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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, 2019.

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 001-38944

Akero Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**81-5266573**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
170 Harbor Way, 3rd Floor **South San Francisco, CA**	**94080**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code **(650) 487-6488**

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	AKRO	The Nasdaq Global Select Market

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted and posted 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 and post such files). Yes ☒ No ☐

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

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

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

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant was $195,939,947 as of June 28, 2019 (based on a closing price of $19.15 per share as quoted by the Nasdaq Global Select Market as of such date). In determining the market value of non-affiliate common stock, shares of the registrant's common stock beneficially owned by officers, directors and affiliates have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 6, 2020, the total number of shares outstanding of the registrant's Common Stock was 28,607,913 shares.

Documents Incorporated by Reference:

Part III of this Annual Report on Form 10-K incorporates by reference certain information from the registrant's definitive Proxy Statement for its 2020 annual meeting of shareholders, which the registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year end of December 31, 2019. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as part of this Form 10-K.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements involve risks, uncertainties, and other factors that may cause actual results, levels of activity, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements. All statements, other than statements of historical facts, contained in this Annual Report on Form 10-K, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management and expected market growth are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

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

- the success, cost and timing of our product development activities and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs;
- our ability to advance any product candidate into or successfully complete any clinical trial;
- our ability or the potential to successfully manufacture our product candidates for clinical trials or for commercial use, if approved;
- the potential for our identified research priorities to advance our technologies;
- our ability to obtain and maintain regulatory approval, if obtained, of AKR-001 or any future product candidates, and any related restrictions, limitations and/or warnings in the label of an approved product candidate;
- the ability to license additional intellectual property relating to any future product candidates and to comply with our existing license agreement;
- our ability to commercialize our products in light of the intellectual property rights of others;
- the success of competing therapies that are or become available;
- our ability to obtain funding for our operations, including funding necessary to complete further development and commercialization of our product candidates;
- the commercialization of our product candidates, if approved;
- our plans to research, develop and commercialize our product candidates;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- future agreements with third parties in connection with the commercialization of our product candidates and any other approved product;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- the rate and degree of market acceptance of our product candidates;
- regulatory developments in the United States and foreign countries;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- our ability to attract and retain key scientific or management personnel;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the impact of laws and regulations; and
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly in the "Risk Factors" section, that could cause actual results or events to differ materially from the forward-looking statements

that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments that we may make or into which we may enter.

You should read this Annual Report on Form 10-K and the documents that we reference herein and have filed or incorporated by reference as exhibits hereto completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

NOTE REGARDING TRADEMARKS

Akero Therapeutics, Inc. is the owner of the AKERO trademark, as well as certain other trademarks, including design versions of some of these trademarks. The symbols ™ and ® are not used in connection with the presentation of these trademarks in this report and their absence does not indicate a lack of trademark rights. Certain other trademarks used in this report are the property of third-party trademark owners and may be presented with or without trademark references.

PART I

All brand names or trademarks appearing in this report are the property of their respective owners. Unless the context requires otherwise, references in this report to "Akero," the "Company," "we," "us" and "our" refer to Akero Therapeutics, Inc. and its subsidiary.

Item 1. Business

Overview

We are a cardio-metabolic nonalcoholic steatohepatitis, or NASH, company dedicated to developing pioneering medicines that restore metabolic balance and improve overall health. NASH is a severe form of nonalcoholic fatty liver disease, or NAFLD, characterized by inflammation and fibrosis in the liver that can progress to cirrhosis, liver failure, cancer and death. Our lead product candidate, AKR-001, is an analog of fibroblast growth factor 21, or FGF21, which is an endogenously expressed hormone that regulates metabolism of lipids, carbohydrates and proteins throughout the body. FGF21 also plays a critical role in protecting many types of cells from various forms of stress. In previous clinical trials in patients with type 2 diabetes, or T2D, administration of AKR-001 was associated with substantial improvements in lipid metabolism and insulin sensitivity. We believe these data, coupled with clinical results from other FGF21 analogs, demonstrate AKR-001's potential to serve as a cornerstone for the treatment of NASH. We are currently conducting a Phase 2a clinical trial, the BALANCED study, which is evaluating AKR-001 in the treatment of NASH patients. We expect to complete collection of data for the BALANCED main study week 12 primary endpoint, and report top-line results related to reductions in liver fat, in the first quarter of 2020. Top-line results related to secondary endpoints, including safety and tolerability as well as paired biopsies, will be reported in the second quarter of 2020. We also plan to expand the BALANCED study to include an additional cohort of subjects with NASH who have compensated cirrhosis (F4), Child-Pugh Class A, with study initiation expected in the second quarter of 2020.

The rapidly rising prevalence of NAFLD and NASH is driven by the global obesity epidemic. Poor diet and lack of exercise lead to caloric overburdening of the liver and accumulation of excessive liver fat. In patients with NASH, excessive liver fat leads to hepatocyte stress, which triggers localized inflammation and, as disease progresses, can lead to fibrosis and ultimately cirrhosis. According to a study published in Hepatology (2018), the prevalence of NASH in the United States is projected to increase from an estimated 17.3 million in 2016 to 27.0 million by 2030. In particular, the prevalence of patients with advanced fibrosis in the United States is projected to more than double between 2016 and 2030. NASH is the liver manifestation of metabolic syndrome and is frequently associated with insulin resistance and T2D. Additionally, patients with NASH have high rates of cardiovascular-related events, such as stroke and heart attack, with cardiovascular disease being the leading cause of death in patients with NASH. There are currently no approved therapies for NASH, while emerging potential NASH therapies in late-stage clinical development have shown limited efficacy or may be limited by unwanted side effects.

AKR-001 is an FGF21 analog with unique properties that we believe has the potential to address the core processes underlying NASH pathogenesis, thereby enabling it to restore healthy fat metabolism in the liver, reduce hepatocyte stress, mitigate inflammation and resolve fibrosis. FGF21 is an endocrine hormone that acts on the liver, pancreas, muscle and adipose tissue to regulate the metabolism of lipids, carbohydrates and proteins. Acting as a paracrine hormone, FGF21 also plays a critical role in protecting cells against stress. These attributes make FGF21 agonism a compelling therapeutic mechanism, but native FGF21 is limited by its short half-life in the bloodstream. AKR-001 has been engineered to increase human FGF21's half-life sufficiently to enable dosing once-weekly or once every two weeks, while retaining the native biological activity of FGF21.

AKR-001 was administered to a total of 83 patients with T2D in two Phase 1 clinical trials. In a Phase 1b clinical trial, it was observed that AKR-001 substantially improved plasma lipoprotein levels, including reductions of up to 69% in triglycerides and 30% in non-high density lipoprotein cholesterol, or non-HDL-C following once-weekly administration. In the Phase 1b clinical trial, it was also observed that once-weekly administration of AKR-001 was associated with substantially improved markers of insulin sensitivity, including reductions of up to 37% in C-peptide and 55% in the homeostatic model assessment of insulin resistance, or HOMA-IR. We believe these results indicate the potential of AKR-001 to redirect calories away from the liver, reduce liver fat, alleviate hepatocyte stress, inhibit inflammation and resolve fibrosis in patients with NASH, as well as reduce susceptibility to cardiovascular disease. This belief is also supported by data from Phase 2 clinical trials of other endocrine FGF analogs in patients with NASH, in which substantial reductions in liver fat content, improvements in biomarkers of liver fibrosis, and improvements in histological measures have been observed.

We therefore believe that AKR-001 has the potential to be a leading endocrine FGF analog, if approved, for treatment of this rapidly growing patient population that lacks effective treatment options.

In June 2018, we acquired exclusive global development and commercialization rights to AKR-001 from Amgen Inc., or Amgen, which leveraged its deep protein engineering expertise to design and develop AKR-001. As of December 31, 2019, our patent portfolio relating to AKR-001 and other peptides included 125 issued patents and 32 pending patents worldwide, with expected patent exclusivity up to 2034 in the United States, including potential patent term extension. Since AKR-001 is a biologic, marketing approval would also provide twelve years of market exclusivity from the approval date of a Biologics License Application, or BLA, in the United States.

Our management team has extensive experience in drug discovery, development and commercialization, and has been involved in the approvals of more than 20 medicines. Our Chief Executive Officer, Andrew Cheng, MD, PhD, previously Chief Medical Officer at Gilead, was responsible for clinical development for Gilead's HIV program. Our Chief Development Officer, Kitty Yale, led global clinical operations and management of Gilead’s oncology, HIV, inflammation and liver disease trials. Our Chief Scientific Officer, Tim Rolph, DPhil, formerly Chief Scientific Officer of Pfizer's Cardiovascular & Metabolic Disease Research Unit, previously oversaw Pfizer's FGF21 program. We believe that our team is well positioned to leverage its collective experience in drug development and in-depth knowledge of FGF21 biology and metabolic diseases to develop and commercialize products that will have significant benefits for patients with NASH and other serious metabolic diseases with high unmet medical need.

Our strategy

Our goal is to become a leading biotechnology company focused on developing and commercializing transformative treatments for serious metabolic diseases with high unmet medical need. The key components of our strategy are to:

Advance AKR-001 through clinical development in NASH. We believe that AKR-001's differentiated profile as an FGF21 analog has the potential to result in a leading endocrine FGF analog, if approved, for the treatment of NASH. Our IND application, which included a Phase 2a clinical trial protocol, was cleared by the FDA on May 24, 2019. We closed enrollment for our Phase 2a clinical trial on December 16, 2019, which is assessing the efficacy and safety of AKR-001 in patients with NASH and inform dose selection for larger, longer-term trials. Consistent with recently published draft guidance from the FDA on NASH development, we are committed to exploring ways to accelerate development of AKR-001 through innovative clinical trial designs.

Scale our capabilities to support development and commercialization of AKR-001. We plan to scale our manufacturing and organizational capabilities to capitalize on our exclusive, global rights to market AKR-001 for all indications. We have contracted with Boehringer Ingelheim to manufacture new drug substance for future clinical trials and support the potential commercialization of AKR-001 with commercial-scale manufacturing. When appropriate, we intend to develop the commercial infrastructure required for bringing AKR-001 to patients with NASH in the United States, if approved. We also plan to evaluate options for delivering AKR-001, if approved, to patients in other key markets, such as Europe, Japan and China, which may include strategic collaborations.

Enhance our position as a leading metabolic disease company by leveraging our knowledge of FGF21 biology. Numerous publications have shown that increases in endogenous FGF21 expression occur in response to various types of metabolic and cellular stress arising from obesity, diabetes, mitochondrial diseases and cardiovascular disease, as well as NASH. AKR-001 has been engineered to reproduce the biological activity profile of native FGF21 while also addressing certain therapeutic limitations, such as a short half-life. We plan to explore opportunities to develop AKR-001 for additional indications where there is a compelling scientific rationale, strong clinical tractability and significant unmet medical need.

Develop, acquire or in-license product candidates that enhance our potential to become a leading metabolic disease company. We are continually evaluating opportunities to build a robust pipeline of potential leading treatments for metabolic diseases. Additional assets may be selected for their potential as stand-alone monotherapies or for eventual use in combination with other products.

NASH overview

We are developing AKR-001 as a potential treatment for patients with NASH, a disease with high unmet medical need and no approved therapies. NASH is a severe form of NAFLD, which is driven by the global obesity epidemic. Patients with NAFLD have an excessive accumulation of fat in the liver resulting from an excess of caloric intake over energy needs. In patients with NASH, excessive liver fat leads to hepatocyte stress, which triggers localized inflammation and can ultimately lead to fibrosis and scarring in the liver, or cirrhosis.

Patients with NASH are at increased risk of liver-related morbidity and mortality, including liver failure and hepatocellular carcinoma. As NASH progresses, cardiovascular-related morbidity and mortality also increase, such that the most frequent cause of death in patients with NASH is cardiovascular disease. In particular, the prevalence of patients with advanced fibrosis in the United States is projected to more than double between 2016 and 2030. We believe that AKR-001 has the potential to be a leading endocrine FGF analog, if approved, for treatment of this rapidly growing patient population. This belief is based, in part, on AKR-001's observed effects on lipoproteins and markers of insulin sensitivity, when viewed in the context of similar measurements taken in clinical trials with other endocrine FGF analogs.

Etiology of NASH

NASH is primarily driven by chronic excess caloric intake, or ingesting more energy than the body expends over a sustained period, which results in people becoming overweight and obese. Body fat, also known as adipose tissue, and muscle respond to becoming saturated with energy by reducing sensitivity to insulin, which would otherwise drive uptake of energy by these peripheral tissues. Consequently, the liver becomes the repository for the energy that is unwanted by the rest of the body.

While there is a lack of scientific consensus on how best to characterize NASH pathogenesis, we believe there are five core processes:

- Caloric overburdening of the liver;
- Excessive liver fat and fat oxidation;
- Hepatocyte cell stress, injury and death;
- Localized inflammation triggered by hepatocyte death; and
- Fibrosis.

These processes can lead to cirrhosis, liver failure, cancer and death. Figures 1 and 2 below illustrate these five processes. Figure 1 shows how multiple organs of the body contribute to caloric overburdening of the liver, which manifests as excessive accumulation of liver fat, or steatosis, and high rates of fat oxidation within the liver. Figure 2 depicts the cellular-level processes that arise from hepatocyte stress caused by high levels of certain lipid molecules, or lipotoxicity, and oxidative stress. Hepatocyte stress leads to cell death, which in turn activates local inflammatory responses in the liver, potentially leading to fibrosis. Parenthetical references in the text below correspond to sequential labels in Figures 1 and 2.

Figure 1—NASH pathogenesis: Caloric overburdening causes excessive deposition of liver fat and high rates of fat oxidation

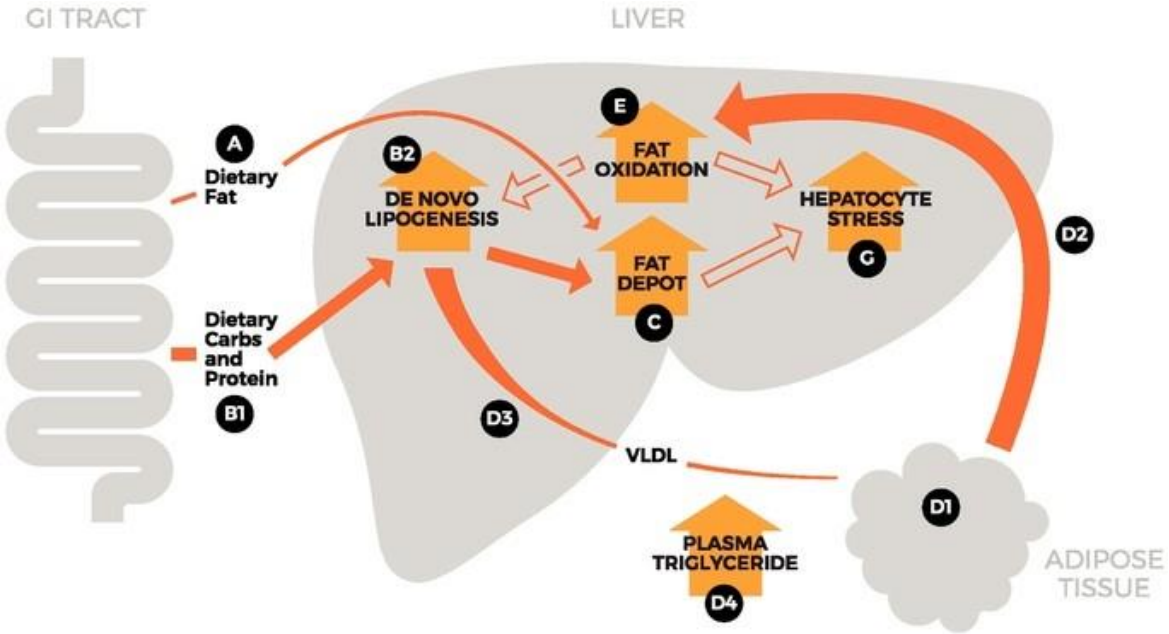
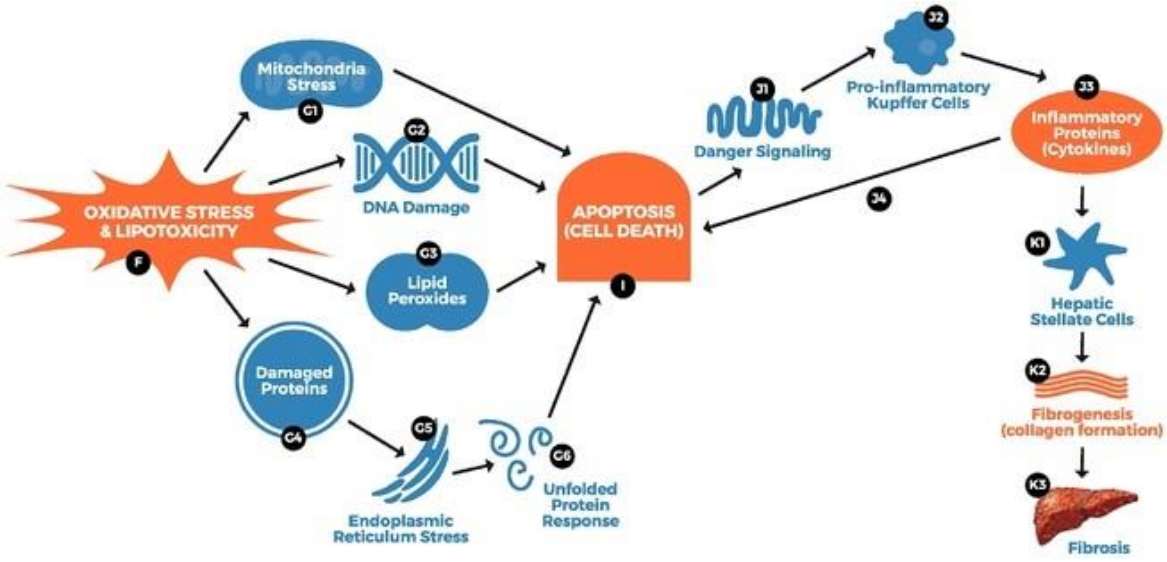


Figure 2—NASH pathogenesis: Oxidative stress and lipotoxicity induce hepatocyte death, local inflammation and fibrosis



Caloric overburdening of the liver

When intake of energy chronically exceeds demand, the body adapts its metabolism to find alternate locations to store the excess energy. Absorption of dietary fat (A), dietary carbohydrates and protein (B1), and lipids from adipose tissue (D1) all contribute to caloric overburdening of the liver.

Excessive deposition of fat and high rates of fat oxidation in the liver

Healthy individuals typically have liver fat levels of less than 5%. In patients with NASH, liver fat levels typically range from 10% to 30%. Liver fat, and fat oxidation, increase in response to caloric overburdening of the liver.

The largest source of liver fat is from adipose tissue (D1), accounting for approximately 40% to 50%, on average, of liver fat in patients with NASH. Flux of fat from adipose tissue to the liver through lipolysis (D2) is driven by resistance to insulin. This resistance to insulin also means dietary fat transported as chylomicrons (A) and very low density lipoprotein, or VLDL (D3), a form of fat packaged by the liver for delivery to the body's organs, are not taken up by adipose tissue. As a result, the level of plasma triglycerides (D4) increases, manifesting as hypertriglyceridemia, which is frequently observed in NASH. The second largest source of fat in liver is from synthesis of new fat, known as de novo lipogenesis, or DNL (B2), which utilizes dietary carbohydrates and protein (B1) to make new fat, and accounts for approximately 30% to 40%, on average, of liver fat in patients with NASH. The final source of liver fat is fat ingested in diet (A), accounting for approximately 10% to 20%, on average, of liver fat in patients with NASH.

The liver responds to increased flow of fat from adipose tissue by increasing the rate at which it burns fat, a process known as fat oxidation (E), which in turn releases substantial amounts of energy. Initially, this surplus energy is consumed by additional DNL. However, if the high rate of DNL continues chronically, hepatocytes become saturated with stores of fat, or fat depots (C), and the rate of DNL slows. In this situation, excess energy from fat oxidation causes oxidative stress, which together with lipotoxicity arising from fat depots, results in hepatocyte stress (G).

Hepatocyte stress, injury and death

Later-stage NASH pathogenesis is driven by hepatocyte stress and cell death, or apoptosis, which lead to inflammation and fibrosis. In particular, increased fat oxidation in the liver leads to formation of highly reactive molecules, known as free radicals, which cause oxidative stress. A free radical is an energetically unstable, reactive entity containing an atom of oxygen with an unpaired electron. A free radical is stabilized by pairing this electron with an electron acquired by the oxygen atom from another molecule. Cells have defense mechanisms to neutralize free radicals by donation of an electron from molecules known as antioxidants. When the quantity of free radicals exceeds the capacity of antioxidants to neutralize them, free radicals react with other constituents of cells such as DNA, proteins, or lipids to acquire an electron. The attack on these macromolecules leads to mitochondrial stress (G1), DNA damage (G2), formation of lipid peroxides (G3) and synthesis of damaged proteins (G4), all of which disrupt cellular processes and homeostasis, thereby increasing hepatocyte stress. Damaged proteins stress the endoplasmic reticulum, or ER (G5), which is the cell's machinery for making proteins. Accumulation of damaged proteins in the ER impairs assembly of proteins, thereby triggering the unfolded protein response.

Apoptosis of hepatocytes manifests as ballooning of the cells, a characteristic microscopic feature of NASH liver tissue. Hepatocyte stress, injury and death are the bridge between oxidative stress and lipotoxicity arising from excessive delivery of fat and calories to the liver and the downstream sequelae of inflammation and fibrosis.

Inflammatory response to hepatocyte stress and death

Hepatocytes undergoing apoptosis release danger signal molecules known as damage-associated molecular patterns, or DAMPs (J1). DAMPs activate a population of specialist immune-effector cells resident within the liver, known as Kupffer cells (J2), which typically clear debris from dying liver cells and defend against microbial infections. Once activated, Kupffer cells release various pro-inflammatory molecules, including cytokines (such as TNF, TGF, IL-1, and IL-6), chemokines (such as MCP-1/CCL2), prostanoids and nitric oxide (J3). Cytokines and chemokines serve to attract other immune system cells stored in the bone marrow, known as monocytes, which in turn become pro-inflammatory macrophages and amplify inflammation within the liver. Among the cytokines released, TNF and TGF also act to induce apoptosis of neighboring hepatocytes (J4), thereby creating a cycle of hepatocyte death that stimulates more inflammation and results in extensive loss of hepatocytes and metabolic capacity. This, in turn, places more stress on the remaining hepatocytes.

Fibrosis and cirrhosis

High local levels of cytokines, particularly TGF, activate another group of liver-resident cells known as hepatic stellate cells, or HSC, (K1). HSCs are normally dormant. However, when activated, they produce large amounts of collagen. At first, in a process known as fibrogenesis (K2), the extracellular collagen forms isolated fibrotic structures largely surrounded by healthy cells. As collagen continues to be deposited, the fibrotic structures interconnect, a process known as bridging fibrosis (K3). When hepatic stellate cells are chronically activated, collagen deposition becomes excessive and ultimately leads to scarring, or cirrhosis. If a liver progresses to cirrhosis, blood flow through the liver is greatly reduced, causing inadequate delivery of oxygen and nutrients, which in extreme cases results in acute liver failure and death.

Disease diagnosis and disease burden

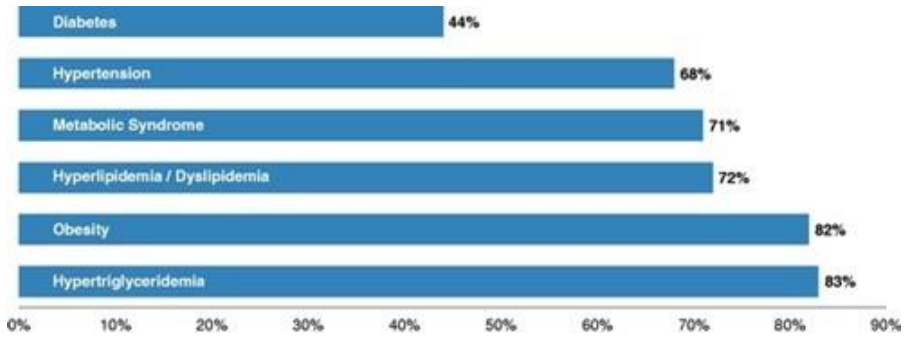
NASH is currently diagnosed only through liver biopsy and its severity is measured using scoring systems that assess the extent and severity of steatosis, lobular inflammation, hepatocellular ballooning and fibrosis. Some patients may be diagnosed with NASH after presenting with symptoms such as general fatigue and nondescript abdominal discomfort. However, NASH diagnosis more commonly follows detection of elevated liver enzymes on routine lab tests or detection of an enlarged steatotic liver by abdominal imaging. Although non-invasive methods, including a combination of imaging such as MRI-PDFF and plasma biomarkers of fibrosis, such as PRO-C3, are being evaluated as potential diagnostic tools, none have yet been validated for use in formal NASH diagnosis.

Two different scoring systems are most commonly used in the United States to measure the severity of NASH: the NAFLD activity score, or NAS, and fibrosis stage. The NAS, which was developed for, and generally only used in, clinical trials, is a measure of liver histology that grades disease activity in patients with NAFLD and NASH. A patient may receive a composite NAS score of zero to eight, which is comprised of three individual scores: (1) steatosis, scored zero to three according to the percentage of a microscopic field showing steatosis, (2) lobular inflammation, scored zero to three according to the number of immune cell foci per 20x optical field in a microscope, and (3) hepatocellular ballooning, scored zero to two according to the number of ballooning cells in a microscopic field. In addition, fibrosis staging is used to classify the extent and severity of fibrosis. A scoring system based on a scale from zero to four (F0-F4) is used. Early, discrete fibrosis is classified as F1 or F2, whereas bridging fibrosis is classified as F3. As more hepatocytes die and scarring becomes extensive, the liver becomes cirrhotic, which is classified as stage F4. F0 corresponds to steatohepatitis with no evidence of fibrosis.

Patients with NASH are at increased risk of liver damage and other complications. Fibrosis is generally reversible in its early-to-mid stages. However, late-stage fibrosis can be irreversible and prevents the liver from performing its natural functions.

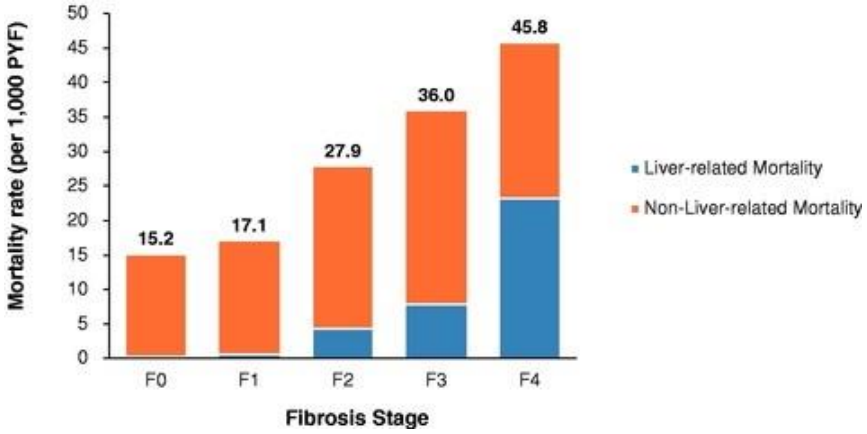
As shown in Figure 3 below, NASH is commonly associated with metabolic comorbidities, including obesity, T2D, dyslipidemia and metabolic syndrome, and with hypertension.

Figure 3—Prevalence of comorbidities among NASH patients



Liver-related mortality increases with fibrosis stage, as shown in Figure 4 below. As compared to healthy individuals, patients with NASH also experience higher all-cause morbidity and mortality resulting from major adverse cardiovascular events, or MACE, and non-liver cancers. The most common cause of death in NASH patients is cardiovascular disease. As with liver-related mortality, all-cause mortality also increases with fibrosis stage.

Figure 4—All-cause NASH mortality

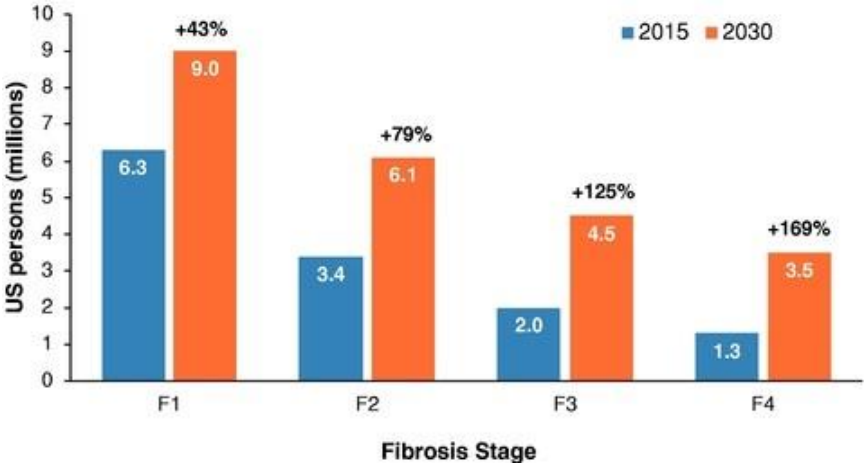


Market size and trends

According to studies published in Hepatology (2018) and F1000Research (2018), more than one billion people worldwide were estimated to have NAFLD in 2016, including an estimated 85 million individuals in the United States. Approximately 10-20% of patients with NAFLD progress to NASH, including an estimated 17.3 million individuals in the United States and 16.4 million aggregate individuals in France, Germany, Italy, Spain, the United Kingdom, and Japan in 2016. As the population ages, the prevalence of NASH is projected to increase approximately 50% by 2030 to a total of 27.0 million individuals in the United States and 22.5 million aggregate individuals in France, Germany, Italy, Spain, the United Kingdom and Japan. However, NASH afflicts all age groups, including teenagers and young adults, for whom the loss of quality-adjusted life years will be very substantial unless progression to late-stage diseases can be halted or reversed. According to a study published in Hepatology (2016), in the absence of approved therapies, direct healthcare costs associated with NAFLD and NASH in the United States were estimated to be approximately $100 billion in 2016.

As shown in Figure 5 below, growth in prevalence of NASH in the United States from 2015 to 2030 is projected to be greatest, at approximately 140%, in patients with stage F3-F4 fibrosis. By 2030, there are projected to be eight million individuals in the United States and six million aggregate individuals in France, Germany, Italy, Spain, the United Kingdom, and Japan with stage F3-F4 NASH. This rapid growth in advanced fibrosis reflects the time required for the late 20th century obesity epidemic to result in patients progressing through NAFLD to advanced NASH.

Figure 5—United States NASH prevalence by fibrosis stage



Emerging therapies in development

There are no therapies currently approved for the treatment of NASH. The current standard of care is diet and exercise. Although diet and exercise are effective in the treatment of NASH when maintained, adherence to this treatment regimen is generally poor.

The multistep progression of NASH pathogenesis offers multiple potential approaches for therapeutic intervention. Some of the most advanced therapeutic candidates in development have targeted inflammation and fibrosis, but not the early stages of NASH pathogenesis. The mechanisms of these therapies are generally labeled as "anti-fibrotic." Early indications from long-term clinical trials suggest that focusing on suppressing inflammation and fibrosis may not deliver sustained reversal or resolution of NASH, because the processes underlying NASH pathogenesis are not being addressed.

Therapeutic mechanisms that target earlier-stages of NASH pathogenesis, including excessive liver fat accumulation, are generally characterized as “metabolic.” Two relevant precedents indicate that targeting the processes underlying inflammation and fibrosis of the liver can lead to reversal of fibrosis, even without a directly anti-fibrotic intervention. First, anti-viral treatment of hepatitis C has been shown to reverse fibrosis when viral load is suppressed, even though the treatment does not act directly on fibrosis. This is attributable to the capacity of liver to regenerate, or heal itself once the chronic underlying driver of inflammation and fibrosis has been addressed. Second, the current standard of care for NASH treatment, diet and exercise, has also been shown to reverse fibrosis. For example, a sustained weight loss of 10% or more through diet and exercise has been shown to reverse NASH fibrosis, including advanced fibrosis, without any direct pharmacological anti-fibrotic effect.

Early indications from Phase 2 clinical trials of third-party agents suggest that metabolic mechanisms may have robust effects on certain measures of NASH disease progression, including reductions in fibrosis. However, some of these metabolic therapeutic mechanisms have unwanted side effects that may limit their ability to be used as treatment for patients with NASH. For instance, some NASH candidates have been shown to substantially increase plasma levels of low-density lipoprotein cholesterol, or LDL-C, or triglycerides, each of which is an independent causal risk factor for cardiovascular disease. We believe interventions that may increase cardiovascular risk will be scrutinized by prescribing physicians, as patients with NASH are already at increased risk for cardiovascular events.

Figure 6 provides some examples of therapeutic approaches to NASH and potential limitations of these therapeutic targets.

Figure 6—Selected NASH interventions under development

Approach	Potential Benefits	Potential Limitations
Diet and Exercise (caloric overburdening of the liver)	Liver shown to partially regenerate if the underlying disease cause is addressed	Long-term adherence is poor
Peroxisome proliferator-activated receptor (PPAR)	Agonism reduces adipose lipolysis; directly anti-inflammatory	Exclusion of patients with heart-failure; weight gain and cancer concerns
Acetyl-CoA (ACC)	Inhibition reduces DNL	Increases triglycerides, thrombocytopenia; minimal suppression of adipose lipolysis
Thyroid Receptor-β (TR- β)	Agonism increases fat oxidation by liver	Limited suppression of adipose lipolysis; narrow therapeutic index due to drug-drug interactions and risk of hypothyroidism with peripheral exposure
Farnesoid X receptor (FXR)	Persistent agonism significantly reduces NASH histopathology	Persistent agonism associated with LDL-C elevation and pruritus; limited suppression of adipose lipolysis; intermittent agonism may be less effective
Fibroblast Growth Factor Receptors (FGFRs)	Agonism of FGFR1c, 2c and 3c associated with robust reductions in liver fat and rapid reductions in fibrosis	Agonism of FGFR4 is associated with increases in LDL-C

Some NASH candidates are being evaluated for use in combination with one or more other candidates that intervene in different processes underlying NASH pathogenesis. In other cases, combination approaches are being evaluated to mitigate unwanted side effects, such as using statins in combination with FXR and FGFR4 agonists to reduce LDL-C. However, combining multiple interventions, particularly multiple small molecules, places an additional burden of drug metabolism and clearance upon already stressed hepatocytes.

Some individual interventions, including PPAR, FGF19 and FGF21 analogs, target multiple processes underlying NASH pathogenesis. Of these, we believe AKR-001 has unique properties with the potential to address each of the five core processes underlying NASH pathogenesis, thereby reducing liver fat, hepatocytes stress and reversing fibrosis in patients with NASH.

Our approach to NASH: harnessing FGF21's natural potential for therapeutic effect

FGF21 is an endogenous hormone that has both local, or paracrine, effects on cells and systemic, or endocrine, effects on metabolic organs. FGF21's natural recruitment to alleviate many forms of cellular stress, and to regulate whole-body metabolism, make it a compelling therapeutic target. However, native FGF21 has several limitations that prevent it from being used effectively as a therapy, including a half-life estimated to be less than two hours, as found in published studies such as the American Journal of Physiology, Endocrinology and Metabolism (2009) and Endocrinology (2007). AKR-001 is a recombinantly-engineered version of FGF21 designed to retain the native biological activity of FGF21 while enhancing its therapeutic utility. Specifically, AKR-001 features Fc-mediated half-life extension and substitution of specific amino acids within the protein sequence of FGF21. AKR-001 has a resulting half-life of three to four days in humans, which enables once-weekly or once every other week subcutaneous administration. Pharmacology studies have shown AKR-001 reproduces the balanced potency of native FGF21, acting specifically on three cell-surface receptors. AKR-001 also reproduces native FGF21's weak potency as an agonist of another cell-surface receptor known to be associated with higher plasma LDL-C.

We believe that AKR-001, with its activity on both liver and adipose tissue, has the potential to intervene in the five core processes relevant to NASH pathogenesis. Specifically, we believe that AKR-001 can:

- Redirect calories away from the liver;
- Restore healthy fat metabolism in the liver;
- Reduce hepatocyte stress;
- Mitigate inflammation; and
- Resolve fibrosis.

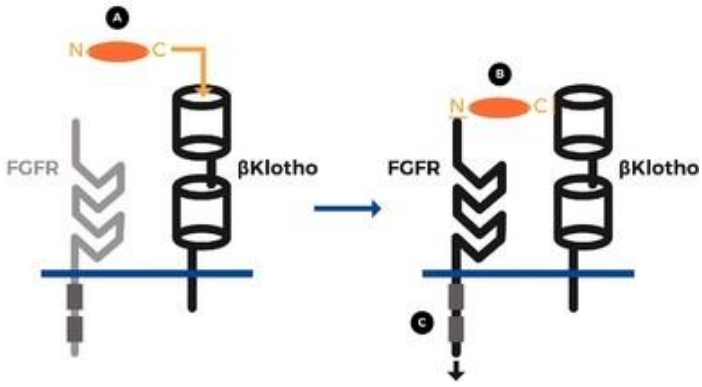
Overview of FGF21 biology

Fibroblast growth factors, or FGFs, are a large family of cell-signaling proteins involved in the regulation of many processes within the body. A sub-family of FGFs, known as endocrine FGFs, which include FGF21 and FGF19, are unique among FGFs because they initiate their biological effects by binding tightly to a cell surface receptor known as *Beta* Klotho, or βKlotho.

After this initial binding, FGF21 and FGF19 trigger signaling pathways within cells, such as hepatocytes and adipocytes, by binding to a second class of cell-surface receptor, known as the FGF receptors, or FGFRs. Both FGF21 and FGF19 bind to three specific FGFRs, known as FGFR1c, FGFR2c, and FGFR3c, which, based on nonclinical studies and clinical trials, appear to be responsible for mediating the desired therapeutic actions of FGF21 and FGF19 in NASH. However, unlike FGF21, FGF19 also binds specifically to another FGFR known as FGFR4. We believe, based on published nonclinical studies and clinical trials, that activation of FGFR4 does not ameliorate the underlying steatosis and insulin resistance and is instead associated with undesirable biological effects such as elevating LDL-C and potentially increasing the risk of developing hepatocellular carcinoma.

As illustrated in Figure 7, the C-terminus of FGF21 initially binds to βKlotho (A). This enables the N-terminus to form an expanded complex with one of the FGFRs (B). Once the co-receptor complex has formed with βKlotho and one of the FGFRs, a series of intracellular signaling cascades is initiated (C). These signaling cascades enable FGF21 to exert its biological functions, which include regulation of energy homeostasis, glucose-lipid-protein metabolism and insulin sensitivity, and modulation of pathways that mitigate against intracellular stress. FGF21 cannot signal through cell membranes without both an intact C-terminus and an intact N-terminus to bind, respectively, to βKlotho and FGFR.

Figure 7—FGF21's two-step receptor binding with βKlotho and FGFRs



Overcoming the limitations of native FGF21 as a therapeutic by rational engineering of a recombinant protein

FGF21's role in regulating whole-body metabolism and alleviating cellular stress makes it an attractive candidate with potential to treat metabolic diseases. Numerous nonclinical studies show that elevated levels of FGF21 protect against development of NASH histopathology and fibrosis resulting from a range of insults, including excess intake of fat and fructose, excess alcohol, a diet deficient in methionine and choline, and chemical toxins, such as carbon tetrachloride and nitrosamine.

However, there are several inherent limitations that mean using an unmodified form of human FGF21 would not be effective:

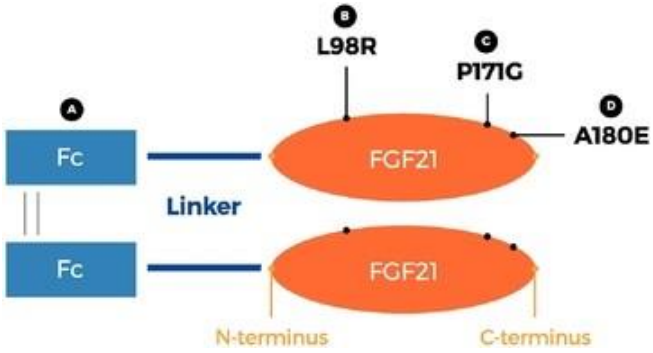
FGF21 is rapidly broken down in the bloodstream and cleared through the kidneys. The half-life of FGF21 is estimated to be less than two hours based on nonclinical studies in rodents and non-human primates. Extending the half-life of FGF21 requires reducing renal clearance and protecting both ends of the protein from proteolysis, the body's natural process for breaking-down a protein by cleaving it at specific sites. If the C-terminus of FGF21 protein is not intact, FGF21 is unable to bind to βKlotho, and if the N-terminus is not intact, FGF21 is unable to signal through one of the FGFRs.

Recombinantly-expressed human FGF21, or rhFGF21, molecules are susceptible to aggregation when formulated into a solution suitable for injection into humans. Aggregation can disrupt binding of rhFGF21 to its receptors, thereby causing it to lose its biological activity. Aggregates of rhFGF21 can become so large they are insoluble and fall out of solution, or precipitate, leading to loss of biological activity in storage.

FGF21's cell signaling depends on binding affinity to a co-receptor complex of βKlotho and FGFR1c/2c/3c, which have tissue-dependent expression. Reproducing native FGF21's biology depends on retaining both binding affinity to βKlotho and balanced signaling through FGFR1c, FGFR2c and FGFR3c. For example, in adipose tissue FGFR1c appears to be the major signaling co-receptor, while in the liver FGFR2c and FGFR3c appear to be more important as signaling receptors. Thus, balanced in vivo FGFR agonism is necessary to ensure effective activation of FGFR1c, 2c and 3c throughout the body.

AKR-001 has been engineered to: (1) protect against proteolysis and reduce renal clearance, (2) provide a half-life of three to four days in humans by protecting against proteolysis, (3) minimize potential for aggregation in solution and (4) improve binding affinity for βKlotho, while (5) retaining balanced agonism across FGFR1c, FGFR2c and FGFR3c. Figure 8 below illustrates the structural engineering of AKR-001, which is also further described in the text that follows. We believe AKR-001’s differentiated profile has the potential to result in a leading endocrine FGF analog, if approved, for treatment of NASH. This belief is based, in part, on AKR-001’s observed effects on lipoproteins and markers of insulin sensitivity, when viewed in the context of similar measurements taken in clinical trials with other endocrine FGF analogs.

Figure 8—Protein engineering of AKR-001



Fc-fusion (A). AKR-001 is an Fc-fusion protein, whereby a modified FGF21 is fused to the fragment crystallizable, or Fc, region of human immunoglobulin, or Ig, sub-type G1 antibody. Fusion with Fc is an established approach for increasing a biological molecule's half-life, enabling a longer dosing interval during which therapeutic concentrations can be maintained. Fc-fusion technology has been leveraged to produce multiple highly successful therapeutics approved by the FDA and the European Medicines Agency, or EMA, including Enbrel and Trulicity. These and other Fc-fusion protein products elicit minimal immune reactions in humans. AKR-001 is manufactured as a dimer, with two Fc-FGF21 molecules linked by two disulfide bridges to form a single molecule. The N-terminus of the FGF21 moiety is connected to the Fc portion of AKR-001 through a polyglycine-serine linker. Our patents include claims directed to Fc fusion with a recombinantly modified FGF21.

FGF21 mutation at position 98 (B). rhFGF21 is susceptible to aggregation, which can disrupt binding of rhFGF21 to its receptors, thereby reducing its biological activity, and cause instability of FGF21 during storage in solution. Substitution of a hydrophilic arginine residue for the hydrophobic leucine residue at position 98, labeled as L98R, was found to yield the lowest rate of aggregation of any FGF21 modification tested during AKR-001's development. We expect that AKR-001's resistance to aggregation will be consistent across large manufacturing lots and confer adequate stability in formulation for injection. Our patents include claims directed to an FGF21 polypeptide comprising this point mutation at position 98 in combination with other advantageous amino acid substitutions.

FGF21 mutation at position 171 (C). FGF21 is cleaved between amino acid positions 171 and 172 near the C-terminus of FGF21 by the proteolytic endopeptidase enzyme fibroblast activation protein, or FAP. FAP's action on FGF21 prevents binding to βKlotho. Therefore, FGF21 loses its biological activity when cleaved by FAP. AKR-001 remedies this limitation through a point mutation that substitutes a glycine for the proline residue at position 171, which is labeled as P171G. An FGF21 analog without protection against FAP is likely to remain susceptible to FAP-induced degradation, thus losing its biological activity even if the N-terminus remains intact. Protecting against FAP appears to be particularly critical to using FGF21 as a therapeutic agent in patients with NASH because FAP is the most over-expressed protein in liver of patients with NASH relative to protein expression by healthy livers. Our patents include claims directed to an FGF21 polypeptide comprising this point mutation at position 171 in combination with other advantageous amino acid substitutions.

FGF21 mutation at position 180 (D). Stabilization of FGF21 at position 171 was found to increase FGF21's susceptibility to degradation at position 180. Subsequent empirical studies led to the discovery that substituting glutamic acid for alanine at position 180, labeled as A180E, confers further resistance to proteolysis and increases affinity for βKlotho. Our patents include claims directed to an FGF polypeptide comprising this point mutation at position 180 in combination with other advantageous amino acid substitutions.

We believe these modifications result in the improved half-life and adequate stability that have been observed with AKR-001, while preserving FGF21's balanced potency.

Demonstrating AKR-001's reproduction of FGF21's balanced potency

The engineering of AKR-001 was an empirical discovery process that incorporated in vitro and in vivo measurements of receptor agonism to assess which of many tested discovery candidates yielded the most attractive drug properties. AKR-001 was selected for clinical evaluation over earlier discovery candidates, which included a proprietary PEGylated FGF21 analog, identified as AMG-PEG21, and two versions of a two-point mutation Fc-fusion protein known as RG (with mutations at positions 98 and 171, but not 180), one of which had the Fc fused to the C-terminus (FGF21-Fc(RG)) while the other had it fused to the N-terminus of the modified FGF21 (Fc-FGF21(RG)). In comparative receptor agonism assays, as shown in Figure 9 below, AKR-001 exhibited the greatest potency for each of FGFR1c, FGFR2c, and FGFR3c among the candidates tested. Furthermore, as shown in Figure 10 below, the potency of AKR-001 for FGFR1c, FGFR2c and FGFR3c was comparable to that of recombinantly-expressed human FGF19, or rhFGF19, and rhFGF21. However, neither rhFGF21 nor AKR-001 are agonists of FGFR4, in contrast to rhFGF19's potent agonism of FGFR4.

Figure 11 shows the EC50 for each of the six compounds referenced above for each of FGFR1c, FGFR2c, FGFR3c, and FGFR4. EC50 refers to the half-maximal effective concentration, or the concentration at which one half of the maximal FGF receptor agonist effect is observed. Non-linear regression is used to model an agonist concentration-response curve, allowing interpolation of the EC50 from the observed data. For very low-potency agonists, such as FGF21's interaction with FGFR4, the agonist effect appears to be partial at the highest dose tested, so the EC50 cannot be calculated precisely.

Figure 9—Comparison of AKR-001's agonism of FGF receptors with three FGF21 discovery candidates identified prior to selecting AKR-001 for clinical evaluation

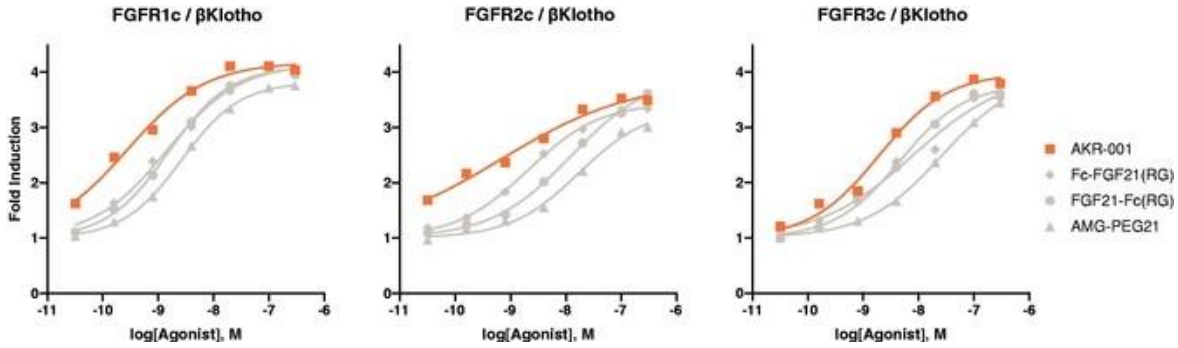


Figure 10—Comparison of AKR-001's agonism of FGF receptors with unmodified rhFGF19 and rhFGF21

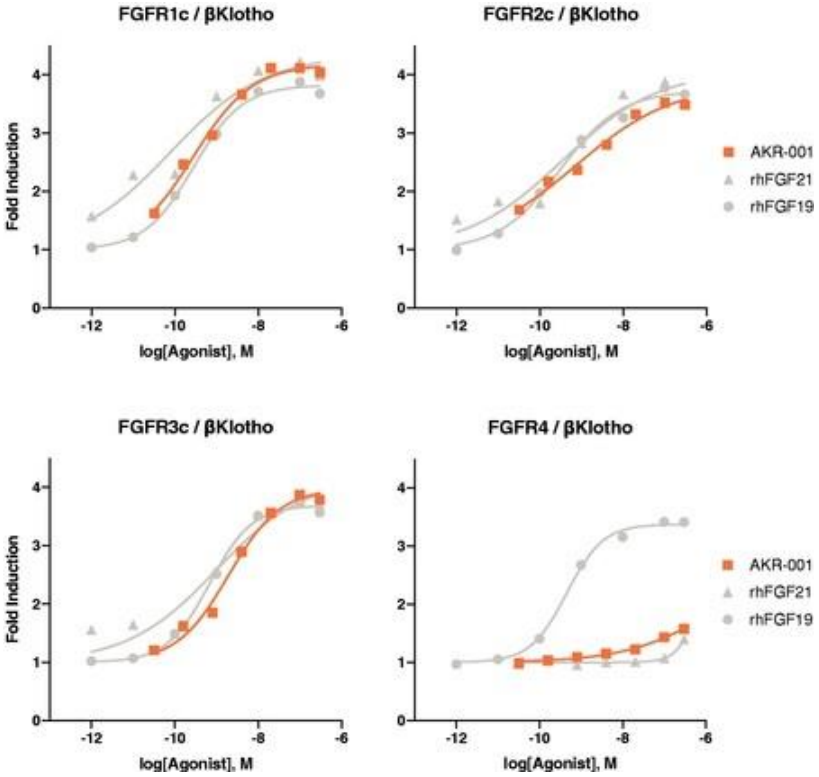


Figure 11—Relative potency of rhFGF21, AKR-001, rhFGF19 and other discovery candidates against FGF receptors

EC_{50} (nM)	FGFR1c	FGFR2c	FGFR3c	FGFR4
FGF21	0.08	0.36	0.99	>5000
AKR-001	0.27	0.69	1.95	>1000
FGF19	0.28	0.30	0.67	0.41
Fc-FGF21(RG)	1.42	2.05	7.89	278
FGF21-Fc(RG)	1.54	12.49	4.64	290
AMG-PEG21	2.66	17.2	26.8	—

Clinical validation of endocrine FGF receptor agonism

Data from clinical trials in NASH or high-risk NAFLD patients evaluating four different FGF compounds acting on FGFR1c, FGFR2c and/or FGFR3c further validate the potential of FGF21 agonism as a NASH treatment. One compound is an FGF19 analog, which has been observed to substantially reduce liver fat, to resolve NASH, and to reverse fibrosis in patients with NASH, but also appears to increase LDL-C. Published nonclinical and clinical data suggest that activation of FGFR4 increases LDL-C but does not meaningfully contribute to the pharmacodynamic effects of FGF19 on lipid metabolism in the liver. Consequently, we believe the optimal NASH therapeutic profile for an endocrine FGF analog is to have high, balanced potency for FGFR1c, 2c and 3c with minimal activity at FGFR4.

A second compound is a PEGylated FGF21 analog, which has been observed to extend FGF21 half-life to approximately 24 hours but does not have any modifications to FGF21's amino acid sequence. Although the effects do not appear to be as substantial as those seen with FGF19 agonism, clinical data suggest that the PEGylated FGF21 analog reduced liver fat and had positive effects on markers of liver injury and fibrosis in NASH patients. PEGylation of other compounds has been shown to result in increased concentrations in liver relative to exposure in other organs, which may lead to greater activity on FGF receptors in the liver (FGFR2c and FGFR3c) than in adipose tissue (FGFR1c). Such an effect could account for the apparently smaller effects on adipose tissue lipolysis than those effects observed with FGF19 agonism or previously tested FGF21 analogs.

Two other compounds are based on a monoclonal antibody, or mAb, designed to target only FGFR1c and its co-receptor, βKlotho. Consistent with nonclinical data, preliminary clinical data in patients with NAFLD suggest that administration of these FGFR1c-specific agonists was associated with substantial reductions in liver fat and improvements in lipoproteins, which may be attributable to lower rates of adipose tissue lipolysis.

Taken together, clinical trials of these three compounds provide important evidence that activation of FGFR1c, FGFR2c, and FGFR3c has significant potential to treat patients with NASH.

AKR-001 has potential to address the five core processes underlying NASH pathogenesis

We believe intervening in the core processes underlying NASH pathogenesis is the most effective way to restore health to the liver of patients with NASH and reduce risk of cardiovascular disease, which is the leading contributor to mortality and morbidity among these patients. Figures 12 and 13 below illustrate how, by mimicking FGF21, AKR-001 has the potential to intervene in each of the five core processes underlying NASH pathogenesis. Figure 12 illustrates how AKR-001 acts to leverage whole-body metabolism to redirect calories away from the liver to peripheral adipose tissue, thereby reducing fat deposited in the liver and decreasing the rate of fat oxidation by the liver. Figure 13 depicts how AKR-001 acts to alleviate hepatocyte stress and to reduce inflammation and fibrosis of the liver. In nonclinical studies, it has been observed that FGF21 agonism protects hepatocytes and other cell types against cellular stress by modulating multiple specialized intracellular proteins called transcription factors, or TFs. As master regulators of gene expression, TFs ensure proteins appropriate to the needs of cells are produced at the right time and in the right amounts.

