 2020 and December 31, 2019, the Company recorded a total stock-based compensation expense of $361,000 and $492,000, respectively, related to the restricted stock awards. As of December 31, 2020, unrecognized stock-based compensation costs related to outstanding unvested restricted stock awards that are expected to vest were approximately $526,000, expected to be recognized over a weighted-average period of 1.14 years.

The following table summarizes the Company's restricted common stock activity for years ended December 31, 2020 and 2019:

	Number of Awards	Weighted-Average Grant Date Fair Value	Aggregate Fair Value
Issued and unvested as of December 31, 2018	1,521,387	$ 0.94	1,430
Restricted stock awards granted	—	$ —	—
Restricted stock awards vested	(694,200)	$ 0.86	(596)
Issued and unvested as of December 31, 2019	827,187	$ 1.01	$ 834
Restricted stock awards granted	—		—
Restricted stock awards vested	(418,776)	$ 0.86	(361)
Issued and unvested as of December 31, 2020	408,411	$ 1.16	$ 473

Stock-based compensation expense was allocated as follows for the years ended December 31, 2020 and December 31, 2019:

(in thousands)	2020	2019
Research and development	$ 1,041	$ 462
General and administrative	1,934	290
Total	$ 2,975	$ 752

10. Fair value

The following tables present the fair value of the Company's financial instruments that are measured or disclosed at fair value on a recurring basis:

	Fair Value Measurements as of December 31, 2020		
(in thousands)	Level 1	Level 2	Level 3
Assets:			
Cash and cash equivalents	$ 220,383	$ —	$ —
U.S. Treasury bonds	23,144	—	—
	$ 243,527	$ —	$ —

	Fair Value Measurements as of December 31, 2019		
(in thousands)	Level 1	Level 2	Level 3
Assets:			
Cash and cash equivalents	$ 69,565	$ —	$ —
U.S. Treasury bonds	58,147	—	—
Liabilities:			
Warrants	—	—	(461)
Convertible Preferred Stock Liability	—	—	(3,174)
	$ 127,712	$ —	$ (3,635)

The level 3 liabilities in the table above are composed of the fair value of Warrants and Conversion Features issued in connection with the Notes, which were subsequently converted into shares of Series A. The fair values of the Warrants and Conversion Features were determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy.

In order to determine the fair value of the Warrants, the Company utilized a probability-weighted multi-scenario Black-Scholes option-pricing model to determine the fair value of the Warrants by accounting for the probability of multiple possible outcomes, including deemed liquidation events, as best estimated by management. Estimates and assumptions impacting the fair value measurement including the fair value of the underlying shares of Series A, the remaining contractual or expected term of the Warrants, risk-free interest rate, expected dividend yield and expected volatility of the price of the underlying preferred stock on an as converted basis. The Company considered the probability of a deemed liquidation event in determining the remaining expected term of the Warrants, which was used as an input to the probability-weighted multi-scenario Black-Scholes option-pricing model adopted in 2019. The Company lacked company-specific historical and implied volatility information of its stock since there was no market prior to the IPO. Therefore, it estimated its expected stock volatility based on the historical volatility of publicly traded guideline companies for a term equal to the remaining contractual or expected term of the Warrants. The risk-free interest rate was determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual or expected term of the Warrants. The Company estimated no expected dividend yield based on the fact that the Company has never paid or declared dividends and does not intend to do so in the foreseeable future.

The Warrants were converted into shares of Series A stock immediately prior to the IPO and therefore they were retired as of December 31, 2020. The Warrants were measured at fair value under the following assumption as of December 31, 2019:

	2020	2019
Exercise price	$ 9.32	$ 9.32
Term (in years)	0.32	2.00 - 3.00
Risk-free interest rate	0.10%	1.63%
Dividend yield	—	—
Volatility	120.00%	75.00%

The fair value of the bifurcated conversion feature was immaterial at inception and is included in the initial fair value of the derivative liabilities. As of December 31, 2020, and 2019, the fair value of the bifurcated conversion feature was $0 as the Notes are converted into shares of Series A preferred stock in August 2018.

The following table sets forth a summary of changes in fair value of the Company's derivative liability for which fair value was determined by Level 3 inputs:

	Warrants	Redeemable Convertible Preferred Stock Liability
Balance as of December 31, 2018	$ 861	$ —
Exercise of warrants	(52)	—
Change in fair value	(348)	3,174
Balance as of December 31, 2019	$ 461	$ 3,174
Exercise of warrants	(137)	—
Change in fair value	296	11,386
Retirement of liability	(620)	(14,560)
Balance as of December 31, 2020	$ —	$ —

Immediately prior to the IPO, the Redeemable Convertible Preferred Stock Liability was converted in shares of Series B-2 Preferred Stock, which then converted into shares of common stock. As of December 31, 2020, the liability was retired.