Figure 12—AKR-001's redirection of calories away from liver leads to lower fat deposition and reduced rate of oxidation of fat

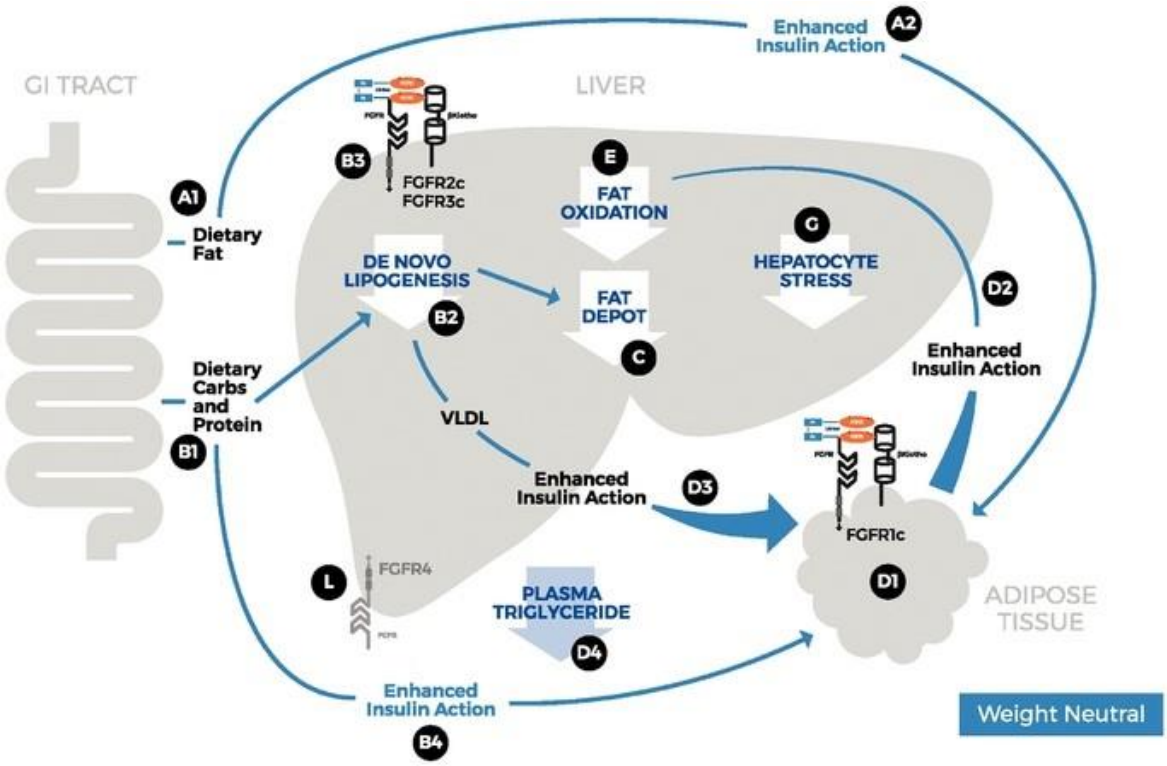
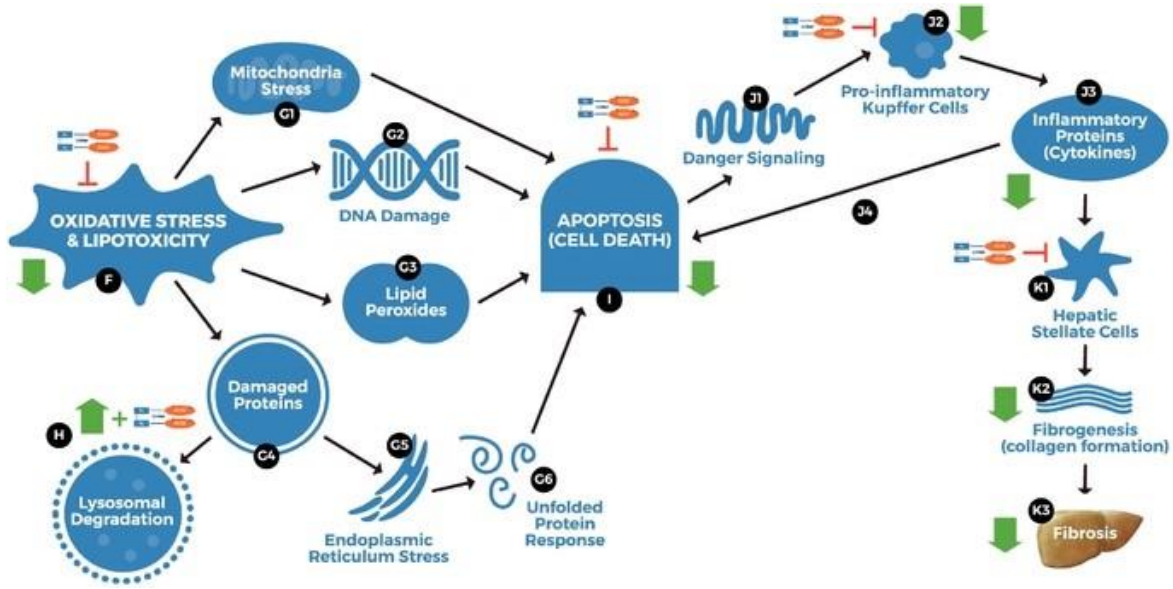


Figure 13—AKR-001's suppression of pathways leading to cell death reduces downstream liver inflammation and fibrosis



FGF21 leverages whole-body metabolism to redirect calories away from liver to peripheral adipose tissue

We believe AKR-001 intervenes in the first step of NASH pathogenesis by redirecting calories, including calories derived from dietary fat (A1), carbohydrates and protein (B1) in the GI tract, away from the liver. This effect of AKR-001 appears to be mediated by enhancing insulin's action (A2 and B4) on adipose tissue to increase uptake of energy, which is stored as fat within adipose tissue (D1). Enhancing insulin's action also suppresses release of fat from adipose tissue, or lipolysis, back to the liver (D2). At the same time, it promotes greater uptake by adipose tissue of two forms of triglyceride transported by blood: VLDL secreted by liver (D3) and chylomicrons secreted by the GI tract (A2), thereby reducing plasma triglycerides (D4). The net effect of a sustained redirection of energy away from liver is to reduce both the amount of fat in liver and the rate of fat oxidation.

The beneficial impact of enhancing adipose tissue's sensitivity to insulin is clinically precedented by the observed ability of pioglitazone to reduce liver fat in patients with NASH. Likewise, FGF21 agonism has also been shown to improve insulin sensitivity in nonclinical studies. Translation of this effect to humans has been observed clinically with AKR-001. However, in contrast with pioglitazone, no weight gain was observed in clinical trials with AKR-001. FGF21 agonism also reduced plasma triglyceride levels in nonclinical studies. Again, the reduction in plasma triglyceride has been observed clinically with AKR-001, and with a third party's FGFR1c-specific FGF21 analog that likely acts primarily on adipose tissue.

Reducing fat deposited in liver and rates of fat oxidation by liver

Redirecting calories away from the liver to peripheral adipose tissue helps reduce accumulation of fat in the liver and decreases the rate of fat oxidation by the liver in patients with NASH. Specifically, AKR-001 is expected to act on all three sources of increased liver fat by:

- reducing flow of fat from adipose tissue to liver by activating the FGFR1c receptor expressed in adipose tissue (D2), which leads to lower rates of fat oxidation (E);
- redirecting carbohydrates and protein absorbed from the GI tract away from the liver to adipose tissue (B1), thereby reducing DNL-dependent deposition of fat in the liver (B2 and C); and

- redirecting fat absorbed from the GI tract (A1) away from liver to adipose tissue (A2), which also reduces the amount of fat deposited in liver (C).

Nonclinical studies provide evidence that FGF21 agonism is associated with reduced steatosis. Mice with five-fold increases in FGF21 plasma levels due to overexpression of FGF21, as well as mice treated with rhFGF21, were observed to have less fat in the liver when fed a high-fat diet than appropriate controls. On the other hand, FGF21 knockout mice had higher liver fat, resulting in liver inflammation and fibrosis.

FGF21 agonism directly suppresses DNL in liver by suppressing a TF known as SREBP1c. Suppression of SREBP1c reduces the amount of lipid droplets, comprised of triglyceride and phospholipid species, deposited within hepatocytes, and lowers the amount of triglyceride secreted as VLDL into the circulation. FGF21's inhibition of SREBP1c is believed to be mediated through FGFRs expressed in the liver, predominantly FGFR2c and 3c (B3). High levels of plasma triglyceride increase susceptibility of NASH patients to cardiovascular disease. Substantial reduction of plasma triglyceride by FGF21 would therefore be predicted to reduce risk of cardiovascular disease.

Reducing liver cell stress, injury and death

A key driver of NASH progression is hepatocyte stress (G), which is triggered by increased oxidative stress as well as stress caused by lipotoxicity, or excessive amounts of certain lipids, in the liver (F). FGF21 inhibits oxidative stress and lipotoxicity in two ways. First, as described above, FGF21 leverages multiple body systems to reduce the flux of fat through the liver, which limits fat oxidation and thus oxidative stress, and reduces levels of lipotoxic species e.g. saturated long-chain fatty acids. Second, FGF21 directly alleviates oxidative stress through induction of TFs known as PGC1 and NRF2, which induce expression of antioxidant enzymes that protect against oxidative stress by neutralizing free radicals. PGC1 also improves mitochondrial function, which reduces oxidative stress.

Alleviating oxidative stress and lipotoxicity reduces hepatocyte stress in the forms of less mitochondrial stress (G1), less DNA damage (G2), fewer lipid peroxides (G3), and less damaged proteins (G4). FGF21 agonism also directly limits stress caused by damaged proteins, through induction of a TF known as TFEB, which increases the capacity of lysosomes to break-down misfolded and damaged proteins arising from oxidative stress (H). This both reduces the UPR and allows cells to synthesize new proteins, such as the antioxidant enzymes necessary to protect against oxidative stress.

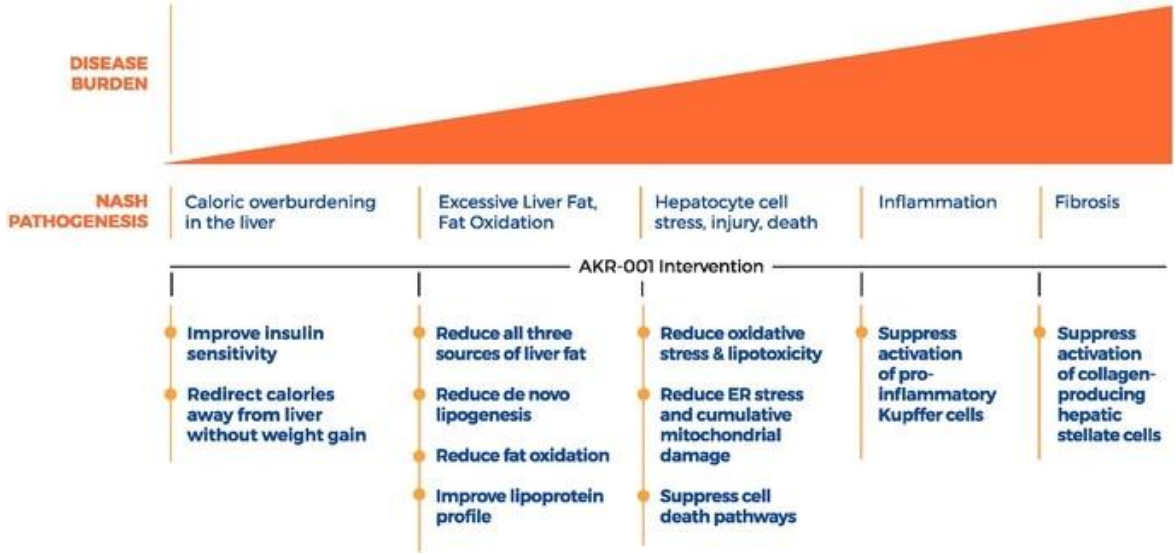
By reducing hepatocyte stress, FGF21 agonism mitigates progression from hepatocyte stress to apoptosis (I). FGF21 agonism also directly inhibits apoptosis by suppressing expression of a TF known as ATF4, which triggers apoptosis, particularly in response to ER stress.

Reducing inflammation and fibrosis

Inhibiting apoptosis helps mitigate the amount of danger signaling through DAMPs that trigger inflammation. In addition, data from nonclinical studies suggest that FGF21 agonism directly suppresses activation of macrophages, and by inference Kupffer cells (J2), thereby reducing release of pro-inflammatory cytokines (J3) and promoting a pro-repair macrophage phenotype. By inhibiting hepatocyte apoptosis and suppressing release of pro-apoptotic TNF and TGF from Kupffer cells, FGF21 agonism interrupts the pathological cycle of increased hepatocyte apoptosis and inflammation (J4). Further, in nonclinical studies in human-derived and rodent-derived hepatic stellate cell lines, FGF21 agonism was observed to directly inhibit collagen-producing myofibroblasts (K1), thereby reducing fibrogenesis (K2) and fibrosis (K3).

In sum, as shown in Figure 14 below, we believe FGF21 acts on both liver and adipose tissue to reduce the caloric burden on the liver, thereby lowering both the level of fat and rate of fat oxidation in hepatocytes, and acts directly and indirectly on the liver to reduce hepatocyte stress.

Figure 14—Potential Benefits of AKR-001 on NASH Pathogenesis



AKR-001 clinical development

Prior to our ongoing Phase 2a clinical trial, AKR-001 was administered to a total of 83 patients with T2D in two Phase 1 clinical trials. In a Phase 1b clinical trial, it was observed that AKR-001 substantially improved plasma lipoprotein levels, including reductions of up to 69% in triglycerides and 30% in non-HDL-C. In these clinical trials, it was also observed that administration of AKR-001 was associated with substantially improved markers of insulin sensitivity, including reductions of up to 37% in C-peptide and 55% in HOMA-IR. No changes in body weight were observed, except for isolated significant reductions at the highest dose tested. AKR-001's effects were observed to be rapid, sustained and durable for at least two to three weeks after cessation of dosing.

These results are consistent with effects that would be expected for balanced agonism of FGFR1c, FGFR2c, and FGFR3c, without activating FGFR4, and suggest that AKR-001 has substantial potential as a treatment for NASH. The observed magnitude and significance of AKR-001's biological effects on lipoprotein parameters and markers of insulin sensitivity are either equivalent to or greater than those reported to date in clinical trials of any other endocrine FGF analog.

On May 24, 2019, the FDA's Division of Gastroenterology and Inborn Errors Products cleared our IND to conduct a Phase 2a clinical trial evaluating AKR-001 in the treatment of NASH patients. We dosed our first patient for our Phase 2a clinical trial on July 2, 2019 and administered the first dose to the last-enrolled patient on December 16, 2019. This trial, the BALANCED study, is assessing the efficacy and safety of AKR-001 in patients with NASH, which will help inform dose selection for larger, longer-term trials.

Phase 1b clinical trial of AKR-001 in patients with T2D for 28 days

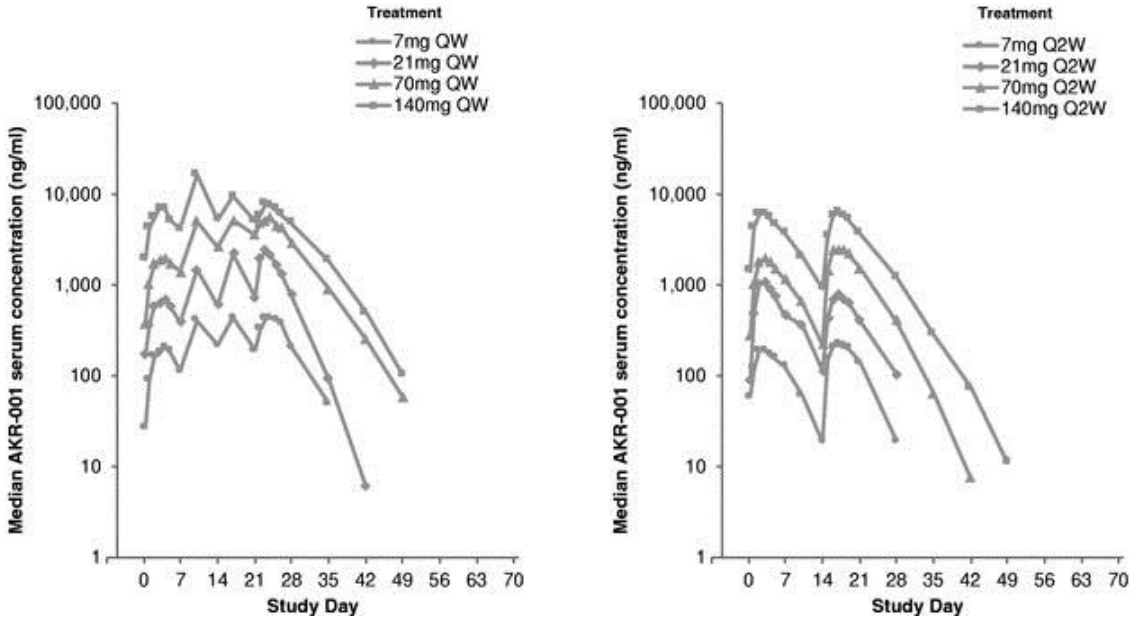
A Phase 1b clinical trial was conducted to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of AKR-001 in patients with T2D. This trial was a multicenter, randomized, double-blind, placebo-controlled, ascending multiple-dose clinical trial. Sixty-nine patients enrolled into one of eight cohorts were randomized to receive AKR-001 or placebo. Fifty-two patients received AKR-001 and 17 received placebo. Doses of 7mg, 21mg, 70mg and 140mg were administered subcutaneously either once every two weeks, or Q2W, or once weekly, or QW, over a 28-day treatment period. Patients in Q2W cohorts received doses of AKR-001 on Days 1 and 15, while subjects in QW cohorts received doses of AKR-001 on Days 1, 8, 15 and 22.

AKR-001 exhibited linear, dose-proportional pharmacokinetics

Linear, dose-proportional pharmacokinetics were observed across the range of AKR-001 doses tested. The observed median time of maximum serum concentration, or Tmax, ranged from two to 3.5 days. The observed half-life of the intact C-terminus of AKR-001 ranged from three to four days. By contrast, half-life of the intact C-terminus of other FGF21 analogs evaluated clinically in T2D or NASH patients has ranged from six to 24 hours. The three-to-four-day half-life of another FGF21 analog, which recently reported data from a Phase 1 single ascending dose study in healthy volunteers, appears similar to the three-to-four-day half-life of AKR-001.

As shown in Figure 15 below, there was an approximately two-fold accumulation of AKR-001 observed in serum following repeated QW administration, with steady state achieved by the third or fourth dose. No meaningful accumulation was observed following administration of two Q2W doses. QW dosing was also associated with a four-fold smaller peak-to-trough ratio than observed with Q2W dosing, suggesting that serum concentrations of AKR-001 are maintained more effectively with QW than Q2W dosing.

Figure 15: Pharmacokinetics of AKR-001 administered weekly and every other week



AKR-001 effects on pharmacodynamic measures of lipoproteins and insulin sensitivity following once-weekly or every-other-week dosing

Figures 16 and 17 below show effects on pharmacodynamic measures for patients treated with AKR-001 either QW or Q2W, respectively. Fasting levels of plasma glucose, insulin, C-peptide, plasma triglyceride, HDL-C, LDL-C and calculated HOMA-IR, as well as post-meal levels of free fatty acids, or FFA, and body weight were analyzed in accordance with the pre-specified statistical analysis plan. Fasting levels of plasma non-HDL-C, adiponectin and apolipoprotein B, or ApoB, have been derived from post-hoc analyses using a statistical methodology similar to that used for all pre-specified endpoints.

As shown in Figure 16 below, dose-related effects on pharmacodynamic measures were observed for the QW cohorts, with maximal or near-maximal effects achieved with the 70mg QW dose of AKR-001. Significant decreases in triglycerides and increases in HDL-C were observed for all dose groups, with additional significant decreases in non-HDL-C observed at doses greater than or equal to 70mg QW. Multiple markers of insulin sensitivity were also observed

to be improved following treatment at a dose of 70mg QW. Significant decreases in C-peptide observed following the fourth dose of 21mg QW suggests that insulin sensitivity may be improved by longer-term treatment with doses lower than 70mg QW.

As discussed above, AKR-001 acts to redirect calories away from the liver to peripheral tissues, such as adipose tissue. Importantly, though, AKR-001 was observed to be weight-neutral in the four-week Phase 1b clinical trial, consistent with reports from earlier clinical studies with third-party FGF21 analogs. With AKR-001, there was a trend toward slight weight loss of up to 3% at 140mg QW and up to 2% at 70mg QW, which we do not believe contributed to the substantial improvement of lipoproteins and markers of insulin sensitivity observed at 70mg QW.

As shown in Figure 17 below, dose-related changes in fasting lipoprotein markers were also observed following Q2W dosing of AKR-001, with significant increases in HDL-C and adiponectin following treatment at doses greater than or equal to 21mg Q2W, and significant decreases in triglycerides at doses greater than or equal to 70mg Q2W, illustrating the biological impact of AKR-001's half-life extension of three to four days even with an inter-dose interval equivalent to four half-lives.

A comparison of the magnitude of pharmacodynamic changes between the 70mg QW and 140mg Q2W cohorts underscores the additional benefit likely to be gained from weekly dosing. These two doses yielded approximately equivalent total drug exposure (7-day exposure of 31,900 day*ng/mL for 70mg QW vs. 14-day exposure of 55,600 day*ng/mL for 140mg Q2W). However, the magnitude and level of significance for effects at 70mg QW were much higher than at 140mg Q2W. On most measures, the effects observed at 70mg QW were two-fold or more higher than the corresponding changes at 140mg Q2W.

In Figures 16 and 17 below, N represents the number of patients in a particular group. P or p-values are commonly interpreted as the probability that random chance caused the result (e.g., a p-value = 0.001 suggests there is a 0.1% probability that the difference between placebo and treatment groups is due to random chance). A p-value of 0.05 or less is a commonly used threshold for statistical significance and may be supportive of a finding of efficacy by regulatory authorities. However, regulatory authorities, including the FDA and EMA, do not set strict statistical significance thresholds as criteria for marketing approval, instead maintaining flexibility to evaluate the overall risks and benefits of a treatment.

Figure 16: Pharmacodynamic effects of AKR-001 administered once-weekly (QW)

	Placebo adjusted change from baseline (%)			
	7mg QW (N=6)	21mg QW (N=6)	70mg QW (N=6)	140mg QW (N=6)
Glucose[a]	+4	+5	-23*	-20
Insulin[a]	-20	-28	-49**	-50**
C-peptide[a]	-22	-29**	-39***	-45***
HOMA-IR[a]	-18	-24	-60***	-60***
Adiponectin[b]	+42	+62	+94**	+143***
Triglycerides[a]	-37**	-60***	-69***	-60***
HDL-C[a]	+28***	+38***	+61***	+37***
Non-HDL-C[a]	-12	-11	-30***	-34***
LDL-C[a]	-6	+7	-15	-28*
ApoB[b]	0	-16	-42***	-18
Post-Meal FFA[a]	+2	-10	-31**	-19**
Body Weight[a]	0	0	-1	-1

[a] Day 25; [b] Day 29; * = p<0.05; ** = p<0.01; *** = p<0.001; all p-values are nominal

Figure 17: Pharmacodynamic effects of AKR-001 administered every other week (Q2W)

	Placebo adjusted change from baseline (%)			
	7mg Q2W (N=6)	21mg Q2W (N=6)	70mg Q2W (N=6)	140mg Q2W (N=6)
Glucose[a]	-3	+3	-6	-1
Insulin[a]	-8	-23	-15	-28
C-peptide[a]	+4	-13	-4	-26*
HOMA-IR[a]	-12	-22	-21	-29
Adiponectin[b]	+60	+73*	+65	+141***
Triglycerides[a]	-19	-29	-42**	-55***
HDL-C[a]	+2	+23*	+26**	+40***
Non-HDL-C[a]	-10	-4	-9	-23**
LDL-C[a]	-3	+13	-1	-15
ApoB[b]	-12	-15	-11	ND
Post-Meal FFA[a]	-18	+21	-4	+31
Body Weight[a]	+1	-1	-1	-2

[a] Day 18; [b] Day 29; * = p<0.05; ** = p<0.01; *** = p<0.001 ; all p-values are nominal; ND, not determined.

AKR-001 dose-related effects within target dose range of 21mg to 70mg QW

We have identified AKR-001 doses in the range of 21mg to 70mg QW as the target dose range for evaluation in future clinical trials in patients with NASH, including in the ongoing BALANCED study. In the Phase 1b clinical trial in patients with T2D, significant decreases in triglycerides and increases in HDL-C were observed even at the 7mg QW dose; however, improvements in insulin sensitivity, which we believe will have a therapeutic effect on NASH pathogenesis, appear to require at least a 21mg QW dose. Among all doses tested to date, 70mg QW appears to offer the greatest potential for the treatment of patients with NASH. The 140mg QW dose level did not appear to confer any meaningful benefit beyond the 70mg QW dose.

Figures 18 and 19 below illustrate the dose-related changes from baseline for lipoproteins and markers of insulin sensitivity, respectively, observed following administration of 21mg and 70mg QW doses of AKR-001, compared to placebo. Significant improvements for each marker of insulin sensitivity were observed at the 70mg QW dose, consistent with agonism of FGFR1c in adipose tissue. At 21mg QW, there were also indications of improved sensitivity to insulin, with a significantly lower level of C-peptide observed after the fourth dose, and a trend toward lower levels of insulin and lower calculated value of HOMA-IR. These data are consistent with the results of our pharmacokinetic and pharmacodynamic modeling, which suggests that a dose between 21mg and 70mg QW could provide roughly 60% to 75% or more of the beneficial effects observed at 70mg QW. Although liver fat was not measured in this trial, we believe the magnitude and robustness of effects on lipoproteins at 21mg and 70mg QW will likely translate into substantial reductions in liver fat with longer-term treatment.

Figure 18: AKR-001 effects (percent change from baseline) on lipoproteins and free fatty acids: placebo, 21mg QW, and 70mg QW

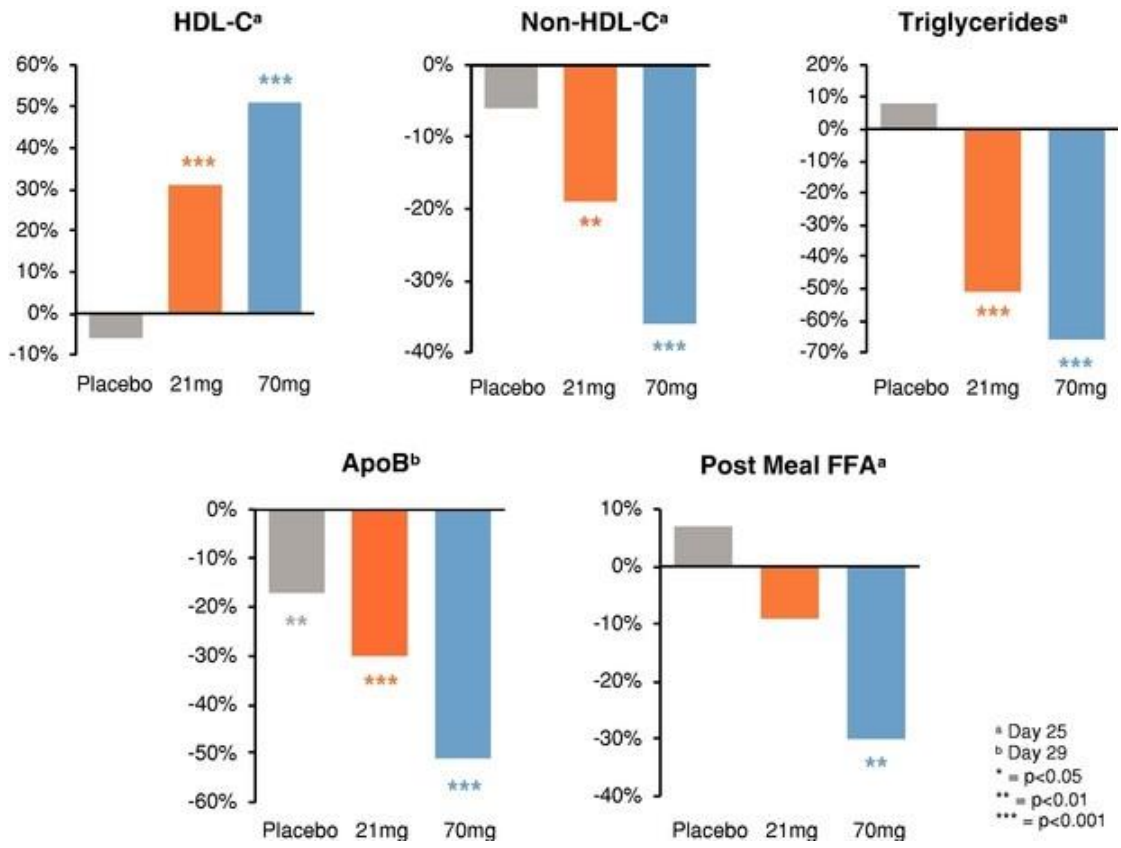


Figure 19: AKR-001 effects (percent change from baseline) on markers of insulin sensitivity: placebo, 21mg QW, and 70mg QW

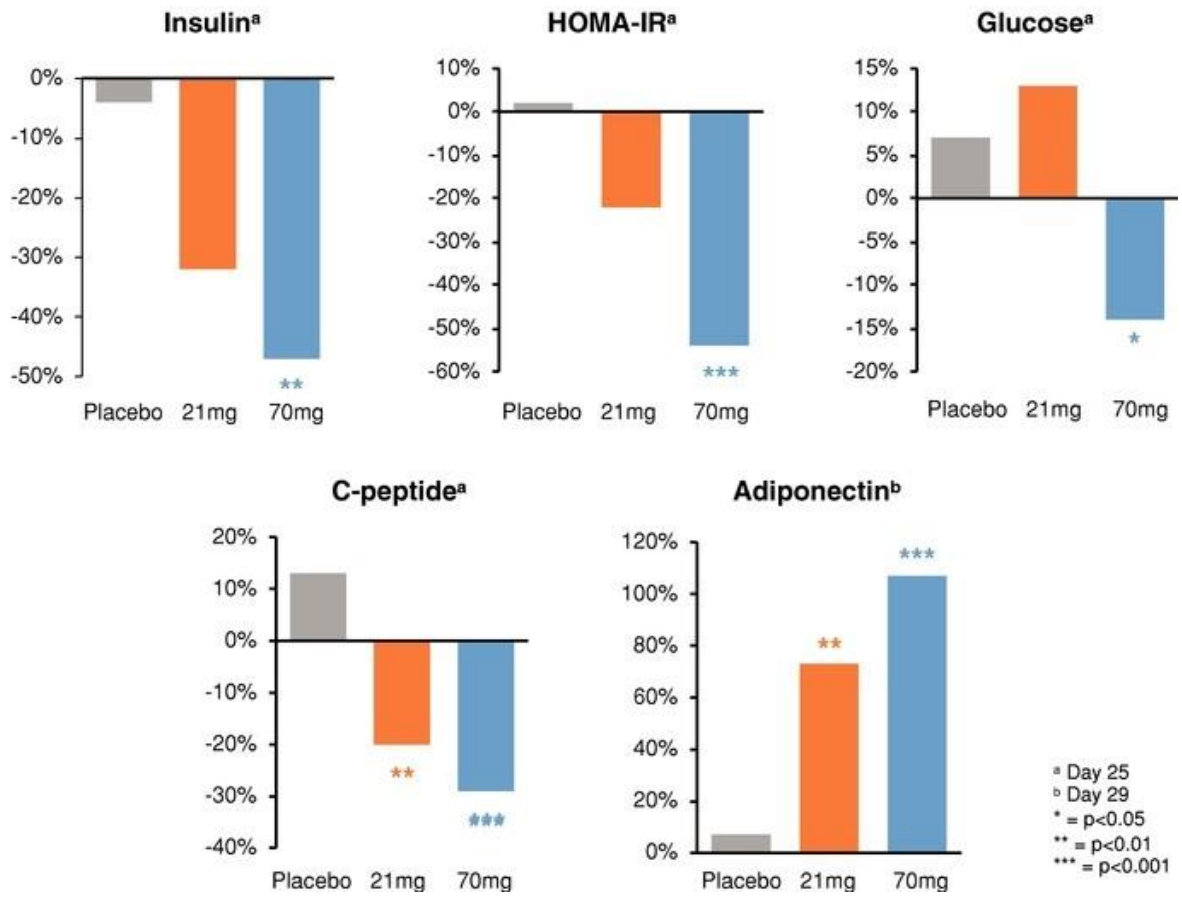


Figure 20 below provides the data underlying Figures 18 and 19, shown in units of mg/dL.

Figure 20: Absolute change in metabolic and lipoprotein parameters at target dose range of 21mg-70mg QW

	Placebo			21 mg QW			70mg QW		
	BL	D25	CFB	BL	D25	CFB	BL	D25	CFB
Triglycerides (mg/dL)	186	195	+9	193	89	-104	190	62	-128
HDL Cholesterol (mg/dL)	45	43	-2	51	67	+14	44	66	+22
LDL Cholesterol (mg/dL)	112	99	-13	135	123	-12	111	84	-27
Non-HDL Cholesterol (mg/dL)	155	139	-16	159	128	-31	151	97	-54
Apolipoprotein B (mg/dL)	99	83[a]	-16	101	71[a]	-30	100	48[a]	-52
Post-meal FFA AUC (hr·mmol/L)	1.23	1.28	+0.05	1.23	1.13	-0.10	1.32	0.93	-0.39
Glucose (mg/dL)	163	176	+13	169	192	+23	189	161	-28
Insulin (mIU/L)	8.8	8.7	-0.1	8.1	5.8	-2.3	13.4	6.8	-6.6
HOMA-IR	3.5	3.8	+0.3	3.4	2.7	-0.7	6.3	2.7	-3.6
C-peptide (mg/dL)	230	260	+30	205	169	-36	275	190	-85
Adiponectin (mg/L)	4.32	4.60[a]	+0.28	4.38	7.56[a]	+3.18	4.92	10.20[a]	+5.28

[a] - D29

AKR-001 70mg QW showed rapid, durable effects

AKR-001's effects on lipoproteins and markers of insulin sensitivity were observed to be rapid, consistent, and durable at the 70mg QW dose, with significant effects persisting after the fourth and final dose (on Day 22) for up to five weeks (on Day 57). Figure 21 below shows the observed effect of AKR-001 administered at the 70mg QW dose on HDL-C, non-HDL-C, and triglycerides at all time points from baseline through Day 57, plotted against serum AKR-001 concentration. Figure 22 below similarly provides an integrated-time course plot for markers of insulin sensitivity: glucose, insulin, C-peptide, and HOMA-IR. Data is shown in both figures as placebo-corrected percent change from baseline, which makes it possible to compare the magnitude of effects on multiple endpoints in the context of exposure to AKR-001. The red arrows indicate dosing on Days 1, 8, 15 and 22.

As shown in Figures 21 and 22, maximal or near maximal effects were observed by the third dose of 70mg QW for lipoproteins, and by the fourth dose for markers of insulin sensitivity. Reductions in triglyceride and increases in HDL-C were significant at all time points from Day 4 through Day 57, while non-HDL-C was significantly lower from Day 15 through Day 57. Taken together with published clinical data for third-party FGF21 analogs, the time-course and magnitude of changes in lipoproteins observed at the 70mg QW dose suggest that AKR-001 has the potential to rapidly and durably reduce liver fat in patients with NASH. Notably, AKR-001’s effects appear to be sustained for three weeks after the final dose, including significant increases of 39% in HDL-C and significant reductions of 28% and 67% in non-HDL-C and triglycerides, respectively, observed on Day 43.

Figure 23 below shows time-course plots for ApoB and adiponectin. These endpoints were measured only on Days 4, 15, 29 and 57. Significant improvements on both measures were observed by Day 15 at the 70mg QW dose of AKR-001. On both measures, a greater effect was observed on Day 29 than Day 15. No results for ApoB were available on day 57 for 70mg QW AKR-001.

Figure 21: Time-course plots of AKR-001 70mg QW lipoprotein effects

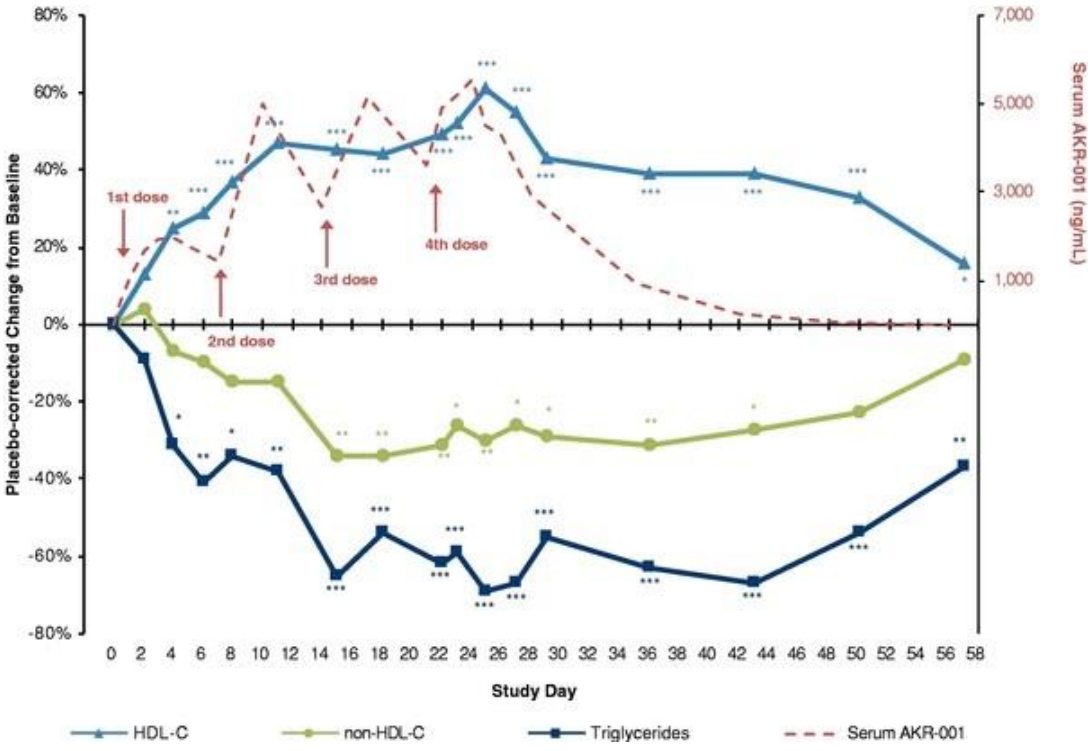


Figure 22: Time-course plots of AKR-001 70mg QW effects on markers of insulin sensitivity

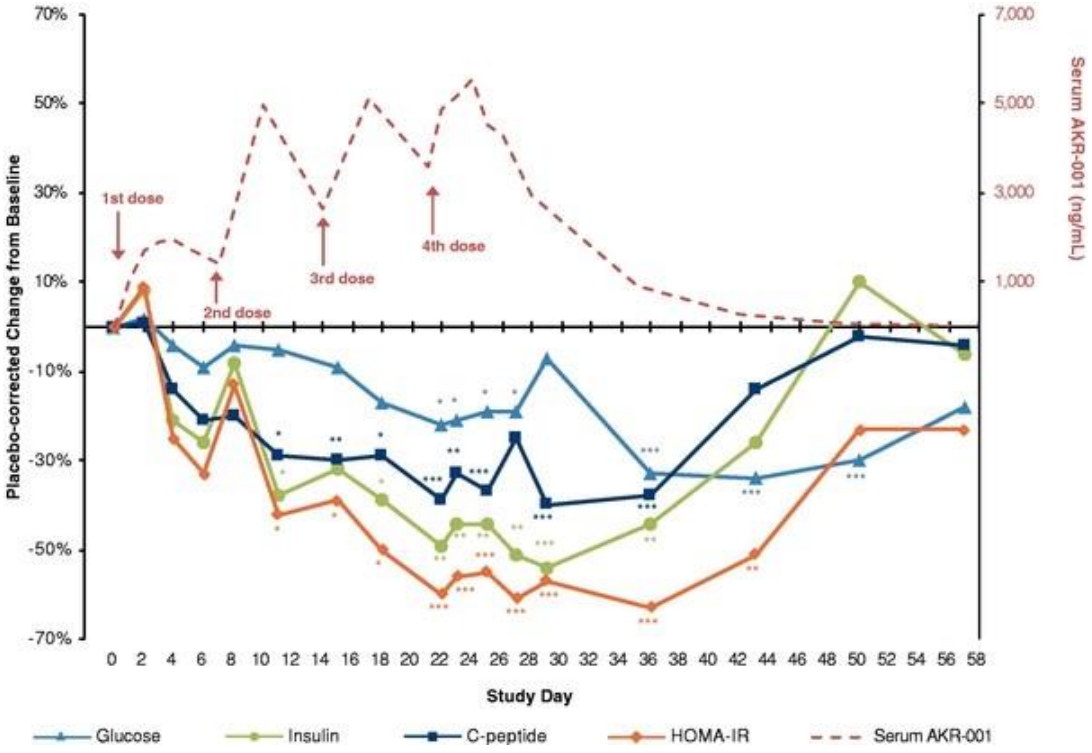
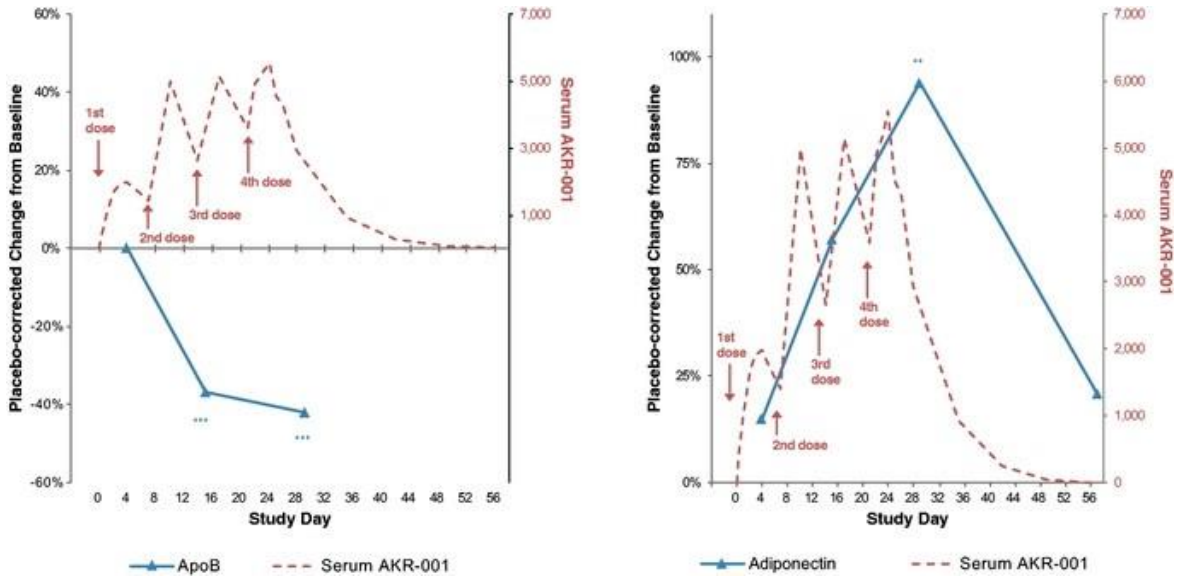


Figure 23: Time-course plots of AKR-001 70mg QW effects on apolipoprotein B and adiponectin



AKR-001 safety and tolerability in Phase 1b clinical trial

AKR-001 was reported to be well-tolerated among 52 patients with T2D in a Phase 1b clinical trial conducted by Amgen. There were no patient deaths and no serious adverse events. The most common adverse events were gastrointestinal disorders, such as mild diarrhea and nausea, consistent with the experience following treatment with other FGF21 investigational drug products.

Withdrawals from investigational product due to adverse events, or AEs, were reported for six subjects in the Phase 1b clinical trial (AKR-001, N=5; placebo, N=1). Four of the patients to withdraw were in the 140mg QW group. We do not plan to investigate this dose level further. The reasons for withdrawal by each of the four subjects dosed at 140mg QW were reported to be diarrhea; vomiting; tremor; and tremor/nausea. The remaining two withdrawals (one following treatment with 7mg QW; one on placebo) were attributed by the investigator to hyperglycemia and were considered unrelated to investigational product. Subjects were washed off anti-diabetic medications two weeks prior to the first dose and remained so until end of study. Figure 24 below provides a summary of investigational product-related treatment-emergent adverse events and withdrawals.

Figure 24: Investigational product (IP)-related, treatment-emergent adverse events with two or more observations, and IP-related withdrawals from treatment

	Placebo QW/Q2W (N=17)	AKR-001 QW 7 mg (N=7)	AKR-001 QW 21 mg (N=6)	AKR-001 QW 70 mg (N=6)	AKR-001 QW 140 mg (N=9)	AKR-001 Q2W 7 mg (N=6)	AKR-001 Q2W 21 mg (N=6)	AKR-001 Q2W 70 mg (N=6)	AKR-001 Q2W 140 mg (N=6)
Subjects reporting IP-related TEAEs All grade/grade 2–4* (n)	3/0	2/0	4/1	5/0	8/2	3/0	3/1	2/0	3/1
Adverse events with two or more observations All grade/grade 2–4* (n)									
Nausea	0/0	1/0	3/0	0/0	6/0	0/0	2/0	1/0	2/2
Diarrhea	1/0	1/0	0/0	2/0	2/0	0/0	1/1	1/0	1/0
Change in appetite†	0/0	1/0	0/0	2/0	5/0	0/0	1/0	0/0	0/0
Vomiting	0/0	0/0	0/0	0/0	3/1	0/0	1/0	0/0	2/1
Gastrointestinal, other‡	1/0	0/0	1/0	0/0	5/0	2/0	1/0	1/0	0/0
Tremor	0/0	0/0	0/0	0/0	4/1	0/0	0/0	0/0	0/0
Headache	1/0	0/0	0/0	0/0	1/0	1/0	1/0	0/0	0/0
Injection-site rash or erythema	0/0	0/0	1/1	2/0	1/0	0/0	0/0	0/0	1/0
Withdrawals	0	0	0	0	4§	0	0	0	0

*Common terminology criteria for adverse events grades
#A single event of the following AEs was observed in the study: dizziness (140 mg QW), dysgeusia (140 mg QW), musculoskeletal pain (7 mg Q2W), muscle spasms (140 mg QW), ventricular extrasystoles (140 mg QW), hyperhidrosis (140 mg QW), flushing (21 mg Q2W)
†Includes increased appetite, decreased appetite, and hunger
‡Includes constipation, dyspepsia, abdominal distension, abdominal pain, abdominal tenderness, and epigastric discomfort
§Reason for withdrawals: nausea and tremor (1 subject), diarrhea (1 subject), nausea (1 subject), tremor (1 subject)

The most common treatment-related, treatment-emergent AEs at doses from 7mg to 70mg QW were nausea, diarrhea and increased appetite. All of these treatment-related AEs were assessed as mild in severity, except for one instance of injection site rash in the 21mg QW cohort assessed as of moderate severity. All of these treatment-related AEs were transient.

Seven of 52 subjects were observed to be positive for anti-AKR-001 antibodies post-baseline. Antibodies from the 7 subjects were non-neutralizing and did not appear to affect the pharmacokinetics or safety profile of AKR-001. Three of seven patients in the Phase 1b clinical trial who developed anti-AKR-001 antibodies returned for follow-up approximately two months after receiving the final dose of AKR-001. In all three of these patients, anti-AKR-001 antibodies could no longer be detected.

Phase 1a clinical trial in type 2 diabetic patients

An earlier Phase 1a, randomized, double-blind, placebo-controlled, ascending single-dose clinical trial was conducted by Amgen in patients with T2D to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of AKR-001. A total of 42 patients received a single-dose of either placebo (N=11) or AKR-001 (N=31) and completed the trial. Single subcutaneous, or SC, AKR-001 doses of 2.1mg, 7mg, 21mg, 70mg, or 210mg (N=6 per cohort) were administered. In addition, one patient received a single 70mg IV dose of AKR-001.

At doses of 21mg SC and higher, significant increases were observed in HDL (up to 50% increase on Day 14 after a single 70mg SC dose, $p<0.001$) along with significant reductions in triglycerides (up to 50% reduction on Day 11 after a single 70mg SC dose, $p<0.001$), compared to placebo. No changes were noted in metabolic parameters of glucose, insulin, glucagon and free fatty acids under fasted conditions at doses of 70mg SC or less. A significant reduction in body weight was observed by Day 5 in all dose groups at or above 21mg SC, with significant decreases in body weight following a single dose of 70mg SC observed on days 5 through 22, up to a maximum of a 2% decrease in body weight.

Doses of 70mg SC or less were reported to be well tolerated. Following administration of a 210mg dose, three of six subjects reported diarrhea and four of six subjects reported increased appetite. Neither diarrhea nor increased appetite were reported for subjects receiving any other dose of AKR-001. No other adverse events were reported by more than one subject. All adverse events were reported as either mild or moderate, with the exception of two adverse events graded as severe but considered unrelated to the investigational product by the investigator.

One subject experienced a severe adverse event of vasovagal syncope secondary to blood draw following randomization to the 2.1mg cohort, but prior to receiving any investigational product. This event was not considered related to investigational product by the investigator. The one subject who received AKR-001 70mg IV had a serious adverse event of cholecystitis initially reported as abdominal pain beginning on Day 11. The subject thereafter reported having experienced intermittent abdominal pain for many years. Findings from a subsequent cholecystectomy were consistent with chronic cholecystitis. This event was considered unrelated to investigational product by the investigator.

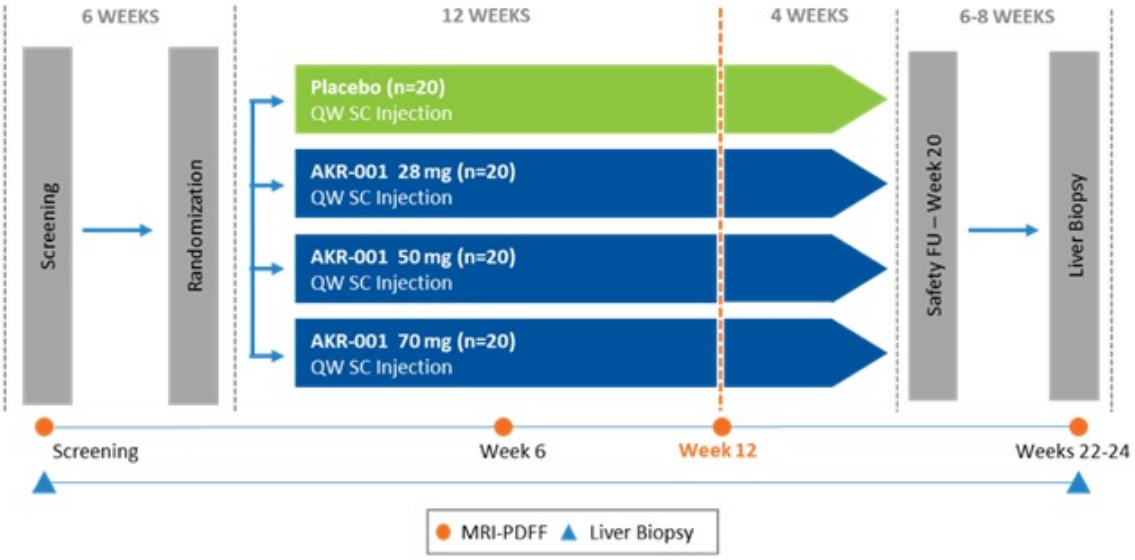
Anti-AKR-001 binding antibodies were detected in four of 31 subjects. In all instances the antibodies were non-neutralizing and did not appear to affect the tolerability profile or pharmacokinetics of AKR-001.

Ongoing Phase 2a clinical trial, the BALANCED study

We submitted our IND application to the FDA on April 24, 2019, which included a Phase 2a clinical trial protocol, audited draft reports for our 120-day toxicology studies in non-human primates and rodents, and stability data on drug product for use in the Phase 2a clinical trial. The FDA recommended additional trial design elements, which were incorporated into our final Phase 2a clinical trial protocol. The FDA cleared our IND on May 24, 2019. We dosed our first patient in the BALANCED study on July 2, 2019, and we closed enrollment for the main part of the study on December 16, 2019. The final liver fat measurement for completion of the primary analysis at week 12 was taken on March 6, 2020. We plan to expand the BALANCED study to include an additional cohort of subjects with NASH who have compensated cirrhosis (F4), Child-Pugh Class A, or Cohort C, with study initiation expected in the second quarter of 2020.

The BALANCED main study is a multicenter, randomized, double-blind, placebo-controlled, dose-ranging trial in biopsy-confirmed patients with NASH. We enrolled 80 total patients who were randomized to receive weekly subcutaneous dosing of AKR-001 or placebo for up to 16 weeks. The three active treatment arms are doses of 28mg, 50mg and 70mg QW, all within the target dose range of 21mg to 70mg QW based on observed results from the Phase 1b clinical trial. Figure 25 below illustrates key design elements of the BALANCED main study.

Figure 25: Clinical Trial Design of BALANCED Main Study



The primary objective of the BALANCED main study is to evaluate absolute change from baseline in hepatic fat fraction assessed by Magnetic Resonance Imaging—Proton Density Fat Fraction, or MRI-PDFF, at Week 12.

The secondary objectives of the BALANCED main study are to:

- Evaluate percent change from baseline in hepatic fat fraction assessed by MRI-PDFF at Week 12;
- Evaluate the proportion of patients who achieve a clinically meaningful reduction of at least 30% in relative liver fat content as measured by MRI-PDFF at Week 12;
- Evaluate the responder based on NAFLD Activity Score (NAS) system of subjects who had a decrease of ≥ 2 points in NAS with at least a 1-point reduction in either lobular inflammation or hepatocellular ballooning and with no concurrent worsening of fibrosis stage; and
- Assess the safety and tolerability of AKR-001 in subjects with NASH, including analyses of treatment-emergent adverse events, clinical chemistry and hematology, vital signs, electrocardiogram, body weight, and incidence of anti-AKR-001 antibodies.

Exploratory objectives of the BALANCED main study include:

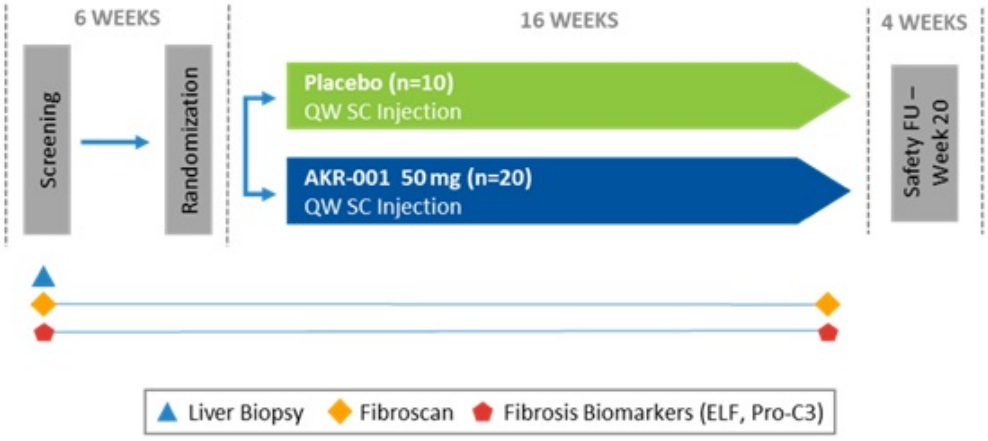
- Change from baseline in markers of liver injury and liver function;
- Changes in biomarkers of liver fibrosis;
- Changes in histological parameters on biopsies; and
- Changes in markers of lipid metabolism, insulin sensitivity and glycemic control.

We plan to report 12-week top-line results related to the primary endpoint—including change from baseline in absolute liver fat and relative reduction in liver fat, as well as the proportion of patients who achieve at least a 30% relative reduction in liver fat—in the first quarter of 2020. As indicated in Figure 25, the study remains blinded through an additional four weeks of treatment to week 16. Safety and tolerability results will therefore be reported following completion of treatment along with secondary endpoints, including biopsy results, which we plan to report in the second quarter of this year.

We plan to expand the BALANCED study in Cohort C by enrolling thirty NASH subjects, demonstrated at baseline by liver biopsy to have cirrhosis with a fibrosis score of 4, who will be randomized 2:1 to receive either 50 mg of AKR-001 or placebo for 16 weeks. The selection of the 50 mg dose for this cohort is based on modeling of data from

the Phase 1b trial in Type 2 diabetes as well as availability of drug product. The primary objective of this expansion Cohort C is to assess safety and tolerability of treatment with AKR-001 in NASH patients at greatest risk of progressing to end-stage liver disease. Additional objectives include evaluating the pharmacokinetics and pharmacodynamics of AKR-001, changes in liver stiffness as measured by fibroscan, and non-invasive markers of fibrosis, including Pro-C3 and ELF. Figure 26 below illustrates key design elements for Cohort C of the BALANCED study.

Figure 26: Clinical Trial Design for Cohort C of the BALANCED Study



Potential improvement of cardiovascular risk factors

We believe the effects observed following treatment with AKR-001 in clinical trials to date indicate that AKR-001 has potential to have cardiovascular benefits when tested in patients with NASH, for whom cardiovascular disease is the leading cause of death. Figure 27 below describes the extent of reduction in cardiovascular risk associated with improvement in individual lipoproteins, which are believed to be causal of cardiovascular disease. We believe these reductions help to provide context for the changes in lipoproteins observed in the Phase 1b clinical trial of AKR-001. If the magnitude of improvement in lipoprotein profiles is reproduced in patients with NASH in larger, longer-term trials, AKR-001 could have the potential to improve cardiovascular outcomes.

Figure 27: Rationale for AKR-001's potential cardiovascular benefits

PD Measure	Evidence for Positive Impact	70 mg AKR-001 QW, post 4th dose (Pbo-adjusted %CFB)
Non-HDL Cholesterol	In a clinical trial of anacetrapib in combination with intensive atorvastatin therapy, an 18% decrease in non-HDL cholesterol was associated with a 9% reduction in cardiovascular risk.	**-30%**
Apolipoprotein B	In a global case-control analysis of lipoprotein levels in humans as markers of risk of myocardial infarction, an increase of 30% in ApoB was associated with a 30% increase in relative risk of myocardial infarction.	**-42%**
Triglycerides and Apolipoprotein C-3	Carriers of mutations that disrupt ApoC3 function have 40% to 50% lower levels of both triglycerides and ApoC3, and a 40% lower risk of cardiovascular disease than non-carriers	**-69%** (TG) **-46%** (ApoC3)

Note: data derived from individual clinical trials with differences in trial design; not from head-to-head clinical trials; AKR-001 data shown only to provide context for effects observed in other clinical trials that evaluated cardiovascular benefit

Additional clinical data supporting FGF21 in treatment of NASH

Other endocrine FGF analogs in development have shown encouraging signs of liver fat reduction, improved lipid profiles and reduced fibrosis in clinical trials in patients with NASH or obese insulin resistant subjects with NAFLD. In a 24-week placebo-controlled clinical trial, daily injections of an FGF19 analog in NASH patients were reported to be associated with a 39% relative reduction in liver fat as measured by MRI-PDFF, compared with 13% for placebo. In addition, 38% of patients treated with active drug were observed to have a ≥1 stage improvement in fibrosis score with no worsening of NASH, compared with 18% for placebo. In a 16-week placebo-controlled clinical trial, daily and weekly injections of a PEGylated FGF21 analog in NASH patients were reported to be associated with 38% and 26% relative reductions in liver fat, respectively, compared with 6% for placebo, along with positive changes in Pro-C3, a marker of liver fibrogenesis. A clinical trial evaluating a single injection of a mAb developed to mimic FGF21's effects on FGFR1c and Klotho, but with no activity on FGFR2c and 3c, was reported in obese insulin resistant subjects with NAFLD to be associated with a 37% relative reduction of liver fat on Day 36. A placebo-controlled clinical trial in NAFLD subjects evaluating a different mAb FGF21 mimetic, also with activity at FGFR1c but not FGFR2c or FGFR3c, was reported to be associated with up to a 38% relative reduction of liver fat at adequately tolerated doses after 12 weeks of treatment. The pattern and magnitude of changes in plasma lipoproteins varied across these four analogs. The FGF19 analog and FGF21 mAbs substantially reduced plasma triglyceride and increased HDL-C in comparison to the PEGylated FGF21 analog. Treatment with the FGF19 analog was associated with a nearly 50% placebo-corrected increase in LDL-C. This increase in LDL-C is consistent with FGF19's potent agonism of FGFR4. Of the four FGF21 analogs tested in insulin resistant or type 2 diabetic subjects, three did not improve markers of insulin sensitivity or glycemic control, FGF19 analog, pegylated FGF21 and one of the FGFR1c-specific mAbs, while one of the FGFR1c-specific mAbs did.

Exclusive license agreement with Amgen Inc.

In June 2018, we entered into an exclusive license agreement with Amgen Inc., or Amgen, pursuant to which we have been granted an exclusive, royalty-bearing license to certain intellectual property rights owned or controlled by Amgen, to commercially develop, manufacture, use, distribute and sell therapeutic products, or Products. In particular, we have been granted licenses under patents filed in both the United States and foreign jurisdictions that are owned or controlled by Amgen, including an exclusive license under certain patents claiming polypeptides comprised of an FGF21 portion with certain point mutations, a linker, and an Fc domain. Our exclusively licensed patents include, but are not limited to, the composition of AKR-001 and methods of using the same. In connection with the license, Amgen also licensed and transferred to us certain know-how related to the manufacture of AKR-001 as well as certain quantities of AKR-001 drug substance manufactured to Good Manufacturing Practices, or GMP, for clinical use, master cell bank, not-for-human use AKR-001 drug product suitable for nonclinical studies and critical reagents.

Pursuant to the terms of the license agreement, we must use commercially reasonable efforts to develop and commercialize a Product in each of several major market territories. In addition, Amgen provided us, at its expense, consulting support in connection with the transfer of the licensed materials and the exploitation of the Products. We are also entitled to sublicense the rights granted to us under the license agreement.

As initial consideration for the license, we paid Amgen an upfront payment of $5.0 million and also issued 2,653,333 shares of our Series A preferred stock to Amgen at the time of the initial closing in June 2018 with a subsequent 3,205,128 shares of our Series A preferred stock issued at the time of the second closing in November 2018, representing 10% of total shares outstanding at such times. In August 2019 we made an additional payment of $2.5 million in connection with dosing the first patient in our Phase 2a clinical trial, which was the first development milestone under the license agreement. As additional consideration for the license, we are required to pay Amgen up to $37.5 million upon the achievement of specified remaining clinical and regulatory milestones and aggregate milestone payments of up to $75.0 million upon the achievement of specific commercial milestones. No commercial milestones have been achieved to date under the license agreement. We are also required to pay tiered royalties of low to high single-digit percentages on annual net sales of the products covered by the license. The royalty rate with respect to the net sales is subject to customary reductions, including in the event that the exploitation of a Product is not covered by a valid claim with the licensed patent rights. The royalty term will terminate on a country-by-country basis on the later of

(i) the expiration date of the last valid claim within the licensed patent rights, (ii) the loss of regulatory exclusivity in such country, and (iii) the tenth anniversary of the first commercial sale of such product in such country.

The license agreement shall expire upon the expiration of the last-to-expire royalty term for the Products in the territory. Upon expiration of the license agreement, the licenses granted to us shall be considered fully paid-up, irrevocable and non-exclusive. Either we or Amgen may terminate the license agreement if the other party commits a material breach of the agreement or defaults in the performance thereunder and fails to cure that breach within 90 days (or 30 days in the case of failure to make any payment as and when due under the agreement) after written notice is provided or in the event of bankruptcy, insolvency, dissolution or winding up. Amgen shall have the right to terminate the license agreement in full upon written notice to us in the event we, our affiliates or sublicensees, directly challenge the patentability, enforceability or validity of any licensed patents, unless, in the event of a sublicensee challenge, we terminate the sublicense within 60 days' notice. We shall have the right to terminate the license agreement within 90 days written notice to Amgen if we conclude, due to scientific, technical, regulatory or commercial reasons, that the exploitation of the Products is no longer commercially practicable.

In connection with the license agreement, Amgen entered into certain stockholder agreements related to this investment. See "Certain relationship and related party transactions."

Intellectual property

Our success depends in part upon our ability to protect our core technology and intellectual property. To protect our intellectual property rights, we rely on patents, trademarks, copyrights and trade secret laws, confidentiality procedures, and employee disclosure and invention assignment agreements. Our intellectual property is critical to our business and we strive to protect it through a variety of approaches, including by obtaining and maintaining patent protection in the United States and internationally for our product candidates, novel biological discoveries, new targets and applications, and other inventions that are important to our business. For our product candidates, we generally intend to pursue patent protection covering compositions of matter, methods of making and methods of use, including combination therapies. As we continue the development of our product candidates, we intend to identify additional means of obtaining patent protection that would potentially enhance commercial success, including through claims covering additional methods of use and biomarkers and complementary diagnostic and/or companion diagnostic related claims. As of December 31, 2019, we have licensed from Amgen Inc. approximately 157 patents and pending patent applications in the U.S. and foreign jurisdictions, including 125 granted U.S. and foreign patents and 32 pending U.S. and foreign patent applications. There are currently no pending U.S. provisional patent applications.

As of December 31, 2019, our patent portfolio relating to AKR-001 includes twelve issued U.S. patents, one pending U.S. patent application, and issued and pending foreign counterpart patents in Europe, Asia, Canada, Australia, and Mexico. Seven issued U.S. patents include claims directed to the AKR-001 product, the FGF21 polypeptide component of the AKR-001 product, nucleic acids encoding the product and related polypeptides, polypeptide multimers, related compositions, and methods of using AKR-001 to, e.g., treat diabetes, lower blood glucose in patients suffering from a metabolic disorder, improve glucose tolerance, lower body weight, or reduce triglyceride levels in patients. These issued U.S. patents are expected to expire in 2029. The pending U.S. patent application and related foreign counterparts are directed to a method of treating a patient with excess bile acid; if issued, the resulting U.S. patent is expected to expire in 2036. The portfolio further includes five issued U.S. patents that are directed to related polypeptides and methods of use.

In addition to patents, we rely upon unpatented trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. However, trade secrets and know-how can be difficult to protect. We seek to protect our proprietary information, in part, by executing confidentiality agreements with our collaborators and scientific advisors, and non-solicitation, confidentiality, and invention assignment agreements with our employees and consultants. We have also executed agreements requiring assignment of inventions with selected scientific advisors and collaborators. The confidentiality agreements we enter into are designed to protect our proprietary information and the agreements or clauses requiring assignment of inventions to us are designed to grant us ownership of technologies that are developed through our relationship with the respective counterparty. We cannot guarantee, however, that we have executed such agreements with all applicable counterparties, such agreements will not be

breached, or that these agreements will afford us adequate protection of our intellectual property and proprietary rights. For more information, see "Risk factors—Risks related to our intellectual property."

Manufacturing and supply

We manage several external commercial manufacturing organizations, or CMOs, to develop and manufacture AKR-001.

AKR-001 drug substance is manufactured by fermentation of a recombinant strain of the bacterium E. coli. Product accumulates as insoluble particles (inclusion bodies) within the cells and is recovered by cell disruption, followed by solubilization of the inclusion bodies, protein refolding and several chromatographic separation steps to yield product with target quality attributes. We have an agreement with Boehringer Ingelheim Biopharmaceuticals GmbH, or Boehringer Ingelheim, to manufacture GMP drug substance for future clinical trials and plan to enter into a future agreement for commercial supply at the appropriate time. We have successfully manufactured AKR-001 drug substance at commercial scale as an engineering run at Boehringer Ingelheim. Yield was comparable to the Good Manufacturing Practice (GMP) drug substance originally manufactured by Amgen. Analysis of the drug substance produced by Boehringer Ingelheim confirmed it met the same release specification as previously used for Amgen GMP drug substance. The Company expects to release drug product produced in compliance with current GMP requirements by the fourth quarter of 2020.

We acquired approximately 475 grams of AKR-001 drug substance, or DS, as part of our license from Amgen, divided into 10 one-liter bottles and stored in frozen storage at –30 degrees Celsius. We used this DS, which was manufactured by Amgen in compliance with GMP, to prepare drug product for our Phase 2a clinical trial and to conduct toxicology studies in rats and non-human primates to support our clinical program. GMP drug product was manufactured for use in our Phase 2a clinical trial by Vetter Pharma International GmbH.

The new GMP drug product used for the BALANCED study is based on an Amgen platform formulation used in the early stages of clinical development. It is stored as a frozen liquid until immediately before administration to trial subjects. We plan to use this same frozen liquid formulation in a Phase 2b clinical trial. We have engaged a third party to develop a new refrigerated liquid or freeze-dried, lyophilized formulation for use in Phase 3 clinical trials. The development of a medical device is envisaged for convenient subcutaneous administration of the new drug product formulation.

Sales and marketing

Successful marketing of a new drug for the treatment of NASH will require a targeted commercial infrastructure. We expect to begin making plans for commercialization following completion of our Phase 2a clinical trial. We have contracted with a third-party manufacturer, Boehringer Ingelheim, to support future clinical trials and the potential commercialization of AKR-001 with commercial-scale manufacturing. When appropriate, we intend to develop the commercial infrastructure required for bringing AKR-001 to patients in the United States, if approved. We also plan to evaluate options for delivering AKR-001, if approved, to patients in other key markets, such as Europe, Japan and China, which may include strategic collaborations.

Competition

The biotechnology industry is intensely competitive and subject to rapid and significant technological change. Our competitors include multinational pharmaceutical companies, specialized biotechnology companies and universities and other research institutions. We understand that a number of pharmaceutical companies, including AbbVie, Inc., Allergan plc, AstraZeneca PLC/MedImmune LLC, Boehringer Ingelheim AG, Bristol-Myers Squibb Company, Inc., Eisai, Inc., Eli Lilly and Company, Johnson & Johnson, Merck & Co., Inc., Novartis Pharmaceuticals Corporation, Novo Nordisk A/S, Pfizer Inc., Roche Holding AG, Sanofi and Takeda Pharmaceutical Company Limited, as well as large and small biotechnology companies such as Albireo Pharma, Inc., Cirius Therapeutics, Inc., CymaBay Therapeutics, Inc., 89bio, Inc., Enanta Pharmaceuticals, Inc., Galectin Therapeutics Inc., Galmed Pharmaceuticals Ltd., Genfit SA, Gilead Sciences, Inc., Intercept Pharmaceuticals, Inc., Inventiva Pharma SA, Madrigal Pharmaceuticals, Inc., MediciNova, Inc.,

Metacrine, Inc., NGM Biopharmaceuticals, Inc., North Sea Pharmaceuticals, 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. 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 have significantly greater experience than we have in undertaking nonclinical studies and human clinical trials of new pharmaceutical products and in obtaining regulatory approvals of human therapeutic products. Accordingly, our competitors may succeed in obtaining FDA approval for superior products. 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. Smaller and earlier-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

Our competitors may obtain regulatory approval of their products more rapidly than we do or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidate or any future product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products 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 these companies, then we may not be able to commercialize our product candidate or any future product candidates or achieve a competitive position in the market. This would adversely affect our ability to generate revenue. Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Government Regulation

The FDA and other regulatory authorities at federal, state, and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of biologics such as those we are developing. We, along with third-party contractors, will be required to navigate the various nonclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates.

U.S. biological product development

In the United States, biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act, or FD&C Act, and the Public Health Service Act, or PHS Act, and other federal, state, local and foreign statutes and regulations. The process required by the FDA before a biological product may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests and animal studies performed in accordance with the FDA's Good Laboratory Practice (GLP) regulation;
- submission to the FDA of an investigational new drug application, or IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval of a clinical trial protocol and related documentation by an independent Institutional Review Board, or IRB, or ethics committee at each clinical site before the trial may be initiated;
- performance of adequate and well-controlled human clinical trials according to FDA's regulations commonly referred to as Good Clinical Practices, or GCPs, and any additional requirements for the protection of human research subjects and their health information, to establish the safety, purity and potency of the proposed biologic product candidate for its intended use;

- preparation of and submission to the FDA of a Biologics License Application, or BLA, for marketing authorization that includes substantive evidence of safety, purity, and potency from results of nonclinical testing and clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with current Good Manufacturing Practices, or cGMPs, and to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity;
- potential FDA audit of the nonclinical and clinical trial sites that generated the data in support of the BLA in accordance with any applicable expedited programs or designations;
- payment of user fees for FDA review of the BLA (unless a fee waiver applies); and
- FDA review and approval, or licensure, of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

Nonclinical and clinical development

Before testing any biological product candidate in humans, the product candidate enters the nonclinical testing stage. Nonclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product biological characteristics, chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the nonclinical tests must comply with federal regulations and requirements including GLPs.

Prior to beginning the first clinical trial with a product candidate, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of the nonclinical tests, including animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls (CMC) information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical trial on a clinical hold within the 30-day time period. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. The FDA also may impose clinical holds on a biological product candidate at any time before or during clinical trials due to, among other considerations, unreasonable or significant safety concerns, inability to assess safety concerns, lack of qualified investigators, a misleading or materially incomplete investigator brochure, study design deficiencies, interference with the conduct or completion of a study designed to be adequate and well-controlled for the same or another investigational drug, insufficient quantities of investigational product, lack of effectiveness, or non-compliance. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing a clinical trial to begin, or that, once begun, issues or circumstances will not arise that delay, suspend or terminate such studies.

Clinical trials involve the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the study sponsor's control, in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, dosing procedures, subject selection and exclusion criteria, and the parameters to be used in monitoring subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events

should occur. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its related documentation before the clinical trial begins at that site, and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of a BLA. The FDA may accept a well-designed and well-conducted foreign clinical study not conducted under an IND if the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

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

Phase 1—The investigational product is initially introduced into healthy human subjects. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. In the cases of some products for severe of life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in the targeted patient population.

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

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

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so called Phase 4 studies may be made a condition to approval of the BLA.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or *in vitro* testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor, acting on its own or based on a recommendation from the sponsor's data safety monitoring board may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being

conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to patients.

Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

BLA submission and review

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. FDA approval of a BLA must be obtained before a biologic may be marketed in the United States. The BLA must include all relevant data available from pertinent nonclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. The submission of a BLA requires payment of a substantial application user fee to FDA, unless a waiver or exemption applies.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the FDA accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Under the performance goals and policies implemented by the FDA under the Prescription Drug User Fee Act, or PDUFA, for original BLAs, the FDA targets ten months from the filing date in which to complete its initial review of a standard application and respond to the applicant, and six months from the filing date for an application with priority review. In both standard and priority reviews, the FDA does not always meet its PDUFA goal dates, and the review process is often significantly extended by FDA requests for additional information or clarification. This review typically takes twelve months from the date the BLA is submitted to the FDA because the FDA has approximately two months to make a "filing" decision. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the BLA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews a BLA to determine, among other things, whether a proposed product is safe, pure and potent, for its intended use, and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. Further, the FDA may convene an advisory committee to provide clinical insight on application review questions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve a product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP requirements. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited development and review programs

The FDA has various programs, including Fast Track designation, breakthrough therapy designation, accelerated approval and priority review, that are intended to expedite or simplify the process for the development and FDA review of biologics that are intended for the treatment of serious or life-threatening diseases or conditions. These programs do not change the standards for approval but may help expedite the development or approval process. To be eligible for Fast Track designation, new biological products must be intended to treat a serious or life-threatening condition and demonstrate the potential to address an unmet medical need for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new biologic may request the FDA to designate the biologic as a Fast Track product at any time during the clinical development of the product. One benefit of Fast Track designation, for example, is that the FDA may consider for review sections of the marketing application for a product that has received Fast Track designation on a rolling basis before the complete application is submitted.

Under the FDA's breakthrough therapy program, products intended to treat a serious or life-threatening disease or condition may be eligible for the benefits of the Fast Track program when preliminary clinical evidence demonstrates that such product may have substantial improvement on one or more clinically significant endpoints over existing therapies. Additionally, the FDA will seek to ensure the sponsor of a breakthrough therapy product receives timely advice and interactive communications to help the sponsor design and conduct a development program as efficiently as possible.

Any product is eligible for priority review if it treats a serious or life-threatening disease or condition and has the potential, if approved, to provide a significant improvement in safety and effectiveness. The FDA will attempt to direct additional resources to the evaluation of an application for a new biological product designated for priority review in an effort to facilitate the review. Under priority review, the FDA's goal is to review an application in six months once it is filed, compared to ten months for a standard review.

Additionally, a product may be eligible for accelerated approval (also referred to as Subpart E approval). Biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that

provide meaningful therapeutic benefit over existing treatments, as demonstrated by a surrogate or intermediate clinical endpoint, may receive accelerated approval. Specifically, this means that they may be approved on the basis of clinical data establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on an intermediate clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a biological product receiving accelerated approval perform adequate and well-controlled post-marketing confirmatory clinical trials. 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 product.

Pediatric information

Under the Pediatric Research Equity Act, a BLA or supplement to a BLA 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. A sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration must submit an initial Pediatric Study Plan, or PSP, 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 the Phase 3 of Phase 2/3 study. The initial PSP 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 PSP. A sponsor can submit amendments to an agreed-upon initial PSP 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.

Post-Approval requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for ongoing compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

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

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;

- fines, warning 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 product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

U.S. patent term restoration and marketing exclusivity

Depending upon the timing, duration and specifics of the FDA approval of the use of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission data of a BLA and the approval of that application. Only one patent applicable to an approved biological product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. In addition, a patent can only be extended once and only for a single product. The United States Patent and Trademark Office, or U.S. PTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may intend to apply for restoration of patent term for one of our patents, if and as applicable, to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

A biological product can obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods, including some regulatory exclusivity periods tied to 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.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. To date, a number of biosimilars have been licensed under the BPCIA, and numerous biosimilars have been approved in Europe. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or

risks of diminished efficacy relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

Under the BPCIA, a reference biological product is granted four and 12 year exclusivity periods from the time of first licensure of the product. FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product, and FDA will not approve an application for a biosimilar or interchangeable product based on the reference biological product until twelve years after the date of first licensure of the reference product. "First licensure" typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity, or potency. Therefore, one must determine whether a new product includes a modification to the structure of a previously licensed product that results in a change in safety, purity, or potency to assess whether the licensure of the new product is a first licensure that triggers its own period of exclusivity. Whether a subsequent application, if approved, warrants exclusivity as the "first licensure" of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, recent government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and impact of the BPCIA is subject to significant uncertainty.

Other U.S. healthcare and Data Privacy laws and compliance requirements

In the United States, our current and future operations are subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare and Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services, or HHS (such as the Office of Inspector General, Office for Civil Rights and the Health Resources and Service Administration), the U.S. Department of Justice, or DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, our clinical research, sales, marketing and scientific/educational grant programs may have to comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the privacy and security provisions of the Health Insurance Portability and Accountability Act, or HIPAA, and similar state laws, each as amended, as applicable.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering, arranging for or recommending the purchase, lease or order of any item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between therapeutic product manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor _does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not meet the criteria for protection under a statutory exception or regulatory safe harbor.

Additionally, the intent standard under the federal Anti-Kickback Statute was amended by the Affordable Care Act, such that a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act codified case law 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 federal False Claims Act, or FCA (discussed below).

The federal false claims and civil monetary penalty laws, including the FCA, which can be enforced by private citizens through civil qui tam actions, prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal government, including federal healthcare programs, such as Medicare and Medicaid, 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, or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. For instance, historically, pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, off-label, and thus generally non-reimbursable, uses.

HIPAA created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the federal Anti-Kickback Statute, the Affordable Care Act amended the intent standard for certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Also, many states have similar, and typically more prohibitive, fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, as well as the California Consumer Privacy Act of 2018 (the "CCPA"), impose requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates, independent contractors, or agents of covered entities, which include certain healthcare providers, health plans, and healthcare clearinghouses, that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, many state laws govern the privacy and security of health information in specified circumstances. For example, in California the CCPA establishes a new privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. Many of the state laws differ from each other in significant ways and are often not pre-empted by HIPAA, and may have a more prohibitive effect than HIPAA, thus complicating compliance efforts.

We may develop products that, once approved, may be administered by a physician. Under currently applicable U.S. law, certain products not usually self-administered (including injectable drugs) may be eligible for coverage under Medicare through Medicare Part B. Medicare Part B is part of original Medicare, the federal health care program that

provides health care benefits to the aged and disabled, and covers outpatient services and supplies, including certain pharmaceutical products, that are medically necessary to treat a beneficiary's health condition. As a condition of receiving Medicare Part B reimbursement for a manufacturer's eligible drugs, the manufacturer is required to participate in other government healthcare programs, including the Medicaid Drug Rebate Program and the 340B Drug Pricing Program. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of HHS as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. Under the 340B Drug Pricing Program, the manufacturer must extend discounts to entities that participate in the program.

In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price, or ASP, and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors.

Additionally, the federal Physician Payments Sunshine Act, or the Sunshine Act, within the Affordable Care Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to CMS information related to certain payments or other transfers of value made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners. In addition, many states also govern the reporting of payments or other transfers of value, many of which differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

Ensuring business arrangements with third parties comply with applicable healthcare laws and regulations is a costly endeavor. If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other current or future governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, 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, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Coverage, pricing and reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may obtain regulatory approval. In the United States and in foreign markets, sales of any products for which we

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 products. In the United States, third-party payors include federal and state healthcare programs, such as Medicare and Medicaid, private managed care providers, health insurers and other organizations. Adequate coverage and reimbursement from third-party payors are critical to new product acceptance.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors. Third-party payors decide which therapeutics they will pay for and establish reimbursement levels. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a therapeutic is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

We cannot be sure that reimbursement will be available for any product that we commercialize and, if coverage and reimbursement are available, what the level of reimbursement will be. Coverage may also be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Reimbursement may impact the demand for, or the price of, any product for which we obtain regulatory approval.

Third-party payors are increasingly challenging the price, examining the medical necessity, and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with branded drugs and drugs administered under the supervision of a physician. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our product on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. A third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, in the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Private third-party payors tend to follow Medicare coverage and reimbursement limitations to a substantial degree, but also have their own methods and approval process apart from Medicare determinations. Therefore, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. 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 product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop.

Different pricing and reimbursement schemes exist in other countries. In the European Union, 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 products 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 product 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 has become intense. As a result, increasingly high barriers are being erected to the entry of new

products. 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 product candidates for which we receive regulatory approval for commercial sale may suffer if third-party payors fail to provide coverage and adequate reimbursement. In addition, emphasis on managed care, the increasing influence of health maintenance organizations, and additional legislative changes in the United States has increased, and we expect will continue to increase, the pressure on healthcare pricing. The downward pressure on the rise in healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become very intense. 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 products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare reform

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product candidates for which marketing approval is obtained. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, the Affordable Care Act has substantially changed healthcare financing and delivery by both governmental and private insurers. Among the Affordable Care Act provisions of importance to the pharmaceutical and biotechnology industries, 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 that began in 2011;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively, and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price, or AMP;

- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70%, the current discount owed as of January 1, 2019 pursuant to the Bipartisan Budget Act of 2018, or BBA) 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 beginning in 2014 and by adding new mandatory eligibility categories for 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 340B Drug Discount Program;

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;

- expansion of healthcare fraud and abuse laws, including the FCA and the federal Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected;
- requirements to report certain financial arrangements with physicians and teaching hospitals;
- a requirement to annually report certain information regarding drug samples that manufacturers and distributors provide to physicians;
- establishment of the Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending; and
- a licensure framework for follow on biologic products.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, various portions of the ACA are currently undergoing legal and constitutional challenges in the Fifth Circuit Court and the United States Supreme Court, and the Trump Administration has issued various Executive Orders which eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Additionally, Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what affect further changes to the ACA would have on our business.

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 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. At the federal level, the Trump administration's budget proposal for fiscal years 2019 and 2020 contain further drug price control measures that could be enacted during the budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Further, the Trump administration released a "Blueprint", or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. HHS has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS’s policy change that was effective January 1, 2019. While a number of these and other proposed measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Further, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to request access to certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can

seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Government regulations outside the United States

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing, among other things, research and development, clinical trials, testing, manufacturing, safety, efficacy, labeling, packaging, storage, record keeping, distribution, reporting, advertising and other promotional practices involving biological products as well as authorization and approval of our products.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the European Union, for example, a Clinical Trial Application, or CTA, must be submitted for each clinical trial to each country's national health authority and an independent ethics committee, much like the FDA and an IRB, respectively. Once the CTA is approved in accordance with a country's requirements, the corresponding clinical trial may proceed. The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

Regulation in the European Union

In the European Union, medicinal products are subject to extensive pre- and post-market regulation by regulatory authorities at both the European Union and national levels. To obtain regulatory approval of an investigational product under European Union regulatory systems, we must submit a Marketing Authorization Application, or MAA. The application used to submit the BLA in the United States is similar to that required in the European Union, with the exception of, among other things, region-specific document requirements. The European Union also provides opportunities for market exclusivity. For example, in the European Union, upon receiving marketing authorization, innovative medicinal products generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic or biosimilar application. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed until the expiration of the market exclusivity. However, there is no guarantee that a product will be considered by the European Union's regulatory authorities to be an innovative medicinal product, and products may not qualify for data exclusivity.

Pediatric development in the European Union

In the European Union, companies developing a new medicinal product must agree upon a Pediatric Investigation Plan, or PIP, with the EMA, and must conduct pediatric clinical trials in accordance with that PIP, unless a waiver applies, (e.g., because the relevant disease or condition occurs only in adults). The marketing authorization application for the product must include the results of pediatric clinical trials conducted in accordance with the PIP,

unless a waiver applies, or a deferral has been granted, in which case the pediatric clinical trials must be completed at a later date. Products that are granted a marketing authorization on the basis of the pediatric clinical trials conducted in accordance with the PIP are eligible for a six month extension of the protection under a supplementary protection certificate (if any is in effect at the time of approval) or, in the case of orphan medicinal products, a two year extension of the orphan market exclusivity. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

Post-approval controls in the European Union

The holder of a marketing authorization must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance, who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new MAAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the marketing authorization. Such risk-minimization measures or postauthorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies. RMPs and PSURs are routinely available to third parties requesting access, subject to limited redactions.

All advertising and promotional activities for the product must be consistent with the approved Summary of Product Characteristics, or SmPC, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the European Union. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each European Union Member State and can differ from one country to another.

European data collection

The collection and use of personal health data in the European Union is governed by the provisions of the Data Protection Directive, and as of May 2018 the General Data Protection Regulation, or GDPR. This directive imposes more stringent requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, notification of data processing obligations to the competent national data protection authorities, and the security and confidentiality of the personal data. The Data Protection Directive and GDPR also impose strict rules on the transfer of personal data out of the European Union to the United States. Failure to comply with the requirements of the Data Protection Directive, the GDPR, and the related national data protection laws of the European Union Member States may result in fines and other administrative penalties. The GDPR introduces new data protection requirements in the European Union and substantial fines for breaches of the data protection rules, specifically fines are increased to levels of up to 4% total worldwide annual turnover or up to €20 million (whichever is higher). The GDPR regulations may impose additional responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. We are subject to the GDPR if we have a presence or "establishment" in the European Union or E.U. (e.g. E.U. based subsidiary or operations), when conducting clinical trials with E.U. based data subjects (whether the trials are conducted directly by us or through a clinical vendor or partner) or offering approved products or services (if relevant) to E.U. based data subjects (regardless of whether involving our E.U. based subsidiary or operations). The GDPR regulations may be onerous and adversely affect our business, financial condition, results of operations, and prospects.

European Union drug marketing

Much like the Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order, or use of medicinal products is also prohibited in the European Union. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of European Union Member States. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain European Union Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization, and/or the regulatory authorities of the individual European Union Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct, applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines, or imprisonment.

Brexit and the Regulatory Framework in the United Kingdom

On June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union (commonly referred to as "Brexit"). Thereafter, on March 29, 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The United Kingdom formally left the European Union on January 31, 2020. A transition period began on February 1, 2020, during which European Union pharmaceutical law remains applicable to the United Kingdom. This transition period is due to end on December 31, 2020. Since the regulatory framework for pharmaceutical products in the United Kingdom covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from European Union directives and regulations, Brexit could materially impact the future regulatory regime which applies to products and the approval of product candidates in the United Kingdom. It remains to be seen how, if at all, Brexit will impact regulatory requirements for product candidates and products in the United Kingdom.

Rest of world regulation

For other countries outside the European Union and the United States, such as countries in Eastern Europe, Latin America, Middle East, or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary from country to country. Additionally, the clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, or criminal prosecution.

Additional regulation

In addition to the foregoing, local, state and federal laws regarding such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations. We may incur significant costs to comply with such laws and regulations now or in the future.

Employees

As of March 6, 2020, we employed 13 full-time employees, including seven in research and development and six in general and administrative and one part-time employee. Five of our employees hold M.D. or Ph.D. degrees. We have never had a work stoppage, and none of our employees is represented by a labor organization or under any collective-bargaining arrangements. We consider our employee relations to be good.

Corporate Information

We were incorporated under the laws of the state of Delaware on in January 2017 as Pippin Pharmaceuticals, Inc. On May 16, 2018, we changed our name to Akero Therapeutics, Inc. Our mailing address and executive offices are located at 170 Harbor Way, 3rd Floor, South San Francisco, California 94080 and our telephone number at that address is (650) 487-6488. We maintain an Internet website at the following address: www.akerotx.com. The information on our website is not incorporated by reference in this Annual Report on Form 10-K or in any other filings we make with the Securities and Exchange Commission, or SEC.

Available Information

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. 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.

A copy of our Corporate Governance Guidelines, Code of Business Conduct and Ethics and the charters of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee are posted on our website, www.akerotx.com, under “Investors – Corporate Governance.”

The SEC maintains an Internet website that contains reports, proxy and information statements, and other information regarding us and other issuers that file electronically with the SEC. The SEC’s Internet website address is http://www.sec.gov.

Item 1A. Risk Factors.

In evaluating the Company and our business, careful consideration should be given to the following risk factors, in addition to the other information set forth in this Annual Report on Form 10-K and in other documents that we file with the SEC. Investing in our common stock involves a high degree of risk. If any such risks or uncertainties actually occur, our business, financial condition or operating results could differ materially from the plans, projections and other forward-looking statements included in this Annual Report, including in the foregoing Business section and later in the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this report and in our other public filings and public statements. The trading price of our common stock could decline due to any of these risks, and as a result, our stockholders may lose all or part of their investment. The risks described below are not intended to be exhaustive and are not the only risks facing the Company. New risk factors can emerge from time to time, and it is not possible to predict the impact that any factor or combination of factors may have on our business, prospects, financial condition or results of operations.

Risks related to our business, financial position, and need for additional capital

We have incurred significant losses since our inception and we expect to incur losses for the foreseeable future.

We have no products approved for commercial sale and have not generated any revenue to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred significant losses in each period since our inception in January 2017. For the years ended December 31, 2019 and 2018, we reported net losses of $43.8 million and $81.7 million, respectively. The net loss for the year ended December 31, 2018 included non-cash charges of $62.2 million related to the change in fair value of our preferred stock tranche obligation and $5.8 million related to the change in fair value of our anti- dilution right liability. As of December 31, 2019, we had an accumulated deficit of $130.3 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidate. We anticipate that our expenses will increase substantially if, and as, we:

- conduct larger scale clinical trials for our product candidate, AKR-001, and any future product candidates;
- discover and develop new product candidates, and conduct nonclinical studies and clinical trials;
- manufacture, or have manufactured, clinical and commercial supplies of our product candidates;
- seek regulatory approvals for our product candidate or any future product candidates;
- commercialize AKR-001 or any future product candidates, if approved;
- attempt to transition from a company with a development focus to a company capable of supporting commercial activities, including establishing sales, marketing and distribution infrastructure;
- hire additional clinical, scientific, and management personnel;
- add operational, financial, and management information systems and personnel;
- identify additional compounds or product candidates and acquire rights from third parties to those compounds or product candidates through licenses; and
- incur additional costs associated with operating as a public company.

Even if we succeed in commercializing AKR-001 or any future product candidates, we may continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We currently have a limited operating history, have not generated any revenue to date, and may never become profitable.

We are a clinical-stage biotechnology company with a limited operating history. Our operations to date have been limited to organizing and staffing our company, acquiring, developing and securing our technology and product candidate, AKR-001, and conducting nonclinical studies and clinical trials of AKR-001. We have not yet demonstrated our ability to complete clinical trials, obtain regulatory approval, formulate and manufacture a commercial-scale product, or conduct sales and marketing activities necessary for successful product commercialization. Investment in biotechnology product development is highly speculative because it entails substantial upfront expenditures in contract research organizations and contract manufacturing organizations and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. Consequently, any predictions you may make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

Though AKR-001 is currently in Phase 2a clinical development, we do not expect to receive revenue from AKR-001 for a number of years, if ever. To date, we have not generated any revenue and we will not be able to generate product revenue unless and until AKR-001, or any future product candidate, successfully completes clinical trials,

receives regulatory approval, and is commercialized. We may seek to obtain revenue from collaboration or licensing agreements with third parties. Our ability to generate future product revenue from AKR-001 or any future product candidates also depends on a number of additional factors, including our, or our current and future contractors' and collaborators', ability to:

- successfully complete nonclinical studies and clinical trials for AKR-001 and any future product candidates;
- seek and obtain marketing approvals for any product candidates that complete clinical development;
- establish and maintain supply and manufacturing relationships with third parties, and ensure adequate and legally compliant manufacturing of bulk drug substances and drug products to maintain that supply;
- launch and commercialize any product candidates for which we obtain marketing approval, and, if launched independently, successfully establish a sales, marketing and distribution infrastructure;
- demonstrate the necessary safety data post-approval to ensure continued regulatory approval;
- obtain coverage and adequate product reimbursement from third-party payors, including government payors;
- achieve market acceptance for any approved products;
- address any competing technological and market developments;
- maintain our rights under our existing license agreement with Amgen Inc., or Amgen, and any similar agreements we may enter into in the future;
- negotiate favorable terms in any collaboration, licensing or other arrangements into which we may enter in the future and performing our obligations in such collaborations;
- establish, maintain, protect and enforce our intellectual property rights; and
- attract, hire and retain qualified personnel.

In addition, because of the numerous risks and uncertainties associated with biotechnology product development, including that our product candidate may not advance through development or achieve the endpoints of applicable clinical trials, we are unable to predict the timing or amount of increased expenses, or if or when we will achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we decide, or are required by the U.S. Food and Drug Administration, or FDA, or foreign regulatory authorities, to perform nonclinical studies or clinical trials in addition to those that we currently anticipate. Even if we complete the development and regulatory processes described above, we anticipate incurring significant costs associated with launching and commercializing any approved product.

If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause you to lose all or part of your investment.

We will require additional capital to finance our operations, which may not be available to us on acceptable terms, or at all. As a result, we may not complete the development and commercialization of our product candidate or develop any future product candidates.

As a research and development company, our operations have consumed substantial amounts of cash since inception. We expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we advance AKR-001 into later-stage clinical development.

As of December 31, 2019, we had $136.4 million of cash, cash equivalents and short-term marketable securities, which includes proceeds from our initial public offering, or IPO, of $95.5 million, net of underwriting discounts, commissions and offering expenses. Any forecast of the period of time through which our financial resources will adequately support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this ‘‘Risk factors’’ section. The assumptions underlying any estimate may prove to be wrong, and we could utilize our available capital

resources sooner than we currently expect. Our future funding requirements, both short and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of nonclinical studies and clinical trials for our product candidate or any future product candidates we may develop;
- the cost and timing of manufacturing our product candidate for use in clinical trials;
- our ability to maintain our license to AKR-001 from Amgen;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more nonclinical studies or clinical trials than those that we currently expect or change their requirements on studies that had previously been agreed to;
- the cost to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing any patents or other intellectual property rights;
- the effect of competing technological and market developments;
- market acceptance of any approved product candidates, including product pricing, as well as product coverage and the adequacy of reimbursement by third-party payors;
- the cost of acquiring, licensing or investing in additional businesses, products, product candidates and technologies;
- the cost and timing of selecting, auditing and potentially validating a manufacturing site for commercial scale manufacturing;
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval and that we determine to commercialize; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems.

We do not have any committed external source of funds or other support for our development efforts and we cannot be certain that additional funding will be available on acceptable terms, or at all. Until we can generate sufficient revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements, and other marketing or distribution arrangements. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted. If we raise additional capital through debt financing, we could be subject to fixed payment obligations and may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. 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 product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. We also could be required to seek collaborators for one or more of our current or any future product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our products or product candidates or one or more of our other research and development initiatives. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

We are heavily dependent on the success of AKR-001, our only product candidate.

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We expect that a substantial portion of our efforts and expenditures over the next several years will be devoted to AKR-001, which is currently our only product candidate. Accordingly, our business currently depends heavily on the successful development, regulatory approval, and commercialization of AKR-001. We cannot be certain

that AKR-001 will receive regulatory approval or be successfully commercialized even if we receive regulatory approval. If we were required to discontinue development of AKR-001 or if AKR-001 does not receive regulatory approval or fails to achieve significant market acceptance, we would be delayed by many years in our ability to achieve profitability, if ever.

The research, testing, manufacturing, safety, efficacy, labeling, approval, sale, marketing, and distribution of AKR-001 is, and will remain, subject to comprehensive regulation by the FDA and foreign regulatory authorities. Failure to obtain regulatory approval for AKR-001 in the United States, Europe, Japan or other jurisdictions will prevent us from commercializing and marketing AKR-001 in such jurisdictions.

Clinical development of AKR-001 prior to the ongoing Phase 2a clinical trial was conducted in patients with type 2 diabetes, or T2D. We believe that the data from clinical trials of AKR-001 in patients with T2D support development of AKR-001 for the treatment of patients with nonalcoholic steatohepatitis, or NASH. We did not conduct any of the development of AKR-001 related to clinical trials in patients with T2D, and we have relied on Amgen to have conducted such research and development in accordance with the applicable protocol, legal, regulatory, and scientific standards, have accurately reported the results of all nonclinical studies and clinical trials conducted prior to our license of AKR-001, and have correctly collected and interpreted the data from these studies and trials. Our ongoing and any future clinical trials may not be able to support continued development of AKR-001 in NASH. To the extent any of the foregoing has not occurred, our expected development time and development costs for AKR-001 may be increased.

Even if we were to successfully obtain approval from the FDA and foreign regulatory authorities for AKR-001, any approval might contain significant limitations related to use, including limitations on the stage of disease AKR-001 is approved to treat, as well as restrictions for specified age groups, warnings, precautions or contraindications. Furthermore, even if we obtain regulatory approval for AKR-001, we will still need to develop a commercial infrastructure or develop relationships with collaborators to commercialize, establish a commercially viable pricing structure and obtain coverage and adequate reimbursement from third-party payors, including government healthcare programs otherwise. If we, or any future collaborators, are unable to successfully commercialize AKR-001, we may not be able to generate sufficient revenue to continue our business.

We may be required to make significant payments under our license agreement for AKR-001.

We acquired worldwide, exclusive rights to AKR-001 pursuant to our license agreement with Amgen, which we refer to as the Amgen Agreement. Under the Amgen Agreement, in consideration for the license, we made an upfront payment of $5.0 million to Amgen and also issued 2,653,333 shares of our Series A convertible preferred stock to Amgen at the time of the initial closing of our Series A Preferred Stock financing in June 2018, with a subsequent 3,205,128 shares of our Series A convertible preferred stock issued at the time of the second closing of the Series A Preferred Stock financing in November 2018. On July 2, 2019, we announced the dosing of the first patient in our Phase 2a clinical study of AKR-001, which resulted in a $2.5 million milestone obligation under the Amgen Agreement. As additional consideration for the license, we are required to pay Amgen remaining aggregate milestone payments of up to $37.5 million upon the achievement of specified remaining clinical and regulatory milestones and aggregate milestone payments of up to $75.0 million upon the achievement of specified commercial milestones. Commencing on the first commercial sale of licensed products, we are obligated to pay tiered royalties of low to high single-digit percentages on annual net sales of the products covered by the license. If milestone or other non-royalty obligations become due, we may not have sufficient funds available to meet our obligations, which will materially adversely affect our business operations and financial condition.

If we are not successful in discovering, developing, receiving regulatory approval for and commercializing AKR-001 and any future product candidates, our ability to expand our business and achieve our strategic objectives would be impaired.

Although we plan to devote a majority of our resources to the continued nonclinical and clinical testing and potential approval of AKR-001 for the treatment of patients with NASH, another key element of our strategy is to discover, develop and commercialize a portfolio of products. We are seeking to do so through the identification and potential development of additional pipeline programs, but our resources are limited, and those that we have are geared towards

nonclinical and clinical testing and seeking regulatory approval of AKR-001 for the treatment of patients with NASH. We may also explore strategic collaborations for the development or acquisition of new product candidates, but we may not be successful in entering into such relationships. AKR-001 is our only product candidate in clinical stages of development. Research programs to identify product candidates require substantial technical, financial and human resources, regardless of whether any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all;
- an approved product may not be accepted as safe and effective by trial participants, the medical community or third-party payors; and
- intellectual property or other proprietary rights of third parties for product candidates we develop may potentially block our entry into certain markets or make such entry economically impracticable.

If we fail to develop and successfully commercialize other product candidates, our business and future prospects may be harmed and our business will be more vulnerable to any problems that we encounter in developing and commercializing our product candidate.

Our product candidate and any future product candidates must undergo rigorous clinical trials and regulatory approvals, and success in nonclinical studies or earlier-stage clinical trials may not be indicative of results in future clinical trials. AKR-001 and any future product candidates will be subject to rigorous and extensive clinical trials and extensive regulatory approval processes implemented by the FDA and similar regulatory bodies in other jurisdictions. The approval process is typically lengthy and expensive, and approval is never certain. As a company, our only experience with clinical trials is our ongoing Phase 2a clinical trial, and we have not yet completed the clinical trials required to obtain regulatory approval. We may not be able to conduct clinical trials at preferred sites, enlist clinical investigators, enroll sufficient numbers of participants or begin or successfully complete clinical trials in a timely fashion, if at all. Our anticipated clinical trials may be insufficient to demonstrate that our potential products will be active, safe or effective. Additional clinical trials may be required if clinical trial results are negative or inconclusive, which will require us to incur additional costs and significant delays.

Success in nonclinical studies and earlier-stage clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the effectiveness and safety of a product candidate. In addition, the design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We may be unable to design and execute a clinical trial to support regulatory approval for a NASH therapy. In addition, there is a high failure rate for drugs and products proceeding through clinical trials. In fact, many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in nonclinical studies and earlier-stage clinical trials. Similarly, the outcome of nonclinical studies may not predict the success of clinical trials. Moreover, data obtained from nonclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including due to changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects. From time to time, we may publish interim ''top-line'' or preliminary data from our clinical trials. Preliminary or interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or interim 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, interim and preliminary

data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business and financial prospects.

We are subject to many manufacturing risks, any of which could substantially increase our costs, delay clinical programs and limit supply of our products.

To date, we have not manufactured the drug substance (active pharmaceutical ingredient, or API) for our product candidate under GMP conditions as a company. While we received a supply of AKR-001 drug substance from Amgen that we believe provides sufficient quantities to complete our ongoing Phase 2a clinical trial, we have contracted with a third-party manufacturer, Boehringer Ingelheim Pharmaceuticals GmbH, to make new drug substance to support future clinical trials and for commercial sale, if approved. To date, transfer of the former Amgen drug substance manufacturing process to our third-party contract manufacturer has been completed successfully at pilot scale. Our contract manufacturer may not be able to scale up the manufacturing process as practiced by Amgen in a timely manner to support our future clinical trials. The process of manufacturing our product is complex, highly regulated and subject to several risks, including:

- the manufacturing process is susceptible to product loss due to contamination by adventitious microorganisms, equipment failure, improper installation or operation of equipment, vendor or operator error and improper storage conditions. Even minor deviations from normal manufacturing processes could result in reduced production yields and quality as well as other supply disruptions. If microbial, viral or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, the manufacturing facilities may need to be closed for an extended period of time to investigate and eliminate the contamination;
- the manufacturing facilities in which our products are made could be adversely affected by equipment failures, labor and raw material shortages, financial difficulties of our contract manufacturers, natural disasters, power failures, local political unrest and numerous other factors; and
- any adverse developments affecting manufacturing operations for our products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls or other interruptions in the supply of our products. We may also have to record inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more expensive manufacturing alternatives.

The manufacture of our product candidate requires significant expertise and capital investment, including the development of advanced manufacturing techniques and in-process controls. Manufacturers of these products sometimes encounter difficulties in production, especially during scale-up from the manufacturing process used for early clinical trials to a validated and qualified process needed for pivotal clinical trials and commercial launch. These problems include failure to meet target production costs and yields, failure to meet product release specifications, including stability of the product, quality assurance system failures, operator error and shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. We cannot assure you that any product quality issues relating to the manufacture of our product candidate or any future product candidates will not occur in the future.

We do not have, and we do not currently plan to acquire or build the facilities or internal capabilities to manufacture bulk drug substance or finished drug product for use in clinical trials or commercialization. To a large extent, that makes us dependent on the goodwill of our contract manufacturing partners to quickly fix deviations that will inevitably occur during the manufacturing of our product. Any delay or interruption in the supply of clinical trial materials could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials altogether.

In addition, we plan to develop a new drug product formulation for late stage clinical trials and commercialization. We have entered into a contract with a formulation development company, Coriolis Pharma Research GmbH, to explore both a new refrigerated liquid formulation and a freeze-dried, or lyophilized, formulation. Based on the results of these parallel efforts, we plan to select one approach to progress for use in Phase 3 clinical development. We also plan to begin development of a pen-type autoinjector for the new drug product formulation in advance of commercialization. There is no assurance that we will be successful in developing a new drug product

formulation or an autoinjector on a timely basis or at all, which could impede our development and commercialization strategy for AKR-001. Further, the FDA or other similar foreign regulatory bodies could require nonclinical studies or clinical trials to support introduction of any new formulation and autoinjector, which could increase our development costs and delay or prevent us from proceeding with future clinical trials or commercialization of AKR-001, if approved.

We may encounter difficulties in managing our growth, which could adversely affect our operations.

As of December 31, 2019, we had thirteen full-time employees. As we continue development and pursue the potential commercialization of our product candidate, as well as function as a public company, we will need to expand our financial, development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic collaborators, suppliers and other third parties. Our future financial performance and our ability to develop and commercialize our product candidate and to compete effectively will depend, in part, on our ability to manage any future growth effectively.

We may acquire additional technology and complementary businesses in the future. Acquisitions involve many risks, any of which could materially harm our business, including the diversion of management's attention from core business concerns, failure to effectively exploit acquired technologies, failure to successfully integrate the acquired business or realize expected synergies or the loss of key employees from either our business or the acquired businesses.

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

We incur significant legal, accounting and other expenses, and expend significant time and effort by management and other personnel, to comply with the rules applicable to us as a public company. We will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, which will require, among other things, that we file with the Securities and Exchange Commission (SEC), annual, quarterly, and current reports with respect to our business and financial condition. Effective internal control over financial reporting is necessary for us to provide reliable financial reports in a timely manner. As a public company, we are subject Section 404, or Section 404, of the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley, and the rules and regulations of Nasdaq. These regulations impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. As a public company, we are now required to comply with the SEC's rules that implement Section 404 of the Sarbanes-Oxley Act, and are therefore required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose, which will require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of our internal control over financial reporting commencing with our second annual report. This assessment will need to include the disclosure of any material weaknesses or significant deficiencies in our internal control over financial reporting identified by our management or our independent registered public accounting firm.

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 our IPO. We intend to take advantage of this new 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, and results of operations. 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. 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.

When we lose our status as an ‘‘emerging growth company,’’ as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act, our independent registered public accounting firm will be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an ‘‘emerging growth company’’ for up to five years from the closing of our initial public offering. An independent assessment of the effectiveness of our internal controls could detect problems that our management’s assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

If we fail to comply with these rules, including maintaining proper and effective systems of internal controls over financial reporting, the accuracy and timeliness of our financial reporting may be adversely affected, and we could be subject to sanctions or other penalties that would harm our business.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate consolidated financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements in accordance with generally accepted accounting principles. If we identify any material weakness or significant deficiency, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting, and our stock price may decline as a result. We also could become subject to investigations by Nasdaq, the Securities and Exchange Commission, or 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. In addition, investors’ perceptions that our internal controls are inadequate or that we are unable to produce accurate consolidated financial statements on a timely basis may harm our stock price and make it more difficult for us to effectively market and sell our products to new and existing customers.

We must attract and retain highly skilled employees in order to succeed. If we are not able to retain our current senior management team and our scientific advisors or continue to attract and retain qualified scientific, technical and business personnel, our business will suffer.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel and we face significant competition for experienced personnel. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. We are dependent on the members of our management team and our scientific advisors for our business success. We do not maintain ‘‘key person’’ insurance for any of our key personnel. An important element of our strategy is to take advantage of the research and development expertise of our current management and to utilize the expertise of our scientific advisors in the NASH field. We currently have employment agreements with all of our executive officers. Our employment agreements with our executive officers are terminable by them without notice and some provide for severance and change in control benefits. The loss of any one of our executive officers or key scientific consultants could result in a significant loss in the knowledge and experience that we, as an organization, possess and could cause significant delays, or outright failure, in the development and further commercialization of our product candidate or any future product candidates.

There is intense competition for qualified personnel, including management, in the technical fields in which we operate, and we may not be able to attract and retain qualified personnel necessary for the successful research, development and commercialization of our product candidate or any future product candidates. In particular, we have experienced a very competitive hiring environment in the San Francisco Bay Area, where we are headquartered. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success with which we can discover and develop product candidates and our business will be limited.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We cannot ensure that our compliance controls, policies, and procedures will in every instance protect us from acts committed by our employees, agents, contractors, or collaborators that would violate the law or regulation, including, without limitation, healthcare, employment, foreign corrupt practices, environmental, competition, and patient privacy and other privacy laws and regulations. Such improper actions could subject us to civil or criminal investigations, and monetary and injunctive penalties, and could adversely impact our ability to conduct business, operating results, and reputation.

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with the laws enforced by the FDA and other similar foreign regulatory bodies, fails to provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, fails to comply with manufacturing standards we have established, fails to comply with healthcare fraud and abuse laws in the United States and similar foreign laws, or fails to report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under these laws will increase significantly, and our costs associated with compliance with these laws are also likely to increase. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. 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. It is not always possible to identify and deter employee misconduct, 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 government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations.

We may develop AKR-001, and potentially future product candidates, in combination with other therapies, which exposes us to additional risks.

We may develop AKR-001 and future product candidates in combination with one or more approved therapies. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. This could result in our own products being removed from the market or being less successful commercially.

We may also evaluate AKR-001 or any other future product candidates in combination with one or more other therapies that 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 AKR-001 or any product 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 AKR-001 or any other product candidate we develop, we may be unable to obtain approval of or market AKR-001 or any other product candidate we develop.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, including difficulties in identifying patients with NASH and significant competition for recruiting such patients in clinical trials.

Identifying and qualifying patients to participate in our current and future clinical trials is critical to our success. We may encounter delays in enrolling or be unable to retain a sufficient number of patients to complete our Phase 2a clinical trial and may encounter delays in enrolling or be unable to enroll or retain a sufficient number of patients in any of our future clinical trials. In particular, as a result of the inherent difficulties in diagnosing NASH and the significant competition for recruiting patients with NASH in clinical trials, there may be delays in enrolling the patients we need to complete clinical trials on a timely basis, or at all. This risk may be more significant for us than other companies conducting clinical trials for the treatment of patients with NASH because we are enrolling only patients with a biopsy-confirmed diagnosis of NASH in our Phase 2a clinical trial and subsequent clinical trials.

Factors that may generally affect patient enrollment include:

- the size and nature of the patient population;
- the number and location of clinical sites we enroll;
- competition with other companies for clinical sites or patients;
- the eligibility and exclusion criteria for the trial;
- the design of the clinical trial;
- inability to obtain and maintain patient consents;
- risk that enrolled participants will drop out before completion; and
- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

In addition, if any significant adverse events or other side effects are observed in any of our future clinical trials, it may make it more difficult for us to recruit patients to our clinical trials and patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. Our inability to enroll a sufficient number of patients for our clinical trials could result in significant delays, which would increase our costs and have an adverse effect on our company.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than us.

The biotechnology industry is intensely competitive and subject to rapid and significant technological change. Our competitors include multinational pharmaceutical companies, specialized biotechnology companies and universities and other research institutions. We understand that a number of pharmaceutical companies, including AbbVie, Inc., Allergan plc, AstraZeneca PLC/MedImmune LLC, Boehringer Ingelheim AG, Bristol-Myers Squibb Company, Inc., Eisai, Inc., Eli Lilly and Company, Johnson & Johnson, Merck & Co., Inc., Novartis Pharmaceuticals Corporation, Novo Nordisk A/S, Pfizer Inc., Roche Holding AG, Sanofi and Takeda Pharmaceutical Company Limited, as well as large and small biotechnology companies such as Albireo Pharma, Inc., Cirius Therapeutics, Inc., CymaBay Therapeutics, Inc., 89bio, Enanta Pharmaceuticals, Inc., Galectin Therapeutics Inc., Galmed Pharmaceuticals Ltd., Genfit SA, Gilead Sciences, Inc., Intercept Pharmaceuticals, Inc., Inventiva Pharma SA, Madrigal Pharmaceuticals, Inc., MediciNova, Inc., Metacrine, Inc., NGM Biopharmaceuticals, Inc., North Sea Pharmaceuticals, 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. 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 have significantly greater experience than we have in undertaking nonclinical studies and human clinical trials of new pharmaceutical products and in obtaining regulatory approvals of human therapeutic products. Accordingly, our competitors may succeed in obtaining FDA approval for superior products. In addition, many competitors have greater name recognition and more extensive collaborative relationships.