As of December 31, 2019, in order to determine the fair value of the Redeemable Convertible Preferred Stock Liability, the Company used a probability weighted multi-scenario Black Scholes hybrid valuation method that accounts for the probability of achieving milestones as estimated by the management. The Redeemable Convertible Preferred Stock Liability has a fair value of $3.2 million at inception, which remained unchanged as of December 31, 2019. The Redeemable Convertible Preferred Stock Liability was measured at fair value under the following assumptions through redemption on October 6, 2020 and as of December 31, 2019:

	2020	2019
Exercise price	$ 11.21	$ 11.21
Term (in years)	0.02-0.75	1.27
Risk-free interest rate	0.08%-0.11%	1.55%
Dividend yield	—	—
Volatility	—%	60.00%

The significant unobservable inputs used in the fair value measurement of the Redeemable Convertible Preferred Stock Liability include the probability of milestone achievement and/or milestone achievement waiver, the Series B-2 current or future value estimate under each scenario, the term, and the equity volatility, which is a statistical measure of the dispersion of returns for a given security. Significant increases (decreases) in the milestone achievement and/or milestone waiver would result in a significantly higher (lower) fair value measurement. Significant decreases (increases) in assumed current or future Series B-2 value would result in a significantly lower

(higher) fair value measurement. Significant increases (decreases) in the term would result in a significantly higher (lower) fair value measurement. Significant increases (decreases) in the volatility would result in significantly higher (lower) fair value measurements.

11. License agreements and collaborations

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, sublicenseable 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. Beginning in June 2022, the license to such patents will become 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.

As consideration for the Emory License Agreement, the Company paid an upfront license fee of $290,000 and issued the Emory Convertible Note of $600,000. As discussed in Note 8, upon issuance of the Series A in August 2018, the Emory Convertible Note and unpaid accrued interest was cancelled and converted into shares of Series A at a conversion price of $9.32 per share.

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 $150,000, 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 terminates one year from the effective date, with the Company having an option to extend for a second year. In connection with the research plan, the Company will provide Emory funding up to $270,000 per year.

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, 2019, the Company had no expenses related to milestone payments. During the year ended December 31, 2020, the Company made a payment of $4.5 million in relation to the first patient dosing in a clinical trial which was the first development milestone per the contract. 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 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. During the years ended December 31, 2020 and December 31, 2019, the Company made no payments associated with royalties.

Agreement with Luxna Biotech Co., Ltd. (Luxna)

On December 19, 2018, the Company entered into a license agreement with Luxna, pursuant to which Luxna granted the Company an exclusive, worldwide, sublicenseable license under certain of Luxna's intellectual property rights to research, develop, make, have made, and commercialize for all therapeutic and prophylactic uses, (i) products containing oligonucleotides targeting the hepatitis B virus genome, (ii) products containing certain oligonucleotides targeting up to three genes which contribute to NASH, which the Company may select at any time during the first eight years of the term, to the extent not licensed to a third party, and (iii) products containing oligonucleotides targeting up to three genes which contribute to hepatocellular carcinoma, which the Company may select at any time during the first three years of the term.

As consideration for this agreement, the Company paid an upfront license fee of $600,000, which was recorded as research and development expense during the period from inception through December 31, 2018 and the year ended December 31, 2019.

In April 2020, the Company amended the license agreement with Luxna. Pursuant to the amended license agreement, Luxna granted the Company an exclusive, worldwide license under the licensed patents to research, develop, make, have made and commercialize products containing oligonucleotides targeting three families of viruses: orthomyxoviridae, paramyxoviridae, and coronaviridae (a family which includes SARS-CoV-2). As consideration for the amended license agreement, the Company paid Luxna a one-time non-refundable fee of $200,000.

The Company is obligated to make payments to Luxna, in aggregate, totaling up to but no more than $55.5 million upon the achievement of specified development, regulatory, and commercial milestones. During the years ended December 31, 2020 and December 31, 2019, the Company recognized no expenses related to milestone payments. The Company is also required to pay Luxna a low-single digit royalty percentage on net sale of applicable products, if any. During the years ended December 31, 2020 and December 31, 2019, the Company made no payments associated with royalties.

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 Centre for Drug Design and Discovery, 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. KU Leuven granted to the Company an exclusive (including as to KU Leuven), worldwide license under certain of KU Leuven's know-how and existing patents, 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, existing KU Leuven patents, 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. 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, 2020 and December 31, 2019, the Company recognized no expenses related to milestone payments.