Smaller and earlier-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

Our competitors may obtain regulatory approval of their products more rapidly than we do or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidate or any future product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products 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 these companies, then we may not be able to commercialize our product candidate or any future product candidates or achieve a competitive position in the market. This would adversely affect our ability to generate revenue. Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our business and operations would suffer in the event of computer system failures, cyber-attacks or deficiencies in our or related parties' cyber security.

Given our limited operating history, we are still in the process of implementing our internal security measures. Our internal computer systems and those of current and future third parties on which we rely may fail and are vulnerable to damage from computer viruses and unauthorized access. Our information technology and other internal infrastructure systems, including corporate firewalls, servers, leased lines and connection to the Internet, face the risk of systemic failure that could disrupt our operations. 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 regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidate or any future product 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, our competitive position could be harmed and the further development and commercialization of our product candidate or any future product candidates could be hindered or delayed.

Business or economic disruptions or global health concerns could seriously harm our development efforts and increase our costs and expenses.

Broad-based business or economic disruptions could adversely affect our ongoing or planned research and development activities. For example, in December 2019 an outbreak of a novel strain of coronavirus originated in Wuhan, China, and has since spread to a number of other countries, including the United States. To date, this outbreak has already resulted in extended shutdowns of certain businesses in the Wuhan region and has had ripple effects to businesses around the world. Global health concerns, such as coronavirus, could also result in social, economic, and labor instability in the countries in which we or the third parties with whom we engage operate. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage, including the suppliers, clinical trial sites, regulators and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the

manner and on the timelines presently planned could be materially and negatively impacted. It is also possible that global health concerns such as this one could disproportionately impact the hospitals and clinical sites in which we conduct any of our clinical trials, which could have a material adverse effect on our business and our results of operation and financial condition.

Changes in tax laws could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. For example, the ‘‘Tax Cuts and Jobs Act,’’ or the Tax Act, significantly revised the Internal Revenue Code of 1986, as amended, or the Code. The Tax Act, among other things, included a reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, a limitation of the tax deduction for net interest expense to 30% of adjusted earnings (except for certain small businesses), a limitation of the deduction for net operating losses to 80% of current year taxable income and an elimination of net operating loss carrybacks, in each case, for losses generated after December 31, 2017 (though any such net operating losses may be carried forward indefinitely), and the modification or repeal of many business deductions and credits (including a reduction to the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as ‘‘orphan drugs’’). Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

We might not be able to utilize a significant portion of our net operating loss carryforwards and research and development tax credit carryforwards.

As of December 31, 2019, we had federal and state net operating loss, or NOL, carryforwards of $51.1 million and $10.2 million, respectively, and federal and state research and development tax credit carryforwards of $1.1 million and $0.2 million, respectively. If not utilized, such NOL carryforwards (other than any federal NOL carryforwards arising in taxable years ending after December 31, 2017) and research and development credits will expire at various dates beginning in 2037 and 2032, respectively. We do not anticipate generating revenue from sales of products for the foreseeable future, if ever, and we may never achieve profitability. These NOL and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Act, NOL carryforwards generated in tax years ending after December 31, 2017 are not subject to expiration. However, utilization of NOL carryforwards generated in tax years beginning after December 31, 2017 are limited to a maximum of 80% of the taxable income for such year determined without regard to such NOL carryforwards. In addition, under Section 382 of the Code, the amount of benefits from our NOL carryforwards may be impaired or limited if we incur a cumulative ownership change of more than 50%, as interpreted by the U.S. Internal Revenue Service, over a three-year period. We experienced ownership changes on March 24, 2017 and on June 7, 2018 as a result of pre-IPO financing activities and we may experience ownership changes again in the future, some of which may be outside our control. As a result, our use of federal NOL carryforwards could be limited. State NOL carryforwards may be similarly limited. Any such disallowances may result in greater tax liabilities than we would incur in the absence of such a limitation and any increased liabilities could adversely affect our business, results of operations, financial position and cash flows.

We use and generate materials that may expose us to material liability.

Our research programs involve the use of hazardous materials and chemicals, which are currently only handled by third parties. We are subject to foreign, federal, state and local environmental and health and safety laws and regulations governing, among other matters, the use, manufacture, handling, storage and disposal of hazardous materials and waste products. We may incur significant costs to comply with these current or future environmental and health and safety laws and regulations. In addition, we cannot completely eliminate the risk of contamination or injury from hazardous materials and may incur material liability as a result of such contamination or injury. In the event of an accident, an injured party may seek to hold us liable for any damages that result. Any liability could exceed the limits or fall outside the coverage of our workers’ compensation, property and business interruption insurance and we may not be

able to maintain insurance on acceptable terms, if at all. We currently carry no insurance specifically covering environmental claims.

Risks related to government regulation

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. Our inability to obtain regulatory approval for AKR-001 or any future product candidate would substantially harm our business.

The time required to obtain approval from the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of nonclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of 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 product candidate's development and may vary among jurisdictions. For example, in December 2018, the FDA published draft guidance regarding NASH clinical development on which we relied, in part, in designing our Phase 2a clinical trial of AKR-001 in that indication. However, this guidance is not yet final and is subject to change, and the FDA or comparable foreign regulatory authorities may adopt new or contradictory guidance in the future.

AKR-001 or our future product candidates could fail to receive regulatory approval from the FDA or a comparable foreign regulatory authority for many reasons, including:

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from nonclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials of our product candidate or any future product candidates to obtain regulatory approval;
- failure to obtain approval of the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies; or
- changes in the approval policies or regulations that render our nonclinical and clinical data insufficient for approval.

The FDA or a comparable foreign regulatory authority may require more information, including additional nonclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program for other reasons. If we were to obtain approval, regulatory authorities may approve any of our product candidate or any future product candidates for fewer or more limited indications than we request, may require labeling or a Risk Evaluation Mitigation Strategy, or REMS, that includes significant use or distribution restrictions or safety warnings, precautions, or contraindications, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

Failures or delays in the commencement or completion of, or ambiguous or negative results from, our planned clinical trials of our product candidates could result in increased costs to us and could delay, prevent, or limit our ability to generate revenue and continue our business.

We do not know whether our Phase 2a clinical trial will be completed or any future clinical trials will begin or be completed on schedule, if at all, as the commencement and completion of clinical trials can be delayed or prevented for a number of reasons, including, among others:

- the FDA or comparable foreign regulatory authorities may not authorize us or our investigators to commence our planned clinical trials or any other clinical trials we may initiate, or may suspend our clinical trials, for

example, through imposition of a clinical hold, and may request additional data to permit allowance of our investigational new drug, or IND;
- delays in filing or receiving allowance of additional IND applications that may be required;
- lack of adequate funding to continue our clinical trials and nonclinical studies;
- negative results from our ongoing nonclinical studies;
- delays in reaching or failing to reach agreement on acceptable terms with prospective CROs and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and study sites;
- inadequate quantity or quality of a product candidate or other materials necessary to conduct clinical trials, for example delays in the manufacturing of sufficient supply of finished drug product;
- difficulties obtaining ethics committee or Institutional Review Board, or IRB, approval to conduct a clinical study at a prospective site or sites;
- challenges in recruiting and enrolling subjects to participate in clinical trials, the proximity of subjects to study sites, eligibility criteria for the clinical study, the nature of the clinical study protocol, the availability of approved effective treatments for the relevant disease, and competition from other clinical study programs for similar indications;
- severe or unexpected drug-related side effects experienced by subjects in a clinical trial;
- we may decide, or regulatory authorities may require us, to conduct additional nonclinical or clinical trials or abandon product development programs;
- delays in validating, or inability to validate, any endpoints utilized in a clinical trial;
- the FDA or comparable foreign regulatory authorities may disagree with our clinical study design and our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials; and
- difficulties retaining subjects who have enrolled in a clinical trial but may be prone to withdraw due to rigors of the clinical trials, lack of efficacy, side effects, personal issues, or loss of interest.

Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical study may be suspended or terminated by us, the FDA or comparable foreign regulatory authorities, the IRBs at the sites where the IRBs are overseeing a clinical study, a data and safety monitoring board, or DSMB, overseeing the clinical study at issue or other regulatory authorities due to a number of factors, including, among others;

- failure to conduct the clinical study in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical study operations or study sites by the FDA or other regulatory authorities that reveals deficiencies or violations that require us to undertake corrective action, including in response to the imposition of a clinical hold;
- unforeseen safety issues or safety signals, including any that could be identified in our ongoing nonclinical studies or clinical trials, adverse side effects or lack of effectiveness;
- changes in government regulations or administrative actions;
- problems with clinical supply materials; and
- lack of adequate funding to continue clinical trials.

Any inability to successfully complete nonclinical and clinical development could result in additional costs to us or impair our ability to generate revenue. In addition, if we make changes to a product candidate, such as changes to the formulation, we may need to conduct additional nonclinical studies or clinical trials to bridge or demonstrate the comparability of our modified product candidate to earlier versions, which could delay our clinical development plan or marketing approval for our current product candidate and any future product candidates. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

We have no experience in conducting clinical trials and have never obtained approval for any product candidates, and may be unable to do so successfully.

As a company, other than our ongoing Phase 2a clinical trial, we have no experience in designing, conducting or completing clinical trials and have never progressed a product candidate through to regulatory approval. In part because of this lack of experience, our clinical trials may require more time and incur greater costs than we anticipate. We cannot be certain that the planned clinical trials will begin or conclude on time, if at all. Large-scale trials will require significant additional financial and management resources. Any performance failure on the part of such third parties could delay the clinical development of our product candidate or any future product candidates or delay or prevent us from obtaining regulatory approval or commercializing our current or any future product candidates, depriving us of potential product revenue and resulting in additional losses.

The advancement of healthcare reform may negatively impact our ability to profitably sell our product candidate or any future product candidates, if approved.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidate or any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act, was enacted, which includes measures that have significantly changed the way health care is financed by both governmental and private insurers. Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, various portions of the ACA are currently undergoing legal and constitutional challenges in the Fifth Circuit Court and the United States Supreme Court, and the Trump Administration has issued various Executive Orders which eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Additionally, Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what affect further changes to the ACA would have on our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. In August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction, which triggered the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2025 unless Congress takes additional action. These reductions were extended through 2029. In January 2013, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Recently, 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 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. At the federal level, the Trump administration's budget proposal for fiscal years 2019 and 2020 contain further drug price control measures that could be enacted during the budget process or in other future legislation, including, for example, measures to permit Medicare

Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. Although a number of these, and other proposed measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that the healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private third-party payors.

Additionally, in December 2019, the FDA issued a draft guidance document outlining a potential pathway for manufacturers to obtain an additional National Drug Code, or NDC, for an FDA-approved drug that was originally intended to be marketed in a foreign country and that was authorized for sale in that foreign country. The regulatory and market implications of the draft guidance are unknown at this time. Proponents of drug reimportation may attempt to pass legislation that would directly allow reimportation under certain circumstances. Legislation or regulations allowing the reimportation of drugs, if enacted, could decrease the price we receive for any products that we may develop and adversely affect our future revenues and prospects for profitability.

Further, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to request access to certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse, transparency and other healthcare laws and regulations, which, if violated, 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 will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare providers, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through

which we research, and if approved, market, sell and distribute our products. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits persons from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for the furnishing or arranging for the furnishing, or the purchase, lease or order, or arranging for or recommending purchase, lease or order, of any good or service for which payment may be made under a federal healthcare program, such as Medicare and Medicaid;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which can be enforced through civil whistleblower or *qui tam* actions, prohibit individuals or entities from, among other things knowingly presenting, or causing to be presented, to the federal government or a government contractor, grantee, or other recipient of federal funds, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense or knowingly and willfully making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their implementing regulations, imposes obligations on certain healthcare providers, health plans and healthcare clearinghouses, known as covered entities, as well as their business associates, which are individuals and entities that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Open Payments program, created under Section 6002 of the Affordable Care Act and its implementing regulations, 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 (as defined above) and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners; and
- analogous state, local, and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign 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 and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug prices; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws that govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found

not to be in compliance with applicable laws, that person or entity may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Failure to comply with health and data protection laws and regulations 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 any potential collaborators may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). 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 and California Consumer Privacy Act of 2018 ("CCPA")), that 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. The state of California, for example, recently adopted the CCPA, which went into effect beginning in January 2020. The CCPA has been characterized as the first "GDPR-like" privacy statute to be enacted in the United States because it mirrors a number of the key provisions of the European Union General Data Protection Regulation ("GDPR") (discussed below in the European Data Collection subsection). The CCPA establishes a new privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. 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. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact some of our business activities. Depending on the facts and circumstances, we could be subject to civil, criminal, and administrative penalties if we 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.

Compliance with U.S. and international data protection laws and regulations, including the EU GDPR and other EU data protection laws could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with these laws and regulations could result in government enforcement actions (which could include civil, criminal and administrative penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects, employees and other individuals about whom we or our potential collaborators obtain personal information, as well as the providers who share this information with us, may limit our ability to collect, use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

In the event we decide to conduct clinical trials or continue to enroll subjects in our ongoing or future clinical trials, we may be subject to additional privacy restrictions. The collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the EU General Data Protection Regulation, or GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers. The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be

required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. Further, the United Kingdom's exit from the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear how data transfers to and from the United Kingdom will be regulated now that the United Kingdom has officially left the EU.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenue, if any.

In some countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our drug candidate to other available procedures. If reimbursement of our drugs is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

Clinical development is uncertain and our clinical trials for AKR-001 and any future product candidates may experience delays, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all, which would have an adverse effect on our business.

We cannot be sure that we will be able to continue development of AKR-001, or submit INDs or similar applications for any future product candidates, on the timelines we expect, if at all. To proceed with our development plans and ultimately commercialization, we may need to conduct and meet regulatory requirements for additional preclinical studies and clinical trials. We cannot be certain of the timely completion or outcomes of our preclinical testing and studies and cannot predict if the FDA or other regulatory authorities will accept our proposed clinical programs or if the outcomes of our preclinical studies and clinical trials will enable any future clinical trials to begin under a proposed protocol.

Even if we are able to obtain regulatory approvals for our product candidate or any future product candidates, if they exhibit harmful side effects after approval, our regulatory approvals could be revoked or otherwise negatively impacted, and we could be subject to costly and damaging product liability claims.

Clinical trials are conducted in representative samples of the potential patient population which may have significant variability. Even if we receive regulatory approval for AKR-001 or any of our future product candidates, we will have tested them in only a small number of patients during our clinical trials. Clinical trials are by design based on a limited number of subjects and of limited duration for exposure to the product used to determine whether, on a potentially statistically significant basis, the planned safety and efficacy of any product candidate can be achieved. As with the results of any statistical sampling, we cannot be sure that all side effects of our product candidates may be uncovered, and it may be the case that only with a significantly larger number of patients exposed to the product candidate for a longer duration, may a more complete safety profile be identified. Further, even larger clinical trials may not identify rare serious adverse effects or the duration of such studies may not be sufficient to identify when those events may occur. If our applications for marketing are approved and more patients begin to use our product, new risks and side effects associated with our products may be discovered. There have been other products that have been approved by the regulatory authorities but for which safety concerns have been uncovered following approval. Such safety concerns have led to labelling changes or withdrawal of products from the market, and any of our product candidates may be subject to similar risks. Additionally, we may be required to conduct additional nonclinical and clinical trials, require additional warnings on the label of our product, reformulate our product or make changes, create a medication guide outlining the risks of such side effects for distribution to patients and obtain new approvals for our and our suppliers' manufacturing facilities for AKR-001 and any future product candidates. We might have to withdraw or recall our products from the marketplace. We may also experience a significant drop in the potential sales of our product

if and when regulatory approvals for such product are obtained, experience harm to our reputation in the marketplace or become subject to lawsuits, including class actions. Any of these results could decrease or prevent any sales of our approved product or substantially increase the costs and expenses of commercializing and marketing our product.

Even if our current product candidate or any future product candidates receive regulatory approval, they will remain subject to extensive regulatory scrutiny and may still face future development and regulatory difficulties.

Even if we obtained regulatory approval for a product candidate, regulatory authorities may still impose significant restrictions on our product candidates, including their indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies. For example, if AKR-001 is approved by the FDA based on a surrogate endpoint pursuant to accelerated approval regulations (also referred to as Subpart E regulations), we will be required to conduct additional confirmatory clinical trials demonstrating the clinical benefit on the ultimate outcome of NASH. Further, even if we obtained regulatory approval for a product candidate, it would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information.

The FDA and comparable foreign regulatory authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of our product candidate or any future product candidates, they may require labeling changes or establishment of a risk evaluation and mitigation strategy or similar strategy, impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP, regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidate or any future product candidates or the manufacturing facilities for our product candidate or any future product candidates fail to comply with applicable regulatory requirements, or undesirable side effects caused by such products are identified, a regulatory agency may:

- issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require that we conduct post-marketing studies;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend marketing of, withdraw regulatory approval of or recall such product;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products or require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product and generate revenue.

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the Department of Justice, the Department of Health and Human Services' Office of Inspector

General, state attorneys general, members of Congress and the public. Violations, including promotion of our products for unapproved (or off-label) uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the government. Additionally, comparable foreign regulatory authorities will heavily scrutinize advertising and promotion of any product candidate that obtains approval outside of the United States.

In the United States, engaging in the impermissible promotion of our products for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to civil and criminal penalties and fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. These false claims statutes include the federal False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government prevails in the lawsuit, the individual will share in any fines or settlement funds. Since 2004, these federal False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements regarding certain sales practices promoting off-label drug uses involving fines in excess of $1 billion. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations and be excluded from Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our approved products, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition and results of operations.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidate or any future product candidates. 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, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Healthcare insurance coverage and reimbursement may be limited or unavailable for our product candidate, if approved, which could make it difficult for us to sell our product candidate or other therapies profitably.

The success of our product candidate, if approved, depends on the availability of coverage and adequate reimbursement from third-party payors including governmental healthcare programs, such as Medicare and Medicaid, commercial payors, and health maintenance organizations. We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we may develop.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from third-party payors is critical to new product acceptance.

Third-party payors decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a third-party payor is a time consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate

reimbursement will be obtained. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS, an agency within HHS, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private third-party payors tend to follow Medicare coverage and reimbursement limitations to a substantial degree, but also have their own methods and approval process apart from Medicare determinations. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high.

Our failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our product candidate or any future product candidates outside the United States.

We intend to market any approved products in the United States, the European Union, Japan and other foreign jurisdictions. Even if our products are approved for marketing in the United States, in order to market and sell our products in other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, we must secure product reimbursement approvals before regulatory authorities will approve the product for sale in that country. 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 products in certain countries. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others.

Also, regulatory approval for our product candidate or any future product candidates may be withdrawn if we fail to comply with regulatory requirements, if problems occur after the product candidate reaches the market or for other reasons. If we fail to comply with the regulatory requirements in international markets and fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidate or any future product candidates will be harmed and our business will be adversely affected. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions. Approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. If we fail to obtain approval of our product candidate or any future product candidates by regulatory authorities in another country, we will be unable to commercialize our product in that country, and the commercial prospects of that product candidate and our business prospects could decline.

Our activities in the United States subject us to various laws relating to foreign investment and the export of certain technologies, and our failure to comply with these laws or adequately monitor the compliance of our suppliers and others we do business with could subject us to substantial fines, penalties and even injunctions, the imposition of which on us could have a material adverse effect on the success of our business.

Because we have substantial operations in the United States, we are subject to U.S. laws that regulate foreign investments in U.S. businesses and access by foreign persons to technology developed and produced in the United States. These laws include Section 721 of the Defense Production Act of 1950, as amended by the Foreign Investment Risk Review Modernization Act of 2018, and the regulations at 31 C.F.R. Parts 800 and 801, as amended, administered by the Committee on Foreign Investment in the United States; and the Export Control Reform Act of 2018, which is being implemented in part through Commerce Department rulemakings to impose new export control restrictions on “emerging and foundational technologies” yet to be fully identified. Application of these laws, including as they are implemented through regulations being developed, may negatively impact our business in various ways, including by restricting our access to capital and markets; limiting the collaborations we may pursue; regulating the export our products, services, and technology from the United States and abroad; increasing our costs and the time necessary to obtain required authorizations and to ensure compliance; and threatening monetary fines and other penalties if we do not.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

Changes in funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new or existing product candidates from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, 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, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Risks related to our intellectual property

Our success depends upon our ability to obtain and maintain intellectual property protection for our products and technologies. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

Our success will depend in significant part on our and our current or future licensors', licensees' or collaborators' ability to establish and maintain adequate protection of our intellectual property covering the product candidates we plan to develop, and the ability to develop these product candidates and commercialize the products resulting therefrom, without infringing the intellectual property rights of others. We strive to protect and enhance the proprietary technologies that we believe are important to our business, including seeking patents intended to cover our

products and compositions, their methods of use, and any other inventions that are important to the development of our business. In addition to taking other steps to protect our intellectual property, we have applied for, and intend to continue to apply for, patents with claims covering our technologies, processes and product candidates when and where we deem it appropriate to do so. Our in-licensed patents and patent applications in both United States and certain foreign jurisdictions relate to AKR-001 and related Fc-fusion polypeptides. There can be no assurance that the claims of our patents or any patent application that issues as a patent, will exclude others from making, using or selling our product candidate or any future product candidates or products that are substantially similar to our product candidate or any future product candidates. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. In countries where we have not and do not seek patent protection, third parties may be able to manufacture and sell our product candidate or any future product candidates without our permission, and we may not be able to stop them from doing so.

With respect to patent rights, we do not know whether any of the pending patent applications for our product candidate or any future product candidates will result in the issuance of patents that effectively protect our technologies, processes and product candidates, or if any of our issued patents or our current or future licensors', licensees' or collaborators' issued patents will effectively prevent others from commercializing competitive technologies, processes and products. 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, until they are issued as a patent. Therefore, we cannot be certain that we or our current or future licensors, licensees or collaborators were the first to make or file on the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our current or future licensors, licensees or collaborators were the first to file for patent protection of such inventions. There is also no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which could be used by a third party to challenge the validity of our patents, should they issue, or prevent a patent from issuing from a pending patent application. Any of the foregoing could harm our competitive position, business, financial condition, results of operations, and prospects.

Any changes we make to our product candidate or any future product candidates, including formulations that may be required for commercialization, or that cause them to have what we view as more advantageous properties may not be covered by our existing patents and patent applications, and we may be required to file new applications and/or seek other forms of protection for any such altered product candidates. The patent landscape surrounding the technology underlying our product candidate or any future product candidates is crowded, and there can be no assurance that we would be able to secure patent protection that would adequately cover an alternative to our product candidate or any future product candidates.

The patent prosecution process is expensive and time-consuming, and we and our current or future licensors, licensees or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our current or future licensors, licensees or collaborators will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection for them. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain or enforce the patents, covering technology that we license from or license to third parties and may be reliant on our current or future licensors, licensees or collaborators to perform these activities, which means that these patent applications may not be prosecuted, and these patents enforced, in a manner consistent with the best interests of our business. If our current or future licensors, licensees or collaborators fail to establish, maintain, protect or enforce such patents and other intellectual property rights, such rights may be reduced or eliminated. If our current or future licensors, licensees or collaborators are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised.

The patent positions of biotechnology and pharmaceutical companies, including our patent position, involve complex legal and factual questions, which in recent years have been the subject of much litigation, and, therefore, the issuance, scope, validity, enforceability, and commercial value of any patent claims that we have rights or may obtain cannot be predicted with certainty. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our

patents or narrow the scope of our patent protection. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors', licensees' or collaborators' patent rights are highly uncertain. Our and our current or future licensors', licensees' or collaborators' pending and future patent applications may not result in patents being issued that protect our technology or product candidates, or products resulting therefrom, in whole or in part, or that effectively prevent others from commercializing competitive technologies and products. The patent examination process may require us or our current or future licensors, licensees or collaborators to narrow the scope of the claims of pending and future patent applications, which would limit the scope of patent protection that is obtained, if any. Our and our current or future licensors', licensees' or collaborators' patent applications cannot be enforced against third parties practicing the technology that is currently claimed in such applications unless and until a patent issues from such applications, and then only to the extent the claims that issue are broad enough to cover the technology being practiced by third parties.

Furthermore, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after the resulting products are commercialized. As a result, our owned and in-licensed patents may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. We expect to seek extensions of patent terms for our issued patents, where available. This includes in the United States under the Hatch-Waxman Act, which permits a patent term extension of up to five years beyond the original expiration date of the patent as compensation for regulatory delays. However, such a patent term extension cannot lengthen the remaining term of a patent beyond a total of 14 years from the product's approval date. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent and within 60 days of product approval. During the period of patent term extension, the claims of a patent are not enforceable for their full scope but are instead limited to the scope of the approved product. In addition, the applicable authorities, including the FDA in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. In addition, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to the expiration of relevant patents or otherwise failing to satisfy applicable requirements. If this occurs, any period during which we have the right to exclusively market our product will be shorter than we would otherwise expect, and our competitors may obtain approval of and launch products earlier than might otherwise be the case.

If we breach our license agreement with Amgen related to AKR-001, we could lose the ability to continue the development and commercialization of AKR-001.

We are dependent on patents, know-how and proprietary technology in-licensed from Amgen. Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidate or any future product candidates and use our and our licensor's proprietary technologies without infringing the proprietary rights of third parties. Amgen may have the right to terminate the license agreement in full in the event we materially breach or default in the performance of any of the obligations under the license agreement. A termination of the license agreement with Amgen could result in the loss of significant rights and could harm our ability to commercialize our product candidates.

Disputes may also arise between us and Amgen, as well as any future potential licensors, 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 our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidate and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

In addition, the Amgen Agreement under which we currently license intellectual property is complex, and certain provisions may be susceptible to multiple interpretations. 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 increase what we believe to be our financial or other obligations under the Amgen Agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangement on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

Patent terms may be inadequate to protect our competitive position on our product candidate or any future product 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. A number of U.S. patents directed to various aspects of AKR-001 will expire in 2029; we currently anticipate that a composition of matter patent will be eligible for patent term extension to 2034. Even if patents covering our product candidate or any future product candidate are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidate or any future product candidate might expire before or shortly after we or our partners commercialize those candidates. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

The legal protection afforded to inventors and owners of intellectual property in countries outside of the United States may not be as protective or effective as that in the United States and we may, therefore, be unable to acquire and enforce intellectual property rights outside the United States to the same extent as in the United States. Whether filed in the United States or abroad, our patent applications may be challenged or may fail to result in issued patents.

In addition, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing or commercializing competing products. Furthermore, others may independently develop or commercialize similar or alternative technologies or drugs, or design around our patents. Our patents may be challenged, invalidated, circumvented or narrowed, or fail to provide us with any competitive advantages. In many foreign countries, patent applications and/or issued patents, or parts thereof, must be translated into the native language. If our patent applications or issued patents are translated incorrectly, they may not adequately cover our technologies; in some countries, it may not be possible to rectify an incorrect translation, which may result in patent protection that does not adequately cover our technologies in those countries.

Filing, prosecuting, enforcing and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States are 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 certain state laws in the United States. Consequently, we and our licensor may not be able to prevent third parties from practicing our and our licensor’s inventions in all countries outside the United States, or from selling or importing products made using our and our licensor’s inventions in and into the

United States or other jurisdictions. Competitors may use our and our licensor's technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we and our licensor have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidate or any future product candidates and our and our licensor's 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 certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology. This could make it difficult for us and our licensor to stop the infringement of our and our licensor's patents or the marketing of competing products in violation of our and our licensor's proprietary rights, generally. Proceedings to enforce our and our licensor's patent rights in foreign jurisdictions could result in substantial costs and divert our and our licensor's efforts and attention from other aspects of our business, could put our and our licensor's patents at risk of being invalidated or interpreted narrowly, could place our and our licensor's patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensor. We or our licensor may not prevail in any lawsuits that we or our licensor initiate and the damages or other remedies awarded, if any, may not be commercially meaningful.

The requirements for patentability differ in certain countries, particularly developing countries. For example, China has a heightened requirement for patentability and, specifically, requires a detailed description of medical uses of a claimed drug. In addition, India, certain countries in Europe and certain developing countries, including Thailand, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensor may have limited remedies if patents are infringed or if we or our licensor are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. Accordingly, our and our licensor's efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

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

Periodic maintenance and annuity fees on issued United States patents and most foreign patent applications and patents must be paid to the U.S. Patent and Trademark Office, or USPTO, and foreign patent agencies, respectively, in order to maintain such patents and patent applications. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application, examination and issuance processes. 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 noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensor fail to maintain the patents and patent applications covering our product candidate or any future product candidates, our competitors might be able to enter the market with similar or identical products or technology, which would have a material adverse effect on our business, financial condition and results of operations.

We may be unable to obtain intellectual property rights or technology necessary to develop and commercialize our product candidate or any future product candidates.

Several third parties are actively researching and seeking and obtaining patent protection in the NASH field, and there are issued third-party patents and published third-party patent applications in these fields. However, we may not be aware of all third-party intellectual property rights potentially relating to our product candidate or any future product candidates and technologies.

Depending on what patent claims ultimately issue and how courts construe the issued patent claims, as well as depending on the ultimate formulation and method of use of our product candidate or any future product candidates, we may need to obtain a license under such patents. There can be no assurance that such licenses will be available on commercially reasonable terms, or at all. If a third party does not offer us a necessary license or offers a license only on terms that are unattractive or unacceptable to us, we might be unable to develop and commercialize one or more of our product candidate or any future product candidates, which would have a material adverse effect on our business, financial condition and results of operations. Moreover, even if we obtain licenses to such intellectual property, but subsequently fail to meet our obligations under our license agreements, or such license agreements are terminated for any other reasons, we may lose our rights to in-licensed technologies.

The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. 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 successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may become involved in lawsuits or other proceedings to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful and have a material adverse effect on the success of our business.

Third parties may infringe our or our licensor's patents or misappropriate or otherwise violate our or our licensor's intellectual property rights. In the future, we or our licensor may initiate legal proceedings to enforce or defend our or our licensor's intellectual property rights, to protect our or our licensor's trade secrets or to determine the validity or scope of intellectual property rights we own or control. Also, third parties may initiate legal proceedings against us or our licensor to challenge the validity or scope of intellectual property rights we own, control or to which we have rights. For example, generic or biosimilar drug manufacturers or other competitors or third parties may challenge the scope, validity or enforceability of our or our licensor's patents, requiring us or our licensor to engage in complex, lengthy and costly litigation or other proceedings. These proceedings can be expensive and time-consuming and many of our or our licensor's adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. Moreover, the outcome following legal assertions of invalidity and unenforceability is unpredictable. Accordingly, despite our or our licensor's efforts, we or our licensor may not be able to prevent third parties from infringing upon or misappropriating intellectual property rights we own, control or have rights to, particularly in countries where the laws may not protect those rights as fully as in the United States. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, if we or our licensor initiated legal proceedings against a third party to enforce a patent covering a product candidate, the defendant could counterclaim that such 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 or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. In an infringement or declaratory judgment proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our or our licensor's patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our or our licensor's patents at risk of being invalidated, narrowed, held unenforceable or interpreted in such a manner that would not preclude third parties from entering the market with competing products.

Third-party pre-issuance submission of prior art to the USPTO, or opposition, derivation, revocation, reexamination, *inter partes* review or interference proceedings, or other pre-issuance or post-grant proceedings or other

patent office proceedings or litigation in the United States or other jurisdictions provoked by third parties or brought by us or our licensor, may be necessary to determine the inventorship, priority, patentability or validity of inventions with respect to our or our licensor's patents or patent applications. An unfavorable outcome could leave our technology or product candidates without patent protection, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or could require us or our licensor to obtain license rights from the prevailing party in order to be able to manufacture or commercialize our product candidate or any future product candidates without infringing third-party patent rights. Our business could be harmed if the prevailing party does not offer us or our licensor a license on commercially reasonable terms, or at all. Even if we or our licensor obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensor. In addition, if the breadth or strength of protection provided by our or our licensor's patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or any future product candidates. Even if we successfully defend such litigation or proceeding, we may incur substantial costs and it may distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on 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 collaborations.

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. In addition, many foreign jurisdictions have rules of discovery that are different than those in the United States and which may make defending or enforcing our or our licensor's patents extremely difficult. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock.

Third parties may initiate legal proceedings against us alleging that we infringe their intellectual property rights or we may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability to develop, manufacture, market and sell any product candidates that we may develop and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Third parties may initiate legal proceedings against us or our licensor alleging that we or our licensor infringe their intellectual property rights or we or our licensor may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, including in oppositions, interferences, revocations, reexaminations, *inter partes* review or derivation proceedings before the USPTO or its counterparts in other jurisdictions. These proceedings can be expensive and time-consuming and many of our or our licensor's adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensor can.

An unfavorable outcome in any such proceeding could require us or our licensor to cease using the related technology or developing or commercializing our product candidate or any future product candidates, or to attempt to license rights to it from the prevailing party, which may not be available on commercially reasonable terms, or at all.

We could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidate or any future product candidates or force us to cease some of our business operations, which could materially harm our business.

We perform searches of patent and scientific databases in order to identify documents that may be of potential relevance to the freedom-to-operate and/or patentability of our product candidate or any future product candidates. In general, such searches are conducted based on keywords, sequences, inventors/authors and assignees/entities to capture U.S. and European patents and patent applications, PCT publications and scientific journal articles.

The patent landscape around our AKR-001 product candidate is complex, and we may not be aware of all third-party intellectual property rights potentially relating to our product candidate or any future product candidates and technologies. Moreover, it is possible that we are or may become aware of patents or pending patent applications that we think do not relate to our product candidate or any future product candidates or that we believe are invalid or unenforceable, but that may nevertheless be interpreted to encompass our product candidate or any future product candidates and to be valid and enforceable. As to pending third-party applications, we cannot predict with any certainty which claims will issue, if any, or the scope of such issued claims. If any third party intellectual property claims are asserted against us, even if we believe the claims are without merit, there is no assurance that a court would find in our favor, e.g., on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could materially and adversely affect our ability and the ability of our licensor to commercialize any product candidates we may develop, and any other product 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 any such third-party patents (including those that may issue from such applications) were successfully asserted against us or our licensor or other commercialization partners and we were unable to successfully challenge the validity or enforceability of any such asserted patents, then we or our licensor and other commercialization partners may be prevented from commercializing our product candidate or any future product candidates, or may be required to pay significant damages, including treble damages and attorneys' fees if we are found to willfully infringe the asserted patents, or obtain a license to such patents, which may not be available on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. Any of the foregoing would have a material adverse effect on our business, financial condition and operating results.

We may be subject to claims by third parties asserting that our employees or we have misappropriated a third party's intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. We may be subject to claims that we or these employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee's former employer, or that third parties have an interest in our patents as an inventor or co-inventor. 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 or sustain other damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms, or at all. Even if we successfully prosecute or defend against such claims, litigation could result in substantial costs and distract management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or 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, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our inability to protect our confidential information and trade secrets would harm our business and competitive position.

In addition to seeking patents for some of our technology and products, in our activities we also rely substantially on trade secrets, including unpatented know-how, technology and other proprietary materials and information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. However, these steps may be inadequate, we may fail to enter into agreements with all such parties or any of these parties may breach the agreements and disclose our proprietary information and there may be no adequate remedy available for such breach of an agreement. We cannot assure you that our proprietary information will not be disclosed or that we can meaningfully protect our trade secrets. 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 both within and outside the United States may be less willing, or unwilling, to protect trade secrets. If a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make products that are similar to any product 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 collaborators, might not have been the first to make the inventions covered by the issued patents and pending patent applications that we license or may own in the future;
- we, or our current or future 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 patent applications or those that we may own 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 patents of others may harm our business; and
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

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

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or the USPTO.

If we or our licensing partner initiate legal proceedings against a third party to enforce a patent covering our product candidate or any future product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. These types of mechanisms include *inter partes* review, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). These types of proceedings could result in revocation or amendment to our patents such that they no longer cover our product candidates. The outcome for any particular patent 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, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our product candidates. A loss of patent protection for our product candidates could have a material adverse impact on our ability to commercialize or license our technology and product candidates and, resultantly, on our business, financial condition, prospects and results of operations.

Likewise, patents directed to our proprietary technologies and our product candidates may expire before or soon after our first product achieves marketing approval in the United States or foreign jurisdictions. Upon the expiration of our current patents, we may lose the right to exclude others from practicing these inventions. The expiration of these patents could also have a similar material adverse effect on our business, financial condition, prospects and results of operations. A number of U.S. patents directed to various aspects of AKR-001 will expire in 2029; we currently anticipate that a composition of matter patent will be eligible for patent term extension to 2034.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidate or any future product candidates.

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involves technological and legal complexity, and obtaining and enforcing biotechnology patents is costly, time-consuming and inherently uncertain. 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, weakening the rights of patent owners in certain situations or ruling that certain subject matter is not eligible for patent protection. In addition to increasing uncertainty with regard to our and our licensor's ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts, the USPTO and equivalent bodies in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our and our licensor's ability to obtain new patents or to enforce existing patents and patents we and our licensor may obtain in the future.

Patent reform laws, such as the Leahy-Smith America Invents Act, or the Leahy-Smith Act, as well as changes in how patent laws are interpreted, could increase the uncertainties and costs surrounding the prosecution of our and our licensor's patent applications and the enforcement or defense of our or our licensor's issued patents, all of which could have a material adverse effect on our business, financial condition and results of operations.

Risks related to our reliance on third parties

We rely and will continue to rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any potential product candidates.

We depend and will continue to depend upon third parties, including independent investigators, to conduct our clinical trials under agreements with universities, medical institutions, CROs, strategic partners and others. We expect to have to negotiate budgets and contracts with CROs and trial sites, which may result in delays to our development timelines and increased costs.

We rely heavily on third parties over the course of our clinical trials, and, as a result, have limited control over the clinical investigators and limited visibility into their day-to-day activities, including with respect to their compliance with the approved clinical protocol. Nevertheless, our reliance on third parties does not relieve us of our regulatory responsibilities and we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards. We and these third parties are required to comply with good clinical practice, or GCP, requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or perform additional nonclinical studies or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, regulatory authorities will determine that any of our clinical trials comply with the GCP requirements. In addition, our clinical trials must be conducted with products produced under current good manufacturing practice, or cGMP, requirements and may require a large number of patients. Our failure or any failure by these third parties to comply with these applicable regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

The third parties who conduct our future clinical trials are not our employees and, except for remedies that may be available to us under our agreements with those third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing nonclinical and clinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates in a timely manner or at all. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

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

If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to the failure (including by clinical sites or investigators) to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize

our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenues could be delayed significantly.

We contract with third parties for the manufacture of our product candidate or any future product candidates for nonclinical testing and expect to continue to do so for clinical trials and for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidate or any future product candidates or medicines or that such supply will not be available to us at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not have any manufacturing facilities. We currently rely, and expect to continue to rely, on third-party manufacturers for the manufacture of our product candidate or any future product candidates for nonclinical and clinical testing and for commercial supply of any of these product candidates for which we obtain marketing approval. Reliance on third-party manufacturers may expose us to different risks than if we were to manufacture product candidates ourselves. To the extent any issues arise with our third-party manufacturers, we may be unable to establish any agreements with any other third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the possible breach of the manufacturing agreement by the third party;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; and
- reliance on the third party for regulatory compliance, quality assurance and safety and pharmacovigilance reporting.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or medicines, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our medicines and harm our business and results of operations.

Any medicines that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply for bulk drug substances. If any one of our current contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidate or any future product candidates, we may incur added costs and delays in identifying and qualifying any such replacement.

Our current and anticipated future dependence upon others for the manufacture of our product candidate or any future product candidates or medicines may adversely affect our future profit margins and our ability to commercialize any medicines that receive marketing approval on a timely and competitive basis.

The manufacture of our product candidates is complex and we may encounter difficulties in production. If we or any of our third-party manufacturers encounter such difficulties, or fail to meet rigorously enforced regulatory standards, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

The processes involved in manufacturing our drug product candidates are complex, expensive, highly-regulated, and subject to multiple risks. Further, as product candidates are developed through nonclinical studies to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development

program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials.

In addition, the manufacturing process for any products that we may develop is subject to FDA and other comparable foreign regulatory authority approval processes and continuous oversight, and we will need to contract with manufacturers who can meet all applicable FDA and foreign regulatory authority requirements, including, for example, complying with cGMPs, on an ongoing basis. If we or our third-party manufacturers are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our contract manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging or comparability nonclinical or clinical trials or the repetition of one or more clinical trials, increase clinical study costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations, and growth prospects.

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

We may pursue collaborations in order to develop and commercialize AKR-001 and any future product candidates. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration 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 likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products and 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 collaborators may also consider alternative product 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 product candidate.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of 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 product 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 product candidate or any future product candidates or bring them to market and generate product revenue.

Risks related to commercialization

Even if we commercialize our product candidate or any future product candidates, these products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing 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 product in a particular country, but then be subject to price regulations that delay or limit our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenue we generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidate or any future product candidates obtain marketing approval.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors such as government health administration authorities, private health insurers and other organizations. Third-party payors determine which medications they will cover and establish reimbursement levels. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval, if any. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which marketing approval is obtained, if any.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a 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 also not be sufficient to cover our costs and may only be temporary. 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 reimbursement rates third-party payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

If, in the future, we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any product candidates we may develop, we may not be successful in commercializing those product candidates if and when they are approved.

We do not currently have an infrastructure for the sales, marketing, and distribution of pharmaceutical products. In order to market our product candidates, if approved by the FDA or any other regulatory body, we must build our sales, marketing, managerial, and other non-technical capabilities, or make arrangements with third parties to perform these services. There are risks involved with both establishing our own commercial capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force or reimbursement specialists is expensive and time-consuming and could delay any product launch. If the commercial

launch of a product candidate for which we recruit a sales force and establish marketing and other commercialization capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our commercialization personnel.

If we enter into arrangements with third parties to perform sales, marketing, commercial support, and distribution services, our product revenue or the profitability of product revenue may be lower than if we were to market and sell any products we may develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to commercialize our product candidates or may be unable to do so on terms that are favorable to us. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively and they could expose our company to regulatory enforcement and legal risk in the execution of their sales and commercialization activities. If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates if approved.

If we are unable to establish adequate sales, marketing, and distribution capabilities, whether independently or with third parties, or if we are unable to do so on commercially reasonable terms, our business, results of operations, financial condition, and prospects will be materially adversely affected.

Our product candidate or any future product candidates may not achieve adequate market acceptance among physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if our product candidate or any future product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, third-party payors, pharmaceutical companies and others in the medical community. Demonstrating the safety and efficacy of our product candidate or any future product candidates and obtaining regulatory approvals will not guarantee future revenue. Our commercial success also depends on coverage and adequate reimbursement of our product candidate or any future product candidates by third-party payors, including government payors and private insurers, which may be difficult or time-consuming to obtain, may be limited in scope and may not be obtained in all jurisdictions in which we may seek to market our products. Third-party payors closely examine medical products to determine whether they should be covered by reimbursement and, if so, the level of reimbursement that will apply. We cannot be certain that third-party payors will sufficiently reimburse sales of our product or enable us to sell our product at a profitable price. Similar concerns could also limit the reimbursement amounts that health insurers or government agencies in other countries are prepared to pay for our products. In many regions, including Europe, Japan and Canada, where we may market our products, the pricing of prescription drugs is controlled by the government or regulatory agencies. Regulatory agencies in these countries could determine that the pricing for our products should be based on prices of other commercially available drugs for the same disease, rather than allowing us to market our products at a premium as new drugs. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the efficacy and safety profile of the product candidate as demonstrated in clinical trials;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- acceptance of the product candidate as a safe and effective treatment by clinics and patients;
- the potential and perceived advantages of the product candidate over alternative treatments, including any similar generic treatments;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement and pricing by third-party payors;
- the relative convenience and ease of administration;
- the frequency and severity of adverse events;
- the effectiveness of sales and marketing efforts; and
- unfavorable publicity relating to our product candidate or any future product candidates.

Sales of medical products also depend on the willingness of physicians to prescribe the treatment, which is likely to be based on a determination by these physicians that the products are safe, therapeutically effective and cost effective. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe the treatment. We cannot predict whether physicians, physicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that our product is safe, therapeutically effective and cost effective as compared with competing treatments. If any product candidate is approved but does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue from that product candidate and may not become or remain profitable.

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

We face an inherent risk of product liability exposure related to the testing of our product candidate or any future product candidates in human clinical trials and will face an even greater risk if we commercialize any resulting products. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, their family members, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against claims that our product candidate or any future product candidates or products that we may develop caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial subjects or patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations;
- the inability to commercialize any products that we may develop; and
- a decline in our stock price.

Our clinical trial liability insurance coverage may not adequately cover all liabilities that we may incur. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our inability to obtain product liability insurance at an acceptable cost or to otherwise protect against potential product liability claims could prevent or delay the commercialization of any products or product candidates that we develop. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for our product candidate or any future product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. Large judgments have been awarded in lawsuits based on drugs that had unanticipated side effects. If we are sued for any injury caused by our products, product candidates or processes, our liability could exceed our product liability insurance coverage and our total assets. Claims against us, regardless of their merit or potential outcome, may also generate negative publicity or hurt our ability to obtain physician adoption of our product or expand our business.

Risks related to our common stock

The market price of our stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock is likely to be volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K, these factors include:

- developments associated with our license with Amgen, including any termination or other change in our relationship with Amgen;
- the success of competitive products or technologies;
- regulatory actions with respect to our product candidate or any future product candidates or our competitors' product candidates or products;
- results of clinical trials of our product candidate or any future product candidates or those of our competitors;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors or collaborators of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- regulatory, legal or payor 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 any of our product candidate or any future product candidates or clinical development programs;
- the results of our efforts to in-license or acquire additional product candidates or products;
- 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;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors; and
- general economic, industry and market conditions.

In addition, the stock market in general, and the market for biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and material adverse impact on the market price of our common stock.

Because of potential volatility in our trading price and trading volume, we may incur significant costs from class action securities litigation.

Holders of stock in companies that have a volatile stock price frequently bring securities class action litigation against the company that issued the stock. We may be the target of this type of litigation in the future. If any of our stockholders were to bring a lawsuit of this type against us, even if the lawsuit is without merit, we could incur substantial costs defending the lawsuit. A stockholder lawsuit could also divert the time and attention of our management. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

We are an "emerging growth company" as defined in the JOBS Act and a "smaller reporting company" as defined in the Exchange Act and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies, which could make our common stock less attractive to investors and adversely affect the market price of our common stock.

For so long as we remain an "emerging growth company" as defined in the JOBS Act, we may take advantage of certain exemptions from various requirements applicable to public companies that are not "emerging growth companies" including:

- the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting;
- the "say on pay" provisions (requiring a non-binding shareholder vote to approve compensation of certain executive officers) and the "say on golden parachute" provisions (requiring a non-binding shareholder vote to approve golden parachute arrangements for certain executive officers in connection with mergers and certain other business combinations) of the Dodd-Frank Act and some of the disclosure requirements of the Dodd-Frank Act relating to compensation of our executive officers; and
- the requirement to provide detailed compensation discussion and analysis in proxy statements and reports filed under the Exchange Act and instead provide a reduced level of disclosure concerning executive compensation.

We may take advantage of these reporting exemptions until we are no longer an emerging growth company, which in certain circumstances could be for up to five years. 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 the 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. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. 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.

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies until the fiscal year following the determination that our voting and non-voting common stock held by non-affiliates is more than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenues are more than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is more than $700.0 million measured on the last business day of our second fiscal quarter.

Although we are still evaluating the JOBS Act, we currently intend to take advantage of some, but not all, of the reduced regulatory and reporting requirements that will be available to us so long as we qualify as an "emerging growth company" and "smaller reporting company." We have elected to avail ourselves of this exemption and, therefore, we are not subject to the same new or revised accounting standards as other public companies that are not emerging growth companies or smaller reporting companies. 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. In addition, our independent registered public accounting firm will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as an "emerging growth company," which may increase the risk that material weaknesses or significant deficiencies in our internal control over financial reporting go undetected. Likewise, so long as we qualify as a "smaller reporting company" or an "emerging growth company," we may elect not to provide you with certain information, including certain financial information and certain information regarding compensation of our executive officers, that we would otherwise have been required to provide in filings we make with the SEC, which may make it more difficult for investors and securities analysts to evaluate our company. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. 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 and may decline.

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

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

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

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

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Anti-takeover provisions under our organizational documents and Delaware law could delay or prevent a change of control, which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our fourth amended and restated certificate of incorporation and second amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of the stockholders may be called only by the board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office, and special meetings of stockholders may not be called by any other person or persons;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds (2/3) of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than a majority of all outstanding shares of our voting stock to amend any bylaws by stockholder action and not less than two-thirds (2/3) of all outstanding shares of our voting stock to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval, which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our fourth amended and

restated certificate of incorporation and second amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our second amended and restated bylaws which became effective upon the effectiveness of our registration statement designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by 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 second amended and restated bylaws that became effective upon the effectiveness of our registration statement provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers, and employees to us or our stockholders, (iii) any action asserting a claim against us or any of our current or former directors, officers, or other employees or stockholders, arising out of or pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our second amended and restated bylaws or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein. This exclusive forum provision will not apply to any causes of action arising under the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. In addition, our second amended and restated bylaws will provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions. Additionally, the forum selection clause in our second amended and restated bylaws may limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

We have chosen the Court of Chancery of the State of Delaware as the exclusive forum for such causes of action because we are incorporated in the State of Delaware and we are familiar with the procedures and rules applicable in such forum.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company or if they cease to cover our company, the trading price for our stock would likely be negatively impacted. In the event that securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

Item 1B. Unresolved Staff Comments.

None

Item 2. Properties.

We lease office space where our corporate headquarters are located, which consists of 3,691 square feet located at 170 Harbor Way, South San Francisco, California. Our lease expires on February 27, 2021, subject to automatic renewals for successive thirty (30) day periods.

On February 14, 2020, the Company entered into a seven-year lease agreement for 6,647 square feet of office space in South San Francisco, California. Under the agreement, the Company is required to make $2.3 million in minimum payments during the lease term, which does not automatically renew. The Company anticipates that it will assume occupancy in June 2020. We believe our current office space is sufficient to meet our office needs until the expiration of the leases, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms, if required.

Item 3. Legal Proceedings.

From time to time, we may be involved in lawsuits, claims, investigations and proceedings, consisting of intellectual property, commercial, employment and other matters which arise in the ordinary course of business. While the outcome of any such proceedings cannot be predicted with certainty, as of December 31, 2019, we were not party to any legal proceedings that we would expect to have a material adverse impact on our financial position, results of operations or cash flow.

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.

On June 20, 2019 our common stock began trading on the Nasdaq Global Select Market under the symbol "AKRO". Prior to that time, there was no public market for our common stock.

Stockholders

As of March 6, 2020, there were 11 stockholders of record of our common stock. The actual number of holders of our common stock 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 or held by other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never paid or declared any cash dividends on our common stock, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. Any future determination to pay dividends will be at the discretion of our board of directors and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors that our board of directors deems relevant.

Equity Compensation Plans

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

Issuer Purchases of Equity Securities

We did not purchase any of our registered equity securities during the period covered by this Annual Report.

Recent Sales of Unregistered Securities

Set forth below is information regarding stock options granted and exercised by us during the period covered by this Annual Report on Form 10-K that were not registered under the Securities Act. Included is the consideration, if any, we received for such shares and options and information relating to the section of the Securities Act or the Securities and Exchange Commission, under which exemption from registration was claimed.

Grants and Exercises of Stock Options under Equity Plans

During the period covered by this Form 10-K, we granted options to purchase an aggregate of 1,111,826 shares of common stock, with exercise prices ranging from $6.36 to $7.01 per share, to directors, employees and consultants pursuant to our 2018 Stock Option and Grant Plan, as amended (the "2018 Plan"). In 2019, 655,710, shares of common stock were issued for gross proceeds of $0.4 million upon the exercise of stock options pursuant to the 2018 Plan.

From January 1, 2019 to our initial public offering on June 19, 2019, 487,933 shares of common stock were issued by us in connection with the exercise of certain employee stock options for a total of $0.3 million, to officers of the Company who render bona fide services under a written agreement, none of which services are in connection with the offer and sale of securities in a capital-raising transaction and are exempt from registration under Rule 701 promulgated under Section 3(b) of the Securities Act.

No underwriters were involved in the foregoing issuance of securities. The issuances of the securities described above were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act or Rule 701 promulgated under the Securities Act as transactions pursuant to compensatory benefit plans. The shares of common stock issued upon the exercise of options are deemed to be restricted securities. All recipients either received adequate information about us or had access, through employment or other relationships, to such information.

Use of Proceeds from our Public Offering of Common Stock

On June 19, 2019, our Registration Statement on Form S-1, as amended (Registration No. 333-231747) was declared effective by the SEC for our initial public offering. At the closing of the offering on June 24, 2019, we sold 6,612,500 shares of common stock, including the exercise in full by the underwriters of their option to purchase up to 862,500 additional shares of common stock, at a public offering price of $16.00 per share. The aggregate net proceeds to us from the public offering, inclusive of the over-allotment exercise and after underwriting discounts and offering expenses, were approximately $95.5 million. J.P. Morgan, Jefferies and Evercore acted as joint book-running managers for the offering. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning 10% or more of any class of our equity securities or to any other affiliates.

Information related to use of proceeds from registered securities is incorporated herein by reference to the "Use of Proceeds" section of our initial public offering as described in our final prospectus dated June 19, 2019 and filed with the SEC on June 20, 2019 pursuant to Rule 424(b)(4) of the Securities Act. There has been no material change in the planned use of proceeds as described in our final prospectus.

Item 6. Selected Financial Data.

Information required by this Item is not applicable as we are electing scaled disclosure requirements available to Smaller Reporting Companies with respect to this Item.

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

The following discussion should be read in conjunction with our financial statements and accompanying footnotes appearing elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. See "Special Note Regarding Forward-Looking Statements." Because of many factors, including those factors set forth in Part 1, Item 1A, "Risk Factors" in this Annual Report on Form 10-K, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

Overview

We are a cardio-metabolic nonalcoholic steatohepatitis, or NASH, company dedicated to developing pioneering medicines that restore metabolic balance and improve overall health for NASH patients. NASH is a severe form of nonalcoholic fatty liver disease, or NAFLD, characterized by inflammation and fibrosis in the liver that can progress to cirrhosis, liver failure, cancer and death. Our lead product candidate, AKR-001, is an analog of fibroblast growth factor 21, or FGF21, which is an endogenously expressed hormone that regulates metabolism of lipids, carbohydrates and proteins throughout the body. FGF21 also plays a critical role in protecting many types of cells from various forms of stress. In previous clinical trials in patients with type 2 diabetes, or T2D, administration of AKR-001 was associated with substantial improvements in lipid metabolism and insulin sensitivity. We believe these data, coupled with clinical results from other FGF21 analogs, demonstrate AKR-001's potential to serve as a cornerstone for the treatment of NASH. We are currently conducting a Phase 2a clinical trial, the BALANCED study, which is evaluating AKR-001 in the treatment of NASH patients. We expect to complete collection of data for the BALANCED main study week 12 primary endpoint, and report top-line results related to reductions in liver fat, in the first quarter of 2020. Top-line results related to secondary endpoints, including safety and tolerability as well as paired biopsies, will be reported in the second quarter of 2020. We also plan to expand the BALANCED study to include an additional cohort of subjects with NASH who have compensated cirrhosis (F4), Child-Pugh Class A, with study initiation expected in the second quarter of 2020.

We were incorporated in January 2017 and have devoted substantially all of our efforts to organizing and staffing our company, business planning, raising capital, in-licensing rights to AKR-001, research and development activities for AKR-001, building our intellectual property portfolio and providing general and administrative support for these operations. To date, we have principally raised capital through the issuance of convertible preferred stock and the initial public offering of our common stock.