Agreement with Merck

In December 2020, the Company and Merck & Co. entered into an exclusive License and Research Collaboration Agreement under which Merck and the Company agreed to apply the Company's oligonucleotide platform technology to discover, research, optimize and develop oligonucleotides directed against a NASH target and up to one additional liver-targeted cardiometabolic and/or fibrosis target. Under the terms of the agreement, the Company received an upfront payment from Merck and may receive an additional upfront payment after finalization of a research plan for such additional target. With respect to each collaboration target, the Company will be eligible for up to $458.0 million in development and commercialization milestones as well as tiered royalties on net sales. The Company will be primarily responsible for designing, preparing and evaluating the oligonucleotide molecules and delivering optimized lead molecules, and Merck will be responsible for subsequent research, clinical development and commercialization efforts. The Company determined that the Merck agreement falls within the scope of ASC 808 and we analogized to ASC 606 for the accounting of payments such as upfront payments and other milestones. During the year ending December 31, 2020 the Company recognized no revenue from collaborative arrangements related to milestone payments. The upfront payment received during 2020 was recorded on the consolidated balance sheet as Deferred Revenue from Collaborations.

12. Income taxes

The components of the current provision for income taxes were as follows for the years ended December 31, 2020 and 2019:

(in thousands)	2020	2019
Current:		
State	$ 1	$ 1
Federal	-	$ -
Foreign	160	$ 85
Total current provision for income taxes	$ 161	$ 86
Deferred:		
State	$ —	$ —
Federal	—	—
Foreign	—	—
Total deferred provision for income taxes	$ —	$ —

The Company did not have any deferred provision for income taxes for the years ended December 31, 2020 and 2019.

A reconciliation of the expected income tax (benefit) computed using the federal statutory income tax rate to the Company's effective income tax rate is as follows for the years ended December 31, 2020 and 2019:

	2020	2019
Income tax computed at federal statutory rate	21.00%	21.00%
State taxes, net of federal benefit	6.90%	8.18%
R&D credit carryovers	1.40%	1.87%
Change in valuation allowance	(27.24)%	(29.71)%
Permanent differences	(0.17)%	(1.32)%
Change in fair value of derivatives	(2.25)%	—
Other	0.21%	(0.18)%
Effective income tax rate	(0.15)%	(0.16)%

The components of the deferred tax assets and liabilities were as follows at December 31:

(in thousands)	2020	2019
Deferred tax assets:		
Federal net operating loss carryforward	$ 31,233	$ 12,106
State net operating loss carryforward	10,664	4,227
Foreign net operating loss carryforward	33	—
Operating lease liabilities	4,453	3,776
Tax credits	4,639	1,865
Other accruals and reserves	1,558	675
Stock-based compensation	209	—
Other	10	7
	52,799	22,656
Valuation allowance	(49,133)	(19,362)
Net deferred tax assets	$ 3,666	$ 3,294
Deferred tax liabilities:		
Right of use assets	$ (2,857)	$ (2,067)
Stock-based compensation	—	(115)
Property and equipment	(809)	(1,112)
Total deferred tax liabilities	$ (3,666)	$ (3,294)
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 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 $29.7 million during the year ended December 31, 2020.

As of December 31, 2020, the Company had $148.7 million of federal and $152.8 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 2038. As of December 31, 2020, the Company had research and development credit carryforwards of $4.1 million and $2.1 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 2038. The California credit carryforwards have no expiration. 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. We performed an IRC Section 382 analysis in 2021 and determined there was an ownership change that resulted in Section 382 limitations. The ownership change limited our ability to utilize net operating losses against future taxable income but will not result in the expiration of any NOLs. We 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, in taxable years beginning after December 31, 2020, 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.

The Company adopted the provisions of FASB Accounting Standards Codification (ASC 740-10), *Accounting for Uncertainty in Income Taxes*, upon the date of incorporation. 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, 2020 and 2019, the Company had not recognized any tax-related penalties or interest. At December 31, 2020, the gross unrecognized tax benefit relating to research and development credit was $1.5 million, none of which if recognized would reduce the effective tax rate in a future period, due to the Company's full valuation allowance on U.S. net deferred tax assets. The Company does not expect that its uncertain tax positions will materially change in the next twelve months. The following table summarizes the changes to the Company's unrecognized tax benefits:

(in thousands)	2020	2019
Balance, beginning of the period	$ 637	$ 79
Increase related to prior year positions	131	—
Increase related to current year positions	768	558
Balance, ending of the period	$ 1,536	$ 637

The Company files income tax returns in the United States, California and Massachusetts, and in foreign jurisdictions. The Company is not currently under examination by income tax authorities in federal, state or other jurisdictions. All tax returns will remain open for examination by the federal and state authorities for three and four years, respectively, from the date of utilization of any NOLs or credits.

In January 2018, the FASB released guidance on the accounting for tax on the global intangible low-taxed income (GILTI) provisions of the Tax Reform Act. The GILTI provisions impose a tax on foreign income in excess of a deemed return on tangible assets of foreign corporations. The guidance allows companies to make an accounting policy election to either (i) account for GILTI as a component of tax expense in the period in which they are subject to the rules (the period cost method), or (ii) account for GILTI in the Company's measurement of deferred taxes (the deferred method). After completing the analysis of the GILTI provisions, the Company elected to account for GILTI using the period cost method.