We have incurred significant operating losses since inception. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of AKR-001 and any future product candidates. Our net losses were $43.8 million and $81.7 million for the years ended December 31, 2019 and 2018, respectively. The net loss for the year ended December 31, 2018 included non-cash charges of $62.2 million related to the change in fair value of our preferred stock tranche obligation and $5.8 million related to the change in fair value of our anti-dilution right liability. As of December 31, 2019, we had an accumulated deficit of $130.3 million. We expect to continue to incur significant expenses for at least the next several years as we advance AKR-001 through later-stage clinical development, develop additional product candidates and seek regulatory approval of any product candidates that complete clinical development. In addition, if we obtain marketing approval for any product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. We may also incur expenses in connection with the in-licensing or acquisition of additional product candidates.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings, or other capital sources, which may include collaborations with other companies or other strategic transactions. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such

agreements as and when needed, we may have to significantly delay, reduce or eliminate the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of December 31, 2019, we had cash, cash equivalents and short-term marketable securities of $136.4 million.

Components of our results of operations

Revenue

We have not generated any revenue since our inception and do not expect to generate any revenue from the sale of products in the near future, if at all. If our development efforts for AKR-001 or additional product candidates that we may develop in the future are successful and result in marketing approval or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from such collaboration or license agreements.

Operating expenses

Research and development expenses

Research and development expenses consist primarily of costs incurred in connection with the development of AKR-001, as well as unrelated discovery program expenses. We expense research and development costs as incurred. These expenses include:

- employee-related expenses, including salaries, related benefits and stock-based compensation expense, for employees engaged in research and development functions;
- expenses incurred under agreements with contract research organizations, or CROs, that are primarily engaged in the oversight and conduct of our clinical trials; contract manufacturing organizations, or CMOs, that are primarily engaged to provide drug substance and product for our clinical trials, research and development programs, as well as investigative sites and consultants that conduct our clinical trials, nonclinical studies and other scientific development services;
- the cost of acquiring and manufacturing nonclinical and clinical trial materials, including manufacturing registration and validation batches;
- costs related to compliance with quality and regulatory requirements; and
- payments made under third-party licensing agreements.

Advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered.

Product candidates in later stages of clinical development, such as AKR-001, generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will increase substantially in connection with our planned clinical development activities in the near term and in the future. At this time, we cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the clinical development of AKR-001 and any future product candidates.

Our clinical development costs may vary significantly based on factors such as:

- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients enrolled in clinical trials;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the cost and timing of manufacturing our product candidates;
- the phase of development of our product candidates; and
- the efficacy and safety profile of our product candidates.

The successful development and commercialization of product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with product development and commercialization, including the following:

- the timing and progress of nonclinical and clinical development activities;
- the number and scope of nonclinical and clinical programs we decide to pursue;
- the ability to raise necessary additional funds;
- the progress of the development efforts of parties with whom we may enter into collaboration arrangements;
- our ability to maintain our current development program and to establish new ones;
- our ability to establish new licensing or collaboration arrangements;
- the successful initiation and completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority;
- the receipt and related terms of regulatory approvals from applicable regulatory authorities;
- the availability of drug substance and drug product for use in production of our product candidate;
- establishing and maintaining agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if our product candidate is approved;
- our ability to obtain and maintain patents, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- our ability to protect our rights in our intellectual property portfolio;
- the commercialization of our product candidate, if and when approved;
- obtaining and maintaining third-party insurance coverage and adequate reimbursement;
- the acceptance of our product candidate, if approved, by patients, the medical community and third-party payors;
- competition with other products; and
- a continued acceptable safety profile of our therapies following approval.

A change in the outcome of any of these variables with respect to the development of our product candidates could significantly change the costs and timing associated with the development of that product candidate. We may never succeed in obtaining regulatory approval for any of our product candidates.

General and administrative expenses

General and administrative expenses consist primarily of salaries and related costs for personnel in 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 administrative consulting services; insurance costs; administrative travel expenses; marketing expenses and other operating costs.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support development of AKR-001 and our continued research activities. We also anticipate that we will incur increased accounting, audit, legal, tax, regulatory, compliance, and director and officer insurance costs, as well as investor and public relations expenses associated with maintaining compliance with exchange listing and SEC requirements.

Other income (expense), net

Change in fair value of preferred stock tranche obligation

In connection with our June 2018 issuance and sale of Series A preferred stock, we provided for a first tranche closing, a second tranche closing, and a call option to purchase additional shares of Series A preferred stock. We classified the preferred stock tranche obligation for the future purchase and option to purchase Series A preferred stock as a liability on our consolidated balance sheets as the preferred stock tranche obligation is a freestanding financial instrument that will require us to transfer equity instruments upon future closings of the Series A preferred stock. The preferred stock tranche obligation liability was initially recorded at fair value upon the date of issuance and was subsequently remeasured to fair value at each reporting date. Changes in the fair value of the preferred stock tranche obligation are recognized as a component of other expense in the consolidated statements of operations and comprehensive loss. Changes in the fair value of the preferred stock tranche obligation were recognized until the tranche obligations were fulfilled or otherwise extinguished in the fourth quarter of 2018.

In November 2018, in connection with our issuance and sale of Series A preferred stock, we satisfied our obligation to issue additional shares under the second tranche closing and accordingly reclassified the carrying value of the preferred stock tranche obligation associated with the future purchase obligation, equal to the then current value of $32.8 million, to the carrying value of the Series A preferred stock. In December 2018, in connection with our issuance and sale of Series B preferred stock, we terminated the option to purchase Series A preferred stock provided under the Series A Preferred Stock Purchase Agreement, or 2018 Series A Agreement. We accounted for the termination of the call option associated with the preferred stock tranche obligation as a liability extinguishment between related parties and recognized a gain on extinguishment of $36.8 million, equal to the then current fair value, within additional paid-in capital in the statement of stockholder's equity (deficit).

Change in fair value of anti-dilution right liability

We classified the anti-dilution right under our license agreement with Amgen Inc., or the Amgen Agreement, as a derivative liability on our consolidated balance sheets as the anti-dilution right represented a freestanding financial instrument that required us to transfer equity instruments upon future equity closings. The anti-dilution right liability was initially recorded at fair value upon the date of issuance and was subsequently remeasured to fair value at each reporting date. The issuance date fair value of the derivative liability was recognized as a research and development expense upon entering into the agreement with Amgen. Changes in the fair value of the anti-dilution right liability were recognized as a component of other expense in the consolidated statements of operations and comprehensive loss. Changes in the fair value of the anti-dilution right liability were recognized until the anti-dilution rights obligation was satisfied in the fourth quarter of 2018.

In November 2018, in connection with our issuance and sale of Series A preferred stock, we satisfied our anti-dilution rights obligation under the Amgen Agreement by issuing 3,205,128 shares of Series A preferred stock to Amgen for a total value of $7.4 million. We reclassified the carrying value of the anti-dilution right liability, equal to the then current fair value of $7.4 million, to the carrying value of the Series A preferred stock.

Other income (expense), net

Other income (expense), net consists primarily of interest income earned on our cash, cash equivalents and short-term marketable securities.

Income taxes

Since our inception, we have not recorded any income tax benefits for the net losses we have incurred in each period or for our earned research and development tax credits, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our net operating loss carryforwards and tax credits will not be realized. As of December 31, 2019, we had U.S. federal and state net operating loss carryforwards of $51.1 million and $10.2 million, respectively, which may be available to offset future income tax liabilities and expire at various dates beginning in 2037. The federal net operating loss carryforwards include $48.8 million, which may be carried forward indefinitely As of December 31, 2019, we also had U.S. federal and state research and development tax credit carryforwards of $1.1 million and $0.2 million, respectively, which may be available to offset future tax liabilities which expire at various dates beginning in 2032. We have recorded a full valuation allowance against our net deferred tax assets at each balance sheet date.

Results of operations

Comparison of the years ended December 31, 2019 and 2018

The following table summarizes our results of operations for the years ended December 31, 2019 and 2018:

	Year Ended December 31,			
	2019	2018	$ Change	% Change
	(in thousands, except percentages)			
Operating expenses:				
Research and development	$ 37,046	$ 11,882	$ 25,164	212 %
General and administrative	8,605	1,896	6,709	354 %
Total operating expenses	45,651	13,778	31,873	231 %
Loss from operations	(45,651)	(13,778)	(31,873)	(231)%
Other income (expense), net:				
Change in fair value of preferred stock tranche obligation	—	(62,150)	62,150	*
Change in fair value of anti-dilution right liability	—	(5,765)	5,765	*
Other income (expense), net	1,896	(21)	1,917	*
Total other income (expense), net	1,896	(67,936)	69,832	*
Net loss	$ (43,755)	$ (81,714)	$ 37,959	46 %

* *Percentage change is not meaningful*

Research and development expenses

The following table summarizes our research and development expenses incurred during the years ended December 31, 2019 and 2018:

	Year Ended December 31,			
	2019	2018	$ Change	% Change
	(in thousands, except percentages)			
Research and development expenses:				
Direct AKR-001 program expenses	$ 33,978	$ 10,894	$ 23,084	212 %
Personnel and related costs	3,068	988	2,080	211 %
Total research and development expenses	$ 37,046	$ 11,882	$ 25,164	212 %

Research and development expenses were $37.0 million for the year ended December 31, 2019, compared to $11.9 million for the year ended December 31, 2018. Direct costs for our AKR-001 program increased $23.1 million during the 2019 period, with $15.3 million related to third-party contract manufacturing, $11.3 million related to external

CRO costs associated with our ongoing Phase 2a clinical trial, $2.0 million related to other third-party development studies and $2.5 million was a clinical milestone paid to Amgen. The 2019 period did not include $8.0 million in one-time cash and non-cash charges associated with the Amgen license that were incurred during the 2018 period. Personnel and related costs increased $2.1 million during the 2019 period related to the hiring of personnel in our research and development department.

General and administrative expenses

General and administrative expenses were $8.6 million for the year ended December 31, 2019 compared to $1.9 million for the year ended December 31, 2018. Increased personnel costs accounted for $3.4 million of the increase, primarily due to hiring additional personnel in our general and administrative functions related to our growth in becoming a public company. Legal, accounting, other professional service fees and rent increased $3.3 million, also related to our growth in becoming a public company.

Other income (expense), net

Other income (expense), net for the year ended December 31, 2019 is comprised primarily of $1.9 million of interest income from our cash, cash equivalents and short-term marketable securities. We did not record interest income for the year ended December 31, 2018.

Other expense for the year ended December 31, 2018 was $67.9 million, consisting of $62.2 million and $5.8 million in expenses related to the changes in fair value of the preferred stock tranche obligation and the fair value of the anti-dilution right liability, respectively.

Liquidity and capital resources

From our inception through December 31, 2019, we have incurred significant operating losses. We have not yet commercialized any products and we do not expect to generate revenue from sales of products for several years, if at all. To date, we have funded our operations primarily with proceeds from the sale of our redeemable convertible preferred stock and common stock in our initial public offering. Through December 31, 2019, we had received gross proceeds of $196.3 million from sales of our redeemable convertible preferred stock and the initial public offering of our common stock. As of December 31, 2019, we had cash, cash equivalents and short-term marketable securities of $136.4 million. We have invested our cash resources primarily in liquid money market accounts and corporate debt securities.

On June 24, 2019, we completed an IPO, at which time we issued 6,612,500 shares of common stock, including the exercise in full by the underwriters of their option to purchase up to 862,500 additional shares of common stock, at a public offering price of $16.00 per share. We received $98.4 million, net of underwriting discounts and commissions, but before deducting offering costs payable by the Company, which were $2.9 million

The following table summarizes our cash flows for the periods indicated:

	Year Ended December 31,	
	2019	2018
	(in thousands)	
Net cash used in operating activities	$ (35,627)	$ (4,625)
Net cash used in investing activities	(71,513)	(5,000)
Net cash provided by financing activities	95,988	85,007
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (11,152)	$ 75,382

Cash flows from operating activities

Cash used in operating activities for the year ended December 31, 2019 was $35.6 million, consisting of a net loss of $43.8 million, which was partially offset by non-cash charges of $1.8 million for stock-based compensation

expense and net cash provided by changes in our operating assets and liabilities of $6.5 million. The change in operating assets and liabilities was primarily due to a reduction in accrued expenses and other current liabilities of $7.4 million, of which $6.1 million was due to the timing of payments to our clinical research organization, or CRO, and contract manufacturing organization, or CMO, vendors and $1.3 million was related to employee compensation. These amounts were partially offset by a $0.5 million increase in prepaid expenses and other current assets and a $0.4 million decrease in accounts payable, both related to the timing of prepayments and payments to our CROs, CMOs and insurance vendors.

Cash used in operating activities for the year ended December 31, 2018 was $4.6 million, resulting from our net loss of $81.7 million, partially offset by non-cash charges of $76.0 million primarily related to our issuance of preferred stock to Amgen, changes in the fair value of preferred stock tranche obligation and anti-dilution right liability and net cash provided by changes in operating assets and liabilities of $1.1 million. Net cash provided by changes in our operating assets and liabilities primarily consisted of a $1.3 million increase in accounts payable due to outstanding invoices to CROs and other vendors in connection with our increased level of operating activities in 2018 and a $0.8 million increase in accrued expenses, which was primarily due to increased costs associated with our AKR-001 program. Increases were partially offset by an increase in prepaid expenses and other assets of $1.1 million primarily attributed to CRO deposits related to our clinical trials for AKR-001.

Cash flows from investing activities

Cash used in investing activities for the year ended December 31, 2019 was $71.5 million, consisting of purchases of short-term marketable securities.

Cash used in investing activities for the year ended December 31, 2018 was $5.0 million, consisting of licensing fees related to the acquisition of technology under the Amgen Agreement.

Cash flows from financing activities

Cash provided by financing activities for the year ended December 31, 2019 was $96.0 million, consisting of $98.4 million of IPO proceeds, net of underwriting discounts and commissions, offset by $2.9 million of related offering costs and $0.5 million in proceeds from the exercise of stock options and the issuance of employee stock purchase shares.

Cash provided by financing activities for the year ended December 31, 2018 was $85.0 million, primarily consisting of proceeds from our issuances of Series A and Series B preferred stock, net of issuance costs of $0.4 million.

Funding requirements

Our primary uses of capital are, and we expect will continue to be, research and development services, compensation and related expenses and general overhead costs. We expect to continue to incur significant expenses and operating losses for the foreseeable future. In addition, with the closing of our IPO, we expect to incur additional costs associated with operating as a public company. We anticipate that our expenses will increase significantly in connection with our ongoing activities. The timing and amount of our operating expenditures will depend largely on:

- the initiation, progress, timing, costs and results of nonclinical studies and clinical trials for AKR-001 or any future product candidates we may develop;
- our ability to maintain our license to AKR-001 from Amgen;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more nonclinical studies or clinical trials than those that we currently expect or change their requirements on studies or trials that had previously been agreed to;
- the cost to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in

connection with licensing, preparing, filing, prosecuting, defending and enforcing any patents or other intellectual property rights;
- the effect of competing technological and market developments;
- market acceptance of any approved product candidates, including product pricing, as well as product coverage and the adequacy of reimbursement by third-party payors;
- the cost of acquiring, licensing or investing in additional businesses, products, product candidates and technologies;
- the cost and timing of selecting, auditing and potentially validating a manufacturing site for commercial scale manufacturing;
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval and that we determine to commercialize; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems.

We expect that we will require additional funding to complete the clinical development of AKR-001, commercialize AKR-001, if we receive regulatory approval, and pursue in-licenses or acquisitions of other product candidates. If we receive regulatory approval for AKR-001 or other product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize AKR-001 ourselves.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, and marketing, distribution or licensing arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interest may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, reduce or eliminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual obligations and other commitments

The following table summarizes our contractual obligations as of December 31, 2019:

	Payments due by period				
	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
	(in thousands)				
Third-party contract research and manufacturing commitments (1)	$ 4,358	$ 4,358	$ —	$ —	$ —
Operating lease commitments (2)	402	322	80	—	—
Total contractual obligations	$ 4,760	$ 4,680	$ 80	$ —	$ —

(1) Amounts reflect the non-cancelable purchase commitments under agreements with our external CROs and CMOs, which we have engaged to conduct clinical and nonclinical development activities and clinical trials and to manufacture clinical development materials.

(2) Amounts reflect minimum payments due under our operating lease for office space in South San Francisco, California and our use agreement for office space in Cambridge, Massachusetts. The lease in South San Francisco was originally due to expire in April 2019 with the option to renew on a month to month basis thereafter. In

March 2019, we amended our lease agreement associated with our office space in South San Francisco, California, extended the term of the lease to March 2021 and expanded the square footage of the existing leased office space.

On February 14, 2020, the Company entered into a seven-year lease agreement for 6,647 square feet of office space in South San Francisco, California. Under the agreement, the Company is required to make $2.3 million in minimum payments during the lease term. Minimum payments due as a result of the new lease agreement are excluded from the table above.

Apart from the contracts with payment commitments that we have reflected in the table, we have entered into other contracts in the normal course of business with certain CROs, CMOs, and other third parties for nonclinical research studies and testing, clinical trials and manufacturing services. These contracts do not contain any minimum purchase commitments and are cancelable by us upon prior notice and, as a result, are not included in the table of contractual obligations and commitments above. Payments due upon cancellation consist only of payments for services provided and expenses incurred, including non-cancelable obligations of our service providers, up to the date of cancellation.

In addition, under the Amgen Agreement, we are required to make milestone payments and pay royalties based upon specified milestones. We have not included any such contingent payment obligations in the table above as the amount, timing and likelihood of such payments are not known. Such contingent payment obligations are described below.

Under the Amgen Agreement, we are obligated to make aggregate milestone payments of up to $37.5 million upon the achievement of specified remaining clinical and regulatory milestones and aggregate milestone payments of up to $75.0 million upon the achievement of specified commercial milestones for all products licensed under the agreement. Commencing on the first commercial sale of licensed products, we are obligated to pay tiered royalties on escalating tiers of annual net sales of licensed products ranging from low to high single-digit percentages. The first clinical milestone, in the amount of $2.5 million, was paid to Amgen in July 2019.

Critical accounting policies and significant judgments and estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States or GAAP. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses, and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events, and various other factors that we believe are 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. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements appearing elsewhere in this Annual Report, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Cash and cash equivalents

We consider all highly liquid investments with original maturities of three months or less at the time of purchase to be cash equivalents. Cash equivalents, which consist primarily of amounts invested in money market accounts, are stated at fair value.

Short-term marketable securities

We invest in short-term marketable securities, primarily money market funds, commercial paper, U.S. treasury securities and corporate debt securities. We classify our short-term marketable securities as available-for-sale securities and report them at fair value in cash equivalents or short-term marketable securities on the consolidated balance sheets

with related unrealized losses included within accumulated other comprehensive loss on the consolidated balance sheets. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity, which is included in other income (expense), net on the consolidated statements of operations and comprehensive loss. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in other income (expense), net. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in other income (expense), net.

We regularly review all of our investments for other-than-temporary declines in estimated fair value. Our review includes the consideration of the cause of the impairment, including the creditworthiness of the security issuers, the number of securities in an unrealized loss position, the severity and duration of the unrealized losses, whether we have the intent to sell the securities and whether it is more likely than not that we will be required to sell the securities before the recovery of their amortized cost basis. When we determine that the decline in estimated fair value of an investment is below the amortized cost basis and the decline is other-than-temporary, we reduce the carrying value of the security and record a loss for the amount of such decline.

Accrued research and development expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of these estimates with the service providers and make adjustments, if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- vendors in connection with nonclinical development activities;
- CROs and investigative sites in connection with nonclinical studies and clinical trials; and
- CMOs in connection with the production of nonclinical and clinical trial materials.

We base the expense recorded related to external research and development on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple CMOs and CROs that supply, conduct and manage nonclinical studies and clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expenses accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Stock-based compensation

We measure all stock-based awards granted to employees and nonemployees based on the fair value on the date of the grant and recognize compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award, on a straight-line basis. We account for forfeitures as they occur. We estimate the fair value of stock option grants using the Black-Scholes option pricing model. Prior to our initial public offering, the exercise price for all stock options granted was at the estimated fair value of the underlying common stock as determined on the date of grant by our board of directors.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model, which requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the option, the risk-free interest rate for a period that approximates the expected term of the option, and our expected dividend yield. We completed our IPO in June 2019 and accordingly, we lack sufficient company-specific historical and implied volatility information for our shares traded in the public markets. Therefore, we estimate our expected share price volatility based on the historical volatility of publicly traded peer companies and expect to continue to do so until such time as we have adequate historical data regarding the volatility of our own traded share price. The expected term of our 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. Expected dividend yield is based on the fact that we have never paid cash dividends on our common stock and do not expect to pay any cash dividends in the foreseeable future. The fair value of each restricted common stock award is estimated on the date of grant based on the fair value of our common stock on that same date.

Compensation expense for purchases under the Employee Stock Purchase Plan is recognized based on the fair value of the common stock estimated based on the closing price of our common stock as reported on the date of offering, less the purchase discount percentage provided for in the plan.

Stock-based compensation expense was $1.8 million and $0.1 million for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, we had $15.6 million of unrecognized stock-based compensation costs, which we expect to recognize over a weighted-average period of 3.08 years.

We have not recognized, and we do not expect to recognize in the near future, any tax benefit related to stock-based compensation expense as a result of the full valuation allowance on our deferred tax assets including deferred tax assets related to our net operating loss carryforwards.

Valuation of preferred stock tranche obligation

In connection with our issuance of Series A preferred stock in June 2018, we recognized a preferred stock tranche obligation. We classified the preferred stock tranche obligation for the future purchase, and option to purchase, Series A preferred stock as a liability on our consolidated balance sheets as the preferred stock tranche obligation is a freestanding financial instrument that required us to transfer equity instruments upon future closings of the Series A preferred stock. The preferred stock tranche obligation was initially recorded at fair value upon the date of issuance and was subsequently remeasured to fair value at each reporting date. Changes in the fair value of the preferred stock tranche obligation were recognized as a component of other expense in the consolidated statements of operations and comprehensive loss. Changes in the fair value of the preferred stock tranche obligation were recognized until the tranche obligations were fulfilled or otherwise extinguished in the fourth quarter of 2018.

The fair value of the liability was estimated based on results of a third-party valuation performed in connection with the issuance of Series A preferred stock in June 2018. We determined that this valuation represented the fair value of the liability at the reporting date. The liability includes (i) an obligation to issue shares in a second tranche of Series A preferred stock and (ii) an obligation to issue shares under the call option to purchase Series A preferred stock following the second tranche.

The fair value of the obligation to purchase a second tranche of Series A preferred stock was estimated by utilizing the future value of the underlying Series A preferred stock, the Series A original issue price and the number of shares subject to future purchase. The future value of the Series A preferred stock was determined through a backsolve calculation. The present value of the forward contract was then multiplied by a probability of occurrence for the second tranche closing.

The fair value of the obligation for the call option to purchase Series A preferred stock was estimated using the hybrid method which employed the Black-Scholes option-pricing model adjusted to reflect the timing and probability of closing a second tranche of Series A preferred stock. The hybrid method incorporates assumptions and estimates to value the obligation. Estimates and assumptions impacting the fair value measurement include the fair value per share of the

underlying shares of our Series A preferred stock, risk-free interest rate, expected dividend yield, expected volatility of the price of the underlying preferred stock, the remaining years to liquidity, the discount rate and probability (expressed as a percentage) of closing a second Tranche. The most significant assumption in the hybrid model impacting the fair value of the call option is the fair value of our preferred stock as of each remeasurement date. We determine the fair value per share of the underlying preferred stock by taking into consideration our most recent sales of our preferred stock, results obtained from third-party valuations and additional factors that are deemed relevant. We have historically been a private company and lack company-specific historical and implied volatility information of our stock. Therefore, we estimate expected stock volatility based on the historical volatility of publicly traded peer companies for a term equal to the remaining contractual term of the call option. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining years to liquidity. We have estimated a 0% dividend yield based on the expected dividend yield and the fact that we have never paid or declared dividends.

In November 2018, in connection with our issuance and sale of Series A preferred stock, we satisfied our obligation to issue additional shares under the second tranche closing. In December 2018, in connection with our issuance and sale of Series B preferred stock, we terminated the option to purchase Series A preferred stock provided under the 2018 Series A Agreement.

Valuation of anti-dilution right

We assessed the anti-dilution rights provided to Amgen pursuant to the Amgen Agreement and determined that the rights (i) met the definition of a freestanding financial instrument that was not indexed to our own stock and (ii) did not meet the definition of a derivative. As the rights did not meet the definition of a derivative and did not qualify for equity classification, we determined to classify the anti-dilution rights as a liability on our consolidated balance sheet. The anti-dilution right liability was initially recorded at fair value upon the license agreement and was subsequently remeasured to fair value at each reporting date. Changes in the fair value of the anti-dilution right liability were recognized as a component of other expense in the consolidated statements of operations and comprehensive loss. Changes in the fair value of the anti-dilution right liability were recognized until the anti-dilution obligation was satisfied in the fourth quarter of 2018.

The fair value of the anti-dilution right was estimated using a probability weighted scenario which considers as inputs the probability of occurrence of events that would trigger the issuance of shares, including a (i) second tranche closing of Series A preferred stock, (ii) initial public offering, and (ii) no future sale of equity securities. The weighted average fair values of each scenario were calculated utilizing the fair value per share of the underlying Series A preferred stock and common stock. Changes in our estimated fair value and the probability of achieving different financing scenarios can have a significant impact on the fair value of the anti-dilution right liability.

In November 2018, in connection with our issuance and sale of Series A preferred stock, we satisfied our anti-dilution rights obligation under the Amgen Agreement.

Income taxes

We account for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in our tax returns. Deferred tax assets and liabilities are determined based on the difference between the consolidated financial statement 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. We assess the likelihood that our deferred tax assets will be recovered from future taxable income and, to the extent we believe, 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 through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

We account for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to

determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. 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 net interest and penalties.

Utilization of our NOL carryforwards may be subject to a substantial annual limitation due to ownership changes that may have occurred or that could occur in the future, as required by Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, and similar state provisions. These ownership change limitations may limit the amount of NOL carryforwards and other tax attributes that can be utilized annually to offset future taxable income and tax, respectively. In general, an "ownership change" as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points (by value) of the outstanding stock of a company by certain stockholders. Since our formation, we have raised capital through the issuance of capital stock on several occasions, which separately or combined with the purchasing stockholders' subsequent disposition of those shares, resulted in such ownership changes on March 24, 2017 and on June 7, 2018, or could result in ownership changes in the future.

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 Securities and Exchange Commission.

Recent accounting pronouncements

See Note 2 to our consolidated financial statements included in Part I, Item 8, "Notes to Consolidated Financial Statements," of this Annual Report on Form 10-K for a description of recent accounting pronouncements applicable to our business.

Emerging Growth Company Status

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (JOBS Act), and are eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. Section 107 of the JOBS Act provides that an emerging growth company may take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933 for complying with new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. Section 107 of the JOBS Act provides that we can elect to opt out of the extended transition period at any time, which election is irrevocable. We have elected to avail ourselves of this exemption from complying with new or revised accounting standards and, therefore, will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

As an emerging growth company, we intend to rely upon other exemptions and reduced reporting requirements under the JOBS Act, including without limitation (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying 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 consolidated financial statements, known as the auditor discussion and analysis. We will remain an emerging growth company until the earlier of (a) the last day of the fiscal year in which we have total annual gross revenue of $1.07 billion or more; (b) the last day of the fiscal year following the fifth anniversary of the date of the completion of our initial public offering; (c) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (d) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

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

Information required by this Item is not applicable as we are electing scaled disclosure requirements available to Smaller Reporting Companies with respect to this Item.

Item 8. Financial Statements and Supplementary Data

AKERO THERAPEUTICS, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2019 and 2018

Report of Independent Registered Public Accounting Firm

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Akero Therapeutics, Inc. and subsidiaries (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows, for each of the two years in the period ended December 31, 2019, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

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/ Deloitte & Touche LLP

Parsippany, NJ

March 16, 2020

We have served as the Company's auditor since 2018.

Akero Therapeutics, Inc.

Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 64,788	$ 75,975
Short-term marketable securities	71,612	—
Prepaid expenses and other current assets	1,649	1,156
Total current assets	138,049	77,131
Other assets	69	20
Total assets	$ 138,118	$ 77,151
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 947	$ 1,373
Accrued expenses and other current liabilities	8,422	969
Total current liabilities	9,369	2,342
Other liabilities	23	—
Total liabilities	9,392	2,342
Commitments and contingencies (Note 12)		
Redeemable convertible preferred stock (Series A and B), $0.0001 par value; no shares authorized, issued and outstanding as of December 31, 2019; 64,730,410 shares authorized, issued and outstanding as of December 31, 2018; aggregate liquidation preference of $0 and $96,358 as of December 31, 2019 and December 31, 2018, respectively	—	124,728
Stockholders' equity (deficit):		
Common stock, $0.0001 par value, 150,000,000 shares authorized as of December 31, 2019 and 75,000,000 shares authorized as of December 31, 2018; 28,567,837 and 238,986 shares issued and outstanding as of December 31, 2019 and December 31, 2018, respectively	3	—
Additional paid-in capital	259,049	36,646
Accumulated other comprehensive loss	(6)	—
Accumulated deficit	(130,320)	(86,565)
Total stockholders' equity (deficit)	128,726	(49,919)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 138,118	$ 77,151

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

Akero Therapeutics, Inc.

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

	Year ended December 31,	
	2019	2018
Operating expenses:		
Research and development	$ 37,046	$ 11,882
General and administrative	8,605	1,896
Total operating expenses	45,651	13,778
Loss from operations	(45,651)	(13,778)
Other income (expense), net:		
Change in fair value of preferred stock tranche obligation	—	(62,150)
Change in fair value of anti-dilution right liability	—	(5,765)
Other income (expense), net	1,896	(21)
Total other income (expense), net	1,896	(67,936)
Net loss	(43,755)	(81,714)
Accretion of redeemable convertible preferred stock to redemption value	—	(520)
Net loss attributable to common stockholders	$ (43,755)	$ (82,234)
Net loss per share attributable to common stockholders - basic and diluted	$ (2.90)	$ (795.28)
Weighted-average number of shares used in computing net loss per share attributable to common stockholders, basic and diluted	15,070,728	103,403
Net loss	$ (43,755)	$ (81,714)
Net unrealized loss on marketable securities	(6)	—
Comprehensive loss	$ (43,761)	$ (81,714)

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

Akero Therapeutics, Inc.

Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(In thousands, except share amounts)

	Redeemable Convertible Preferred Stock		Common Stock		Treasury Stock		Additional Paid-In-	Other Comprehensive	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Loss	Deficit	(Deficit)
Balances at December 31, 2017	5,000,000	$ 5,000	226,400	$ —	—	$ —	$ —	$ —	$ (4,564)	$ (4,564)
Repurchase of founders' stock	—	—	(75,467)	—	75,467	—	—	—	—	—
Issuance of treasury stock as founders' stock	—	—	75,467	—	(75,467)	—	—	—	—	—
Issuance of Series A redeemable convertible preferred stock, net of issuance costs of $216	17,653,333	8,787	—	—	—	—	—	—	—	—
Issuance of Series A redeemable convertible preferred stock in connection with Second Tranche Closing, net of issuance costs of $4	25,000,001	24,996	—	—	—	—	—	—	—	—
Settlement of future purchase obligation	—	32,750	—	—	—	—	—	—	—	—
Issuance of Series A redeemable convertible preferred stock, in settlement of anti-dilution right liability	3,205,128	7,404	—	—	—	—	—	—	—	—
Issuance of Series B redeemable convertible preferred stock, net of issuance costs of $229	13,871,948	45,271	—	—	—	—	—	—	—	—
Extinguishment of call option liability	—	—	—	—	—	—	36,750	—	—	36,750
Exercise of stock options	—	—	12,586	—	—	—	8	—	—	8
Stock based compensation expense	—	—	—	—	—	—	121	—	—	121
Accretion of redeemable convertible preferred stock to redemption value	—	520	—	—	—	—	(233)	—	(287)	(520)
Net loss	—	—	—	—	—	—	—	—	(81,714)	(81,714)
Balances at December 31, 2018	64,730,410	124,728	238,986	—	—	—	36,646	—	(86,565)	(49,919)
Conversion of convertible preferred stock into common stock upon closing of public offering	(64,730,410)	(124,728)	21,056,136	2	—	—	124,726	—	—	124,728
Issuance of common stock upon closing of initial public offering, net of issuance costs and underwriting fees of $10,348	—	—	6,612,500	1	—	—	95,452	—	—	95,453
Issuance of restricted common stock upon early exercise of stock options	—	—	491,207	—	—	—	—	—	—	—
Exercise of stock options	—	—	164,503	—	—	—	130	—	—	130
Vesting of restricted common stock	—	—	—	—	—	—	240	—	—	240
Issuance of common stock pursuant to ESPP purchases	—	—	4,505	—	—	—	85	—	—	85
Stock-based compensation expense	—	—	—	—	—	—	1,770	—	—	1,770
Net unrealized loss on marketable securities	—	—	—	—	—	—	—	(6)	—	(6)
Net loss	—	—	—	—	—	—	—	—	(43,755)	(43,755)
Balances at December 31, 2019	—	$ —	28,567,837	$ 3	—	$ —	$ 259,049	$ (6)	$ (130,320)	$ 128,726

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

Akero Therapeutics, Inc.

Consolidated Statements of Cash Flows
(In thousands)

	Year ended December 31,	
	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (43,755)	$ (81,714)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,770	121
Shares issued in connection with Amgen Agreement	—	1,353
Acquisition of technology in connection with Amgen Agreement	—	5,000
Issuance date fair-value of anti-dilution liability	—	1,639
Change in fair value of preferred stock tranche liability	—	62,150
Change in fair value of anti-dilution right liability	—	5,765
Net amortization of premiums and discounts on short-term investments	(104)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(507)	(1,059)
Accounts payable	(426)	1,313
Accrued expenses and other current liabilities	7,395	807
Net cash used in operating activities	(35,627)	(4,625)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of short-term marketable securities	(71,513)	—
Acquisition of technology in connection with Amgen Agreement	—	(5,000)
Net cash used in investing activities	(71,513)	(5,000)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of Series A redeemable convertible preferred stock	—	40,000
Proceeds from issuance of Series B redeemable convertible preferred stock	—	45,500
Proceeds from issuance of common stock in initial public offering, net of issuance costs and underwriting fees	95,452	—
Proceeds from the early exercise of stock options in exchange for restricted common stock	321	—
Proceeds from the exercise of stock options	130	8
Proceeds from the issuance of common stock pursuant to employee stock purchase plan purchases	85	—
Payment of initial public offering costs	—	(52)
Payment of preferred stock issuance costs	—	(449)
Net cash provided by financing activities	95,988	85,007
Net (decrease) increase in cash, cash equivalents and restricted cash	(11,152)	75,382
Cash and restricted cash at the beginning of the year	76,000	618
Cash, cash equivalents and restricted cash at the end of the year	$ 64,848	$ 76,000
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING INFORMATION:		
Conversion of convertible preferred stock into common stock	$ 124,728	$ —
Net unrealizable loss on marketable securities	$ (6)	$ —
Accretion of redeemable convertible preferred stock to redemption value	$ —	$ 520
Issuance date fair value of preferred stock tranche obligation	$ —	$ 7,350
Deferred offering costs included in accounts payable and accrued expenses and other current liabilities	$ —	$ 309
Shares issued in connection with Amgen Agreement	$ —	$ 1,353
Settlement of future purchase obligation	$ —	$ 32,750
Issuance of Series A redeemable convertible preferred stock in settlement of anti dilution right liability	$ —	$ 7,404
Extinguishment of call option liability	$ —	$ 36,750

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

Akero Therapeutics, Inc.

Notes to Consolidated Financial Statements
(Amounts in thousands, except share and per share data)

1. Nature of the business and basis of presentation

Akero Therapeutics, Inc., together with its wholly owned subsidiary Akero Securities Corporation, ("Akero" or the "Company") is a clinical-stage biotechnology company dedicated to developing pioneering medicines that restore metabolic balance and improve overall health for patients with nonalcoholic steatohepatitis, or NASH. NASH is a severe form of nonalcoholic fatty liver disease, or NAFLD, characterized by inflammation and fibrosis in the liver that can progress to cirrhosis, liver failure, cancer and death. Our lead product candidate is AKR-001, an analog of fibroblast growth factor 21 ("FGF21"). We are currently conducting a Phase 2a clinical trial, the BALANCED study, which is evaluating AKR-001 in the treatment of NASH patients.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, ability to secure additional capital to fund operations, completion and success of clinical testing, compliance with governmental regulations, development by competitors of new technological innovations, dependence on key personnel and protection of proprietary technology. AKR-001 will require extensive clinical testing prior to regulatory approval and commercialization. These efforts require significant amounts of additional capital, adequate personnel, and infrastructure and extensive compliance-reporting capabilities. Even if the Company's drug development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

Basis of presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and include the accounts of the Company after elimination of all intercompany accounts and transactions. All adjustments necessary for the fair presentation of the Company's consolidated financial statements for the periods have been reflected.

Initial public offering

On June 24, 2019, Akero completed its initial public offering or IPO at which time the Company issued 6,612,500 shares of common stock, including the exercise in full by the underwriters of their option to purchase up to 862,500 additional shares of common stock, at a public offering price of $16.00 per share. The Company received $98,394, net of underwriting discounts and commissions, but before deducting offering costs payable by the Company, which were $2,942. Upon the closing of the IPO, all outstanding shares of redeemable convertible preferred stock converted into 21,056,136 shares of common stock (see Note 6). In connection with the completion of its IPO in June 2019, the Company amended its certificate of incorporation to authorize the issuance of up to 150,000,000 shares of $0.0001 par value common stock and 10,000,000 shares of $0.0001 par value preferred stock designated as undesignated preferred stock.

Reverse stock split

On June 6, 2019, the Company effected a one-for-3.07418 reverse stock split of the Company's common stock. All common stock, stock options and per share information presented have been adjusted to reflect the reverse stock split on a retroactive basis for all periods presented. There was no change in the par value of the Company's common stock. The ratio by which shares of preferred stock are convertible into shares of common stock was adjusted to reflect the effects of the reverse stock split.

Akero Therapeutics, Inc.

Notes to Consolidated Financial Statements
(Amounts in thousands, except share and per share data)

Liquidity

In accordance with Accounting Standards Update ("ASU") No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40)*, the Company has evaluated whether there are certain conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued.

Since its inception, the Company has funded its operations primarily with proceeds from sales of redeemable convertible preferred stock and most recently with proceeds from the IPO. The Company has incurred recurring losses since its inception, including a net loss of $43,755 and $81,714 for the years ended December 31, 2019 and 2018, respectively. In addition, as of December 31, 2019, the Company had an accumulated deficit of $130,320. The Company expects to continue to generate operating losses for the foreseeable future. As of March 16, 2020, the issuance date of these consolidated financial statements, the Company expects that its existing cash, cash equivalents and short-term marketable securities of $136,400 as of December 31, 2019, will be sufficient to fund its operating expenses and capital expenditure requirements for at least 12 months from the issuance date of these consolidated financial statements. The Company expects that it will require additional funding beyond this time to complete the clinical development of AKR-001, commercialize AKR-001, if it receives regulatory approval, and pursue in-licenses or acquisitions of other product candidates.

If the Company is unable to obtain funding, the Company will be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

2. Summary of significant accounting policies

Use of estimates

The preparation of the Company's consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses during the reporting period. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the accrual of research and development expenses and the valuations of common stock, preferred stock tranche obligation, anti-dilution right liability and the valuation allowance for deferred tax assets. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates when there are changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates.

Cash and cash equivalents

The Company considers all highly liquid investments with original maturities of three months or less at the time of purchase to be cash equivalents. Cash equivalents, which consist primarily of amounts invested in money market accounts, are stated at fair value.

Akero Therapeutics, Inc.

Notes to Consolidated Financial Statements
(Amounts in thousands, except share and per share data)

Short-term marketable securities

The Company invests in short-term marketable securities, primarily money market funds, commercial paper, U.S. treasury securities and corporate debt securities. The Company classifies its short-term marketable securities as available-for-sale securities and reports them at fair value in short-term marketable securities on the consolidated balance sheets with related unrealized losses included within accumulated other comprehensive loss on the consolidated balance sheets. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity, which is included in other income (expense), net on the consolidated statements of operations and comprehensive loss. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in other income (expense), net. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in other income (expense), net.

The Company regularly reviews all its investments for other-than-temporary declines in estimated fair value. This review includes the consideration of the cause of the impairment, including the creditworthiness of the security issuers, the number of securities in an unrealized loss position, the severity and duration of the unrealized losses, whether the Company has the intent to sell the securities and whether it is more likely than not that the Company will be required to sell the securities before the recovery of their amortized cost basis. When the Company determines that the decline in estimated fair value of an investment is below the amortized cost basis and the decline is other-than-temporary, the carrying value of the security will be reduced and a loss will be recorded for the amount of such decline.

Restricted cash

As of December 31, 2019 and 2018, the Company was required to maintain separate cash balances of $40 and $20, respectively, to collateralize corporate credit cards with a bank, which are classified within other assets (non-current) on the consolidated balance sheets.

As of December 31, 2019 the Company was required to maintain a separate cash balance of $20 for the benefit of the landlord in connection with the Company’s office space lease in South San Francisco, California (the “Lease”), which is classified within other assets (non-current) on the 2019 consolidated balance sheet (see Note 12). As of December 31, 2018, the Company was required to maintain a separate cash balance of $5 for the benefit of the landlord in connection with the Lease, which is classified within other current assets on the 2018 consolidated balance sheet.

Concentrations of credit risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents and short-term marketable securities. Periodically, the Company maintains deposits in accredited financial institutions in excess of federally insured limits. The Company deposits its cash investments 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. At December 31, 2019 and 2018, all of the Company's cash, cash equivalents and short-term investments were held at one accredited financial institution.

Deferred offering costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process preferred stock or common equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded as a reduction to the carrying value of redeemable convertible preferred stock or in stockholders' equity (deficit) as a reduction of additional paid-in

capital generated as a result of such offering. Should an in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statements of operations and comprehensive loss. As of December 31, 2019, the Company did not have any deferred offering costs. As of December 31, 2018, the Company recorded deferred offering costs of $361, which are classified within prepaid expenses and other current assets on the 2018 consolidated balance sheet.

Segment information

The Company manages its operations as a single operating segment for the purposes of assessing performance and making operating decisions. The Company's singular focus is developing and commercializing transformative treatments for serious metabolic diseases, with an initial focus on NASH.

Research and development costs

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred to discover, research and develop drug candidates, including personnel expenses, stock-based compensation expense, third-party license fees and external costs including fees paid to consultants and clinical research organizations ("CROs"), in connection with drug product manufacturing, nonclinical studies and clinical trials, and other related clinical trial fees, such as for investigator grants, patient screening, laboratory work, clinical trial database management, clinical trial material management and statistical compilation and analysis. Non-refundable prepayments for goods or services that will be used or rendered for future research and development activities are recorded as prepaid expenses. Such amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered.

Costs incurred in obtaining technology licenses are charged immediately to research and development expense if the technology licensed has not reached technological feasibility and has no alternative future uses.

Research contract costs and accruals

The Company has entered into various research and development and other agreements with commercial firms, researchers and others for provisions of goods and services. These agreements are generally cancelable, and the related costs are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research and development costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or clinical trials, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ materially from the Company's estimates.

Patent costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses.

Stock-based compensation

The Company measures all stock-based awards granted to employees and nonemployees based on the fair value on the date of the grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award, on a straight-line basis. The Company accounts for forfeitures as they occur. The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model.

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Prior to our initial public offering, the exercise price for all stock options granted was at the estimated fair value of the underlying common stock as determined on the date of grant by the Company's board of directors.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model, which requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the option, the risk-free interest rate for a period that approximates the expected term of the option, and the Company's expected dividend yield. The Company went public in June 2019 and accordingly, lacks sufficient company-specific historical and implied volatility information for its shares traded in the public markets. Therefore, it estimates its expected share price volatility based on the historical volatility of publicly traded peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded share 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. Expected dividend yield is based on the fact that the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future. The fair value of each restricted common stock award is estimated on the date of grant based on the fair value of the Company's common stock on that same date.

Compensation expense for purchases under the Employee Stock Purchase Plan is recognized based on the fair value of the common stock estimated based on the closing price of our common stock as reported on the date of offering, less the purchase discount percentage provided for in the plan.

The Company classifies stock-based compensation expense in its consolidated statement of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

Preferred stock tranche obligation

The Company classified the preferred stock tranche obligation for the future purchase, and option to purchase, Series A Preferred Stock (see Note 6) as a liability on its consolidated balance sheets as the preferred stock tranche obligation was a freestanding financial instrument that required the Company to transfer equity instruments upon future closings of the Series A Preferred Stock. The preferred stock tranche obligation was initially recorded at fair value upon the date of issuance and was subsequently remeasured to fair value at each reporting date. Changes in the fair value of the preferred stock tranche obligation were recognized as a component of other expense in the consolidated statements of operations and comprehensive loss. Changes in the fair value of the preferred stock tranche obligation were recognized until the tranche obligations were fulfilled or otherwise extinguished in the fourth quarter of 2018.

In November 2018, in connection with the Company's issuance and sale of Series A Preferred Stock, the Company satisfied its obligation to issue additional shares under the Second Tranche Closing. In December 2018, in connection with the Company's issuance and sale of Series B Preferred Stock, the Company terminated the option to purchase Series A Preferred Stock provided under the 2018 Series A Agreement (see Notes 3 and 6).

Anti-dilution right liability

The Company classified the anti-dilution right under its license agreement with Amgen Inc. ("Amgen") (see Note 9) as a derivative liability on its consolidated balance sheets as the anti-dilution right represented a freestanding financial instrument that required the Company to transfer equity instruments upon future equity closings. The anti-dilution right liability was initially recorded at fair value upon the date of issuance and was subsequently remeasured to fair value at each reporting date. The issuance date fair value of the anti-dilution right liability was recognized as a

research and development expense upon entering into the agreement with Amgen. Changes in the fair value of the anti-dilution right liability were recognized as a component of other expense in the consolidated statements of operations and comprehensive loss. Changes in the fair value of the anti-dilution right liability were recognized until the anti-dilution right was satisfied in the fourth quarter of 2018.

In November 2018, in connection with the Company's issuance and sale of Series A Preferred Stock, the Company satisfied its anti-dilution right under the Amgen Agreement (see Notes 6 and 9).

Classification and accretion of redeemable convertible preferred stock

The Company has classified its redeemable convertible preferred stock outside of stockholders' equity (deficit) because the shares contain certain redemption features that are not solely within the control of the Company. Costs incurred in connection with the issuance of redeemable convertible preferred stock, as well as the recognition of the preferred stock tranche obligation, are recorded as a reduction of gross proceeds from issuance. The net carrying value of redeemable convertible preferred stock were accreted to their redemption values through a charge to additional paid-in capital or accumulated deficit over the period from date of issuance to the earliest date on which the holders could, at their option, elect to redeem their shares. In December 2018, in connection with the Company's issuance and sale of Series B Preferred Stock, the Company terminated the redemption rights associated with the Series A Preferred Stock that allowed the holders, at their option, to elect to redeem their shares at a specified date. Accordingly, the Company ceased accreting the net carrying value of the Series A redeemable convertible preferred stock to the redemption value.

Comprehensive loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders. Our comprehensive loss is comprised of net loss and changes in unrealized gains and losses on our short-term marketable securities.

Income taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined based on the difference between the consolidated financial statement 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 through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. 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 net interest and penalties.

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Net loss per share

The Company follows the two-class method when computing net loss per share as the Company has issued shares that meet the definition of participating securities. The two-class method determines net loss per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period. Diluted net loss attributable to common stockholders is computed by adjusting net loss attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net loss per share attributable to common stockholders is computed by dividing the diluted net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period, including potential dilutive common shares. For purpose of this calculation, unvested restricted common stock and redeemable convertible preferred stock are considered potential dilutive common shares.

The Company's redeemable convertible preferred stock contractually entitles the holders of such shares to participate in dividends but does 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 attributable to common stockholders, such losses are not allocated to such participating securities. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss attributable to common stockholders for the years ended December 31, 2019 and 2018.

Emerging growth company

The Company is an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, as amended (the "JOBS Act"). Under the JOBS Act, companies have extended transition periods available for complying with new or revised accounting standards. The Company has elected this exemption to delay adopting new or revised accounting standards until such time as those standards apply.

Recently issued accounting pronouncements not yet adopted

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, subsequently amended by ASU 2018-10, ASU 2018-11, ASU 2019-01 and ASU 2019-10 (collectively, "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 will determine 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 on the consolidated balance sheets. Leases with a term of 12 months or less may be accounted for similar to existing guidance for operating leases today. The Company intends to utilize the modified retrospective approach to adopting ASU 2016-02 effective January 1, 2020. Further, the Company intends to utilize the package of available practical expedients which allows it to i) not reassess whether any expired or existing contracts are or contain leases; ii) not reassess the lease classification for expired or existing leases; and iii) not reassess the treatment of initial direct costs for any existing leases. The Company is in the

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process of completing a review of its existing lease agreements under ASC 842 and does not expect that the impact of the adoption of ASU 2016-02 on its consolidated balance sheets will be material and does not expect the adoption to have a material impact on its results of operations or cash flows. In February 2020 the Company entered into a new office lease agreement (see Note 15). The Company is in the process of determining the impact on its consolidated financial statements of the adoption of ASU 2016-02 related to this new lease.

In August 2018, the FASB issued No. ASU 2018-13, *Fair Value Measurement (Topic 820)—Disclosure Framework* ("ASU 2018-13"), which improves the disclosure requirements for fair value measurements. For non-public entities, ASU 2018-13 is effective for annual reporting periods beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted for any removed or modified disclosures. The Company is currently evaluating the impact that the adoption of ASU 2018-13 will have on its consolidated financial statements.

3. Fair value of financial assets and liabilities

Certain assets and liabilities of the Company are carried at fair value under 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.

The following table summarizes our financial assets measured at fair value on a recurring basis as of December 31, 2019:

	Fair Value Measurements as of December 31, 2019 Using:			
	Total	Level 1	Level 2	Level 3
Money market funds	$ 49,948	$ 49,948	$ —	$ —
Commercial paper	49,114	—	49,114	—
U.S. treasury securities	6,048	6,048	—	—
Corporate debt securities	20,143	—	20,143	—
	$ 125,253	$ 55,996	$ 69,257	$ —

At December 31, 2018, the Company did not have any financial assets or liabilities measured at fair value on a recurring basis. The carrying values of the Company's prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities.

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In November 2018, in connection with the Company's issuance and sale of Series A Preferred Stock under the Second Tranche Closing, the Company satisfied its obligation to issue additional shares at the Second Tranche Closing and accordingly reclassified the carrying value of the preferred stock tranche obligation associated with the future purchase obligation, equal to the then current fair value of $32,750, to the carrying value of the Series A Preferred Stock. In November 2018, in connection with the Company's Second Tranche Closing, the Company issued 3,205,128 shares of Series A Preferred Stock to Amgen for a total value of $7,404 satisfying its anti-dilution obligation under the Amgen Agreement. The Company reclassified the carrying value of the anti-dilution right liability, equal to the then current fair value of $7,404, to the carrying value of the Series A Preferred Stock.

In December 2018, in connection with the Company's issuance and sale of Series B Preferred Stock, the Company terminated the option to purchase Series A Preferred Stock provided under the 2018 Series A Agreement. The Company accounted for the termination of the call option associated with the preferred stock tranche obligation as a liability extinguishment between related parties and recognized a gain on extinguishment of $36,750, equal to the then current fair value, within additional paid-in capital in the statement of stockholder's equity (deficit).

During the years ended December 31, 2019 and December 31, 2018, there were no transfers between Level 1, Level 2 and Level 3.

Valuation of cash equivalents and short-term investments

Commercial paper and corporate debt securities were valued by the Company using quoted prices in active markets for similar securities, which represent a Level 2 measurement within the fair value hierarchy.

Valuation of preferred stock tranche obligation

The fair value of the preferred stock tranche obligation recognized in connection with the Company's issuance of Series A Preferred Stock in June 2018 (see Note 6) was determined based on significant inputs not observable in the market, which represented a Level 3 measurement within the fair value hierarchy. The fair value of the liability was estimated based on results of a third-party valuation performed in connection with the June 2018 Series A issuance. The Company determined that this valuation represented the fair value of the liability at the reporting date. The liability included (i) an obligation to issue shares in a second tranche of Series A Preferred Stock and (ii) an obligation to issue shares under the call option to purchase Series A Preferred Stock following the Second Tranche Closing.

The fair value of the obligation to purchase a second tranche of Series A Preferred Stock was estimated by utilizing the future value of the underlying Series A Preferred stock, the Series A original issue price and the number of shares subject to future purchase. The future value of the Series A Preferred Stock was determined through a backsolve calculation. The present value of the forward contract was then multiplied by a probability of occurrence for the Second Tranche Closing.

The fair value of the obligation for the call option to purchase Series A Preferred Stock was estimated using the hybrid model, which employed the Black-Scholes option-pricing model adjusted to reflect the timing and probability of closing a second tranche of Series A Preferred Stock. The hybrid method incorporates assumptions and estimates, to value the obligation. Estimates and assumptions impacting the fair value measurement include the fair value of the underlying shares of Series A Preferred Stock, the remaining contractual term of the preferred stock tranche obligation, risk-free interest rate, expected dividend yield, expected volatility of the price of the underlying preferred stock, the remaining years to liquidity, the discount rate and probability (expressed as a percentage) of closing a second tranche. The most significant assumption in the hybrid model impacting the fair value of the call option is the fair value of the preferred stock as of each remeasurement date. The Company determined the fair value per share of the underlying preferred stock by taking into consideration the most recent sales of preferred stock, results obtained from third-party

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valuations and additional factors that are deemed relevant. The Company has historically been a private company and lack company-specific historical and implied volatility information of its stock. Therefore, the Company estimated expected stock volatility based on the historical volatility of publicly traded peer companies for a term equal to the remaining contractual term of the call option. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining years to liquidity. The Company has estimated a 0% dividend yield based on the expected dividend yield and the fact that the Company has never paid or declared dividends.

Valuation of anti-dilution right liability

The fair value of the anti-dilution right liability recognized in connection with the anti-dilution provisions set forth in the Company's license agreement with Amgen (see Note 9) was determined based on significant inputs not observable in the market, which represented a Level 3 measurement within the fair value hierarchy.

The fair value of the anti-dilution right was estimated using a probability weighted scenario which considered as inputs the probability of occurrence of events that would trigger the issuance of shares, including a (i) Second Tranche Closing of Series A Preferred Stock, (ii) initial public offering, and (ii) no future sale of equity securities. The weighted average fair values of each scenario were calculated utilizing the fair value per share of the underlying Series A Preferred Stock and common stock. Changes in the estimated fair value and the probability of achieving different financing scenarios can have a significant impact on the fair value of the anti-dilution right liability.

The following table presents a roll forward of the fair values of the Company's preferred stock tranche obligation and anti-dilution right liability for the year ended December 31, 2018, for which fair value is determined using Level 3 inputs:

	Preferred stock tranche obligation	Anti-dilution right liability
Balance as of December 31, 2017	$ —	$ —
Initial fair value of anti-dilution right liability in connection with Amgen license agreement	—	1,639
Initial fair value of preferred stock tranche obligation in connection with the issuance of Series A Preferred Stock	7,350	—
Change in fair value	62,150	5,765
Settlement of future purchase obligation	(32,750)	—
Settlement of anti-dilution right liability upon issuance of Series A preferred stock	—	(7,404)
Extinguishment of call option liability	(36,750)	—
Balance as of December 31, 2018	$ —	$ —

4. Short-term marketable securities

The following is a summary of short-term marketable securities presented on the Company's consolidated balance sheet as of December 31, 2019:

	December 31, 2019			
	Amortized Cost	Gross unrealized gains	Gross unrealized losses	Fair value
Money market funds	$ 49,948	$ —	$ —	$ 49,948
Commercial paper	49,114	—	—	49,114

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U.S. treasury securities	6,048	—	—	6,048
Corporate debt securities	20,149	—	(6)	20,143
	$ 125,259	$ —	$ (6)	$ 125,253

Cash and cash equivalents	$ 53,641
Short-term marketable securities	71,612
	$ 125,253

The Company did not have any short-term marketable securities as of December 31, 2018.

5. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31,	
	2019	2018
Accrued employee compensation and benefits	$ 1,606	$ 304
Accrued external research and development expenses	6,361	430
Accrued legal and professional fees	370	106
Other	85	129
	$ 8,422	$ 969

6. Redeemable convertible preferred stock

As of December 31, 2019 and 2018, 0 shares and 64,730,410 shares, respectively, of redeemable convertible preferred stock were issued and outstanding and were classified outside of stockholders' equity (deficit) because the shares contained redemption features that were not solely within the control of the Company.

Upon completion of the Company’s IPO on June 24, 2019, all outstanding shares of our Series A and Series B redeemable convertible preferred stock (the “Preferred Stock”) were converted into 21,056,136 shares of common stock and the related carrying value was reclassified to common stock and additional paid-in capital. Accordingly, there were no shares of redeemable convertible preferred stock outstanding as of December 31, 2019.

In June 2018, the Company entered into a Series A Preferred Stock Agreement ("2018 Series A Agreement"), which provided for a First Tranche Closing, Second Tranche Closing and a call option to purchase additional shares of Series A Preferred Stock.

In June 2018, the Company completed its First Tranche Closing, and issued and sold 15,000,000 shares of Series A Preferred Stock at a price of $1.00 ("2018 Series A Agreement Purchase Price") per share for aggregate proceeds of $14,784, net of issuance costs of $216. Upon the execution of the Company's license agreement with Amgen (see Note 9), the Company issued an additional 2,653,333 shares of Series A Preferred Stock to Amgen in June 2018 for a total value of $1,353.

The Second Tranche Closing was contingent upon the achievement of the Second Tranche Closing Milestone Event ("Milestone Event"), as reasonably determined by a majority of the Company's board of directors, prior to

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December 31, 2019 or waiver of the Milestone Event through written elections by a majority of the purchasers of shares of Series A Preferred Stock. Upon achievement or waiver of the Milestone Event, Amgen would be issued a number of additional shares for no consideration provided that Amgen's total holdings equal ten percent (10%) of the total outstanding and issued common stock of the Company on a fully diluted and as converted basis of the Second Tranche Closing. Additionally, the 2018 Series A Agreement contained a call option such that, following the Second Tranche Closing, the stockholders of Series A Preferred Stock have the right, but not the obligation, to purchase up to $20,000 of additional shares of Series A Preferred Stock at any time prior to January 14, 2022 at a price equal to the 2018 Series A Agreement Purchase Price.

The Company concluded that the rights to participate in the future issuance of Series A Preferred Stock met the definition of a freestanding financial instrument that was required to be recognized as a liability at fair value as (i) the instruments were legally detachable from the Series A Preferred Stock and (ii) required the Company to transfer equity instruments upon future closings of the Series A Preferred Stock. Upon the First Tranche Closing, the Company recognized a preferred stock tranche obligation of $7,350 with a corresponding reduction to the carrying value of the Series A Preferred Stock.

Upon the First Tranche Closing in June 2018, the initial carrying value of the Series A Preferred Stock was recorded at $8,787, equal to $15,000 of gross proceeds received by the Company and the fair value of $1,353 for the issuance of shares to Amgen, reduced by accrued issuance costs of $216 and the fair value of the preferred stock tranche obligation of $7,350.

Upon issuance of each tranche of Preferred Stock, the Company assessed the embedded conversion and liquidation features of the securities and determined that such features did not require the Company to separately account for these features. The Company also concluded that no beneficial conversion feature existed on the issuance date of each tranche of Preferred Stock.

In November 2018, upon the waiver of the Milestone Event through written elections by a majority of the shareholders of Series A Preferred Stock, the Company closed the second tranche of its Series A preferred financing through the issuance and sale of an aggregate of 25,000,001 shares of Series A Preferred Stock, at an issuance price of $1.00 per share, for proceeds of $25,000, before issuance costs of $4. In November 2018, in connection with the Company's issuance and sale of Series A Preferred Stock, the Company satisfied its obligation to issue additional shares under the Second Tranche Closing. Accordingly, the preferred stock tranche obligation associated with the future purchase obligation was adjusted to fair value immediately prior to the issuance of the Series A Preferred Stock, and upon issuance of the Series A Preferred Stock, the preferred stock tranche obligation associated with the future purchase obligation of $32,750, equal to then current fair value, was reclassified to the carrying value of the Series A Preferred Stock.

In November 2018, pursuant to the terms of the Amgen Agreement, the Company issued an additional 3,205,128 shares of Series A Preferred Stock valued at $7,404 to Amgen upon completion of the Series A Second Tranche Closing, satisfying its anti-dilution right under the Amgen Agreement.

In December 2018, the Company issued and sold 13,871,948 shares of Series B Preferred Stock, at an issuance price of $3.28 per share, for proceeds of $45,500 before issuance costs of $229. In connection with the Company's issuance and sale of Series B Preferred Stock, the Company terminated the option to purchase Series A Preferred Stock provided under the 2018 Series A Agreement.

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As of December 31, 2018, redeemable convertible preferred stock consisted of the following:

	Preferred stock authorized	Preferred stock issued and outstanding	Carrying value	Liquidation preference	Common stock issuable upon conversion
Series A Preferred Stock	50,858,462	50,858,462	$ 79,457	$ 50,858	16,543,739
Series B Preferred Stock	13,871,948	13,871,948	$ 45,271	$ 45,500	4,512,397
	64,730,410	64,730,410	$ 124,728	$ 96,358	21,056,136

7. Stockholders' equity (deficit)

Common stock

As of December 31, 2019 and 2018, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue 150,000,000 shares and 75,000,000 shares of $0.0001 par value common stock, respectively. Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. The holders of common stock, voting exclusively and as a separate class, have the exclusive right to vote for the election of directors of the Company. Common stockholders are entitled to receive dividends, as may be declared by the board of directors. Through December 31, 2019, no cash dividends had been declared or paid.

On June 24, 2019, the Company completed its IPO at which time the Company issued 6,612,500 shares of common stock, including the exercise in full by the underwriters of their option to purchase up to 862,500 additional shares of common stock, at a public offering price of $16.00 per share. The Company received $98,394, net of underwriting discounts and commissions, but before deducting offering costs payable by the Company, which were $2,942. Upon the closing of the IPO, all outstanding shares of convertible preferred stock converted into 21,056,136 shares of common stock (see Note 6). As of December 31, 2019 and December 31, 2018, there were 28,567,837 and 238,986 shares of common stock issued and outstanding, respectively.

The following shares of common stock were reserved for issuance as follows:

	December 31,	
	2019	2018
Conversion of outstanding shares of preferred stock	—	21,056,136
Options outstanding under the 2018 Stock Option and Grant Plan	2,296,029	1,839,913
Options outstanding under the 2019 Stock Option and Incentive Plan	800,526	—
Options available for future grant	1,771,931	1,219,461
2019 Employee Stock Purchase Plan	269,364	—
	5,137,850	24,115,510

Undesignated preferred stock

As of December 31, 2019, the Company's fourth amended and restated certificate of incorporation authorized the Company to issue up to 10,000,000 shares of undesignated preferred stock, par value $0.0001 per share. There were no undesignated preferred shares issued or outstanding as of December 31, 2019.

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Restricted common stock

In March 2017, the Company issued an aggregate of 226,400 shares of restricted common stock under restricted stock agreements with the founders. Pursuant to the terms of the agreements, the restricted common stock was initially subject to a vesting schedule over a four-year period commencing in January 2017 and culminating in January 2021. During the vesting period, the Company has the right to repurchase up to all unvested shares at the amount paid if the relationship between the recipient and the Company ceases. Subject to the continued employment or other business relationship with the Company, all of the restricted common stock becomes fully vested within four years of the date of issuance.

In October 2017, 75,467 shares of restricted common stock were subject to repurchase by the Company when one of the founders terminated his relationship with the Company. The Company repurchased the shares in March 2018 for an immaterial amount and immediately reissued the shares to the remaining founders. In connection with the repurchase and reissuance of the shares, the Company amended the restricted stock agreements with the remaining founders such that the restricted common stock is now subject to a vesting schedule over a two-year period commencing in May 2018 and culminating in May 2020.

The Company accounted for the acceleration of vesting under the amended restricted stock agreement as a modification of the original awards and recognized the remaining unvested shares prospectively over the revised vesting period. The grant date fair value of restricted stock vested during the years ended December 31, 2019 and 2018 was insignificant.

In April, June and July 2019, the Company amended certain option grant agreements granted under the Company's 2018 Stock Option and Grant Plan to allow the holders the right to early exercise unvested options, subject to a repurchase right held by the Company equal to the lesser of the original exercise price per share or the fair value of the shares on the repurchase date. The unvested shares issued as a result of the early exercise are deemed restricted stock pursuant to a restricted stock agreement and a vesting schedule identical to the vesting schedule of the original grant agreement. The proceeds related to unvested restricted common stock are recorded as liabilities until the stock vests, at which point they are reclassified to additional paid-in capital. Common shares issued for the early exercise of options are included in issued and outstanding shares.

The following table summarizes restricted stock activity since December 31, 2017:

	Number of Shares	Grant-Date Fair Value
Unvested restricted common stock as of December 31, 2017	226,400	$ —
Shares vesting	(146,210)	—
Unvested restricted common stock as of December 31, 2018	80,190	—
Early exercise of unvested stock options	491,207	0.65
Shares vesting	(416,248)	0.65
Unvested restricted common stock as of December 31, 2019	155,149	$ 0.65

As of December 31, 2019, there were 155,149 shares of unvested restricted common stock subject to repurchase, consisting of 23,598 shares from unvested restricted common stock awards under restricted stock agreements with the founders and 131,551 shares from the early exercise of stock options.

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8. Stock-based awards

2018 Stock option and grant plan

The Company's 2018 Stock Option and Grant Plan (the "2018 Plan") provided for the Company to grant incentive stock options or nonqualified stock options, restricted stock awards and other stock-based awards to employees, directors and consultants of the Company. The 2018 Plan was administered by the board of directors or, at the discretion of the board of directors, by a committee of the board of directors. The exercise prices, vesting and other restrictions were determined at the discretion of the board of directors, or its committee if so delegated.

The total number of shares of common stock that could have been issued under the 2018 Plan was 3,071,960 shares, of which 107,635 shares remained available for grant on June 18, 2019, the date that the Company's 2019 Stock Option and Incentive Plan (the "2019 Plan") became effective. Upon the effectiveness of the 2019 Plan, the 107,635 remaining shares available under the 2018 Plan were transferred and became available for issuance under the 2019 Plan. Shares of common stock underlying outstanding awards under the 2018 Plan that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without the issuance of stock, expire or are otherwise terminated (other than by exercise) will be added to the shares of common stock available for issuance under the 2019 Plan.

2019 Stock option and incentive plan

The 2019 Plan was adopted and approved by the Company's board of directors in May 2019 and by the Company's stockholders in June 2019. The 2019 Plan became effective on June 18, 2019 and replaced the Company's 2018 Plan on that date. The 2019 Plan allows the board of directors or the compensation committee of the board of directors to make equity-based incentive awards to the Company's officers, employees, directors or other key persons (including consultants). The number of shares initially reserved for issuance under the 2019 Plan is 2,572,457, which includes the 107,635 shares transferred from the 2018 Plan, and shall be cumulatively increased on January 1, 2020 and each January 1 thereafter by 4% of the number of shares of the Company's common stock outstanding on the immediately preceding December 31 or such lesser number of shares determined by the Company's board of directors or compensation committee of the board of directors.

The 2019 Plan is administered by the board of directors or, at the discretion of the board of directors, by a committee of the board of directors. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, or its committee if so delegated, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the share of common stock on the date of grant and the term of stock option may not be greater than ten years. All incentive options granted to any person possessing more than 10% of the total combined voting power of all classes of shares may not have an exercise price of less than 110% of the fair market value of the common stock on the grant date. Stock options granted to employees, officers, members of the board of directors and consultants will typically vest over a four-year period.

Shares that are expired, terminated, surrendered or canceled under the 2019 Plan without having been fully exercised will be available for future awards.

2019 Employee stock purchase plan

The 2019 Employee Stock Purchase Plan (the "2019 ESPP") was adopted and approved by the Company's board of directors in May 2019 and by the Company's stockholders in June 2019. The 2019 ESPP became effective on June 18, 2019, at which time 273,869 shares were reserved for issuance. The 2019 ESPP provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2020 and

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each January 1 thereafter through January 1, 2029, by the least of (i) 1% of the outstanding number of shares of the Company's common stock on the immediately preceding December 31, (ii) 410,803 shares or (iii) such number of shares as determined by the compensation committee.

Stock option valuation

The assumptions that the Company used to determine the grant-date fair value of stock options granted to employees, directors and consultants were as follows, presented on a weighted average basis:

	Year Ended December 31,	
	2019	2018
Weighted average risk-free interest rate	2.12 %	2.99 %
Expected term (in years)	6.0	6.0
Expected volatility	73.75 %	70.88 %
Expected dividend yield	0 %	0 %

Stock options

The following table summarizes the Company's stock option activity since December 31, 2017:

	Number of Options	Weighted-Average Exercise Price per Share	Weighted-Average remaining contractual term (years)	Aggregate Intrinsic Value (000's)
Balance Outstanding, December 31, 2017	—	$ —	—	$ —
Options granted	1,883,067	0.61	9.74	
Options exercised	(12,586)	0.61		
Options cancelled	(30,568)	0.61		
Balance Outstanding, December 31, 2018	1,839,913	0.61	9.74	10,577
Options granted	1,912,352	12.42		
Options exercised	(655,710)	0.69		
Balance Outstanding, December 31, 2019	3,096,555	$ 7.89	9.19	$ 44,323
Exercisable, December 31, 2019	175,300	$ 3.54	8.88	$ 3,270
Vested and expected to vest, December 31, 2019	3,096,555	$ 7.89	9.19	$ 44,323

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

The weighted average grant-date fair value per share of stock options granted during the year ended December 31, 2019 was $8.34

Stock-based compensation

The Company recorded $1,770 in stock-based compensation expense for the year ended December 31, 2019, with $485 classified as research and development expense and $1,285 classified as general and administrative expense in the consolidated statements of operations and comprehensive loss. The Company recorded $121 in stock-based compensation expense for the year ended December 31, 2018 , with $41 classified as research and development expense

and $80 classified as general and administrative expense in the consolidated statements of operations and comprehensive loss.

As of December 31, 2019, total unrecognized compensation cost related to the unvested stock-based awards was $15,584, which is expected to be recognized over a weighted average period of 3.08 years.

In April, June and July 2019, certain option holders early exercised options to purchase 491,207 shares of common stock, at an average exercise price of $0.65 per share, for cash proceeds of $321 (See Note 7). Stock-based compensation expense related to these options will continue to be recognized over the requisite service period of the awards based on the grant-date fair value which was determined using the Black-Scholes option-pricing model.

9. Amgen license agreement

In June 2018, the Company entered into a license agreement (the "Amgen Agreement") with Amgen pursuant to which the Company was granted an exclusive license to certain patents and intellectual property related to a long-acting FGF21 analog in order to commercially develop, manufacture, use and distribute FGF21 as a treatment for NASH and other serious metabolic diseases. The Amgen Agreement provides the Company with exclusive global rights to the licensed products and the right to grant sublicenses that cover AKR-001 to third parties.

In exchange for these rights, the Company made in 2018 an upfront payment of $5,000 and issued 2,653,333 shares of Series A Preferred Stock with a fair value of $1,353 to Amgen. The total consideration transferred to Amgen under the agreement of $6,353 is included within research and development expense in the consolidated statements of operations and comprehensive loss for 2018. The Company accounted for the acquisition of technology as an asset acquisition because it did not meet the definition of a business. The Company recorded the total consideration transferred to Amgen as research and development expense in the consolidated statements of operations and comprehensive loss for 2018 because the acquired technology represented in-process research and development and had no alternative future use.

In addition, under the Amgen Agreement, Amgen was entitled to maintain a 10% ownership interest of the outstanding shares of the Company's common stock, on a fully diluted and converted basis, through the second closing of the Company's Series A Preferred Stock financing. The Company assessed the Amgen anti-dilution right and determined that the right (i) met the definition of a freestanding financial instrument that was not indexed to the Company's own stock and (ii) met the definition of a derivative and did not qualify for equity classification. The anti-dilution right liability was initially valued at $1,639 which the Company recorded as research and development expense in June 2018. Changes in the fair value of the anti-dilution right liability continued to be recognized until the Company satisfied the obligation which occurred in November 2018. The Company recognized expense of $5,765 within other expense in the consolidated statements of operations and comprehensive loss for the year ended December 31, 2018, related to the change in fair value of the anti-dilution right liability prior to its extinguishment in November 2018.

In November 2018, in connection with the second closing of the Company's Series A Preferred Stock financing, the Company issued 3,205,128 shares of Series A Preferred Stock to Amgen for a total value of $7,404 satisfying its anti-dilution obligation under the Amgen Agreement. At the time, the Company reclassified the carrying value of the anti-dilution right liability, equal to the then current fair value of $7,404, to the carrying value of the Series A Preferred Stock.

Under the Amgen Agreement, the Company made a milestone payment of $2,500 in connection with dosing the first patient in our Phase 2a clinical trial and is obligated to make aggregate remaining milestone payments to Amgen of up to $37,500 upon the achievement of specified clinical and regulatory milestones and aggregate milestone payments of up to $75,000 upon the achievement of specified commercial milestones for all products licensed under the agreement.

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Under the Amgen Agreement, the Company is obligated to pay Amgen tiered royalties ranging from a low to high single-digit percentages on annual net sales of the licensed products, beginning on the first commercial sale of such licensed products in each country and expiring on a country-by-country basis on the latest of (i) the expiration of the last valid patent claim covering such licensed products in such country, (ii) the loss of regulatory exclusivity in such country, and (iii) ten years after the first commercial sale of such licensed product in such country. The royalty payments are subject to reduction under specified conditions set forth in the agreement.

The Company is solely responsible for all development, manufacturing, and commercial activities and costs of the licensed products, including clinical studies or other tests necessary to support the use of a licensed product. The Company is also responsible for costs related to the filing, prosecution and maintenance of the licensed patent rights.

The Amgen Agreement will remain in effect until the expiration of the royalty term in all countries for all licensed products. The agreement may be terminated by either party with at least 90 days' notice in the event of material breach by the other party that remains uncured for 90 days, by either party for insolvency or bankruptcy of the other party and immediately by Amgen if the Company challenges the licensed patents. The Company may also terminate the agreement with 90 days' written notice for discretionary reasons such as scientific, technical, regulatory or commercial issues, as defined in the agreement.

During the year ended December 31, 2019, the Company recorded research and development expense of $2,500 related to the achievement of a clinical milestone, as specified in the agreement. During the year ended December 31, 2018, the Company recorded research and development expense of $8,016 in connection with the Amgen Agreement, including the upfront cash payment of $5,000, the fair value of $1,353 of shares of Series A Preferred Stock issued to Amgen, the fair value of $1,639 for the issuance of the anti-dilution right liability and $24 of other research and development expenses.

10. Income taxes

During the years ended December 31, 2019 and 2018, the Company recorded no income tax benefits for the net operating losses incurred or for the research and development tax credits generated in each period due to its uncertainty of realizing a benefit from those items. All of the Company’s operating losses since inception have been generated in the United States.

A summary of the Company’s current and deferred tax provision is as follows:

	Year ended December 31,	
	2019	2018
Current income tax provision:		
Federal	$ —	$ —
State	24	—
Total current income tax provision	24	—
Deferred income tax benefit:		
Federal	(9,400)	(4,199)
State	688	(1,239)
Total deferred income tax benefit	(8,712)	(5,438)
Change in deferred tax asset valuation allowance	(8,712)	(5,438)
Total provision for income taxes	$ 24	$ —

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The $24 provision for income taxes for the year ended December 31, 2019 is classified within general and administrative expense on the Consolidated Statements of Operations and Comprehensive Loss.

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,	
	2019	2018
Federal statutory income tax rate	21.0 %	21.0 %
State income taxes, net of federal benefit	(1.6)	1.5
Research and development tax credits	1.9	0.1
Change in preferred stock tranche obligation	-	(16.0)
Change in deferred tax asset valuation allowance	(19.9)	(6.6)
Effect of Section 382 limitation	(1.5)	-
Effective income tax rate	(0.1)%	0.0 %

Net deferred tax assets as of December 31, 2019 and 2018 consisted of the following:

	December 31,	
	2019	2018
Deferred tax assets		
Net operating loss carry forwards	$ 11,380	$ 2,899
Research and development tax credit carry forwards	969	231
License fees	3,232	3,669
Stock based compensation	196	—
Accruals, reserves and other	44	1
Total deferred tax assets	15,821	6,800
Deferred tax liabilities		
Prepaid expenses	(309)	—
Total deferred tax liabilities	(309)	—
Net deferred tax assets	15,512	6,800
Valuation allowance	(15,512)	(6,800)
Total net deferred tax assets	$ —	$ —

As of December 31, 2019, the Company had U.S. federal and state net operating loss carryforwards of $51,094 and $10,222, respectively, which may be available to offset future taxable income and begin to expire in 2037. The federal net operating loss carryforwards include $48,757, which may be carried forward indefinitely. As of December 31, 2019, the Company also had U.S. federal and state research and development tax credit carryforwards of $1,058 and $187, respectively, which may be available to offset future tax liabilities and begin to expire in 2032. During the year ended December 31, 2019, gross deferred tax assets, before valuation allowance, increased by $8,712, due primarily to the operating loss incurred by the Company during that period.

Utilization of the U.S. federal and state net operating loss carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, and corresponding provisions of state law, due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income or tax liabilities. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50% over a three-year period. The annual limitation is determined by multiplying the value of

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the Company's stock at the time of such ownership change by the applicable long-term tax-exempt rate. Such limitations may result in expiration of a portion of the NOL carryforwards before utilization. As of December 31, 2019, the Company determined that ownership changes occurred on March 24, 2017 and June 7, 2018. As a result of the ownership changes, approximately $2.2 million and $3.7 million of the NOLs will expire unutilized for federal and state purposes, respectively. The ability of the Company to use its remaining NOL carryforwards may be further limited if the Company experiences a Section 382 ownership change as a result of future changes in its stock ownership.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize its deferred tax assets at each reporting period. In doing so, the Company has considered its history of cumulative net losses incurred and its lack of commercialization of any products or generation of any revenue from product sales and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been recorded against the net deferred tax assets as of December 31, 2019 and 2018.

Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2019 and 2018 related primarily to increases in net operating loss carryforwards and research and development tax credit carryforwards, as follows:

	2019	2018
Valuation allowance as of January 1,	$ (6,800)	$ (1,362)
Increases recorded to income tax provision	—	—
Decreases recorded as a benefit to income tax provision	(8,712)	(5,438)
Valuation allowance as of December 31,	$ (15,512)	$ (6,800)

As of December 31, 2019, the Company had gross unrecognized tax benefits of $237 which were derived during the preceding twelve months, 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’s policy is to record interest and penalties related to income taxes as part of its income tax provision. As of December 31, 2019, the Company had not accrued interest or penalties related to uncertain tax positions and no amounts had been recognized in the Company’s consolidated statements of operations and comprehensive loss. For the year ended December 31, 2019, the Company will file income tax returns in the U.S., California, Connecticut, Massachusetts, Maryland, New York, and Pennsylvania, as prescribed by the tax laws of the jurisdictions in which it operates. The Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending tax examinations. The Company is open to future tax examination under statute from 2017 to the present.

A reconciliation of the beginning and ending unrecognized tax benefits for the year ended December 31, 2019 is as follows

	2019
Balance as of December 31, 2018	$ —
Increases related to prior year tax positions	—
Decreases related to prior year tax positions	—
Increases related to current year tax positions	237
Settlements	—
Lapse of statute of limitations	—
Balance as of December 31, 2019	$ 237

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11. Net loss per share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows:

	Year Ended December 31,	
	2019	2018
Numerator:		
Net loss	$ (43,755)	$ (81,714)
Accretion of redeemable convertible preferred stock to redemption value	—	(520)
Net loss attributable to common stockholders, basic and diluted	$ (43,755)	$ (82,234)
Denominator:		
Weighted average common shares outstanding, basic and diluted	15,070,728	103,403
Net loss per share attributable to common stockholders, basic and diluted	$ (2.90)	$ (795.28)

The Company excluded 49,568 shares and 125,790 shares of restricted common stock, presented on a weighted average basis, from the calculations of basic net loss per share attributable to common stockholders for the years ended December 31, 2019 and 2018, respectively, because those shares had not vested.

The Company's potentially dilutive securities, which include stock options, unvested restricted common stock and redeemable convertible preferred stock, have been excluded from the computation of diluted net loss per share attributable to common stockholders as the effect would be to reduce the net loss per share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Year Ended December 31,	
	2019	2018
Options to purchase common stock	3,096,555	1,839,913
Unvested restricted common stock	155,149	80,190
Redeemable convertible preferred stock (as converted to common stock)	—	21,056,136
	3,251,704	22,976,239

12. Commitments and contingencies

Lease agreements

The Company entered into a use and occupancy agreement for office space in Cambridge, Massachusetts on August 15, 2018, with Atlas Venture Life Science Advisors, LLC, a related party (See Note 13). The parties terminated the agreement in September 2019.

In October 2018, the Company entered into a lease agreement for office space in South San Francisco, California. In March 2019, the Company amended this lease agreement (the "First Amendment") to extend the term of the lease and expand the square footage of the existing leased office space. The First Amendment lease expires in March 2021. The Company provided a security deposit of $20, which is included as a component of other assets (non-current) on the Company's consolidated balance sheets as of December 31, 2019 and 2018.

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In September 2019 the Company entered into an agreement to use office space in Cambridge, Massachusetts. The agreement is for an initial six-month term with rolling six-month extensions.

The Company recognizes rent expense on a straight-line basis over the respective lease periods and has recorded rent expense of $305 and $12 for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, total future minimum commitments due ender our leases are $401, of which $321 is due in 2020 and $80 is due in 2021.

Research and manufacturing commitments

The Company has entered into agreements with contract research organizations and contract manufacturing organizations to provide services in connection with its nonclinical studies and clinical trials and to manufacture clinical development materials. As of December 31, 2019, the Company had non-cancelable purchase commitments under these agreements totaling $4,358.

Indemnification agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and its executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not currently aware of any indemnification claims and has not accrued any liabilities related to such obligations in its consolidated financial statements as of December 31, 2019 or 2018.

Legal proceedings

The Company is not a party to any litigation and does not have contingency reserves established for any litigation liabilities. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company intends to expense as incurred the costs related to such legal proceedings if they should arise.

13. Related party transactions

Apple Tree Life Sciences, Inc.

During 2018, the Company issued 8,000,000 shares of Series A Preferred Stock and 880,568 shares of Series B Preferred Stock to entities affiliated with Apple Tree Life Sciences, Inc. ("Apple Tree") and a principal of Apple Tree was elected to the board of directors. The Company's founders, including the current Executive Vice President and Chief Operating Officer and Chief Scientific Officer, were formerly employees of Apple Tree until April 2017. During the years ended December 31, 2019 and 2018, the Company incurred fees for certain general and administrative services from Apple Tree totaling $20 and $0, respectively. As of December 31, 2019 and 2018, the Company did not owe any amounts to Apple Tree.

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Atlas Venture Life Science Advisors, LLC

During 2018, the Company issued 10,666,667 shares of Series A Preferred Stock and 722,737 shares of Series B Preferred Stock to entities affiliated with Atlas Venture ("Atlas") and a principal of Atlas was elected to the board of directors.

During the years ended December 31, 2019 and 2018, the Company incurred fees for certain research and development consulting services from Atlas totaling $0 and $23, respectively. In August 2018, the Company entered into a use and occupancy agreement for office space in Cambridge, Massachusetts with Atlas (See Note 12). The parties terminated the agreement in September of 2019. During the years ended December 31, 2019 and 2018, the Company incurred fees under the use and occupancy agreement with Atlas totaling $22 and $8, respectively. As of December 31, 2019, the Company did not owe any amounts to Atlas. As of December 31, 2018, the Company owed $12 to Atlas, which was included in accounts payable on the Company's consolidated balance sheet.

Versant Venture Capital VI, L.P.

During 2018, the Company issued 10,666,667 shares of Series A Preferred Stock and 722,737 shares of Series B Preferred Stock to entities affiliated with Versant Venture Capital VI, L.P. ("Versant") and a principal of Versant at that time was elected to the board of directors. During the years ended December 31, 2019 and 2018, the Company incurred fees for certain general and administrative services from Versant totaling $0 and $4, respectively. As of December 31, 2019 and 2018, the Company did not owe any amounts to Versant.

venBio Global Strategic Fund II, L.P.

During 2018, the Company issued 10,666,667 shares of Series A Preferred Stock and 722,737 shares of Series B Preferred Stock to entities affiliated with venBio Global Strategic Fund II, L.P. ("venBio"). A principal of venBio served on the Company's board of directors from June 2018 to August 2019. During the years ended December 31, 2019 and 2018, the Company incurred fees for certain general and administrative services from venBio totaling $0 and $35, respectively. As of December 31, 2019, the Company did not owe any amounts to venBio. As of December 31, 2018, the Company owed $35 to venBio, which was included in accounts payable on the Company's consolidated balance sheet.

14. Benefit plans

The Company established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan covers 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. Matching contributions to the plan may be made at the discretion of the Company's board of directors. The Company did not make any matching contributions to the plan during the years ended December 31, 2019 and 2018, respectively.

15. Subsequent events

The Company evaluated subsequent events through March 16, 2020, the date on which these financial statements were issued.

On February 14, 2020, the Company entered into a seven-year lease agreement for 6,647 square feet of office space in South San Francisco, California. Under the agreement, the Company is required to make $2.3 million in minimum payments during the lease term. The Company anticipates that it will begin occupancy and commence the lease on or about June 1, 2020.

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

The Company has established disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) designed to ensure that information required to be disclosed in the reports that the Company files or submits under the Securities Exchange Act of 1934, as amended, or Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and is accumulated and communicated to management, including the principal executive officer (our Chief Executive Officer) and principal financial officer (our Chief Financial Officer), to allow timely decisions regarding required disclosure. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of December 31, 2019. Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2019.

Remediation of Prior Material Weakness

A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal control over financial reporting such that it is reasonable possible that a material misstatement of the annual or interim consolidated financial statements will not be prevented or detected on a timely basis. We previously identified and disclosed in our Registration Statement on Form S-1 filed with the SEC on May 24, 2019, as well in our quarterly reports for June 30, 2019 and September 30, 2019, a material weakness related to a lack of segregation of duties associated with the design of our internal controls.

During 2019, we implemented the following changes to our process to improve our internal controls over financial reporting with respect to the segregation of duties as follows:

- We added finance personnel to the organization which has facilitated the proper segregation of duties in the initiation of transactions, the recording of transactions, and the custody of assets. These personnel include a Chief Financial Officer, a Controller and a Director of Financial Planning and Accounting;
- We implemented an accounting software system with the design and functionality to segregate incompatible accounting duties; and
- We engaged a 3rd party to assess and document the design of our internal controls over financial reporting including the evaluation of proper segregation of duties, and to identify and evaluate any weaknesses in our information systems

These actions resulted in an improved internal control environment with enhanced segregation of duties that were in place for a period of time to allow for our management to conclude, based on evidence obtained in validating the design and implementation of these controls, that we have fully remediated this material weakness as of as of December 31, 2019.

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 our internal control over financial reporting or an attestation report of our independent registered accounting firm due to a transition period established by rules of the SEC for newly public companies. Additionally, our independent registered accounting firm will not be required to opine on the effectiveness of our internal control over financial reporting pursuant to Section 404 until we are no longer an "emerging growth company" as defined in the JOBS Act.

Changes in Internal Control over Financial Reporting

We have described the changes that have had or are likely to have a material impact on internal control over financial reporting in the above discussion “Remediation of Prior Material Weakness.”

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Except as set forth below, the information required by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2020 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2019.

We have adopted a Code of Business Conduct and Ethics that applies to all of our directors, officers and employees, including our principal executive officer and principal financial officer. The Code of Business Conduct and Ethics is posted on our website at https://ir.akerotx.com/corporate-governance/governance-overview.

We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of this Code of Business Conduct and Ethics by posting such information on our website, at the address and location specified above and, to the extent required by the listing standards of The NASDAQ Global Select Stock Market, by filing a Current Report on Form 8-K with the SEC, disclosing such information.

Item 11. Executive Compensation.

The information called for by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2020 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2019.

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

The information called for by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2020 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2019.

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

The information called for by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2020 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2019.

Item 14. Principal Accounting Fees and Services

The information called for by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2020 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2019.

Part IV

Item 15. Exhibits, Financial Statement Schedules

(a) The following documents are filed as part of this Annual Report on Form 10-K:

1) The consolidated financial statements filed as part of this Annual Report on Form 10-K are listed in the "Index to Consolidated Financial Statements" under Part II, Item 8 of this Annual Report on Form 10-K.

2) No schedules are submitted because they are not applicable, not required or because information is included in the consolidated financial statements or the notes thereto.

3) The exhibits required by Item 601 of Regulation S-K and Item 15(b) of this Annual Report on Form 10-K are listed in the Exhibit Index immediately preceding the signature page of this Annual Report on Form 10-K. The exhibits listed in the Exhibit Index are incorporated by reference herein.

Item 16. Form 10-K Summary

The Company has elected not to include summary information.

Item 6. Exhibits.

EXHIBIT INDEX

Exhibit Number	Exhibit Description
3.1	Fourth Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K (File No. 001-38944) filed on June 24, 2019)
3.2	Second Amended and Restated Bylaws of the Registrant and the amendments thereto, as currently in effect (incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K (File No. 001-38944) filed on June 24, 2019)
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form S-1/A (File No. 333-231747) filed on June 10, 2019)
4.2	Amended and Restated Investors' Rights Agreement among the Registrant and certain of its stockholders, dated December 5, 2018 (incorporated by reference to Exhibit 4.2 of the Registrant's Registration Statement on Form S-1 (File No. 333-231747) filed on May 24, 2019).
4.3*	Description of Securities
10.1#	2018 Stock Option and Grant Plan, as amended, and form of award agreements thereunder (incorporated by reference to Exhibit 10.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-231747) filed on May 24, 2019)
10.2#	2019 Stock Option and Grant Plan, and form of award agreements thereunder. (incorporated by reference to Exhibit 10.2 of the Registrant's Registration Statement on Form S-1/A (File No. 333-231747) filed on June 10, 2019)
10.3#	2019 Employee Stock Purchase Plan. (incorporated by reference to Exhibit 10.3 of the Registrant's Registration Statement on Form S-1/A (File No. 333-231747) filed on June 10, 2019)
10.4#	2019 Senior Executive Cash Bonus Plan (incorporated by reference to Exhibit 10.5 of the Registrant's Registration Statement on Form S-1 (File No. 333-231747) filed on May 24, 2019)
10.5#	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers (incorporated by reference to Exhibit 10.4 of the Registrant's Registration Statement on Form S-1 (File No. 333-231747) filed on May 24, 2019)
10.6#	Form of Amended and Restated Employment Agreement for Executive Officers (incorporated by reference to Exhibit 10.8 of the Registrant's Registration Statement on Form S-1/A (File No. 333-231747) filed June 10, 2019)
10.7#	Amended and Restated Employment Agreement for Andrew Cheng (incorporated by reference to Exhibit 10.9 of the Registrant's Registration Statement on Form S-1/A (File No. 333-231747) filed June 10, 2019)
10.8#	Amended and Restated Employment Agreement for William White (incorporated by reference to Exhibit 10.10 of the Registrant's Registration Statement on Form S-1/A (File No. 333-231747) filed on June 10, 2019)

Exhibit Number	Exhibit Description
10.9 **	Exclusive License Agreement, by and between the Registrant and Amgen Inc., dated June 7, 2018 (incorporated by reference to Exhibit 10.9 of the Registrant's Registration Statement on Form S-1 (File No. 333-231747) filed on May 24, 2019)
10.10	Sublease Agreement between the Registrant and Trucode Gene Repair, Inc., dated October 23, 2018, as amended by the First Amendment to Sublease Agreement, dated as of February 27, 2019 and the First Amendment to Consent to Sublease Agreement dated as of March 12, 2019 (incorporated by reference to Exhibit 10.7 of the Registrant's Registration Statement on Form S-1 (File No. 333-231747) filed on May 24, 2019)
10.11*	Amended and Restated Non-Employee Director Compensation Policy
10.12*	Office Lease between Gateway Center LP and the Registrant, dated as of February 14, 2020
21.1*	List of Subsidiaries of the Registrant
23.1*	Consent of Deloitte & Touche LLP, independent registered public accounting firm
24.1*	Power of Attorney (included on the signatures pages hereto)
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 amended
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 amended
32.1+	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.

Indicates a management contract or any compensatory plan, contract or arrangement.
* Filed herewith.
** Confidential treatment has been granted by the Securities and Exchange Commission as to certain portions.
+ The certifications furnished in Exhibit 32.1 hereto are deemed to be furnished with this Annual Report on Form 10-K and will not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

SIGNATURES

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

Date: March 16, 2020

AKERO THERAPEUTICS, INC.
By: /s/ ANDREW CHENG
Andrew Cheng, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Andrew Cheng, Jonathan Young, and William White, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file 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 attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed by the following persons in the capacities indicated below and on the dates indicated:

Signature	Title	Date
/s/ ANDREW CHENG Andrew Cheng, M.D., Ph.D.	Chief Executive Officer, President and Director (Principal Executive Officer)	March 16, 2020
/s/ WILLIAM WHITE William White	Executive Vice President, Chief Financial Officer and Head of Corporate Development (Principal Financial and Accounting Officer)	March 16, 2020
/s/ KEVIN BITTERMAN Kevin Bitterman, Ph.D.	Director	March 16, 2020
/s/ SETH L. HARRISON Seth L. Harrison, M.D.	Director	March 16, 2020
/s/ JANE P. HENDERSON Jane P. Henderson	Director	March 16, 2020
/s/ MARK IWICKI Mark Iwicki	Director	March 16, 2020
/s/ GRAHAM WALMSLEY Graham Walmsley, M.D., Ph.D	Director	March 16, 2020

Exhibit 4.3

Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934, as amended+

The summary of the general terms and provisions of the registered securities of Akero Therapeutics, Inc.("Akero," "we," or "our") set forth below does not purport to be complete and is subject to and qualified in its entirety by reference to our Fourth Amended and Restated Certificate of Incorporation (our "certificate of incorporation") and our Second Amended and Restated By-laws (our "by-laws" and, together with our certificate of incorporation, our "Charter Documents"), each of which is incorporated by reference as an exhibit to our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission. We encourage you to read our Charter Documents and the applicable provisions of the General Corporation Law of the State of Delaware (the "DGCL") for additional information.

General

Our authorized capital stock consists of One Hundred Fifty Million (150,000,000) shares of common stock, par value $0.0001 per share and Ten Million (10,000,000) shares of undesignated preferred stock, par value $0.0001 per share.

Common stock

The holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights. Holders of our common stock are entitled to receive ratably any dividends declared by our board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding convertible preferred stock. Our common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions.

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding convertible preferred stock.

Our common stock is listed on the Nasdaq Global Select Market under the trading symbol "AKRO."

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A.

Preferred stock

Our board of directors will have 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. No shares of convertible preferred stock are outstanding, and we have no present plan to issue any shares of convertible preferred stock.

Registration rights

Certain holders of our common stock are entitled to rights with respect to the registration of these securities under the Securities Act. These rights are provided under the terms of an amended and restated investors' rights agreement between us and holders of our convertible preferred stock. The amended and restated investors' rights agreement includes demand registration rights, short-form registration rights and piggyback registration rights. All fees, costs and expenses of underwritten registrations under this agreement will be borne by us and all selling expenses, including underwriting discounts and selling commissions, will be borne by the holders of the shares being registered.

Demand registration rights

Certain holders of our common stock are entitled to demand registration rights. Under the terms of the amended and restated investors' rights agreement, we will be required, upon the written request of a majority of the holders of convertible preferred stock, to file a registration statement and use best efforts to effect the registration of all or a portion of these shares for public resale at an aggregate price of at least $10.0 million. We are required to effect only one registration pursuant to this provision of the amended and restated investors' rights agreement.

Short-Form registration rights

Pursuant to the amended and restated investors' rights agreement, if we are eligible to file a registration statement on Form S-3, upon the written request of at least 20% of these holders to sell registrable securities at an aggregate price of at least $5.0 million, we will be required to use commercially reasonable efforts to effect a registration of such shares. We are required to effect only one registration in any twelve-month period pursuant to this provision of the investors' rights agreement. The right to have such shares registered on Form S-3 is further subject to other specified conditions and limitations.

Piggyback registration rights

Pursuant to the amended and restated investors' rights agreement, if we register any of our securities either for our own account or for the account of other security holders, the holders of these shares are entitled to include their shares in the registration. Subject to certain exceptions contained in the amended and restated investors' rights agreement, we and the underwriters may terminate or withdraw any registration initiated before the effective date of such registration in our sole discretion.

Indemnification

Our amended and restated investors' rights agreement contains customary cross-indemnification provisions, under which we are obligated to indemnify holders of registrable securities in the event of material misstatements or omissions in the registration statement attributable to us, and they are obligated to indemnify us for material misstatements or omissions attributable to them.

Expiration of registration rights

The demand registration rights and short form registration rights granted under the investors' rights agreement will terminate on the third anniversary of the completion of our initial public offering or at such time after this offering when the holders' shares may be sold without restriction pursuant to Rule 144 within a three-month period.

Anti-Takeover effects of our certificate of incorporation and bylaws and Delaware law

Our certificate of incorporation and bylaws include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Board composition and filling vacancies

Our certificate of incorporation provides for the division of our board of directors into three classes serving staggered three-year terms, with one class being elected each year. Our certificate of incorporation also provides that directors may be removed only for cause and then only by the affirmative vote of the holders of two-thirds or more of the shares then entitled to vote at an election of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum. The classification of directors, together with the limitations on removal of directors and treatment of vacancies, has the effect of making it more difficult for stockholders to change the composition of our board of directors.

No written consent of stockholders

Our certificate of incorporation provides that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our bylaws or removal of directors by our stockholders without holding a meeting of stockholders.

Meetings of stockholders

Our certificate of incorporation and bylaws provide that only a majority of the members of our board of directors then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance notice requirements

Our bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our bylaws specify the requirements as to form and content of all stockholders' notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

Amendment to certificate of incorporation and bylaws

Any amendment of our certificate of incorporation must first be approved by a majority of our board of directors, and if required by law or our certificate of incorporation, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to stockholder action, board composition, limitation of liability and certificate of incorporation must be approved by not less than two-thirds of the outstanding shares entitled to vote on the amendment, and not less than two-thirds of the outstanding shares of each class entitled to vote thereon as a class. Our bylaws may be amended by the affirmative vote of a majority of the directors then in office, subject to any limitations set forth in the bylaws; and may also be amended by the affirmative vote of a majority of the outstanding shares entitled to vote on the amendment.

Undesignated preferred stock

Our certificate of incorporation provides for 10,000,000 authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our certificate of incorporation grants our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Choice of forum

Our bylaws provide that, unless we consent in writing to the selection of an alternative form, the Court of Chancery of the State of Delaware (or, if the Chancery Court does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) will be the sole and exclusive forum for state law claims for (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders; (3) any action asserting a claim against us, or any current or former director, officer, or other employee or stockholder, arising out of or pursuant to any provision of the General Corporation Law of the State of Delaware or our certificate of incorporation or bylaws;

and (4) any action asserting a claim against us or any current or former director or officer or other employee governed by the internal affairs doctrine. The choice of forum provision does not apply to any causes of action arising under the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Our bylaws also provides that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to this choice of forum provision. It is possible that a court of law could rule that the choice of forum provision contained in our bylaws is inapplicable or unenforceable if it is challenged in a proceeding or otherwise. Additionally, the forum selection clause in our second amended and restated bylaws may limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Section 203 of the Delaware general corporation law

Upon completion of this offering, we will be subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or
- at or after the time the stockholder became interested, the business combination was approved by our board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, lease, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
  subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Exhibit 10.11

AKERO THERAPEUTICS, INC.

AMENDED AND RESTATED

NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

The purpose of this Amended and Restated Non-Employee Director Compensation Policy of Akero Therapeutics, Inc. (the "Company"), is to provide a total compensation package that enables the Company to attract and retain, on a long-term basis, high-caliber directors who are not employees or officers of the Company or its subsidiaries.

In furtherance of the purpose stated above, the Company shall pay cash retainers to the members of its Board of Directors (the "Board") and the committees thereof as set forth below, such retainers to be (i) paid for the directors' general availability and participation in meetings and conference calls, (ii) paid quarterly in arrears and (iii) pro-rated based on the number of actual days served by the director on the Board or applicable committee during such calendar quarter or year.

Cash Retainers

Annual Retainer for Board Membership:	$40,000
Annual Retainer for Non-Executive Chair of the Board:	$70,000
Annual Committee Chair Compensation:	
Audit Committee Chair:	$15,000
Compensation Committee Chair:	$10,000
Nominating and Corporate Governance Committee Chair:	$8,000
Annual Committee Member Compensation:	
Audit Committee member:	$7,500
Compensation Committee member:	$5,000
Nominating and Corporate Governance Committee member:	$4,000

Note: Chair and committee member retainers are in addition to retainers for members of the Board of Directors.

Each non-employee director may elect to receive all or a portion of her or his cash compensation in the form of unrestricted shares having a grant date fair value equal to the amount (or portion thereof) of such compensation. Any such election (i) shall be made (x) for any continuing non-employee director, before the start of the calendar year with respect to any cash compensation for such calendar year and (y) for any new non-employee director, within 30 days of her or his election to the Board, (ii) shall be irrevocable with respect to such calendar year and (iii) shall

automatically apply to the cash compensation for each subsequent calendar year unless otherwise revoked prior to the start of such calendar year.

Equity Retainers

Initial Award: An initial, one-time stock option award (the "Initial Award") of 26,000 shares will be granted to each new non-employee director upon his or her election to the Board of Directors, which shall vest in equal monthly installments over three years, provided, however, that all vesting shall cease if the director resigns from the Board of Directors or otherwise ceases to serve as a director of the Company. The Initial Award shall expire ten years from the date of grant, and shall have a per share exercise price equal to the Fair Market Value (as defined in the Company's 2019 Stock Option and Incentive Plan) of the Company's common stock on the date of grant. This Initial Award applies only to non-employee directors who are first elected to the Board of Directors subsequent to the Company's initial public offering.

Annual Award: On each date of the Company's Annual Meeting of Stockholders following the completion of the Company's initial public offering (the "Annual Meeting"), each continuing non-employee member of the Board of Directors, other than a director receiving an Initial Award, will receive an annual stock option award (the "Annual Award") of 13,000 shares, which shall vest in full upon the earlier to occur of the first anniversary of the date of grant or the date of the next Annual Meeting; provided, however, that all vesting shall cease if the director resigns from the Board of Directors or otherwise ceases to serve as a director, unless the Board of Directors determines that the circumstances warrant continuation of vesting. Such Annual Award shall expire ten years from the date of grant, and shall have a per share exercise price equal to the Fair Market Value (as defined in the Company's 2019 Stock Option and Incentive Plan) of the Company's common stock on the date of grant.

Expenses

The Company will reimburse all reasonable out-of-pocket expenses incurred by non-employee directors in attending meetings of the Board or any Committee.

Adopted May 3, 2019; effective as of June 19, 2019.

As amended on November 8, 2019.

601 GATEWAY BOULEVARD

OFFICE LEASE

This Office Lease (the "**Lease**"), dated as of the date set forth in Section 1 of the Summary of Basic Lease Information (the "**Summary**"), below, is made by and between 601 & 651 GATEWAY CENTER LP, a Delaware limited partnership ("**Landlord**"), and AKERO THERAPEUTICS, INC., a Delaware corporation ("**Tenant**").

SUMMARY OF BASIC LEASE INFORMATION

TERMS OF LEASE		DESCRIPTION
1. Date:		February 14, 2020.
2. Premises (Article 1).		
2.1	Building:	601 Gateway Boulevard, South San Francisco, California, containing 215,832 rentable square feet of space.
2.2	Premises:	6,647 rentable square feet of space located on the third (3rd) floor of the Building and commonly known as Suite 350, as further set forth in **Exhibit A** to the Office Lease.
3. Lease Term (Article 2).		
3.1	Lease Term:	Seven (7) years.
3.2	Lease Commencement Date:	The earlier to occur of (i) the date upon which Tenant first commences to conduct business in the Premises, and (ii) the date upon which the Premises are Ready for Occupancy, which Lease Commencement Date is anticipated to be June 1, 2020.
3.3	Lease Expiration Date:	If the Lease Commencement Date shall be the first day of a calendar month, then the day immediately preceding the seventh (7th) anniversary of the Lease Commencement Date; or if the Lease Commencement Date shall be other than the first day of a calendar month, then the last day of the month in which

the seventh (7th) anniversary of the Lease Commencement Date occurs.

4. Base Rent (Article 3):

Period During Lease Term	Annual Base Rent	Monthly Installment of Base Rent	Monthly Base Rental Rate Per Rentable Square Foot
Lease Year 1*	$ 299,115.00	$ 24,926.25	$ 3.75
Lease Year 2	$ 308,088.48	$ 25,674.04	$ 3.86
Lease Year 3	$ 317,331.12	$ 26,444.26	$ 3.98
Lease Year 4	$ 326,851.08	$ 27,237.59	$ 4.10
Lease Year 5	$ 336,656.52	$ 28,054.71	$ 4.22
Lease Year 6	$ 346,756.32	$ 28,896.36	$ 4.35
Lease Year 7	$ 357,159.00	$ 29,763.25	$ 4.48

*Notwithstanding the foregoing Base Rent schedule or any contrary provision of this Lease, but subject to the terms of Section 3.2, below, Tenant shall not be obligated to pay Base Rent with respect to the Premises during the first (1st) full calendar month of the Lease Term.

5. Base Year (Article 4): Calendar year 2020.

6. Tenant's Share (Article 4): 3.0797%.

7. Permitted Use (Article 5): General office use.

8. Letter of Credit (Article 21): $107,953.86

9. Address of Tenant (Article 28):

Akero Therapeutics, Inc.
170 Harbor Way, 3rd Floor
South San Francisco, CA 94080
Attention: Controller
(Prior to Lease Commencement Date)
and

		Akero Therapeutics, Inc. The Premises Attention: Controller (After Lease Commencement Date)
10.	Address of Landlord (Article 28):	See Article 28 of the Lease.
11.	Broker(s) (Section 29.24):	Landlord: Cushman & Wakefield Tenant: CBRE
12.	Tenant Improvement Allowance (**Exhibit B**):	None. Landlord shall construct the Tenant Improvements pursuant to the terms of the Tenant Work Letter, attached to this Lease as **Exhibit B**.

ARTICLE 1

PREMISES, BUILDING, PROJECT, AND COMMON AREAS

1.1 **Premises, Building, Project and Common Areas**.

1.1.1 **The Premises**. Landlord hereby leases to Tenant and Tenant hereby leases from Landlord the premises set forth in Section 2.2 of the Summary (the "Premises"). The outline of the Premises is set forth in **Exhibit A** attached hereto and each floor or floors of the Premises has the number of rentable square feet as set forth in Section 2.2 of the Summary. The parties hereto agree that the lease of the Premises is upon and subject to the terms, covenants and conditions herein set forth, and Tenant covenants as a material part of the consideration for this Lease to keep and perform each and all of such terms, covenants and conditions by it to be kept and performed and that this Lease is made upon the condition of such performance. The parties hereto hereby acknowledge that the purpose of **Exhibit A** is to show the approximate location of the Premises in the "Building," as that term is defined in Section 1.1.2, below, only, and such Exhibit is not meant to constitute an agreement, representation or warranty as to the construction of the Premises, the precise area thereof or the specific location of the "Common Areas," as that term is defined in Section 1.1.3, below, or the elements thereof or of the accessways to the Premises or the "Project," as that term is defined in Section 1.1.2, below. Except as specifically set forth in this Lease and in the Tenant Work Letter attached hereto as **Exhibit B** (the "**Tenant Work Letter**"), Tenant shall accept the Premises in its presently existing "as-is" condition and Landlord shall not be obligated to provide or pay for any improvement work or services related to the improvement of the Premises. Tenant also acknowledges that neither Landlord nor any agent of Landlord has made any representation or warranty regarding the condition of the Premises, the Building or the Project or with respect to the suitability of any of the foregoing for the conduct of Tenant's business, except as specifically set forth in this Lease and the Tenant Work Letter. Notwithstanding anything in this Lease to the contrary, Landlord shall deliver possession of the Premises to Tenant in good, vacant, broom clean condition, with all Building Systems serving the Premises in good working order, and otherwise in substantially the same condition as of the date hereof, except with all the Tenant Improvements constructed in accordance with the Tenant Work Letter. If it is determined that any portion of the Building Systems serving the Premises were not in good working order on the delivery date, then Landlord shall not be liable to Tenant for any damages, but as Tenant's sole remedy, Landlord, at no cost to Tenant (and not as an Operating Expense), shall promptly commence such work or take such other action as may be necessary to place the same in good working order, and shall thereafter diligently pursue the same to completion.

1.1.2 **The Building and The Project**. The Premises are a part of the building set forth in Section 2.1 of the Summary (the "**Building**"). The Building is part of an office project known as "Gateway Center." The term "**Project,**" as used in this Lease, shall mean (i) the Building and the Common Areas, (ii) the land (which is improved with landscaping, subterranean parking facilities and other improvements) upon which the Building and the Common Areas are located, (iii) those certain other office buildings located in the vicinity of the Building and known as 611 and 651 Gateway Boulevard**,** respectively, and the land upon which such office buildings are located, and (iv) at Landlord's discretion, any additional real property, areas, land, buildings or other improvements added thereto outside of the Project.

1.1.3 **Common Areas**. Tenant shall have the non-exclusive right to use in common with other tenants in the Project, and subject to the rules and regulations referred to in Article 5 of this Lease, those portions of the Project which are provided, from time to time, for use in common by Landlord, Tenant and any other tenants of the Project (such areas are collectively referred to herein as the "**Common Areas**")**.** The Common Areas shall consist of the "Project Common Areas" and the "Building Common Areas." The term "**Project Common Areas**," as used in this Lease, shall mean the portion of the Project designated as such by Landlord, which Project Common Areas may include, from time to time, in Landlord's sole discretion, a conference center and other amenities. The term "**Building Common Areas**," as used in this Lease, shall mean the portions of the Common Areas located within the Building designated as such by Landlord. The manner in which the Common Areas are maintained and operated shall be at the sole discretion of Landlord and the use thereof shall be subject to such rules, regulations and restrictions as Landlord may make from time to time. Provided the same do not unreasonably interfere with Tenant's use of or access to the Premises or materially increase the obligations or decrease the rights of Tenant under this Lease, Landlord reserves the right to close temporarily, make alterations or additions to, or change the location of elements of the Project and the Common Areas.

1.2 **Rentable Square Feet of Premises and Building**. For purposes of this Lease, "**rentable square feet**" in the Premises and the Building, as the case may be, shall be calculated pursuant to Landlord's then current method for measuring rentable square footage. Landlord and Tenant hereby stipulate and agree that the rentable area of the Premises is as set forth in Section 2.2 of the Summary and the rentable square feet of the Building is as set forth in Section 2.1 of the Summary.

ARTICLE 2

LEASE TERM

The terms and provisions of this Lease shall be effective as of the date of this Lease. The term of this Lease (the "**Lease Term**") shall commence on the "**Lease Commencement Date**," as that term is set forth in Section 3.2 of the Summary, and shall terminate on the "**Lease Expiration Date**," as that term is set forth in Section 3.3 of the Summary, unless this Lease is sooner terminated as hereinafter provided. For purposes of this Lease, the term "**Lease Year**" shall mean each consecutive twelve (12) month period during the Lease Term; provided that the first Lease Year shall include any partial month at the commencement of the Lease Term. At any time during the Lease Term, Landlord may deliver to Tenant a notice in the form as set forth in **Exhibit C**, attached hereto, as a confirmation only of the information set forth therein, which Tenant shall execute and return to Landlord within ten (10) days of receipt thereof; provided, however, Tenant's failure to execute and return such notice to Landlord within such time shall be conclusive upon Tenant that the information set forth in such notice is as specified therein.