On March 27, 2020, the "Coronavirus Aid, Relief and Economic Security (CARES) Act" (the "Act") was signed into law. The Act includes provisions relating to refundable payroll tax credits, deferment of the employer portion of certain payroll taxes, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property. The Company analyzed the provisions of the Act and determined there was no significant impact to its income taxes for the year ended December 31, 2020.

On June 29, 2020, the California Governor signed Assembly Bill 85 ("A.B. 85"), which now becomes California law. A.B. 85, which includes several tax measures, provides for a three-year suspension of the use of net operating losses for medium and large businesses and a three-year cap on the use of business incentive tax credits to offset no more than $5 million of tax per year. Generally, A.B. 85 suspends the use of net operating losses for taxable years 2020, 2021, and 2022 for taxpayers with taxable income of $1 million or more." Since the Company is

not expected to generate California source taxable income of more than $1 million, no material impact is anticipated at this time.

On December 27, 2020, the "Consolidated Appropriations Act, 2021" (the "CAA") was signed into law. The CAA includes provisions meant to clarify and modify certain items put forth in CARES Act, while providing aid to businesses affected by the pandemic. The CAA allows deductions for expenses paid for by Paycheck Protection Program ("PPP") and Economic Injury Disaster Loan ("EIDL") Program, clarifies forgiveness of EIDL advances, and other business provisions. The Company analyzed the provisions of the CAA and determined there was no significant impact to its 2020 tax provision.

13. 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. The Company had no contingent liabilities requiring accrual as of December 31, 2020 and 2019.

14. 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 $432,000 and $274,000 to the plan during the years ended December 31, 2020 and 2019, 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 stockholders' 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 1.75% 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.

Net periodic benefit costs and other amounts recognized in other comprehensive loss for the Regular Pension Plan include the following components for the years ended December 31, 2020 and December 31, 2019:

(in thousands)	2020	2019
Service cost	$ 186	$ 94
Expected return on plan assets	(4)	(2)
Interest costs	5	6
Amortization of actuarial gains/(losses)	2	-
Other costs	46	29
Prior service costs	33	58
	268	185
Net actuarial loss (gain) in plan asset and projected benefit obligation recognized in other comprehensive loss	82	86
Total recognized	$ 350	$ 271

The net periodic benefit costs, excluding service costs, are included in interest and other income (expense), net on the Company's consolidated statements of operations and comprehensive loss.

The activities under the Regular Pension Plan are as follow:

(in thousands)	2020	2019
Change in benefit obligation:		
Benefit obligation, beginning of year	$ 560	$ 317
Service cost	186	94
Interest cost	5	6
Prior service cost	62	58
Actuarial loss (gain)	84	85
Benefit obligation, end of year	897	560
Change in plan assets:		
Fair value of plan assets, beginning of year	470	317
Company contributions	186	182
Expected net return on plan assets	4	2
Other costs	(23)	(30)
Actuarial loss	(1)	(1)
Fair value of plan assets, end of year	636	470
Funded status	$ (261)	$ (90)

The underfunded amount of $261,000 and $90,000 is recognized in accrued liabilities on the consolidated balance sheet as of December 31, 2020 and 2019, respectively. In addition, $84,000 and $85,000 of actuarial loss is recognized in accumulated other comprehensive (loss) income for the years ended December 31, 2020 and December 31, 2019, respectively.

The accumulated benefit obligation for the defined benefit plan was $0.9 million and $0.6 million as of December 31, 2020 and 2019, respectively.

The weighted-average rates used to determine the net periodic benefit costs and projected benefit obligations were as follows:

	2020	2019
Discount rate	0.40%	0.90%
Rate of increased salary levels	1.80%	1.80%
Expected long-term rate of return on assets	0.53%	0.65%

The discount rate used in 2020 and 2019 is based on a yield curve constructed from a portfolio of high-quality, Euro-denominated fixed income investments with various maturities up to 12 years. Each year's expected future benefit payments are discounted to their present value at the appropriate yield curve rate, thereby generating the overall discount rate for the projected benefit obligation.

The expected long-term rate of return on plan assets is deemed to equal 0.75%, as guaranteed by the insurance company that holds the fund investments, less 0.1% of asset management fee, resulting in 0.65% prior to July 1, 2020, and a guaranteed rate of return of 0.5%, less 0.1% of asset management fee, resulting in 0.4% for all accruals after July 1, 2020.

The fair values of the Regular Pension Plan assets as of December 31, 2020 and 2019 are as follows:

(in thousands)	Significant Unobservable Inputs (Level 3)
2020:	
Sundry liabilities	$ -
Insurance policies	706
Current account with insurer	(70)
	$ 636
2019:	
Current account with insurer	$ (15)
Insurance policies	485
	$ 470

The following table sets forth a summary of changes in fair value of the Regular Pension Plan assets for which fair value was determined by Level 3 inputs:

(in thousands)	2020	2019
Unobservable inputs - beginning	$ 470	$ 317
Actual return on plan assets	3	1
Net purchases, sales and settlements	186	182
Transfers out of Level 3 assets	(23)	(30)
Unobservable inputs - ending	$ 636	$ 470

The Company anticipates making $297,000 funding contributions to the Regular Pension Plan in 2021.

Estimated future benefit payments are as follows:

Fiscal year (in thousands):	
2021	$ 6
2022	4
2023	4
2024	3
2025	3
2026−2030	23
	$ 43

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 1.75%. 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.

Net periodic benefit costs and other amounts recognized in other comprehensive loss for the Top Hat Plan included the following components for the years ended December 31, 2020 and December 31, 2019, respectively:

(in thousands)	2020	2019
Prior service costs	$ 794	$ 348
Interest costs	8	5
Other costs	114	27
	$ 916	$ 380
Net actuarial loss in plan asset and projected benefit obligation recognized in other comprehensive loss	52	32
Total recognized	$ 968	$ 412

The net periodic benefit costs, excluding prior service costs, are included in other expenses on the Company's consolidated statements of operations and comprehensive loss.

The activities under the Top Hat Plan were as follow for the years ended December 31, 2020 and December 31, 2019, respectively:

(in thousands)	2020	2019
Change in benefit obligation:		
Benefit obligation, beginning of year	$ 649	$ 261
Prior service cost	834	348
Internal transfer	180	—
Interest expense	8	5
Actuarial loss	58	35
Benefit obligation, end of year	$ 1,729	$ 649
Change in plan assets:		
Fair value of plan assets, beginning of year	$ 237	$ (20)
Company contributions	496	281
Other costs	(100)	(27)
Internal transfer	(10)	—
Actuarial gain	6	3
Fair value of plan assets, end of year	$ 629	$ 237
Funded status	$ (1,100)	$ (412)

The underfunded amounts of $1.1 million and $412,000 is recognized in accrued liabilities on the consolidated balance sheet as of December 31, 2020 and December 31, 2019, respectively. In addition, $52,000 and $32,000 of actuarial loss is recognized in accumulated other comprehensive (loss) income for the years ended December 31, 2020 and December 31, 2019, respectively.

The accumulated benefit obligation for the Top Hat Plan was $1.7 million and $0.6 million as of December 31, 2020 and December 31, 2019, respectively.

The weighted-average rates used to determine the net periodic benefit costs and projected benefit obligations were as follows:

	2020	2019
Discount rate	0.40%	1.90%
Rate of increased salary levels	1.80%	1.80%
Expected long-term rate of return on assets	0.00%	0.00%

The discount rate used in 2020 and 2019 is based on a yield curve constructed from a portfolio of high-quality, Euro-denominated fixed income investments with various maturities up to 12 years. Each year's expected future benefit payments are discounted to their present value at the appropriate yield curve rate, thereby generating the overall discount rate for the projected benefit obligation.

The expected long-term rate of return on plan assets is deemed to equal 0.00%, as there is no guarantee of return from the insurance company holding the investments.

The fair values of the Top Hat Plan assets as of December 31, 2020 and December 31, 2019 were as follows:

(in thousands)	Significant Unobservable Inputs (Level 3) 2020	2019
Sundry liabilities	$ (797)	$ (27)
Insurance policies	1,426	264
	$ 629	$ 237

The following table sets forth a summary of changes in fair value of the Top Hat Plan assets in 2020 and 2019 for which fair value was determined by Level 3 inputs:

(in thousands)	2020	2019
Unobservable inputs - beginning	$ 237	$ (20)
Actual return on plan assets	6	3
Net purchases, sales and settlements	496	281
Transfers out of Level 3 assets	(110)	(27)
Unobservable inputs - ending	$ 629	$ 237

The Company anticipates making $0.6 million in funding contributions to the Top Hat Plan in 2021.

Estimated future benefit payments are as follows:

Fiscal year (in thousands):	2020	2019
2021	$ 4	$ 2
2022	4	2
2023	4	2
2024	4	2
2025	5	2
2026 - 2030	39	10
	$ 60	$ 20

15. 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, 2020	2019
Net loss	$ (108,543)	$ (52,264)
Weighted average common stock outstanding, basic and diluted	9,988,191	2,007,173
Net loss per share – basic and diluted	$ (10.87)	$ (26.04)

The Company's potentially dilutive securities, which include redeemable convertible preferred stock, forward contracts to issue Preferred Stock, options to purchase common stock and unvested restricted 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,	
	2020	2019
Convertible preferred stock	—	19,163,877
Forward contract to issue convertible preferred stock	—	3,569,630
Options to purchase common stock	3,344,765	884,623
Unvested restricted stock	408,396	827,187
Warrants to purchase preferred stock	—	120,701
	3,753,161	24,566,018

16. Subsequent events

The Company has evaluated all events occurring past the balance sheet date, during which time, nothing has occurred outside the normal course of business operations that would require disclosure.

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, 2020, our disclosure controls and procedures were effective.