ARTICLE 3

BASE RENT

3.1 **Base Rent**. Commencing on the Lease Commencement Date, Tenant shall pay, without prior notice or demand, base rent ("**Base Rent**") as set forth in Section 4 of the Summary, payable in equal monthly installments as set forth in Section 4 of the Summary in advance on or before the first day of each and every calendar month during the Lease Term, without any setoff or deduction whatsoever. The Base Rent for the first full month of the Lease Term which occurs after the expiration of any free rent period shall be paid at the time of Tenant's execution of this Lease. If any Rent payment date (including the Lease Commencement Date) falls on a day of the month other than the first day of such month or if any payment of Rent is for a period which is shorter than one month, the Rent for any fractional month shall accrue on a daily basis for the period from the date such payment is due to the end of such calendar month or to the end of the Lease Term at a rate per day which is equal to 1/365 of the applicable annual Rent. All other payments or adjustments required to be made under the terms of this Lease that require proration on a time basis shall be prorated on the same basis. Until notice of some other designation is given to Tenant in accordance with the provisions of Article 28 of this Lease, Base Rent and all other charges shall be paid by remittance to or for the order of 601 & 651 Gateway Center LP by one of the following methods:

(i) **By ACH Transfer & Direct Deposit**.

Bank of America
345 Montgomery Street, Concourse Level #1499
San Francisco, California 94101
ABA# 121-000-358
Account: Boston Properties L.P. Operating Account
Account Number: 14993-06215
Amount: [fill in appropriate dollar amount]
Reference: [fill in Tenant Name and Tenant Number]

or

(ii) **By Mail**.

601 & 651 Gateway Center LP
P.O. Box 742841
Los Angeles, California 90074-2841

or

(iii) **By Overnight Delivery**.

Bank of America Lock Box Services
Lockbox LAC-742841
2706 Media Center Drive
Los Angeles, California 90065.

3.2 **Abated Base Rent**. Provided that Tenant is not then in default of this Lease beyond and applicable notice and cure period expressly set forth in this Lease, then during the first (1st) full calendar month of the Lease Term (the "**Rent Abatement Period**"), Tenant shall not be obligated to pay any Base Rent otherwise attributable to the Premises during such Rent Abatement Period (the "**Rent Abatement**"). Landlord and Tenant acknowledge that the aggregate amount of the Rent Abatement equals $24,926.25. Tenant acknowledges and agrees that the foregoing Rent Abatement has been granted to Tenant as additional consideration for entering into this Lease, and for agreeing to pay the rental and performing the terms and conditions otherwise required under this Lease. If Tenant shall be in default under this Lease, and shall fail to cure such default within the notice and cure period, if any, permitted for cure pursuant to terms and conditions of the Lease, or if this Lease is terminated for any reason other than Landlord's breach of this Lease, then the dollar amount of the unapplied portion of the Rent Abatement as of the date of such default or termination, as the case may be, shall be converted to a credit to be applied to the Base Rent applicable at the end of the Lease Term and Tenant shall immediately be obligated to begin paying Base Rent for the Premises in full.

ARTICLE 4

ADDITIONAL RENT

4.1 **General Terms**. In addition to paying the Base Rent specified in Article 3 of this Lease, Tenant shall pay (i) "Tenant's Share" of the annual "Building Direct Expenses," as those terms are defined in Sections 4.2.10 and 4.2.2 of this Lease, respectively, which are in excess of the amount of Building Direct Expenses applicable to the "Base Year," as that term is defined in Section 4.2.1 of this Lease, and (ii) Tenant's Share of "Capital Expenses," as that term is defined in Section 4.2.9, below, pursuant to Section 4.6 of this Lease; provided, however, that in no event shall any decrease in Building Direct Expenses for any "Expense Year," as that term is defined in Section 4.2.6 of this Lease, below Building Direct Expenses for the Base Year entitle Tenant to any decrease in Base Rent or any credit against sums due under this Lease. Such payments by Tenant, together with any and all other amounts payable by Tenant to Landlord pursuant to the terms of this Lease, are hereinafter collectively referred to as the "**Additional Rent**," and the Base Rent and the Additional Rent are herein collectively referred to as "**Rent.**" All amounts due under this Article 4 as Additional Rent shall be payable for the same periods and in the same manner as the Base Rent. Without limitation on other obligations of Tenant which survive the expiration of the Lease Term, the obligations of Tenant to pay the Additional Rent provided for in this Article 4 shall survive the expiration of the Lease Term. Landlord may upon expiration of the Lease Term deliver to Tenant an estimate of any Base Rent, Additional Rent or other obligations outstanding, and Landlord may either deduct such amount from any funds otherwise payable to Tenant upon expiration or require Tenant to pay such funds immediately. Landlord shall make necessary adjustments for differences between actual and estimated Additional Rent in accordance with Section 4.4, below.

4.2 **Definitions of Key Terms Relating to Additional Rent**. As used in this Article 4, the following terms shall have the meanings hereinafter set forth:

4.2.1 "**Base Year**" shall mean the period set forth in Section 5 of the Summary.

4.2.2 "**Building Direct Expenses**" shall mean "Building Operating Expenses" and "Building Tax Expenses", as those terms are defined in Sections 4.2.3 and 4.2.4, below, respectively.

4.2.3 "**Building Operating Expenses**" shall mean the portion of "Operating Expenses," as that term is defined in Section 4.2.7 below, allocated to the tenants of the Building pursuant to the terms of Section 4.3.1 below.

4.2.4 "**Building Tax Expenses**" shall mean that portion of "Tax Expenses", as that term is defined in Section 4.2.8 below, allocated to the tenants of the Building pursuant to the terms of Section 4.3.1 below.

4.2.5 "**Direct Expenses**" shall mean "Operating Expenses" and "Tax Expenses."

4.2.6 "**Expense Year**" shall mean each calendar year in which any portion of the Lease Term falls, through and including the calendar year in which the Lease Term expires, provided that Landlord, upon notice to Tenant, may change the Expense Year from time to time to any other twelve (12) consecutive month period, and, in the event of any such change, Tenant's Share of Building Direct Expenses and Capital Expenses shall be equitably adjusted for any Expense Year involved in any such change.

4.2.7 "**Operating Expenses**" shall mean all expenses, costs and amounts of every kind and nature which Landlord pays or accrues during any Expense Year because of or in connection with the ownership, management, maintenance, security, repair, replacement, restoration or operation of the Project, or any portion thereof. Without limiting the generality of the foregoing, Operating Expenses shall specifically include any and all of the following: (i) the cost of supplying all utilities, the cost of operating, maintaining, repairing, replacing, renovating and managing the utility systems, mechanical systems, sanitary, storm drainage systems, communication systems and escalator and elevator systems, and the cost of supplies, tools, and equipment and maintenance and service contracts in connection therewith; (ii) the cost of licenses, certificates, permits and inspections and the cost of contesting any governmental enactments which may affect Operating Expenses, and the costs incurred in connection with a government mandated transportation system management program or similar program; (iii) the cost of all insurance carried by Landlord in connection with the Project as reasonably determined by Landlord (including, without limitation, commercial general liability insurance, physical damage insurance covering damage or other loss caused by fire, earthquake, flood and other water damage, explosion, vandalism and malicious mischief, theft or other casualty, rental interruption insurance and such insurance as may be required by any lessor under any present or future ground or underlying lease of the Building or Project or any holder of a mortgage, trust deed or other encumbrance now or hereafter in force against the Building or Project or any portion thereof); (iv) the cost of landscaping, decorative lighting, and relamping, the cost of maintaining fountains, sculptures, bridges and all supplies, tools, equipment and materials used in the operation, repair and maintenance of the Project, or any portion thereof; (v) the cost of parking area repair, restoration, and maintenance, including, without limitation, resurfacing, repainting, restriping and cleaning; (vi) fees, charges and other costs, including management fees (or amounts in lieu thereof), consulting fees (including, without limitation, any consulting fees incurred in connection with the

procurement of insurance), legal fees and accounting fees, of all contractors, engineers, consultants and all other persons engaged by Landlord or otherwise incurred by or charged by Landlord in connection with the management, operation, administration, maintenance and repair of the Building and the Project; (vii) payments under any equipment rental agreements or management agreements (including the cost of any actual or charged management fee and the actual or charged rental of any management office space); (viii) wages, salaries and other compensation and benefits, including taxes levied thereon, of all persons engaged in the operation, maintenance and security of the Project (other than a person generally considered to be higher in rank than the position of a person, regardless of title, who supervises property managers that manage the Project and other projects of Landlord and affiliates of Landlord); (ix) costs under any instrument pertaining to the sharing of costs by the Project; (x) operation, repair, maintenance and replacement of all systems and equipment and components thereof of the Project; (xi) the cost of janitorial, alarm, security and other services, replacement of wall and floor coverings, ceiling tiles and fixtures in common areas, maintenance and replacement of curbs and walkways, repair to roofs and re-roofing; (xii) amortization (including interest on the unamortized cost at an annual interest rate determined by Landlord over the reasonable useful life of the item in question) of the cost of acquiring or the rental expense of personal property used in the maintenance, operation and repair of the Project, or any portion thereof; (xiii) costs, fees, charges or assessments imposed by, or resulting from any mandate imposed on Landlord by, any federal, state or local government for fire and police protection, trash removal, community services, or other services which do not constitute "Tax Expenses" as that term is defined in Section 4.2.8, below; (xiv) [Intentionally Omitted]; (xv) payments under any easement, license, operating agreement, declaration, restrictive covenant, or instrument pertaining to the sharing of costs by the Project or related to the use or operation of the Project; and (xvi) all costs of applying and reporting for the Project or any part thereof to seek or maintain certification under the U.S. EPA's Energy Star® rating system, the U.S. Green Building Council's Leadership in Energy and Environmental Design (LEED) rating system or a similar system or standard. Notwithstanding anything to the contrary in this Lease, the following items shall be excluded from Operating Expenses:

(a) any items included in or expressly excluded in subparts (i), (iii) or (a)-(d) of Section 4.2.8.3 from, Tax Expenses;

(b) except as permitted pursuant to items (xii) and (xiii), above, principal or interest on indebtedness, debt amortization or ground rent paid by Landlord in connection with any mortgages, deeds of trust or other financing encumbrances, or ground leases of the Building or the Project;

I capital improvements and repairs to the Building or the Project, and capital repairs, capital equipment, and capital tool, and rental payments and other related expenses incurred in leasing air conditioning systems, elevators or other equipment ordinarily considered to be of a capital nature, except (i) equipment which is used in providing janitorial or similar services and which is not affixed to the Building, and (ii) equipment rented to remedy or ameliorate an emergency condition (provided this exclusion I shall not be deemed to limit or otherwise affect Capital Expenses allowed under this Lease);

(d) legal, auditing, consulting and professional fees and other costs paid or incurred in connection with financings, refinancings or sales of any interest in Landlord or of

Landlord's interest in the Building or the Project or in connection with any ground lease (including, without limitation, recording costs, mortgage recording taxes, title insurance premiums and other similar costs, but excluding those legal, auditing, consulting and professional fees and other costs incurred in connection with the normal and routine maintenance and operation of the Building and/or the Project);

I legal fees, space planner's fees, architect's fees, leasing and brokerage commissions, advertising and promotional expenditures and any other marketing expense incurred in connection with the leasing of space in the Building (including new leases, lease amendments, lease terminations and lease renewals);

(f) the cost of any items to the extent to which such cost is reimbursed to Landlord by tenants of the Project (other than as a reimbursement of operating expenses), or other third parties, or is covered by a warranty to the extent of reimbursement for such coverage;

(g) expenditures for any leasehold improvement which is made in connection with the preparation of any portion of the Building for occupancy by any tenant of the Building or the Project;

(h) the cost of performing work or furnishing service to or for any tenant other than Tenant, at Landlord's expense, to the extent such work or service is in excess of any work or service Landlord is obligated to provide to Tenant or generally to other tenants in the Building at Landlord's expense;

(i) the cost of repairs or replacements incurred by reason of fire or other casualty, or condemnation, to the extent Landlord actually receives proceeds of property and casualty insurance policies or condemnation awards or would have received such proceeds had Landlord maintained the insurance required to be maintained by Landlord under this Lease;

(j) the cost of acquiring sculptures, paintings or other objects of fine art in the Building or the Project in excess of amounts typically spent for such items in Class A office buildings of comparable quality in the South San Francisco geographic area;

(k) bad debt loss, rent loss, or reserves for bad debt or rent loss;

(l) unfunded contributions to operating expense reserves by other tenants;

(m) contributions to charitable or political organizations in excess of $50,000.00 in the aggregate in any single Expense Year;

(n) expenses related solely and exclusively to the operation of the retail space in the Project;

(o) damage and repairs necessitated by the gross negligence or willful misconduct of Landlord Parties;

(p) fees, costs and expenses incurred by Landlord in connection with or relating to claims against or disputes with tenants of the Building or the Project;

(q) interest, fines or penalties for late payment or violations of Applicable Laws by Landlord, except to the extent incurring such expense is caused by a corresponding late payment or violation of an Applicable Law by Tenant, in which event Tenant shall be responsible for the full amount of such expense;

I the cost of remediation and removal of, or other cost that would not have been incurred by Landlord but for the presence of, "Hazardous Substance," as that term is defined in Section 5.2, below, in the Building or on the Project, provided, however, that the provisions of this sub-item I shall not preclude the inclusion of costs with respect to materials (whether existing at the Project as of the date of this Lease or subsequently introduced to the Project) which are not, as of the date of this Lease, deemed to be Hazardous Substance under applicable laws but which are subsequently deemed to be Hazardous Substance under applicable laws (it being understood and agreed that Tenant shall nonetheless be responsible under Section 5.2 of this Lease for all costs of remediation and removal of Hazardous Substance to the extent caused by Tenant Parties);

(s) costs for the original construction and development of the Building and nonrecurring costs for the repair or replacement of any structural portion of the Building made necessary as a result of defects in the original design, workmanship or materials;

(t) costs and expenses incurred for the administration of the entity which constitutes Landlord, as the same are distinguished from the costs of operation, management, maintenance and repair of the Building and/or the Project, including, without limitation, entity accounting and legal matters;

(u) the wages and benefits of any employee who does not devote substantially all of his or her employed time to the Project unless such wages and benefits are prorated on a reasonable basis;

(v) except as may be otherwise expressly provided in this Lease with respect to specific items, including, without limitation, any management fee paid by Landlord, the cost of any services or materials provided by any party related to Landlord, to the extent such cost exceeds, the reasonable cost for such services or materials absent such relationship in Class A office buildings of comparable quality in the San Francisco financial district area;

(w) depreciation for the Building, except as permitted pursuant to items (xii) and (xiii), above; and

(x) reserves for future improvements, repairs, additions, etc.

If Landlord is not furnishing any particular work or service (the cost of which, if performed by Landlord, would be included in Operating Expenses) to a tenant who has undertaken to perform such work or service in lieu of the performance thereof by Landlord, Operating Expenses shall be deemed to be increased by an amount equal to the additional Operating Expenses which would reasonably have been incurred during such period by Landlord if it had at its own expense furnished such work or service to such tenant. If the Project is not at least one hundred percent (100%) occupied during all or a portion of the Base Year or any Expense Year, Landlord may elect to make (and shall make with respect to the Base Year) an appropriate adjustment to the components of Operating Expenses for such year to determine the amount of Operating Expenses

that would have been incurred had the Project been one hundred percent (100%) occupied; and the amount so determined shall be deemed to have been the amount of Operating Expenses for such year. Operating Expenses for the Base Year shall include market-wide cost increases (including utility rate increases) due to extraordinary circumstances, including, but not limited to, Force Majeure, boycotts, strikes, conservation surcharges, security concerns, embargoes or shortages ("**Temporary Costs**"), provided that for any Expense Year in which such Temporary Costs are not included, the Base Year Operating Expenses shall be adjusted to remove such Temporary Costs. In no event shall the components of Direct Expenses for any Expense Year related to Tax Expenses, Project utility, services, or insurance costs, in the aggregate for each such category, be less than the components of Direct Expenses related to Tax Expenses, Project utility, services, or insurance costs in the Base Year.

4.2.8 **Taxes**.

4.2.8.1 "**Tax Expenses**" shall mean all federal, state, county, or local governmental or municipal taxes, fees, charges or other impositions of every kind and nature, whether general, special, ordinary or extraordinary (including, without limitation, real estate taxes, general and special assessments, transit taxes, business taxes, leasehold taxes or taxes based upon the receipt of rent, including gross receipts or sales taxes applicable to the receipt of rent, unless required to be paid by Tenant, personal property taxes imposed upon the fixtures, machinery, equipment, apparatus, systems and equipment, appurtenances, furniture and other personal property used in connection with the Project, or any portion thereof), which shall be paid or accrued during any Expense Year (without regard to any different fiscal year used by such governmental or municipal authority) because of or in connection with the ownership, leasing and operation of the Project, or any portion thereof.

4.2.8.2 Tax Expenses shall include, without limitation: (i) Any tax on the rent, right to rent or other income from the Project, or any portion thereof, or as against the business of leasing the Project, or any portion thereof; (ii) Any assessment, tax, fee, levy or charge in addition to, or in substitution, partially or totally, of any assessment, tax, fee, levy or charge previously included within the definition of real property tax, it being acknowledged by Tenant and Landlord that Proposition 13 was adopted by the voters of the State of California in the June 1978 election ("**Proposition 13**") and that assessments, taxes, fees, levies and charges may be imposed by governmental agencies for such services as fire protection, street, sidewalk and road maintenance, refuse removal and for other governmental services formerly provided without charge to property owners or occupants, and, in further recognition of the decrease in the level and quality of governmental services and amenities as a result of Proposition 13, Tax Expenses shall also include any governmental or private assessments or the Project's contribution towards a governmental or private cost-sharing agreement for the purpose of augmenting or improving the quality of services and amenities normally provided by governmental agencies; (iii) Any assessment, tax, fee, levy, or charge allocable to or measured by the area of the Premises, the tenant improvements in the Premises, or the Rent payable hereunder, including, without limitation, any business or gross income tax or excise tax with respect to the receipt of such rent, or upon or with respect to the possession, leasing, operating, management, maintenance, alteration, repair, use or occupancy by Tenant of the Premises, or any portion thereof; (iv) Any assessment, tax, fee, levy or charge, upon this transaction or any document to which Tenant is a party, creating or transferring an interest or an estate in the Premises; and (v) All of the real estate taxes and assessments imposed

upon or with respect to the Building and all of the real estate taxes and assessments imposed on the land and improvements comprising the Project.

4.2.8.3 If Tax Expenses for any period during the Lease Term or any extension thereof are increased after payment thereof for any reason, including, without limitation, error or reassessment by applicable governmental or municipal authorities, Tenant shall pay Landlord upon demand Tenant's Share of any such increased Tax Expenses included by Landlord as Building Tax Expenses pursuant to the terms of this Lease. Notwithstanding anything to the contrary contained in this Section 4.2.8, there shall be excluded from Tax Expenses (i) all excess profits taxes, franchise taxes, gift taxes, capital stock taxes, transfer taxes, inheritance and succession taxes, estate taxes, federal and state income taxes, and other taxes to the extent applicable to Landlord's general or net income (as opposed to rents, receipts or income attributable to operations at the Project), (ii) any items included as Operating Expenses, and (iii) any items paid by Tenant under Section 4.5 of this Lease. If the property tax assessment for the Project (or any portion thereof) (or Tax Expenses) for the Base Year or any Expense Year does not reflect an assessment (or Tax Expenses) for a one hundred percent (100%) leased, completed and occupied project (such that existing or future leasing, tenant improvements and/or occupancy may result in an increased assessment and/or increased Tax Expenses), Tax Expenses shall be adjusted, on a basis consistent with sound real estate accounting principles, to reflect an assessment for (and Tax Expenses for) a one hundred percent (100%) leased, completed and occupied project. In addition, notwithstanding anything in this Lease to the contrary, neither Tax Expenses nor Operating Expenses shall include and Tenant shall not be required to pay any portion of any tax or assessment expense or any increase therein (a) in excess of the amount which would be payable if such tax or assessment expense were paid in installments over the longest permitted term; (b) imposed on land and improvements other than the Project; (c) resulting from the improvement of any of the Project for the sole use of other occupants; or (d) results from Landlord's failure to timely pay taxes.

4.2.8.4 Notwithstanding anything to the contrary set forth in this Lease, the amount of Tax Expenses for the Base Year and any Expense Year shall be calculated without taking into account any decreases in real estate taxes obtained in connection with Proposition 8, and, therefore, the Tax Expenses in the Base Year and/or an Expense Year may be greater than those actually incurred by Landlord, but shall, nonetheless, be the Tax Expenses due under this Lease; provided that (i) any costs and expenses incurred by Landlord in securing any Proposition 8 reduction shall not be deducted from Tax Expenses nor included in Direct Expenses for purposes of this Lease, and (ii) tax refunds under Proposition 8 shall not be deducted from Tax Expenses nor refunded to Tenant, but rather shall be the sole property of Landlord. Landlord and Tenant acknowledge that the preceding sentence is not intended to in any way affect (A) the inclusion in Tax Expenses of the statutory two percent (2.0%) annual increase in Tax Expenses (as such statutory increase may be modified by subsequent legislation), or (B) the inclusion or exclusion of Tax Expenses pursuant to the terms of Proposition 13. Notwithstanding anything to the contrary set forth in this Lease, only Landlord may institute proceedings to reduce Tax Expenses and the filing of any such proceeding by Tenant without Landlord's consent shall constitute an event of default by Tenant under this Lease. Notwithstanding the foregoing, Landlord shall not be obligated to file any application or institute any proceeding seeking a reduction in Tax Expenses. Notwithstanding the foregoing, upon a reassessment of the Building and/or the Project pursuant to the terms of Proposition 13 (a "**Reassessment**") occurring after the Base Year which results in a decrease in Tax Expenses, the component of Tax Expenses for the Base Year which is attributable

to the assessed value of the Building and/or the Project under Proposition 13 prior to the Reassessment (without taking into account any Proposition 8 reductions) (the "**Base Year Prop 13 Taxes**") shall be reduced, if at all, for the purposes of comparison to all subsequent Expense Years (commencing with the Expense Year in which the Reassessment takes place) to an amount equal to the real estate taxes based upon such Reassessment, and if thereafter, in connection with a subsequent Reassessment, the assessed value of the Building and/or the Project under Proposition 13 shall increase, the current Base Year Prop 13 Taxes shall be increased for purposes of comparison to all subsequent Expense Years (commencing with the Expense Year in which the Reassessment takes place) to an amount equal to the lesser of the original Base Year Prop 13 Taxes and an amount equal to the real estate taxes based upon such Reassessment.

4.2.9 "**Capital Expenses**" shall mean all cost of capital repair, improvements or expenditures incurred by Landlord in connection with the Project (A) which are principally intended to effect economies in the operation, cleaning or maintenance of the Project, or any portion thereof, (B) that are required to comply with present or anticipated conservation programs, (C) which are replacements or modifications of nonstructural items located in the Common Areas required to keep the Common Areas in good order or condition, or (D) that are required under any governmental law or regulation, except for capital expenditures to remedy a condition existing prior to the Lease Commencement Date which an applicable governmental authority, if it had knowledge of such condition prior to the Lease Commencement Date, would have then required to be remedied pursuant to then-current governmental laws or regulations in their form existing as of the Lease Commencement Date and pursuant to the then-current interpretation of such governmental laws or regulations by the applicable governmental authority as of the Lease Commencement Date. In no event shall Capital Expenses include any costs incurred by Landlord prior to or during the Base Year. The cost of Capital Expenses shall be amortized as set forth in Section 4.2.7(xii). Notwithstanding anything in this Lease to the contrary, "**Capital Expenses**" shall not include any expenses specifically excluded from Operating Expenses.

4.2.10 "**Tenant's Share**" shall mean the percentage set forth in Section 6 of the Summary. Tenant's Share was calculated by multiplying the number of rentable square feet of the Premises, as set forth in Section 2.2 of the Summary, by 100, and dividing the product by the total number of rentable square feet in the Building.

4.3 **Allocation of Direct Expenses**.

4.3.1 **Method of Allocation**. The parties acknowledge that the Building is a part of a multi-building project and that the costs and expenses incurred in connection with the Project (*i.e.*, the Direct Expenses) should be shared between the tenants of the Building and the tenants of the other buildings in the Project. Accordingly, as set forth in Section 4.2 above, Direct Expenses (which consists of Operating Expenses and Tax Expenses) and Capital Expenses are determined annually for the Project as a whole, and a portion of the Direct Expenses and Capital Expenses, which portion shall be determined by Landlord on an equitable basis, shall be allocated to the tenants of the Building (as opposed to the tenants of any other buildings in the Project) and such portion shall be the Building Direct Expenses and Capital Expenses for purposes of this Lease. Such portion of Direct Expenses and Capital Expenses allocated to the tenants of the Building shall include all Direct Expenses attributable solely to the Building (and not any Direct

Expenses and Capital Expenses attributable solely to other buildings) and an equitable portion of the Direct Expenses attributable to the Project as a whole.

4.3.2 **Cost Pools**. Landlord shall have the right, from time to time, to equitably allocate some or all of the Direct Expenses for the Project among different portions or occupants of the Project (the "**Cost Pools**"), in Landlord's reasonable discretion. Such Cost Pools may include, but shall not be limited to, the office space tenants of a building of the Project or of the Project, and the retail space tenants of a building of the Project or of the Project. The Direct Expenses and Capital Expenses allocable to each such Cost Pool shall be allocated to such Cost Pool and charged to the tenants within such Cost Pool in an equitable manner.

4.4 **Calculation and Payment of Direct Expenses**. If for any Expense Year ending or commencing within the Lease Term, Tenant's Share of Building Direct Expenses for such Expense Year exceeds Tenant's Share of Building Direct Expenses applicable to the Base Year, then Tenant shall pay to Landlord, in the manner set forth in Section 4.4.1, below, and as Additional Rent, an amount equal to the excess (the "**Excess**").

4.4.1 **Statement of Actual Building Direct Expenses and Payment by Tenant**. Landlord shall give to Tenant within four (4) months following the end of each Expense Year, a statement (the "**Statement**") which shall state the Building Direct Expenses incurred or accrued for such preceding Expense Year, and which shall indicate the amount of the Excess. Upon receipt of the Statement for each Expense Year commencing or ending during the Lease Term, if an Excess is present, Tenant shall pay, within thirty (30) days, the full amount of the Excess for such Expense Year, less the amounts, if any, paid during such Expense Year as "Estimated Excess," as that term is defined in Section 4.4.2, below. If the amounts paid by Tenant during an Expense Year as Estimated Excess exceed the Excess for such Expense Year, then such difference shall be reimbursed by Landlord to Tenant within thirty (30) days, provided that any such reimbursement, at Landlord's option, may be credited against the Rent next coming due under this Lease unless the Lease Term has expired, in which event Landlord shall refund the appropriate amount to Tenant. The failure of Landlord to timely furnish the Statement for any Expense Year shall not prejudice Landlord or Tenant from enforcing its rights under this Article 4. Even though the Lease Term has expired and Tenant has vacated the Premises, when the final determination is made of Tenant's Share of Building Direct Expenses for the Expense Year in which this Lease terminates, if an Excess is present, Tenant shall immediately pay to Landlord such amount. The provisions of this Section 4.4.1 shall survive the expiration or earlier termination of the Lease Term.

4.4.2 **Statement of Estimated Building Direct Expenses**. In addition, Landlord shall endeavor to give Tenant a yearly expense estimate statement (the "**Estimate Statement**") which shall set forth Landlord's reasonable estimate (the "**Estimate**") of what the total amount of Building Direct Expenses for the then-current Expense Year shall be and the estimated excess (the "**Estimated Excess**") as calculated by comparing the Building Direct Expenses for such Expense Year, which shall be based upon the Estimate, to the amount of Building Direct Expenses for the Base Year. The failure of Landlord to timely furnish the Estimate Statement for any Expense Year shall not preclude Landlord from enforcing its rights to collect any Estimated Excess under this Article 4, nor shall Landlord be prohibited from revising any Estimate Statement or Estimated Excess theretofore delivered to the extent necessary. Thereafter, Tenant shall pay, with its next installment of Base Rent due at least thirty (30) days after delivery

of such Statement, a fraction of the Estimated Excess for the then-current Expense Year (reduced by any amounts paid pursuant to the last sentence of this Section 4.4.2). Such fraction shall have as its numerator the number of months which have elapsed in such current Expense Year, including the month of such payment, and twelve (12) as its denominator. Until a new Estimate Statement is furnished (which Landlord shall have the right to deliver to Tenant at any time), Tenant shall pay monthly, with the monthly Base Rent installments, an amount equal to one-twelfth (1/12) of the total Estimated Excess set forth in the previous Estimate Statement delivered by Landlord to Tenant.

4.5 **Taxes and Other Charges for Which Tenant Is Directly Responsible**.

4.5.1 Tenant shall be liable for and shall pay thirty (30) days before delinquency, taxes levied against Tenant's equipment, furniture, fixtures and any other personal property located in or about the Premises. If any such taxes on Tenant's equipment, furniture, fixtures and any other personal property are levied against Landlord or Landlord's property or if the assessed value of Landlord's property is increased by the inclusion therein of a value placed upon such equipment, furniture, fixtures or any other personal property and if Landlord pays the taxes based upon such increased assessment, which Landlord shall have the right to do regardless of the validity thereof but only under proper protest if requested by Tenant, Tenant shall within thirty (30) days after demand repay to Landlord the taxes so levied against Landlord or the proportion of such taxes resulting from such increase in the assessment, as the case may be.

4.5.2 If the tenant improvements in the Premises, whether installed and/or paid for by Landlord or Tenant and whether or not affixed to the real property so as to become a part thereof, are assessed for real property tax purposes at a valuation higher than the valuation at which tenant improvements conforming to Landlord's "building standard" in other space in the Building are assessed, then the Tax Expenses levied against Landlord or the property by reason of such excess assessed valuation shall be deemed to be taxes levied against personal property of Tenant and shall be governed by the provisions of Section 4.5.1, above.

4.5.3 Notwithstanding any contrary provision herein, Landlord may charge Tenant directly, and Tenant shall pay prior to delinquency as Additional Rent (and not as a part of Direct Expenses) any (i) gross receipts or other rent tax or sales tax, service tax, transfer tax or value added tax, business tax or any other applicable tax on the rent or services herein or otherwise respecting this Lease, (ii) taxes assessed upon or with respect to the possession, leasing, operation, management, maintenance, alteration, repair, use or occupancy by Tenant of the Premises or any portion of the Project, including the Project parking facility and taxes or assessments due to any type of ballot measure, including an initiative adopted by the voters or local agency, or a state proposition approved by the voters; or (iii) taxes assessed upon this transaction or any document to which Tenant is a party creating or transferring an interest or an estate in the Premises.

4.5.4 Landlord may charge Tenant the estimated amount of taxes and other charges for which Tenant is directly responsible pursuant to this Section 4.5 on a monthly basis, provided that Landlord shall reconcile the amount actually paid by Tenant with the amount that Tenant should have paid, as part of Landlord's Statement following the end of each Expense Year.

4.6 **Calculation and Payment of Capital Expenses**. Notwithstanding any provision to the contrary contained in this Lease, Tenant shall pay to Landlord, on a monthly basis. As Additional Rent and in addition to Tenant's Share of Building Direct Expenses, an amount equal to Tenant's Share of all Capital Expenses incurred by Landlord for any Expense Year following the Base Year; provided, however, any such Capital Expenses shall be amortized (including interest on the unamortized cost at an annual interest rate reasonably determined by Landlord) over its useful life as Landlord shall reasonably determine, and Tenant shall only be obligated to pay Tenant's Share of such amortized amount; provided further, however, if Landlord reasonably concludes on the basis of engineering estimates that a particular capital expenditure will effect savings in Operating Expenses, including, without limitation, energy related costs, and that such projected savings will, on an annual basis ("**Projected Annual Savings**"), exceed the annual amortization therefor, then and in such event the amount of amortization for such capital expenditure shall be increased to an amount equal to the Projected Annual Savings; and in such circumstance, the increased amortization (in the amount of the Projected Annual Savings) shall be made for such period of time as it would take to fully amortize the cost of the item in question, together with interest thereon at the interest rate as aforesaid in equal monthly payments, each in the amount of $1/12^{th}$ of the Projected Annual Savings, with such payment to be applied first to interest and the balance to principal. The amount of Capital Expenses incurred by Landlord, as well as Tenant's Share of such Capital Expenses, shall be set forth on each Statement and each Estimate Statement delivered by Landlord to Tenant and Tenant shall pay Tenant's Share of such Capital Expenses at the same time and in the same manner as Tenant shall pay Tenant's Share of Building Direct Expenses.

ARTICLE 5

USE OF PREMISES

5.1 **Permitted Use**. Tenant shall use the Premises solely for the Permitted Use set forth in Section 7 of the Summary and Tenant shall not use or permit the Premises or the Project to be used for any other purpose or purposes whatsoever without the prior written consent of Landlord, which may be withheld in Landlord's sole discretion.

5.2 **Prohibited Uses**. Tenant further covenants and agrees that Tenant shall not use, or permit any of its employees, agents, or contractors to use, the Premises or any part thereof for any use or purpose contrary to the provisions of the Rules and Regulations set forth in **Exhibit D**, attached hereto, or in violation of the laws of the United States of America, the State of California, or the ordinances, regulations or requirements of the local municipal or county governing body or other lawful authorities having jurisdiction over the Project, including, without limitation, any such laws, ordinances, regulations or requirements relating to hazardous materials or substances, as those terms are defined by applicable laws now or hereafter in effect. Tenant shall not do or permit anything to be done in or about the Premises which will in any way damage the reputation of the Project or materially obstruct or interfere with the rights of other tenants or occupants of the Building, or injure or annoy them or use or allow the Premises to be used for any improper or unlawful purpose, nor shall Tenant cause, maintain or permit any nuisance in, on or about the Premises. Tenant shall comply with, and Tenant's rights and obligations under the Lease and Tenant's use of the Premises shall be subject and subordinate to, all recorded easements, covenants, conditions, and restrictions now or hereafter affecting the Project, provided the same do not

unreasonably interfere with Tenant's use of the Premises as permitted under this Lease. Except for small quantities customarily used in business offices in compliance with applicable laws and its recommended uses, Tenant shall not cause or permit any "Hazardous Substance," as that term is defined below, to be used, stored, produced, generated or disposed of (into the sewage or waste disposal system or otherwise) on or in the Premises by Tenant or Tenant's agents, employees, contractors, assignees or sublessees, without first obtaining Landlord's written consent. Tenant shall immediately notify, and shall direct Tenant's agents, employees contractors, invitees, assignees and sublessees to immediately notify, Landlord of any incident in, on or about the Premises that would require the filing of a notice under any federal, state, local or quasi-governmental law (whether under common law, statute or otherwise), ordinance, decree, code, ruling, award, rule, regulation or guidance document now or hereafter enacted or promulgated, as amended from time to time, in any way relating to or regulating any Hazardous Substance. As used herein, "**Hazardous Substance**" means any substance which is toxic, ignitable, reactive, or corrosive and which is regulated by any local government, the State of California, or the United States government. "Hazardous Substance" includes any and all material or substances which are defined as "hazardous waste," "extremely hazardous waste" or a "hazardous substance" pursuant to state, federal or local governmental law. "Hazardous Substance" also includes asbestos, polychlorobiphenyls (*i.e.*, PCB's) and petroleum.

ARTICLE 6

SERVICES AND UTILITIES

6.1 **Standard Tenant Services**. Landlord shall provide the services specified below and on **Exhibit F** attached hereto, on all days (unless otherwise stated below or in **Exhibit F**) during the Lease Term.

6.1.1 Subject to limitations imposed by all governmental rules, regulations and guidelines applicable thereto, Landlord shall provide heating, ventilation and air conditioning ("**HVAC**") when necessary for normal comfort for normal office use in the Premises from 7:00 A.M. to 6:00 P.M. Monday through Friday (collectively, the "**Building Hours**"), except for the date of observation of New Year's Day, Independence Day, Labor Day, Memorial Day, Thanksgiving Day, Christmas Day and, at Landlord's discretion, other locally or nationally recognized holidays (collectively, the "**Holidays**"). Tenant shall cooperate fully with Landlord at all times and abide by all regulations and requirements that Landlord may reasonably prescribe for the proper functioning and protection of the HVAC, electrical, mechanical and plumbing systems.

6.1.2 Landlord shall provide electricity to the Premises (including adequate electrical wiring and facilities for connection to Tenant's lighting fixtures and incidental use equipment) for lighting and power suitable for the Permitted Use as reasonably determined by Landlord, provided that Tenant's electrical usage shall be subject to applicable laws and regulations. Tenant shall bear the cost of replacement of lamps, starters and ballasts for non-Building standard lighting fixtures within the Premises.

6.1.3 Landlord shall provide city water from the regular Building outlets for drinking, office kitchen, lavatory and toilet purposes in the Building Common Areas.

6.1.4 Landlord shall provide nonexclusive, non-attended automatic passenger elevator service during the Building Hours, shall have one elevator available at all other times, including on the Holidays, except in the event of emergency, and shall provide nonexclusive, non-attended automatic passenger escalator service during Building Hours only.

6.1.5 Landlord shall provide nonexclusive freight elevator service subject to reasonable scheduling by Landlord.

6.1.6 Landlord shall provide customary weekday janitorial services to the Premises, except the date of observation of the Holidays, in and about the Premises and customary occasional window washing services, each in a manner consistent with other Class "A" office buildings located in the vicinity of the Project.

6.1.7 Subject to Landlord's rules, regulations, and restrictions and the terms of this Lease, Landlord shall permit Tenant to utilize its reasonable share of available existing Building risers, raceways, shafts and conduit to make connections to the Premises, subject to Landlord's commercially reasonable standard fees for such use.

Notwithstanding anything in this Lease to the contrary, if Landlord or any affiliate of Landlord has elected to qualify as a real estate investment trust ("**REIT**"), any service required or permitted to be performed by Landlord pursuant to this Lease, the charge or cost of which may be treated as impermissible tenant service income under the laws governing a REIT, may be performed by a taxable REIT subsidiary that is affiliated with either Landlord or Landlord's property manager, an independent contractor of Landlord or Landlord's property manager (the "**Service Provider**"). If Tenant is subject to a charge under this Lease for any such service, then, at Landlord's direction, Tenant will pay such charge either to Landlord for further payment to the Service Provider or directly to the Service Provider, and, in either case, (i) Landlord will credit such payment against Additional Rent due from Tenant under this Lease for such service, and (ii) such payment to the Service Provider will not relieve Landlord from any obligation under the Lease concerning the provisions of such service.

6.2 **Overstandard Tenant Use**. Tenant shall not, without Landlord's prior written consent, use heat-generating machines, machines other than normal fractional horsepower office machines, or equipment or lighting other than Building standard lights in the Premises, which may materially affect the temperature otherwise maintained by the air conditioning system or increase the water normally furnished for the Premises by Landlord pursuant to the terms of Section 6.1 of this Lease. If Tenant uses water, electricity, heat or air conditioning in excess of that supplied by Landlord pursuant to Section 6.1 of this Lease, Tenant shall pay to Landlord, upon billing, the cost of such excess consumption, the reasonable, actual cost of the installation, operation, and maintenance of equipment which is installed in order to supply such excess consumption, and the cost of the increased wear and tear on existing equipment caused by such excess consumption; and Landlord may install devices to separately meter (or sub-meter) any increased use and in such event Tenant shall pay the increased cost directly to Landlord, within thirty (30) days after demand, at the rates charged by the public utility company furnishing the same, including the cost of such additional metering (or sub-metering) devices. In addition, in the event that there is located in the Premises a data center containing high density computing equipment, as defined in the U.S. EPA's Energy Star® rating system ("**Energy Star**"), Landlord may require the installation in accordance

with Energy Star of separate metering or check metering equipment, in which event (i) Tenant shall pay the costs of any such meter or check meter directly to Landlord, on demand, including the installation and connectivity thereof, (ii) Tenant shall directly pay to the utility provider all electric consumption on any meter, and (iii) Tenant shall pay to Landlord, as Additional Rent, all electric consumption on any check meter within thirty (30) days after being billed thereof by Landlord, in addition to other electric charges payable by Tenant under the Lease. In the event that Tenant purchases any utility service directly from the provider, Tenant shall promptly provide to Landlord either permission to access Tenant's usage information from the utility service provider or copies of the utility bills for Tenant's usage of such services in a format reasonably acceptable to Landlord. Tenant's use of electricity shall never exceed the capacity of the feeders to the Project or the risers or wiring installation. If Tenant desires to use heat, ventilation or air conditioning during hours other than those for which Landlord is obligated to supply such utilities pursuant to the terms of Section 6.1 of this Lease, Tenant shall give Landlord such prior notice, if any, as Landlord shall from time to time reasonably and uniformly establish as appropriate, of Tenant's desired use in order to supply such utilities, and Landlord shall supply such utilities to Tenant at such hourly cost to Tenant (which shall be treated as Additional Rent) as Landlord shall from time to time reasonably and uniformly establish. Landlord shall have the exclusive right, but not the obligation, upon Tenant's request, to provide any additional services which may be required by Tenant, including, without limitation, locksmithing, lamp replacement, additional janitorial service, and additional repairs and maintenance. If Tenant requests any such additional services, the cost of such additional services will include Landlord's standard fee for its involvement with such additional services. Tenant shall pay to Landlord such cost of such additional services within thirty (30) days after being billed for same.

6.3 **Interruption of Use**. Tenant agrees that Landlord shall not be liable for damages, by abatement of Rent or otherwise, for failure to furnish or delay in furnishing any service (including telephone and telecommunication services), or for any diminution in the quality or quantity thereof, when such failure or delay or diminution is occasioned, in whole or in part, by breakage, repairs, replacements, or improvements, by any strike, lockout or other labor trouble, by inability to secure electricity, gas, water, or other fuel at the Building or Project after reasonable effort to do so, by any riot or other dangerous condition, emergency, accident or casualty whatsoever, by act or default of Tenant or other parties, or by any other cause beyond Landlord's reasonable control; and such failures or delays or diminution shall never be deemed to constitute an eviction or disturbance of Tenant's use and possession of the Premises or relieve Tenant from paying Rent or performing any of its obligations under this Lease. Furthermore, Landlord shall not be liable under any circumstances for a loss of, or injury to, property or for injury to, or interference with, Tenant's business, including, without limitation, loss of profits, however occurring, through or in connection with or incidental to a failure to furnish any of the services or utilities as set forth in this Article 6.

ARTICLE 7

REPAIRS

Landlord shall at all times during the Lease Term maintain in good condition and operating order the structural portions of the Building, including, without limitation, the foundation, floor slabs, ceilings, roof, columns, beams, shafts, stairs, stairwells, escalators, elevators, base building

restrooms and all Common Areas (collectively, the "**Building Structure**", and the Base Building mechanical, electrical, life safety, plumbing, sprinkler and HVAC systems installed or furnished by Landlord (collectively, the "**Building Systems**"). Landlord shall also maintain and repair the solar window film on the inside of the exterior Building windows, provided that if damage to such solar window film is caused by Tenant, then Tenant shall pay the cost for any such repairs. Except as specifically set forth in this Lease to the contrary, Tenant shall not be required to repair the Building Structure and/or the Building Systems except to the extent required because of Tenant's use of the Premises for other than normal and customary business office operations (which repairs shall be performed by Landlord at Tenant's cost and expense). Tenant shall, at Tenant's own expense, keep the Premises, including all improvements, fixtures and furnishings therein, and the floor coverings within the Premises, in good order, repair and condition at all times during the Lease Term. In addition, subject to Section 10.3, Articles 11 and 13 of this Lease, Tenant shall, at Tenant's own expense, but under the supervision and subject to the prior approval of Landlord, and within any reasonable period of time specified by Landlord, promptly and adequately repair all damage to the Premises and replace or repair all damaged, broken, or worn fixtures and appurtenances, except for damage caused by ordinary wear and tear or beyond the reasonable control of Tenant; provided however, that, if Tenant fails to do so, Landlord shall have the exclusive right, at Landlord's option, but not the obligation, to make such repairs and replacements, and Tenant shall pay to Landlord the cost thereof, including Landlord's standard fee for its involvement with such repairs and replacements, promptly upon being billed for same. Landlord may, but shall not be required to, enter the Premises, as provided in Article 27, below, at all reasonable times to make such repairs, alterations, improvements or additions to the Premises or to the Project or to any equipment located in the Project as Landlord shall desire or deem necessary or as Landlord may be required to do by governmental or quasi-governmental authority or court order or decree. Tenant hereby waives any and all rights under and benefits of subsection 1 of Section 1932 and Sections 1941 and 1942 of the California Civil Code or under any similar law, statute, or ordinance now or hereafter in effect.

ARTICLE 8

ADDITIONS AND ALTERATIONS

8.1 **Landlord's Consent to Alterations**. Tenant may not make or permit its employees, agents or contractors to make any improvements, alterations, additions, changes, or repairs (pursuant to Article 7 or otherwise) to the Premises or any mechanical, plumbing or HVAC facilities or systems pertaining to the Premises (collectively, the "**Alterations**") without first procuring the prior written consent of Landlord to such Alterations, which consent shall be requested by Tenant in accordance with the terms and conditions of this Article 8, and which consent shall not be unreasonably withheld by Landlord, provided it shall be deemed reasonable for Landlord to withhold its consent to any Alteration which adversely affects the structural portions or the systems or equipment of the Building or is visible from the exterior of the Building. Landlord may impose, as a condition of its consent to any and all Alterations or repairs of the Premises or about the Premises, such requirements as Landlord in its reasonable discretion may deem desirable. The construction of the initial improvements to the Premises shall be governed by the terms of the Tenant Work Letter and not the terms of this Article 8.

8.2 **Manner of Construction**. Landlord shall have the exclusive right, at Landlord's option, but not the obligation, upon Tenant's request that Landlord perform such work, to make the Alterations at Tenant's sole cost and expense. If Landlord elects to make the Alterations pursuant to the immediately preceding sentence, then Tenant shall retain Landlord to construct such Alterations and Landlord shall hold all applicable construction contracts. Prior to the commencement of construction of any Alterations or repairs, Tenant shall submit to Landlord, for Landlord's review and approval in its reasonable discretion, four (4) copies signed by Tenant of all plans, specifications and working drawings relating thereto. Tenant, at its sole cost and expense, shall retain an architect/space planner selected by Tenant, and reasonably approved by Landlord, to prepare such plans, specifications and working drawings; provided that, Tenant shall also retain the engineering consultants reasonably approved by Landlord to prepare all plans and engineering working drawings, if any, relating to the structural, mechanical, electrical, plumbing, HVAC, life safety and sprinkler work of the Alterations. Tenant shall be required to include in its contracts with the architect and the engineers a provision which requires ownership of all architectural and engineering drawings to be transferred to Tenant upon the substantial completion of the Alteration and Tenant hereby grants to Landlord a non-exclusive right to use such drawings, including, without limitation, a right to make copies thereof. Tenant shall cause each architect/space planner and engineer retained by Tenant to follow Landlord's reasonable standard construction administration procedures and to utilize the standard specifications and details for the Building (unless otherwise approved by Landlord), all as promulgated by Landlord from time to time. Tenant and Tenant's architect/space planner shall verify, in the field, the dimensions and conditions as shown on the relevant portions of the "Base Building" plans, and Tenant and Tenant's architect/space planner shall be solely responsible for the same, and Landlord shall have no responsibility in connection therewith. In addition, at Landlord's option, Landlord may submit Tenant's plans, specifications and working drawings to a third-party architect and/or engineer, selected by Landlord, for their review, at Tenant's sole cost and expense. Landlord's review of plans, specifications and working drawings as set forth in this Section 8.2, shall be for its sole purpose and shall not imply Landlord's review of the same, or obligate Landlord to review the same, for quality, design, compliance with applicable building codes or other like matters. Accordingly, notwithstanding that any plans, specifications or working drawings are reviewed by Landlord or its space planner, architect, engineers and consultants, and notwithstanding any advice or assistance which may be rendered to Tenant by Landlord or Landlord's space planner, architect, engineers, and consultants, Landlord shall have no liability whatsoever in connection therewith and shall not be responsible for any omissions or errors contained in the plans, specifications and working drawings for the Alterations, and Tenant's waiver and indemnity set forth in Section 10.1 of this Lease, below, shall specifically apply to the plans, specifications and working drawings for the Alterations. Following Landlord's approval in its reasonable discretion of all plans, specifications and working drawings for the Alterations, a contractor to construct the Alterations shall be selected by Tenant and reasonably approved by Landlord. Landlord shall provide to Tenant an itemized statement of costs, as set forth in the proposed contract with such contractor Tenant shall approve and deliver to Landlord the itemized statement of costs provided to Tenant in accordance with this Section 8.2, and upon receipt of such itemized statement of costs by Landlord, Landlord shall be released by Tenant (i) to retain the contractor who submitted such itemized statement of costs, and (ii) to purchase the items set forth in such itemized statement of costs and to commence the construction relating to such items. Landlord hereby assigns to Tenant all warranties and guaranties by the contractor selected in accordance with this Section 8.2 to

construct the Alterations, and Tenant hereby waives all claims against Landlord relating to, or arising out of the construction of, the Alterations. In the event Tenant requests any Alterations in the Premises which require or give rise to governmentally required changes to the "Base Building," as that term is defined below, then Landlord shall, at Tenant's expense, make such changes to the Base Building. As used in this Lease, the "**Base Building**" shall mean the Building Structure and the Building Systems. In performing the work of any Alterations for which Tenant is responsible, Tenant shall have the work performed in such manner so as not to unreasonably obstruct access to the Project or any portion thereof, by any other tenant of the Project, and so as not to unreasonably obstruct the business of Landlord or other tenants in the Project. Tenant shall not use (and upon notice from Landlord shall cease using) contractors, services, workmen, labor, materials or equipment that, in Landlord's reasonable judgment, would disturb labor harmony with the workforce or trades engaged in performing other work, labor or services in or about the Building or the Common Areas. In addition to Tenant's obligations under Article 9 of this Lease, upon completion of any Alterations, Tenant agrees to cause a Notice of Completion to be recorded in the office of the Recorder of the County in which the Project is located in accordance with Section 3093 of the Civil Code of the State of California or any successor statute, and Tenant shall deliver to the Project construction manager a reproducible copy of the "as built" drawings of the Alterations in CAD format as well as all permits, approvals and other documents issued by any governmental agency in connection with the Alterations.

8.3 **Payment for Improvements**. Tenant shall pay to Landlord within thirty (30) days after being billed for the same, all costs related to the construction of the Alterations, including, without limitation, the following items and costs: (i) all amounts actually paid by Landlord to any architect/space planner, engineer, consultant, contractor, subcontractor, mechanic, materialman or other person, whether retained by Landlord or Tenant, in connection with the Alterations, and all fees incurred by, and the actual cost of documents and materials supplied by, Landlord and Landlord's consultants in connection with the preparation and review of all plans, specifications and working drawings for the Alterations; (ii) all plan check, permit and license fees relating to construction of the Alterations paid by Landlord; (iii) the cost of any changes in the Base Building when such changes are required by any plans, specifications or working drawings for the Alterations (including if such changes are due to the fact that such work is prepared on an unoccupied basis), such cost to include all direct architectural and/or engineering fees and expenses incurred by Landlord in connection therewith; (iv) the cost of any changes to the plans, specifications and working drawings for the Alterations or to the Alterations themselves required by all applicable zoning and building codes and other laws and paid by Landlord; (v) sales and use taxes and Title 24 fees imposed on, assessed against or paid by Landlord; (vi) Landlord's standard fee in the amount of five percent (5%) of the hard cost of such Alterations for its involvement with such Alterations; and (vii) all other costs incurred by Landlord in connection with the construction of the Alterations. Landlord, at its option, may render bills to Tenant in advance of, or during, construction of the Alterations so as to enable Landlord to pay all costs and expenses incurred by Landlord in connection with the Alterations (including, without limitation, costs of the contractor retained to construct the Alterations) without advancing Landlord's own funds. At Landlord's election in its reasonable discretion, Tenant shall deliver to Landlord prior to commencement of construction of the Alterations cash in an amount equal to all estimated costs related to the construction of such Alterations, or such lesser amount as Landlord shall specify, to be held by Landlord and disbursed by Landlord for costs related to the construction of the Alterations, as such costs are incurred. In the event that, after Tenant's approval of a cost proposal for the

Alterations in accordance with Section 8.2, above, any revisions, changes or substitutions shall be made to the plans, specifications and working drawings or the Alterations, any additional costs which arise in connection with such revisions, changes or substitutions or any other additional costs shall be paid by Tenant to Landlord immediately upon Landlord's request. Any surplus funds delivered by Tenant and held by Landlord in connection with the Alterations shall be refunded to Tenant when all costs related to the construction of the Alterations have been paid in full.

8.4 **Construction Insurance**. In the event that any Alterations are made pursuant to this Article 8, prior to the commencement of such Alterations, Tenant shall provide Landlord with certificates of insurance evidencing compliance with the requirements of Section 10.14 of this Lease, it being understood and agreed that all of such Alterations shall be insured by Tenant pursuant to Article 10 of this Lease immediately upon completion thereof. In addition, Landlord may, in its reasonable discretion, require Tenant to obtain a lien and completion bond or some alternate form of security satisfactory to Landlord in an amount sufficient to ensure the lien-free completion of such Alterations and naming Landlord as a co-obligee.

8.5 **Landlord's Property**. All Alterations, improvements, fixtures, equipment and/or appurtenances which may be installed or placed in or about the Premises, from time to time, shall be at the sole cost of Tenant and shall be and become the property of Landlord (other than Tenant's personal property and trade fixtures) at the expiration of the Lease Term, or the earlier termination thereof; provided, however, Landlord may, by written notice to Tenant prior to the end of the Lease Term, or given following any earlier termination of this Lease, require Tenant, at Tenant's expense, to remove any Alterations or improvements and to repair any damage to the Premises and Building caused by such removal and return the affected portion of the Premises to their condition existing prior to the installation of such Alterations or improvements; provided; however, that notwithstanding the foregoing, upon request by Tenant at the time of Tenant's request for Landlord's consent to any Alteration or improvement, Landlord shall notify Tenant whether the applicable Alteration or improvement will be required to be removed pursuant to the terms of this Section 8.5. If Tenant fails to complete such removal and/or to repair any damage caused by the removal of any Alterations or improvements in the Premises and return the affected portion of the Premises to their condition existing prior to the installation of such Alterations or improvements, prior to the expiration or earlier termination of this Lease, then Rent shall continue to accrue under this Lease in accordance with Article 16, below, after the end of the Lease Term after Landlord delivers written notice to Tenant of its failure to surrender the Premises in the required condition until such work shall be completed, and Landlord shall have the right, but not the obligation, to perform such work and to charge the cost thereof to Tenant. Except to the extent due to the gross negligence or willful misconduct or violation of this Lease by Landlord or its agents, employees or contractors, Tenant hereby protects, defends, indemnifies and holds Landlord harmless from any liability, cost, obligation, expense or claim of lien, including but not limited to, court costs and reasonable attorneys' fees, in any manner relating to the installation, placement, removal or financing of any such Alterations, improvements, fixtures and/or equipment in, on or about the Premises, which obligations of Tenant shall survive the expiration or earlier termination of this Lease.

ARTICLE 9

COVENANT AGAINST LIENS

Tenant shall keep the Project and Premises free from any liens or encumbrances arising out of the work performed, materials furnished or obligations incurred by or on behalf of Tenant, and shall protect, defend, indemnify and hold Landlord harmless from and against any claims, liabilities, judgments or costs (including, without limitation, reasonable attorneys' fees and costs) arising out of same or in connection therewith. Tenant shall give Landlord notice at least five (5) business days prior to the commencement of any work on the Premises which may give rise to a lien on the Premises, Building or Project (or such additional time as may be necessary under applicable laws) to afford Landlord the opportunity of posting and recording appropriate notices of non-responsibility. Tenant shall remove any such lien or encumbrance by bond or otherwise within twenty (20) days after notice by Landlord, and if Tenant shall fail to do so, Landlord may pay the amount necessary to remove such lien or encumbrance, without being responsible for investigating the validity thereof. The amount so paid shall be deemed Additional Rent under this Lease payable upon demand, without limitation as to other remedies available to Landlord under this Lease. Nothing contained in this Lease shall authorize Tenant to do any act which shall subject Landlord's title to the Building or Premises to any liens or encumbrances whether claimed by operation of law or express or implied contract. Any claim to a lien or encumbrance upon the Building or Premises arising in connection with any such work or respecting the Premises not performed by or at the request of Landlord shall be null and void, or at Landlord's option shall attach only against Tenant's interest in the Premises and shall in all respects be subordinate to Landlord's title to the Project, Building and Premises.