Management's annual report on internal control over financial reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the company's registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

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, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

As a result of the COVID-19 pandemic, in March 2020, substantially all of our employees began working remotely. We have not identified any material changes in our internal control over financial reporting as a result of these changes to the working environment, in part because our internal control over financial reporting was designed to operate in a remote working environment. We are continually monitoring and assessing the COVID-19 situation to determine any potential impacts on the design and operating effectiveness of our internal controls 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.

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.

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 2021 Annual Meeting of Stockholders, which will be filed with the SEC no later than 120 days after December 31, 2020.

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	Amended and Restated Certificate of Incorporation.	8-K	10/20/2020	3.1	
3.2	Amended and Restated Bylaws.	8-K	10/20/2020	3.2	
4.1	Reference is made to Exhibits 3.1 and 3.2.				
4.2	Form of Common Stock Certificate.	S-1/A	10/9/2020	4.2	
4.3	Description of Securities.				X
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)	
10.2(a)†	License Agreement by and between Aligos Therapeutics, Inc. and Luxna Biotech Co., Ltd., dated December 19, 2018.	S-1	9/25/2020	10.2(a)	
10.2(b)†	Amendment to License Agreement by and between Aligos Therapeutics, Inc. and Luxna Biotech Co., Ltd., dated April 8, 2020.	S-1	9/25/2020	10.2(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	Amended and Restated Investors' Rights Agreement dated October 9, 2020.	S-1/A	10/9/2020	10.4	
10.5(a)#	2018 Equity Incentive Plan, as amended.	S-1	9/25/2020	10.5(a)	
10.5(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)	
10.5(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)	
10.5(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)	
10.6(a)#	2020 Incentive Award Plan.	S-1/A	10/9/2020	10.6(a)	
10.6(b)#	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)	
10.6(c)#	Form of Restricted Stock Award Agreement under the 2020 Incentive Award Plan.	S-1/A	10/9/2020	10.6(c)	
10.6(d)#	Form of Restricted Stock Unit Award Grant Notice under the 2020 Incentive Award Plan.	S-1/A	10/9/2020	10.6(d)	
10.7#	2020 Employee Stock Purchase Plan.	S-1/A	10/9/2020	10.7	
10.8#	Employment Agreement by and between Aligos Therapeutics, Inc. and Lawrence M. Blatt, Ph.D., dated August 16, 2018.	S-1/A	10/9/2020	10.8	
10.9#	Employment Agreement by and between Aligos Therapeutics, Inc. and Leonid Beigelman, Ph.D., dated August 16, 2018.	S-1/A	10/9/2020	10.9	
10.10#	Confirmatory Employment Letter by and between Aligos Therapeutics, Inc. and Lucinda Quan, J.D., dated May 14, 2019.	S-1/A	10/9/2020	10.10	
10.11#	Non-Employee Director Compensation Program.	S-1/A	10/9/2020	10.11	

10.12	Form of Indemnification Agreement for directors and officers.	S-1/A	10/9/2020	10.12	
21.1	Subsidiaries of Registrant.	S-1	9/25/2020	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
101.INS	XBRL Instance Document.				X
101.SCH	XBRL Taxonomy Extension Schema Document.				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.				X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.				X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.				X

† Portions of the exhibit, marked by brackets, have been omitted because the omitted information (i) is not material and (ii) would likely cause competitive harm if publicly disclosed.
# 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 23, 2021

By: /s/ Lawrence M. Blatt
Lawrence M. Blatt, Ph.D.
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., Lesley Ann Calhoun and Lucinda Quan, J.D., 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.	Chief Executive Officer and Director *(Principal Executive Officer)*	March 23, 2021
/s/ Lesley Ann Calhoun Lesley Ann Calhoun	Executive Vice President, Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 23, 2021
/s/ Leonid Beigelman Leonid Beigelman, Ph.D.	President and Director	March 23, 2021
/s/ K. Peter Hirth K. Peter Hirth, Ph.D.	Director	March 23, 2021
/s/ Jack B. Nielsen Jack B. Nielsen	Director	March 23, 2021
/s/ Peter Moldt Peter Moldt, Ph.D.	Director	March 23, 2021
/s/ Carole Nuechterlein Carole Nuechterlein	Director	March 23, 2021
/s/ Thomas Woiwode Thomas Woiwode, Ph.D.	Director	March 23, 2021
/s/ Kathleen Sereda Glaub Kathleen Sereda Glaub	Director	March 23, 2021

Description of Capital Stock

The following summary describes the capital stock of Aligos Therapeutics, Inc. (the "Company," "we," "us" and "our") and the material provisions of our amended and restated certificate of incorporation and our amended and restated bylaws, the amended and restated investors' rights agreement to which we and certain of our stockholders are parties and of the Delaware General Corporation Law. Because the following is only a summary, it does not contain all of the information that may be important to you. For a complete description, you should refer to our amended and restated certificate of incorporation, amended and restated bylaws and amended and restated investors' rights agreement, copies of which are incorporated by reference as Exhibits 3.1, 3.2 and 10.4, respectively, to our Annual Report on Form 10-K.

General

Our authorized capital stock consists of 300,000,000 shares of common stock, $0.0001 par value per share, 20,000,000 shares of non-voting common stock, $0.0001 par value per share, and 10,000,000 shares of preferred stock, $0.0001 par value per share.

Common Stock and Non-Voting Common Stock

Voting Rights

The holders of our common stock and non-voting common stock have identical rights, provided that, (i) except as otherwise expressly provided in our amended and restated certificate of incorporation or as required by applicable law, on any matter that is submitted to a vote by our stockholders, holders of our common stock are entitled to one vote per share of common stock, and holders of our non-voting common stock are not entitled to any votes per share of non-voting common stock, including for the election of directors, and (ii) holders of our common stock have no conversion rights, while holders of our non-voting common stock have the right to convert each share of non-voting common stock into one share of common stock at such holder's election, provided that as a result of such conversion, such holder, together with its affiliates and any members of a Schedule 13(d) group with such holder, would not beneficially own in excess of 4.99% of our common stock immediately prior to and following such conversion, unless otherwise expressly provided for in our amended and restated certificate of incorporation. However, this ownership limitation may be increased to any other percentage designated by such holder of non-voting common stock upon 61 days' notice to us or decreased at any time upon notice to us.

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our stockholders do not have cumulative voting rights in the election of directors. Accordingly, holders of a majority of the voting shares are able to elect all of the directors. In addition, the affirmative vote of holders of 66-2/3% of the voting power of all of the then outstanding voting stock will be required to take certain actions, including amending certain provisions of our amended and restated certificate of incorporation, such as the provisions relating to amending our amended and restated bylaws, our classified board and director liability.

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of our common stock and non-voting common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

Rights Upon Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock and non-voting common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of preferred stock.

Other Rights

Holders of our common stock and non-voting common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to our common stock or non-voting common stock. The rights, preferences and privileges of the holders of our common stock and non-voting common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of our preferred stock that we may designate in the future.

Fully Paid and Nonassessable

All of our outstanding shares of common stock and non-voting common stock are fully paid and nonassessable.

Preferred Stock

Our board of directors has the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action.

Registration Rights

Under our amended and restated investors' rights agreement, certain holders of shares of common stock and non-voting common stock, or their transferees, have the right to require us to register their shares under the Securities Act of 1933, as amended, so that those shares may be publicly resold, and certain holders of shares of common stock and non-voting common stock, or their transferees, have the right to include their shares in any registration statement we file, in each case as described below.

Form S-1 Demand Registration Rights

Certain holders of shares of our common stock and non-voting common stock, or their transferees, are entitled to certain Form S-1 demand registration rights. Beginning April 14, 2021, the holders of at least 30% of these shares can request that we register all or a portion of their shares (including the shares of common stock into which any shares of non-voting common stock held by such investors may be converted), so long as such holders request that we register at least 20% of the shares entitled to these demand registration rights and the aggregate proceeds, net of underwriting discounts and commissions, would exceed $20 million if the first offering or $5 million after the first offering. These stockholders may make up to two requests for registration on Form S-1.

Form S-3 Demand Registration Rights

Certain holders of shares of our common stock and non-voting stock, or their transferees, are entitled to certain Form S-3 demand registration rights. If we are eligible to use a Form S-3 registration statement, the holders of these shares can request that we register all or a portion of their shares on a Form S-3 registration statement if the anticipated aggregate offering price is at least $2 million, net of underwriting discounts and commissions and certain other expenses related to the sale of the shares. These stockholders may make unlimited requests for registration on Form S-3, provided that we are not obligated to effect, or take any action to effect, a registration on Form S-3 if we have effected two registrations on Form S-3 pursuant to requests by these stockholders within the twelve month period immediately preceding such request.

Piggyback Registration Rights

In the event that we determine to register any of our common stock under the Securities Act of 1933, as amended, (subject to certain exceptions), either for our own account or for the account of other security holders, certain holders of shares of our common stock and non-voting common stock or their transferees will be entitled to certain "piggyback" registration rights allowing the holders to include their shares in such registration, subject to certain marketing and other limitations and the conversion of non-voting common stock into shares of common stock prior to registration thereof. As a result, whenever we propose to file a registration statement under the Securities Act of 1933, as amended, other than with respect to certain registrations, including related to the sale of securities to employees pursuant to employee benefit plans, the offer and sale of convertible debt securities, an SEC Rule 145 transaction, or a registration on any form that does not include substantially the same information as would be required to be included in a registration statement covering the sale of the registerable shares, the holders of these shares are entitled to notice of the registration and have the right to include their shares of common stock in the registration. In an underwritten offering, the underwriters have the right, subject to specified conditions, to limit the number of shares such holders may include.

Expenses of Registration

We will pay the registration expenses, excluding underwriting discounts and commissions and certain other expenses, of the holders of the shares registered pursuant to the Form S-1 demand, Form S-3 demand and piggyback registration rights described above, including the reasonable expenses of one counsel for the selling holders not to exceed $50,000.

Expiration of Registration Rights

The Form S-1 demand, Form S-3 demand and piggyback registration rights described above will terminate, with respect to any particular stockholder, upon the earlier of (i) three years after the consummation of our initial public offering, (ii) the date that Rule 144 or another similar exemption under the Securities Act of 1933, as amended, is available to such stockholder for the sale of all of such stockholder's shares without limitation during a three-month period, or (iii) upon the consummation of a merger or consolidation.

Anti-takeover Effects of Provisions of our Amended and Restated Certificate of Incorporation, our Amended and Restated Bylaws and Delaware Law

Some provisions of Delaware law and our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could make the following transactions more difficult: acquisition of us by means of a tender offer; acquisition of us by means of a proxy contest or otherwise; or removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions that might result in a premium over the market price for our shares.

These provisions, summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Delaware Anti-takeover Statute

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits persons deemed "interested stockholders" from engaging in a "business combination" with a publicly-held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an

“interested stockholder” is a person who, together with affiliates and associates, beneficially owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation’s voting stock. Generally, a “business combination” includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors, such as discouraging takeover attempts that might result in a premium over the market price of our common stock.

Undesignated Preferred Stock

The ability to authorize undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to institute a change of control of our company. These and other provisions may have the effect of deterring hostile takeovers or delaying changes in control or management of our company.

Special Stockholder Meetings

Our amended and restated bylaws provide that a special meeting of stockholders may only be called by our board of directors, Chief Executive Officer or, in the absence of a chief executive officer, our President.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Elimination of Stockholder Action by Written Consent

Our amended and restated certificate of incorporation and our amended and restated bylaws eliminate the right of stockholders to act by written consent without a meeting.

Classified Board; Election and Removal of Directors; Filling Vacancies

Our board of directors is divided into three classes. The directors in each class serve for a three-year term, one class being elected each year by our stockholders. Only one class of directors is elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because our stockholders do not have cumulative voting rights, our stockholders holding a majority of the shares of common stock outstanding will be able to elect all of our directors. Our amended and restated certificate of incorporation provides for the removal of any of our directors only for cause and requires a stockholder vote by the holders of at least a 66-2/3% of the voting power of the then outstanding voting stock. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of the board, may only be filled by a resolution of the board of directors unless the board of directors determines that such vacancies will be filled by the stockholders. This system of electing and removing directors and filling vacancies may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of our directors.

Choice of Forum

Our amended and restated certificate of incorporation provides 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 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 are 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 of 1933, as amended.

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 would not apply to suits brought to enforce any liability or duty created by the Securities Exchange Act of 1934, as amended.

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 are not 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.

Amendment of Certificate of Incorporation Provisions

The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue undesignated preferred stock, would require approval by a stockholder vote by the holders of at least a 66-2/3% of the voting power of the then outstanding voting stock.

The provisions of the Delaware General Corporation Law, our amended and restated certificate of incorporation and our amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Nasdaq Global Select Market Listing

Our common stock is listed on the Nasdaq Global Select Market under the symbol “ALGS.”

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Continental Stock Transfer & Trust Co. The transfer agent and registrar’s address is 1 State Street, 30th Floor, New York, NY 10004.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-249568) pertaining to the 2018 Equity Incentive Plan, 2020 Incentive Award Plan, and 2020 Employee Stock Purchase Plan of Aligos Therapeutics, Inc. of our report dated March 23, 2021, with respect to the consolidated financial statements of Aligos Therapeutics, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2020.

/s/ Ernst & Young LLP

Redwood City, California
March 23, 2021

Exhibit 31.1

CERTIFICATION 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

I, Lawrence M. Blatt, Ph.D., certify that:

1. I have reviewed this Annual Report on Form 10-K of Aligos Therapeutics, Inc.;

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

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

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

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

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

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

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

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

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

Date: March 23, 2021

By: /s/ Lawrence M. Blatt
Lawrence M. Blatt, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION 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

I, Lesley Ann Calhoun, certify that:

1. I have reviewed this Annual Report on Form 10-K of Aligos Therapeutics, Inc.;

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

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

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

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

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

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

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

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

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

Date: March 23, 2021

By: /s/ Lesley Ann Calhoun
Lesley Ann Calhoun
Executive Vice President, Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the Annual Report of Aligos Therapeutics, Inc. (the "Company") on Form 10-K for the period ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 23, 2021

By: /s/ Lawrence M. Blatt
Lawrence M. Blatt, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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

In connection with the Annual Report of Aligos Therapeutics, Inc. (the "Company") on Form 10-K for the period ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 23, 2021

By: /s/ Lesley Ann Calhoun
Lesley Ann Calhoun
Executive Vice President, Chief Financial Officer
(Principal Financial and Accounting Officer)