ARTICLE 10

INDEMNITY AND INSURANCE

10.1 **Tenant's Indemnity**.

10.1.1 **Indemnity**. To the maximum extent permitted by law, Tenant waives any right to contribution against the "Landlord Parties," as that term is defined in Section 10.13, below, and agrees to indemnify and save harmless the Landlord Parties from and against all claims of whatever nature arising from or claimed to have arisen from (i) any act, omission or negligence of the "Tenant Parties," as that term is defined in Section 10.13, below; (ii) any accident, injury or damage whatsoever caused to any person, or to the property of any person, occurring in or about the Premises from the earlier of (A) the date on which any Tenant Party first enters the Premises for any reason or (B) the Lease Commencement Date, and thereafter throughout and until the end of the Lease Term and after the end of the Lease Term for as long as Tenant or anyone acting by, through or under Tenant is in occupancy of the Premises or any portion thereof; (iii) any accident, injury or damage whatsoever occurring outside the Premises but within the Project, where such accident, injury or damage results, or is claimed to have resulted, from any act, omission or negligence on the part of any of the Tenant Parties; or (iv) any breach of this Lease by Tenant. Tenant shall pay such indemnified amounts as they are incurred by the Landlord Parties. This indemnification shall not be construed to deny or reduce any other rights or obligations of indemnity that a Landlord Party may have under this Lease or the common law. Notwithstanding

anything contained herein to the contrary, Tenant shall not be obligated to release or indemnify a Landlord Party for any claims to the extent that any Landlord Party's damages in fact result from any Landlord Party's gross negligence or willful misconduct or violation of this Lease.

10.1.2 **Breach**. In the event that Tenant breaches any of its indemnity obligations hereunder or under any other contractual or common law indemnity: (i) Tenant shall pay to the Landlord Parties all liabilities, loss, cost, or expense (including reasonable attorney's fees) incurred as a result of said breach; and (ii) the Landlord Parties may deduct and offset from any amounts due to Tenant under this Lease any amounts owed by Tenant pursuant to this section.

10.1.3 **No limitation**. The indemnification obligations under this Section shall not be limited in any way by any limitation on the amount or type of damages, compensation or benefits payable by or for Tenant or any subtenant or other occupant of the Premises under workers' compensation acts, disability benefit acts, or other employee benefit acts. Tenant waives any immunity from or limitation on its indemnity or contribution liability to the Landlord Parties based upon such acts.

10.1.4 **Subtenants and other occupants**. Tenant shall require its subtenants and other occupants of the Premises to provide similar indemnities to the Landlord Parties in a form reasonably acceptable to Landlord.

10.1.5 **Survival**. The terms of this section shall survive any termination or expiration of this Lease.

10.1.6 **Costs**. The foregoing indemnity and hold harmless agreement shall include indemnity for all costs, expenses and liabilities (including, without limitation, attorneys' fees and disbursements) incurred by the Landlord Parties in connection with any such claim or any action or proceeding brought thereon, and the defense thereof. In addition, in the event that any action or proceeding shall be brought against one or more Landlord Parties by reason of any such claim, Tenant, upon request from the Landlord Party, shall resist and defend such action or proceeding on behalf of the Landlord Party by counsel appointed by Tenant's insurer (if such claim is covered by insurance without reservation) or otherwise by counsel reasonably satisfactory to the Landlord Party. The Landlord Parties shall not be bound by any compromise or settlement of any such claim, action or proceeding without the prior written consent of such Landlord Parties.

10.2 **Tenant's Risk**. Tenant agrees to use and occupy the Premises, and to use such other portions of the Building and the Project as Tenant is given the right to use by this Lease at Tenant's own risk. The Landlord Parties shall not be liable to the Tenant Parties for any damage, injury, loss, compensation, or claim (including, but not limited to, claims for the interruption of or loss to a Tenant Party's business) based on, arising out of or resulting from any cause whatsoever, including, but not limited to, repairs to any portion of the Premises or the Building or the Project, any fire, robbery, theft, mysterious disappearance, or any other crime or casualty, any cyber attack affecting the Building systems or any computer systems in the Premises or the Building, the actions of any other tenants of the Building or of any other person or persons, or any leakage in any part or portion of the Premises or the Building or the Project, or from water, rain or snow that may leak into, or flow from any part of the Premises or the Building or the Project, or from drains, pipes or plumbing fixtures in the Building or the Project. Any goods, property or personal effects stored

or placed in or about the Premises shall be at the sole risk of the Tenant Party, and neither the Landlord Parties nor their insurers shall in any manner be held responsible therefor. The Landlord Parties shall not be responsible or liable to a Tenant Party, or to those claiming by, through or under a Tenant Party, for any loss or damage that may be occasioned by or through the acts or omissions of persons occupying adjoining premises or any part of the premises adjacent to or connecting with the Premises or any part of the Building or otherwise. Notwithstanding the foregoing, the Landlord Parties shall not be released from liability for any injury, loss, damages or liability to the extent arising from any gross negligence or willful misconduct of the Landlord Parties on or about the Premises or Landlord's violation of this Lease; provided, however, in no event shall the Landlord Parties have any liability to a Tenant Party based on any loss with respect to or interruption in the operation of Tenant's business. The provisions of this section shall be applicable until the expiration or earlier termination of the Lease Term, and during such further period as Tenant may use or be in occupancy of any part of the Premises or of the Building.

10.3 **Tenant's Commercial General Liability Insurance**. Tenant agrees to maintain in full force on or before the earlier of (i) the date on which any Tenant Party first enters the Premises for any reason or (ii) the Lease Commencement Date throughout the Lease Term of this Lease, and thereafter for so long as Tenant is in occupancy of any part of the Premises, a policy of commercial general liability insurance, on an occurrence basis, issued on a form at least as broad as Insurance Services Office ("ISO") Commercial General Liability Coverage "occurrence" form CG 00 01 10 01 or another ISO Commercial General Liability "occurrence" form providing equivalent coverage. Such insurance shall include contractual liability coverage, specifically covering but not limited to the indemnification obligations undertaken by Tenant in this Lease. The minimum limits of liability of such insurance shall be $5,000,000.00 per occurrence, which may be satisfied through a combination of primary and excess/umbrella insurance. In addition, in the event Tenant hosts a function in the Premises, Tenant agrees to obtain, and cause any persons or parties providing services for such function to obtain, the appropriate insurance coverages as determined by Landlord (including liquor liability coverage, if applicable) and provide Landlord with evidence of the same.

10.4 **Tenant's Property Insurance**. Tenant shall maintain at all times during the Lease Term, and during such earlier time as Tenant may be performing work in or to the Premises or have property, fixtures, furniture, equipment, machinery, goods, supplies, wares or merchandise on the Premises, and continuing thereafter so long as Tenant is in occupancy of any part of the Premises, business interruption insurance and insurance against loss or damage covered by the so-called "all risk" or equivalent type insurance coverage with respect to (i) Tenant's property, fixtures, furniture, equipment, machinery, goods, supplies, wares and merchandise, (ii) the "Tenant Improvements," as that term is defined in the Tenant Work Letter, and any other additions, alterations and improvements which exist in the Premises as of the Lease Commencement Date (excluding the Base Building) (the "**Original Improvements**"), and all alterations, improvements and other modifications made by or on behalf of the Tenant in the Premises, and (iii) other property of Tenant located at the Premises (the foregoing items in (i), and (iii), collectively "**Tenant's Property**"). The business interruption insurance required by this section shall be in minimum amounts typically carried by prudent tenants engaged in similar operations, but in no event shall be in an amount less than the Base Rent then in effect during any Lease Year, plus any Additional Rent due and payable for the immediately preceding Lease Year. The "all risk" insurance required by this section shall be in an amount at least equal to the full replacement cost of Tenant's Property.

In addition, during such time as Tenant is performing work in or to the Premises, Tenant, at Tenant's expense, shall also maintain, or shall cause its contractor(s) to maintain, builder's risk insurance for the full insurable value of such work. Landlord and such additional persons or entities as Landlord may reasonably request shall be named as loss payees, as their interests may appear, on the policy or policies required by subpart (ii), above. In the event of loss or damage covered by the "all risk" insurance required by this section, the responsibilities for repairing or restoring the loss or damage shall be determined in accordance with Article 11 of this Lease, below. To the extent that Landlord is obligated to pay for the repair or restoration of the loss or damage covered by the policy, Landlord shall be paid the proceeds of the "all risk" insurance covering the loss or damage. To the extent Tenant is obligated to pay for the repair or restoration of the loss or damage, covered by the policy, Tenant shall be paid the proceeds of the "all risk" insurance covering the loss or damage. If both Landlord and Tenant are obligated to pay for the repair or restoration of the loss or damage covered by the policy, the insurance proceeds shall be paid to each of them in the pro rata proportion of their obligations to repair or restore the loss or damage. If the loss or damage is not repaired or restored (for example, if the Lease is terminated pursuant to Section 11.2 of this Lease, below), the insurance proceeds shall be paid to Landlord and Tenant in the pro rata proportion of their relative contributions to the cost of the leasehold improvements covered by the policy. The insurance required to be maintained by Tenant pursuant to this section may be carried under blanket insurance policies covering the Premises and other properties owned or leased by Tenant or Tenant's Affiliates, so long as such policies comply with this Lease. The coverage provided by such policies shall at all times meet the requirements of this Lease, without co-insurance.

10.5 **Tenant's Other Insurance**. Tenant agrees to maintain in full force on or before the earlier of (i) the date on which any Tenant Party first enters the Premises for any reason or (ii) the Lease Commencement Date, and thereafter throughout the end of the Lease Term, and after the end of the Lease Term so long as Tenant is in occupancy of any part of the Premises (1) automobile liability insurance (covering any automobiles owned or operated by Tenant at the Project); (2) worker's compensation insurance as required by Applicable Laws; and (3) employer's liability insurance. Such automobile liability insurance shall be in an amount not less than One Million Dollars ($1,000,000) for each accident. Such employer's liability insurance shall be in an amount not less than One Million Dollars ($1,000,000) for each accident, One Million Dollars ($1,000,000) disease-policy limit, and One Million Dollars ($1,000,000) disease-each employee.

10.6 **Requirements For Insurance**. All insurance required to be maintained by Tenant pursuant to this Lease shall be maintained with responsible companies that are admitted to do business, and are in good standing, in the jurisdiction in which the Premises are located and that have a rating of at least "A" and are within a financial size category of not less than "Class X" in the most current Best's Key Rating Guide or such similar rating as may be reasonably selected by Landlord. All such insurance shall: (1) be acceptable in form and content to Landlord; and (2) contain a clause requiring the insurer to provide Landlord thirty (30) days' prior written notice of cancellation or failure to renew. All commercial general liability, excess/umbrella liability and automobile liability insurance policies shall be primary and noncontributory. No such policy shall contain any self-insured retention greater than $25,000.00 for property insurance and $25,000.00 for commercial general liability insurance. Any deductibles and such self-insured retentions shall be deemed to be "insurance" for purposes of the waiver in Section 10.13 of this Lease, below. Landlord reserves the right from time to time to require Tenant to obtain higher minimum amounts

of insurance based on such limits as are customarily carried with respect to similar properties in the area in which the Premises are located. The minimum amounts of insurance required by this Lease shall not be reduced by the payment of claims or for any other reason. In the event Tenant shall fail to obtain or maintain any insurance meeting the requirements of this Article, or to deliver such policies or certificates as required by this Article, Landlord may, at its option, on five (5) days' notice to Tenant, procure such policies for the account of Tenant, and the cost thereof shall be paid to Landlord within five (5) days after delivery to Tenant of bills therefor.

10.7 **Additional Insureds**. The commercial general liability and auto insurance carried by Tenant pursuant to this Lease, and any additional liability insurance carried by Tenant pursuant to Section 10.3 of this Lease, above, shall include Landlord, Landlord's managing agent, and such other persons as Landlord may reasonably request from time to time as additional insureds (collectively "**Additional Insureds**") with respect to liability arising out of or related to this Lease or the operations of Tenant. Such insurance shall provide primary coverage without contribution from any other insurance carried by or for the benefit of Landlord, Landlord's managing agent, or other Additional Insureds. For the avoidance of doubt, each primary policy and each excess/umbrella policy through which Tenant satisfies its obligations under this Section must provide coverage to the Additional Insureds that is primary and non-contributory.

10.8 **Certificates Of Insurance**. On or before the earlier of (i) the date on which any Tenant Party first enters the Premises for any reason or (ii) the Lease Commencement Date, Tenant shall furnish Landlord with certificates evidencing the insurance coverage required by this Lease, and renewal certificates shall be furnished to Landlord at least annually thereafter, and at least ten (10) days prior to the expiration date of each policy for which a certificate was furnished. (Acceptable forms of such certificates for liability and property insurance, respectively, are attached hereto as **Exhibit G**, however other forms of certificates may satisfy the requirements of this Section.) Failure by the Tenant to provide the certificates or letters required by this Section shall not be deemed to be a waiver of the requirements in this Section.

10.9 **Subtenants And Other Occupants**. Tenant shall require its subtenants and other occupants of the Premises to provide written documentation evidencing the obligation of such subtenant or other occupant to indemnify the Landlord Parties to the same extent that Tenant is required to indemnify the Landlord Parties pursuant to Section 10.1 of this Lease, above, and to maintain insurance that meets the requirements of this Article, and otherwise to comply with the requirements of this Article, provided that the terms of this Section 10.9 shall not relieve Tenant of any of its obligations to comply with the requirements of this Article. Tenant shall require all such subtenants and occupants to supply certificates of insurance evidencing that the insurance requirements of this Article have been met and shall forward such certificates to Landlord on or before the earlier of (i) the date on which the subtenant first enters the Premises or (ii) the commencement of the sublease. Tenant shall be responsible for identifying and remedying any deficiencies in such certificates or policy provisions.

10.10 **No Violation Of Building Policies**. Tenant shall not commit or permit its agents, employees or contractors to commit any violation of the policies of fire, boiler, sprinkler, water damage or other insurance covering the Project and/or the fixtures, equipment and property therein carried by Landlord, or do or permit anything to be done, or keep or permit anything to be kept, in the Premises, which in case of any of the foregoing (i) would result in termination of any such

policies, (ii) would adversely affect Landlord's right of recovery under any of such policies, or (iii) would result in reputable and independent insurance companies refusing to insure the Project or the property of Landlord in amounts reasonably satisfactory to Landlord.

10.11 **Tenant To Pay Premium Increases**. If, because of anything done by Tenant or its agents, employees or contractors (or its subtenant or other occupants of the Premises), the rates for liability, fire, boiler, sprinkler, water damage or other insurance on the Project or on the property and equipment of Landlord shall be higher than they otherwise would be, Tenant shall reimburse Landlord for the additional insurance premiums thereafter paid by Landlord which shall have been charged because of the aforesaid reasons, such reimbursement to be made from time to time on Landlord's demand.

10.12 **Landlord's Insurance**.

10.12.1 **Required insurance**. Landlord shall maintain insurance against loss or damage with respect to the Building on an "all risk" or equivalent type insurance form, with customary exceptions, subject to such deductibles and self-insured retentions as Landlord may determine, in an amount equal to at least the replacement value of the Building. The cost of such insurance shall be treated as a part of Operating Expenses. Such insurance shall be maintained with an insurance company selected by Landlord. Payment for losses thereunder shall be made solely to Landlord.

10.12.2 **Optional insurance**. Landlord may maintain such additional insurance with respect to the Building and the Project, including, without limitation, earthquake insurance, terrorism insurance, flood insurance, liability insurance and/or rent insurance, as Landlord may in its reasonable discretion elect. Landlord may also maintain such other insurance as may from time to time be required by a "Mortgagee," as that term is defined in Section 18.2 of this Lease, below. The cost of all such additional insurance shall also be part of the Operating Expenses, subject to the terms and condition of Section 4.2.7.

10.12.3 **Blanket and self-insurance**. Any or all of Landlord's insurance may be provided by blanket coverage maintained by Landlord or any affiliate of Landlord under its insurance program for its portfolio of properties, or by Landlord or any affiliate of Landlord under a program of self-insurance, and in such event Operating Expenses shall include the portion of the reasonable cost of blanket insurance or self-insurance that is equitably allocated to the Building.

10.12.4 **No obligation**. Landlord shall not be obligated to insure, and shall not assume any liability of risk of loss for, Tenant's Property, including any such property or work of tenant's subtenants or occupants. Landlord will also have no obligation to carry insurance against, nor be responsible for, any loss suffered by Tenant, subtenants or other occupants due to interruption of Tenant's or any subtenant's or occupant's business.

10.13 **Waiver Of Subrogation**. To the fullest extent permitted by law, and notwithstanding any term or provision of this Lease to the contrary, the parties hereto waive and release any and all rights of recovery against the other, and agree not to seek to recover from the other or to make any claim against the other, and in the case of Landlord, against all Tenant Parties, and in the case of Tenant, against all Landlord Parties (including, but not limited to, each

Additional Insured), for any loss or damage incurred by the waiving/releasing party to the extent such loss or damage is caused by or results from a risk which is actually insured under any insurance policy required by this Lease or which would have been so insured had the party carried the insurance it was required to carry hereunder without regard to the negligence of the entity so released. Tenant shall obtain from its subtenants and other occupants of the Premises a similar waiver and release of claims against any or all of Tenant or Landlord. In addition, the parties hereto (and in the case of Tenant, its subtenants and other occupants of the Premises) shall procure an appropriate clause in, or endorsement on, any insurance policy required by this Lease pursuant to which the insurance company waives subrogation so long as no material additional premium is charged for such waiver. The insurance policies required by this Lease shall contain no provision that would invalidate or restrict the parties' waiver and release of the rights of recovery in this section. The parties hereto covenant that no insurer shall hold any right of subrogation against the parties hereto by virtue of such insurance policy.

The term "**Landlord Party**" or "**Landlord Parties**" shall mean Landlord, any affiliate of Landlord, Landlord's managing agents for the Building, each Mortgagee, each ground lessor, and each of their respective direct or indirect partners, officers, shareholders, directors, members, trustees, beneficiaries, servants, employees, principals, contractors, licensees, agents or representatives. For the purposes of this Lease, the term "**Tenant Party**" or "**Tenant Parties**" shall mean Tenant, any affiliate of Tenant, any permitted subtenant or any other permitted occupant of the Premises, and each of their respective direct or indirect partners, officers, shareholders, directors, members, trustees, beneficiaries, servants, employees, principals, contractors and agents.

10.14 **Tenant's Work**. During such times as Tenant is performing work or having work or services performed in or to the Premises, Tenant shall require its contractors, and their subcontractors of all tiers, to obtain and maintain commercial general liability, automobile, workers compensation, employer's liability, builder's risk, and equipment/property insurance in such amounts and on such terms as are customarily required of such contractors and subcontractors on similar projects. The amounts and terms of all such insurance are subject to Landlord's written approval, which approval shall not be unreasonably withheld. The commercial general liability and auto insurance carried by Tenant's contractors and their subcontractors of all tiers pursuant to this section shall name the Additional Insured as additional insureds with respect to liability arising out of or related to their work or services. Such insurance shall provide primary coverage . Such insurance shall also waive any right of subrogation against each Additional Insured. Tenant shall obtain and submit to Landlord, prior to the earlier of (i) the entry onto the Premises by such contractors or subcontractors or (ii) commencement of the work or services, certificates of insurance evidencing compliance with the requirements of this section.

ARTICLE 11

DAMAGE AND DESTRUCTION

11.1 **Repair of Damage to Premises by Landlord**. Tenant shall promptly notify Landlord of any damage to the Premises resulting from fire or any other casualty. If the Premises or any Common Areas necessary to Tenant's use of or access to the Premises shall be damaged by fire or other casualty, Landlord shall promptly and diligently, subject to reasonable delays for insurance adjustment or other matters beyond Landlord's reasonable control, and subject to all

other terms of this Article 11, restore the Base Building and such Common Areas. Such restoration shall be to substantially the same condition of the Base Building and the Common Areas prior to the casualty, except for modifications required by zoning and building codes and other laws or by the holder of a mortgage on the Building or Project or any other modifications to the Common Areas deemed desirable by Landlord, provided that access to the Premises and any common restrooms serving the Premises shall not be materially impaired. Upon the occurrence of any damage to the Premises, upon notice (the "**Landlord Repair Notice**") to Tenant from Landlord, Tenant shall assign to Landlord (or to any party designated by Landlord) all insurance proceeds payable to Tenant under Tenant's insurance required under item (ii) of Section 10.4 of this Lease, and Landlord shall repair any injury or damage to the Tenant Improvements and the Original Improvements installed in the Premises and shall return such Tenant Improvements and Original Improvements to their original condition; provided that if the cost of such repair by Landlord exceeds the amount of insurance proceeds received by Landlord from Tenant's insurance carrier, as assigned by Tenant, the cost of such repairs shall be paid by Tenant to Landlord prior to Landlord's commencement of repair of the damage. In the event that Landlord does not deliver the Landlord Repair Notice within sixty (60) days following the date the casualty becomes known to Landlord, Tenant shall, at its sole cost and expense, repair any injury or damage to the Tenant Improvements and the Original Improvements installed in the Premises and shall return such Tenant Improvements and Original Improvements to their original condition. Whether or not Landlord delivers a Landlord Repair Notice, prior to the commencement of construction, Tenant shall submit to Landlord, for Landlord's review and approval, all plans, specifications and working drawings relating thereto, and Landlord shall select the contractors to perform such improvement work. Landlord shall not be liable for any inconvenience or annoyance to Tenant or its visitors, or injury to Tenant's business resulting in any way from such damage or the repair thereof; provided, however, if such fire or other casualty shall have damaged the Premises or a portion thereof or Common Areas necessary to Tenant's occupancy, then Landlord shall allow Tenant a proportionate abatement of Rent during the time and to the extent and in the proportion that the Premises or such portion thereof are unfit for occupancy for the purposes permitted under this Lease, and are not occupied by Tenant as a result thereof, provided, however, if the damage or destruction is due to the gross negligence or willful misconduct of Tenant or any of its agents, employees or contractors, then Tenant shall be responsible for any reasonable, applicable insurance deductible (which shall be payable to Landlord upon demand) and there shall be no rent abatement. In the event that Landlord shall not deliver the Landlord Repair Notice, Tenant's right to rent abatement pursuant to the preceding sentence shall terminate as of the date which is reasonably determined by Landlord to be the date Tenant should have completed repairs to the Premises assuming Tenant used reasonable due diligence in connection therewith.

11.2 **Landlord's Option to Repair**. Notwithstanding the terms of Section 11.1 of this Lease, Landlord may elect not to rebuild and/or restore the Premises, Building and/or Project, and instead terminate this Lease, by notifying Tenant in writing of such termination within sixty (60) days after the date of discovery of the damage, such notice to include a termination date giving Tenant sixty (60) days to vacate the Premises, but Landlord may so elect only if the Building shall be damaged by fire or other casualty or cause, whether or not the Premises are affected, and one or more of the following conditions is present: (i) in Landlord's reasonable judgment, repairs cannot reasonably be completed within one hundred eighty (180) days after the date of discovery of the damage (when such repairs are made without the payment of overtime or other premiums); (ii) the holder of any mortgage on the Building or Project or ground lessor with respect to the

Building or Project shall require that the insurance proceeds or any portion thereof be used to retire the mortgage debt, or shall terminate the ground lease, as the case may be; (iii) at least $500,000.00 of the cost to repair the damage is not covered by Landlord's insurance policies or that portion of the proceeds from Landlord's insurance policies allocable to the Building or the Project, as the case may be; or (iv) the damage occurs during the last twelve (12) months of the Lease Term; or (vi) any owner of any other portion of the Project, other than Landlord, does not intend to repair the damage to such portion of the Project; provided, however, that if such fire or other casualty shall have damaged the Premises or a portion thereof or Common Areas necessary to Tenant's occupancy and as a result of such damage the Premises are unfit for occupancy, and provided that Landlord does not elect to terminate this Lease pursuant to Landlord's termination right as provided above, and either (a) the repairs cannot, in the reasonable opinion of Landlord's contractor, be completed within two hundred ten (210) days after the date of discovery of the damage, or (b) the damage occurs during the last twelve (12) months of the Lease Term and will reasonably require in excess of sixty (60) days after the date of the damage to repair, Tenant may elect, no earlier than sixty (60) days after the date of the damage and not later than ninety (90) days after the date of such damage, to terminate this Lease by written notice to Landlord effective as of the date specified in the notice, which date shall not be less than thirty (30) days nor more than sixty (60) days after the date such notice is given by Tenant. Notwithstanding the foregoing, Landlord may not terminate this Lease if Landlord actually intends to restore the casualty damage in the following one hundred eighty (180) days.

11.3 **Waiver of Statutory Provisions**. The provisions of this Lease, including this Article 11, constitute an express agreement between Landlord and Tenant with respect to any and all damage to, or destruction of, all or any part of the Premises, the Building or the Project, and any statute or regulation of the State of California, including, without limitation, Sections 1932(2) and 1933(4) of the California Civil Code, with respect to any rights or obligations concerning damage or destruction in the absence of an express agreement between the parties, and any other statute or regulation, now or hereafter in effect, shall have no application to this Lease or any damage or destruction to all or any part of the Premises, the Building or the Project.

ARTICLE 12

NONWAIVER

No provision of this Lease shall be deemed waived by either party hereto unless expressly waived in a writing signed thereby. The waiver by either party hereto of any breach of any term, covenant or condition herein contained shall not be deemed to be a waiver of any subsequent breach of same or any other term, covenant or condition herein contained. The subsequent acceptance of Rent hereunder by Landlord shall not be deemed to be a waiver of any preceding breach by Tenant of any term, covenant or condition of this Lease, other than the failure of Tenant to pay the particular Rent so accepted, regardless of Landlord's knowledge of such preceding breach at the time of acceptance of such Rent. No acceptance of a lesser amount than the Rent herein stipulated shall be deemed a waiver of Landlord's right to receive the full amount due, nor shall any endorsement or statement on any check or payment or any letter accompanying such check or payment be deemed an accord and satisfaction, and Landlord may accept such check or payment without prejudice to Landlord's right to recover the full amount due. No receipt of monies by Landlord from Tenant after the termination of this Lease shall in any way alter the length of the

Lease Term or of Tenant's right of possession hereunder, or after the giving of any notice shall reinstate, continue or extend the Lease Term or affect any notice given Tenant prior to the receipt of such monies, it being agreed that after the service of notice or the commencement of a suit, or after final judgment for possession of the Premises, Landlord may receive and collect any Rent due, and the payment of said Rent shall not waive or affect said notice, suit or judgment. No payment of Rent by Tenant after a breach by Landlord shall be deemed a waiver of any breach by Landlord.

ARTICLE 13

CONDEMNATION

If the whole or any material part of the Premises or Building required for access to the Premises shall be taken by power of eminent domain or condemned by any competent authority for any public or quasi-public use or purpose, or if any adjacent property or street shall be so taken or condemned, or reconfigured or vacated by such authority in such manner as to require the use, reconstruction or remodeling of any material part of the Premises or Building required for access to the Premises, or if Landlord shall grant a deed or other instrument in lieu of such taking by eminent domain or condemnation, Landlord shall have the option to terminate this Lease effective as of the date possession is required to be surrendered to the authority. If all or any portion of the Premises is taken, or if all reasonable access to the Premises is substantially impaired, in each case for a period in excess of one hundred eighty (180) days, Tenant shall have the option to terminate this Lease effective as of the date possession is required to be surrendered to the authority. Tenant shall not because of such taking assert any claim against Landlord or the authority for any compensation because of such taking and Landlord shall be entitled to the entire award or payment in connection therewith, except that Tenant shall have the right to file any separate claim available to Tenant for any taking of Tenant's personal property and fixtures belonging to Tenant and removable by Tenant upon expiration of the Lease Term pursuant to the terms of this Lease, and for moving expenses and relocation costs, so long as such claims do not diminish the award available to Landlord, its ground lessor with respect to the Building or Project or its mortgagee, and such claim is payable separately to Tenant. All Rent shall be apportioned as of the date of such termination. If any part of the Premises shall be taken, and this Lease shall not be so terminated, the Rent shall be proportionately abated. Tenant hereby waives any and all rights it might otherwise have pursuant to Section 1265.130 of the California Code of Civil Procedure. Notwithstanding anything to the contrary contained in this Article 13, in the event of a temporary taking of all or any portion of the Premises for a period of one hundred eighty (180) days or less, then this Lease shall not terminate but the Base Rent and the Additional Rent shall be abated for the period of such taking in proportion to the ratio that the amount of rentable square feet of the Premises taken bears to the total rentable square feet of the Premises. Landlord shall be entitled to receive the entire award made in connection with any such temporary taking.

ARTICLE 14

ASSIGNMENT AND SUBLETTING

14.1 **Transfers**. Tenant shall not, without the prior written consent of Landlord, assign, mortgage, pledge, hypothecate, encumber, or permit any lien to attach to, or otherwise transfer,

this Lease or any interest hereunder, permit any assignment, or other transfer of this Lease or any interest hereunder by operation of law, sublet the Premises or any part thereof, or enter into any license or concession agreements or otherwise permit the occupancy or use of the Premises or any part thereof by any persons other than Tenant and its employees and contractors (all of the foregoing are hereinafter sometimes referred to individually as a "**Transfer,**" and, collectively, as "**Transfers**" and any person to whom any Transfer is made or sought to be made is hereinafter sometimes referred to as a "**Transferee**"). If Tenant desires Landlord's consent to any Transfer, Tenant shall notify Landlord in writing, which notice (the "**Transfer Notice**") shall include (i) the proposed effective date of the Transfer, which shall not be less than thirty (30) days nor more than one hundred eighty (180) days after the date of delivery of the Transfer Notice, (ii) a description of the portion of the Premises to be transferred (the "**Subject Space**"), (iii) all of the terms of the proposed Transfer and the consideration therefor, including calculation of the "Transfer Premium", as that term is defined in Section 14.3 below, in connection with such Transfer, the name and address of the proposed Transferee, and a copy of all existing executed and/or proposed documentation pertaining to the proposed Transfer, including all existing operative documents to be executed to evidence such Transfer or the agreements incidental or related to such Transfer, and (iv) current financial statements of the proposed Transferee certified by an officer, partner or owner thereof, business credit and personal references and history of the proposed Transferee and any other information required by Landlord which will enable Landlord to determine the financial responsibility, character, and reputation of the proposed Transferee, nature of such Transferee's business and proposed use of the Subject Space. Any Transfer made without Landlord's prior written consent shall, at Landlord's option, be null, void and of no effect, and shall, at Landlord's option, constitute a default by Tenant under this Lease after the expiration of any applicable notice and cure period expressly set forth in this Lease. Whether or not Landlord consents to any proposed Transfer, Tenant shall pay Landlord's review and processing fees, as well as any reasonable professional fees (including, without limitation, attorneys', accountants', architects', engineers' and consultants' fees) incurred by Landlord, not to exceed Three Thousand Five Hundred and 00/100 Dollars ($3,500.00) for a Transfer in the ordinary course of business, within thirty (30) days after written request by Landlord.

14.2 **Landlord's Consent**. Landlord shall not unreasonably withhold its consent to any proposed Transfer of the Subject Space to the Transferee on the terms specified in the Transfer Notice. Without limitation as to other reasonable grounds for withholding consent, the parties hereby agree that it shall be reasonable under this Lease and under any applicable law for Landlord to withhold consent to any proposed Transfer where one or more of the following apply:

14.2.1 The Transferee is of a character or reputation or engaged in a business which is not consistent with the quality of the Building or the Project, or would be a significantly less prestigious occupant of the Building than Tenant;

14.2.2 The Transferee intends to use the Subject Space for purposes which are not permitted under this Lease;

14.2.3 The Transferee is either a governmental agency or instrumentality thereof;

14.2.4 The Transferee is not a party of reasonable financial worth and/or financial stability in light of the responsibilities to be undertaken in connection with the Transfer on the date consent is requested;

14.2.5 The proposed Transfer would constitute a breach by Landlord of its obligations under another lease for space in the Project, or would give a tenant of the Project a right to then cancel its lease;

14.2.6 Landlord has suitable space available and either the proposed Transferee, or any person or entity which directly or indirectly, controls, is controlled by, or is under common control with, the proposed Transferee, (i) occupies space in the Project at the time of the request for consent, or (ii) is negotiating or has negotiated a letter of intent or other lease proposal with Landlord to lease space in the Project, or (iii) has toured space in the Project with Landlord in the preceding six (6) months;

14.2.7 In Landlord's reasonable judgment, the use of the Premises by the proposed Transferee would materially increase the use of the space to more than a reasonable density of occupants per square foot of the Premises (which shall be based on other tenants of the Project or of Comparable Buildings), or would require a material increase of services by Landlord unless Tenant agrees to pay for the increased cost of providing such services;

14.2.8 The proposed Transfer would result in the existence of, in the aggregate, more than three (3) subtenants occupying the Premises at any given time during the Lease Term; or

14.2.9 Any part of the rent payable under the proposed Transfer shall be based in whole or in part on the income or profits derived from the Subject Space or if any proposed Transfer shall potentially have any adverse effect on the real estate investment trust qualification requirements applicable to Landlord and its affiliates.

If Landlord consents to any Transfer pursuant to the terms of this Section 14.2 (and does not exercise any recapture rights Landlord may have under Section 14.4 of this Lease), Tenant may within six (6) months after Landlord's consent, but not later than the expiration of said six-month period, enter into such Transfer of the Premises or portion thereof, upon substantially the same terms and conditions as are set forth in the Transfer Notice furnished by Tenant to Landlord pursuant to Section 14.1 of this Lease, provided that if there are any changes in the terms and conditions from those specified in the Transfer Notice (i) such that Landlord would initially have been entitled to refuse its consent to such Transfer under this Section 14.2, or (ii) which would cause the proposed Transfer to be materially more favorable to the Transferee than the terms set forth in Tenant's original Transfer Notice, Tenant shall again submit the Transfer to Landlord for its approval and other action under this Article 14 (including Landlord's right of recapture, if any, under Section 14.4 of this Lease). Notwithstanding anything to the contrary in this Lease, if Tenant or any proposed Transferee claims that Landlord has unreasonably withheld or delayed its consent under Section 14.2 or otherwise has breached or acted unreasonably under this Article 14, their sole remedies shall be a suit for contract damages (other than damages for injury to, or interference with, Tenant's business including, without limitation, loss of profits, however occurring) or a declaratory judgment and an injunction for the relief sought, and Tenant hereby waives the

provisions of Section 1995.310 of the California Civil Code, or any successor statute, and all other remedies, including, without limitation, any right at law or equity to terminate this Lease, on its own behalf and, to the extent permitted under all applicable laws, on behalf of the proposed Transferee. Tenant shall indemnify, defend and hold harmless Landlord from any and all liability, losses, claims, damages, costs, expenses, causes of action and proceedings involving any third party or parties (including without limitation Tenant's proposed subtenant or assignee) who claim they were damaged by Landlord's wrongful withholding or conditioning of Landlord's consent.

14.3 **Transfer Premium**. If Landlord consents to a Transfer, as a condition thereto which the parties hereby agree is reasonable, Tenant shall pay to Landlord fifty percent (50%) of any "Transfer Premium," as that term is defined in this Section 14.3, received by Tenant from such Transferee. "**Transfer Premium**" shall mean all rent, additional rent or other consideration payable by such Transferee in connection with the Transfer in excess of the Rent and Additional Rent payable by Tenant under this Lease during the term of the Transfer on a per rentable square foot basis if less than all of the Premises is transferred, after first deducting the reasonable expenses incurred by Tenant for (i) any changes, alterations and improvements to the Premises, or allowances in lieu thereof, in connection with the Transfer, (ii) any free base rent reasonably provided to the Transferee in connection with the Transfer (provided that such free rent shall be deducted only to the extent the same is included in the calculation of total consideration payable by such Transferee), and (iii) any brokerage commissions in connection with the Transfer and (iv) legal fees reasonably incurred in connection with the Transfer (collectively, "**Tenant's Subleasing Costs**"). "Transfer Premium" shall also include, but not be limited to, key money, bonus money or other cash consideration paid by Transferee to Tenant in connection with such Transfer, and any payment in excess of fair market value for services rendered by Tenant to Transferee or for assets, fixtures, inventory, equipment, or furniture transferred by Tenant to Transferee in connection with such Transfer. Landlord shall make a determination of the amount of Landlord's applicable share of the Transfer Premium on a monthly basis as rent or other consideration is paid by Transferee to Tenant under the Transfer. For purposes of calculating the Transfer Premium on a monthly basis, Tenant's Subleasing Costs shall be deemed to be expended by Tenant in equal monthly amounts over the entire term of the Transfer.

14.4 **Landlord's Option as to Subject Space**. Notwithstanding anything to the contrary contained in this Article 14, Landlord shall have the option, by giving written notice to Tenant within thirty (30) days after receipt of any Transfer Notice, to (i) recapture the Subject Space, or (ii) take an assignment or sublease of the Subject Space from Tenant; provided, however, that Landlord hereby acknowledges and agrees that Landlord shall not have the right to recapture or take an assignment or sublease of the Subject Space from Tenant hereunder with respect to, a sublease of less than the entire Premises for less than the remainder of the Lease Term (for purposes hereof, a sublease shall be deemed to be for the remainder of the Lease Term if, assuming all sublease renewal or extension rights are exercised, such sublease shall expire during the final twelve (12) months of the Lease Term). Such recapture or sublease or assignment notice, shall cancel and terminate this Lease, or create a sublease or assignment, as the case may be, with respect to the Subject Space as of the date stated in the Transfer Notice as the effective date of the proposed Transfer. In the event of a recapture by Landlord, if this Lease shall be canceled with respect to less than the entire Premises, then (i) the Rent reserved herein shall be prorated on the basis of the number of rentable square feet retained by Tenant in proportion to the number of rentable square feet contained in the Premises; (ii) this Lease as so amended shall continue thereafter in full force

and effect, and upon request of either party, the parties shall execute written confirmation of the same; and (iii) Landlord shall construct or cause to be constructed a demising wall separating that portion of the Premises recaptured by Landlord from that portion of the Premises retained by Tenant; provided that, Tenant hereby agrees that, notwithstanding Tenant's occupancy of its retained portion of the Premises during the construction of such demising wall by Landlord, Landlord shall be permitted to construct such demising wall during normal business hours, without any obligation to pay overtime or other premiums, and the construction of such demising wall by Landlord shall in no way constitute a constructive eviction of Tenant nor entitle Tenant to any abatement of Rent, and Landlord shall have no responsibility or for any reason be liable to Tenant for any direct or indirect injury to or interference with Tenant's business arising from the construction of such demising wall, nor shall Tenant be entitled to any compensation or damages from Landlord for loss of the use of the whole or any part of its retained portion of the Premises or of Tenant's personal property or improvements resulting from the construction of such demising wall, or for any inconvenience or annoyance occasioned by the construction of such demising wall; and provided further that, Tenant shall be responsible for, and shall pay to Landlord promptly upon being billed therefor, fifty percent (50%) of all costs related to the construction of such demising wall, including Landlord's standard fee for its involvement with such demising wall. If Landlord declines, or fails to elect in a timely manner, to recapture, sublease or take an assignment of the Subject Space under this Section 14.4, then, provided Landlord has consented to the proposed Transfer, Tenant shall be entitled to proceed to transfer the Subject Space to the proposed Transferee, subject to provisions of this Article 14.

14.5 **Effect of Transfer**. If Landlord consents to a Transfer, then (i) the terms and conditions of this Lease shall in no way be deemed to have been waived or modified; (ii) such consent shall not be deemed consent to any further Transfer by either Tenant or a Transferee; (iii) Tenant shall deliver to Landlord, promptly after execution, an original executed copy of all documentation pertaining to the Transfer in form and content reasonably acceptable to Landlord, including, without limitation, at Landlord's option, a "Transfer Agreement," as that term is defined in this Section 14.5, below; (iv) Tenant shall furnish upon Landlord's request a complete statement, certified by an independent certified public accountant, or Tenant's chief financial officer, setting forth in detail the computation of any Transfer Premium Tenant has derived and shall derive from such Transfer; and (v) no Transfer relating to this Lease or agreement entered into with respect thereto, whether with or without Landlord's consent, shall relieve Tenant or any guarantor of the Lease from any liability under this Lease, including, without limitation, in connection with the Subject Space, and, in the event of a Transfer of Tenant's entire interest in this Lease, the liability of Tenant and such Transferee shall be joint and several. Landlord or its authorized representatives shall have the right at all reasonable times to audit the books, records and papers of Tenant relating to any Transfer, and shall have the right to make copies thereof. If the Transfer Premium respecting any Transfer shall be found understated, Tenant shall, within thirty (30) days after demand, pay the deficiency, and if understated by more than two percent (2%), Tenant shall pay Landlord's costs of such audit. Notwithstanding anything to the contrary contained in this Article 14, Landlord, at its option in its sole and absolute discretion, may require, as a condition to the validity of any Transfer, that both Tenant and such Transferee enter into a commercially reasonable separate written agreement directly with Landlord (a "**Transfer Agreement**"), which Transfer Agreement, among other things, shall create privity of contract between Landlord and such Transferee with respect to the provisions of this Article 14, and shall contain such terms and provisions as Landlord may reasonably require, including, without limitation, the following: (A)

except to the extent expressly provided to the contrary in a sublease, such Transferee's agreement to be bound by all the obligations of Tenant under this Lease (including, but not limited to, Tenant's obligation to pay Rent), provided that, in the event of a Transfer of less than the entire Premises, the obligations to which such Transferee shall agree to be so bound shall be prorated on the basis of the number of rentable square feet of the Subject Space in proportion to the number of rentable square feet in the Premises; (B) such Transferee's acknowledgment of, and agreement that such Transfer shall be subordinate and subject to, Landlord's rights under Section 19.3 of this Lease; and (C) Tenant's and such Transferee's recognition of and agreement to be bound by all the terms and provisions of this Article 14, including, but not limited to, any such terms and provisions which Landlord, at its option, requires to be expressly set forth in such Transfer Agreement. Upon the occurrence of any default by Transferee under such Transfer, Landlord shall have the right, at its option, but not the obligation, on behalf of Tenant, to pursue any or all of the remedies available to Tenant under such Transfer or at law or in equity (all of which remedies shall be distinct, separate and cumulative).

14.6 **Occurrence of Default**. Any Transfer hereunder, whether or not such Transferee shall have executed a Transfer Agreement, shall be subordinate and subject to the provisions of this Lease, and if this Lease shall be terminated during the term of any Transfer, then Landlord shall have all of the rights set forth in Section 19.3 of this Lease with respect to such Transfer. In addition, if Tenant shall be in default under this Lease beyond any applicable notice and cure period expressly set forth in this Lease, then Landlord is hereby irrevocably authorized, as Tenant's agent and attorney-in-fact, to direct any Transferee to make all payments under or in connection with a Transfer directly to Landlord (which payments Landlord shall apply towards Tenant's obligations under this Lease) until such default is cured. Such Transferee shall rely on any representation by Landlord that Tenant is in default hereunder, beyond any applicable notice and cure period expressly set forth in this Lease, without any need for confirmation thereof by Tenant. Upon any assignment, the assignee shall assume in writing all obligations and covenants of Tenant thereafter to be performed or observed under this Lease. No collection or acceptance of rent by Landlord from any Transferee shall be deemed a waiver of any provision of this Article 14 or the approval of any Transferee or a release of Tenant from any obligation under this Lease, whether theretofore or thereafter accruing. In no event shall Landlord's enforcement of any provision of this Lease against any Transferee be deemed a waiver of Landlord's right to enforce any term of this Lease against Tenant or any other person. If Tenant's obligations hereunder have been guaranteed, Landlord's consent to any Transfer shall not be effective unless the guarantor also consents to such Transfer.

14.7 **Additional Transfers**. For purposes of this Lease, the term "Transfer" shall also include (i) if Tenant is a partnership or a limited liability company, the withdrawal or change, voluntary, involuntary or by operation of law, of fifty percent (50%) or more of the partners, officers or members, as applicable, or transfer of fifty percent (50%) or more of partnership, ownership or membership interests (as applicable), within a twelve (12)-month period, or the dissolution of the partnership or limited liability company without immediate reconstitution thereof, and (ii) if Tenant is a closely held corporation (*i.e.*, whose stock is not publicly held and not traded through an exchange or over the counter), (A) the dissolution, merger, consolidation or other reorganization of Tenant or (B) the sale or other transfer of an aggregate of fifty percent (50%) or more of the voting shares of Tenant (other than to immediate family members by reason of gift or death), within a twelve (12) month period, or (C) the sale of an aggregate of fifty percent

(50%) or more of the value of the unencumbered assets of Tenant within a twelve (12)-month period other than pursuant to a collaboration or joint venture agreement or (D) the sale of substantially all of the assets of Tenant. Tenant shall provide prompt written notice to Landlord of any mortgage, hypothecation or pledge of an aggregate of fifty percent (50%) or more of the value of the unencumbered assets of Tenant within a twelve (12) month period.

14.8 **Deemed Consent Transfers**. Notwithstanding anything to the contrary contained in this Lease, (A) an assignment or subletting of all or a portion of the Premises to an affiliate of Tenant (an entity which is controlled by, controls, or is under common control with, Tenant as of the date of this Lease), (B) a sale of corporate shares of capital stock in Tenant in connection with an initial public offering of Tenant's stock on a nationally-recognized stock exchange, (C) an assignment of this Lease to an entity which acquires all or substantially all of the stock or assets of Tenant, (D) an assignment of the Lease to an entity which is the resulting entity of a merger or consolidation of Tenant during the Lease Term, or I a deemed assignment under Section 14.7(ii)(B) or (C), shall not be deemed a Transfer requiring Landlord's consent under this Article 14 or be subject to Sections 14.3 or 14.4 of this Lease (any such assignee or sublessee described in items (A) through (D) or Tenant under item I of this Section 14.8 hereinafter referred to as a "**Permitted Non-Transferee**"), provided that (i) Tenant notifies Landlord at least thirty (30) days prior to the effective date of any such assignment or sublease and promptly supplies Landlord with any documents or information reasonably requested by Landlord regarding such transfer or transferee as set forth above, (ii) Tenant is not in default, beyond any applicable notice and cure period, and such assignment or sublease is not a subterfuge by Tenant to avoid its obligations under this Lease, and (iii) such Permitted Non-Transferee shall be of a character and reputation consistent with the quality of the Building, (iv) such Permitted Non-Transferee shall have a tangible net worth (not including goodwill as an asset) computed in accordance with generally accepted accounting principles ("**Net Worth**") at least equal to the greater of (1) the Net Worth of Original Tenant on the date of this Lease, and (2) the Net Worth of Tenant on the day immediately preceding the effective date of such assignment or sublease, and (v) no assignment relating to this Lease, whether with or without Landlord's consent, shall relieve Tenant from any liability under this Lease, and, in the event of an assignment of Tenant's entire interest in this Lease, the liability of Tenant and such transferee shall be joint and several. Landlord shall not have the right to recapture under Section 14.4 of this Lease with respect to a Transferee that would qualify as a Permitted Non-Transferee but for the failure to meet the requirements of clause (iv)(1) in the immediately preceding sentence. An assignee of Tenant's entire interest in this Lease who qualifies as a Permitted Non-Transferee may also be referred to herein as a "**Non-Transferee Assignee**." "**Control**," as used in this Section 14.8, shall mean the ownership, directly or indirectly, of at least fifty-one percent (51%) of the voting securities of, or possession of the right to vote, in the ordinary direction of its affairs, of at least fifty-one percent (51%) of the voting interest in, any person or entity.

ARTICLE 15

SURRENDER OF PREMISES; OWNERSHIP AND

REMOVAL OF TRADE FIXTURES

15.1 **Surrender of Premises**. No act or thing done by Landlord or any agent or employee of Landlord during the Lease Term shall be deemed to constitute an acceptance by

Landlord of a surrender of the Premises unless such intent is specifically acknowledged in writing by Landlord. The delivery of keys to the Premises to Landlord or any agent or employee of Landlord shall not constitute a surrender of the Premises or effect a termination of this Lease, whether or not the keys are thereafter retained by Landlord, and notwithstanding such delivery Tenant shall be entitled to the return of such keys at any reasonable time upon request until this Lease shall have been properly terminated. The voluntary or other surrender of this Lease by Tenant, whether accepted by Landlord or not, or a mutual termination hereof, shall not work a merger, and at the option of Landlord shall operate as an assignment to Landlord of all subleases or subtenancies affecting the Premises or terminate any or all such subleases or subtenancies.

15.2 **Removal of Tenant Property by Tenant**. Upon the expiration of the Lease Term, or upon any earlier termination of this Lease, Tenant shall, subject to the provisions of this Article 15, quit and surrender possession of the Premises to Landlord in as good order and condition as when Tenant took possession and as thereafter improved by Landlord and/or Tenant, reasonable wear and tear and repairs which are specifically made the responsibility of Landlord hereunder excepted. Upon such expiration or termination, Tenant shall, without expense to Landlord, remove or cause to be removed from the Premises all debris and rubbish, such items of furniture, equipment, business and trade fixtures, free-standing cabinet work, movable partitions and other articles of personal property owned by Tenant or installed or placed by Tenant at its expense in the Premises, and such similar articles of any other persons claiming under Tenant, as Landlord may, in its sole discretion, require to be removed, and Tenant shall repair at its own expense all damage to the Premises and Building resulting from such removal.

ARTICLE 16

HOLDING OVER

If Tenant holds over after the expiration of the Lease Term or earlier termination thereof, with the express or implied consent of Landlord, such tenancy shall be from month-to-month only, and shall not constitute a renewal hereof or an extension for any further term, and in such case Rent shall be payable at a monthly rate equal to (i) one hundred fifty percent (150%) of the Rent applicable during the last rental period of the Lease Term under this Lease during the first month of such holdover and (ii) two hundred percent (200%) of the Rent applicable during the last rental period of the Lease Term under this Lease thereafter. Such month-to-month tenancy shall be subject to every other applicable term, covenant and agreement contained herein. Nothing contained in this Article 16 shall be construed as consent by Landlord to any holding over by Tenant, and Landlord expressly reserves the right to require Tenant to surrender possession of the Premises to Landlord as provided in this Lease upon the expiration or other termination of this Lease. The provisions of this Article 16 shall not be deemed to limit or constitute a waiver of any other rights or remedies of Landlord provided herein or at law. If Tenant fails to surrender the Premises upon the termination or expiration of this Lease, in addition to any other liabilities to Landlord accruing therefrom, Tenant shall protect, defend, indemnify and hold Landlord harmless from all loss, costs (including reasonable attorneys' fees) and liability resulting from such failure, including, without limiting the generality of the foregoing, any claims made by any succeeding tenant founded upon such failure to surrender and any lost profits to Landlord resulting therefrom.

ARTICLE 17

ESTOPPEL CERTIFICATES

Within ten (10) days following a request in writing by Landlord, Tenant shall execute, acknowledge and deliver to Landlord an estoppel certificate, which, as submitted by Landlord, shall be substantially in the form of **Exhibit E**, attached hereto (or such other form as may be reasonably required by any prospective mortgagee or purchaser of the Project, or any portion thereof), indicating therein any exceptions thereto that may exist at that time, and shall also contain any other information reasonably requested by Landlord or Landlord's mortgagee or prospective mortgagee. Any such certificate may be relied upon by any prospective mortgagee or purchaser of all or any portion of the Project. Tenant shall execute and deliver whatever other instruments may be reasonably required for such purposes. At any time during the Lease Term, Landlord may require Tenant to provide Landlord with a current financial statement and financial statements of the two (2) years prior to the current financial statement year. Such statements shall be prepared in accordance with generally accepted accounting principles and, if such is the normal practice of Tenant, shall be audited by an independent certified public accountant. Upon written request by Tenant, Landlord shall enter into a commercially reasonable confidentiality agreement covering any financial statements disclosed by Tenant pursuant to this Article 17. Failure of Tenant to timely execute, acknowledge and deliver such estoppel certificate or other instruments shall constitute an acceptance of the Premises and an acknowledgment by Tenant that statements included in the estoppel certificate are true and correct, without exception.

ARTICLE 18

MORTGAGE OR GROUND LEASE

18.1 **Subordination**. This Lease shall be subject and subordinate to all present and future ground or underlying leases of the Building or Project and to the lien of any mortgage, trust deed or other encumbrances now or hereafter in force against the Building or Project or any part thereof, if any, and to all renewals, extensions, modifications, consolidations and replacements thereof, and to all advances made or hereafter to be made upon the security of such mortgages or trust deeds, unless the holders of such mortgages, trust deeds or other encumbrances, or the lessors under such ground lease or underlying leases, require in writing that this Lease be superior thereto. Tenant covenants and agrees in the event any proceedings are brought for the foreclosure of any such mortgage or deed in lieu thereof (or if any ground lease is terminated), to attorn, without any deductions or set-offs whatsoever, to the lienholder or purchaser or any successors thereto upon any such foreclosure sale or deed in lieu thereof (or to the ground lessor), if so requested to do so by such purchaser or lienholder or ground lessor, and to recognize such purchaser or lienholder or ground lessor as the lessor under this Lease, provided such lienholder or purchaser or ground lessor shall agree to accept this Lease and not disturb Tenant's occupancy, so long as Tenant timely pays the rent and observes and performs the terms, covenants and conditions of this Lease to be observed and performed by Tenant within applicable notice and cure periods expressly set forth in this Lease. Landlord's interest herein may be assigned as security at any time to any lienholder. Tenant shall, within ten (10) days of request by Landlord, execute such further instruments or assurances as Landlord may reasonably deem necessary to evidence or confirm the subordination or superiority of this Lease to any such mortgages, trust deeds, ground leases or underlying leases.

Tenant waives the provisions of any current or future statute, rule or law which may give or purport to give Tenant any right or election to terminate or otherwise adversely affect this Lease and the obligations of the Tenant hereunder in the event of any foreclosure proceeding or sale.

18.2 **Notice to Lienholder or Ground Lessor**. Notwithstanding anything to the contrary contained in Article 28, below, or elsewhere in this Lease, upon receipt by Tenant of notice from any holder of a mortgage, trust deed or other encumbrance in force against the Building or the Project or any part thereof which includes the Premises or any lessor under a ground lease or underlying lease of the Building or the Project, or from Landlord, which notice sets forth the address of such lienholder or ground lessor, no notice from Tenant to Landlord shall be effective unless and until a copy of the same is given to such lienholder or ground lessor at the appropriate address therefor (as specified in the above-described notice or at such other places as may be designated from time to time in a notice to Tenant in accordance with Article 28, below), and the curing of any of Landlord's defaults by such lienholder or ground lessor within a reasonable period of time after such notice from Tenant (including a reasonable period of time to obtain possession of the Building or the Project, as the case may be, if such lienholder or ground lessor elects to do so) shall be treated as performance by Landlord. For the purposes of this Article 18, the term "mortgage" shall include a mortgage on a leasehold interest of Landlord (but not a mortgage on Tenant's leasehold interest hereunder).

18.3 **Assignment of Rents**. With reference to any assignment by Landlord of Landlord's interest in this Lease, or the Rent payable to Landlord hereunder, conditional in nature or otherwise, which assignment is made to any holder of a mortgage, trust deed or other encumbrance in force against the Building or the Project or any part thereof which includes the Premises or to any lessor under a ground lease or underlying lease of the Building or the Project, Tenant agrees as follows:

18.3.1 The execution of any such assignment by Landlord, and the acceptance thereof by such lienholder or ground lessor, shall never be treated as an assumption by such lienholder or ground lessor of any of the obligations of Landlord under this Lease, unless such lienholder or ground lessor shall, by notice to Tenant, specifically otherwise elect.

18.3.2 Notwithstanding delivery to Tenant of the notice required by Section 18.3.1, above, such lienholder or ground lessor, respectively, shall be treated as having assumed Landlord's obligations under this Lease only upon such lienholder's foreclosure of any such mortgage, trust deed or other encumbrance, or acceptance of a deed in lieu thereof, and taking of possession of the Building or the Project or applicable portion thereof, or such ground lessor's termination of any such ground lease or underlying leases and assumption of Landlord's position hereunder, as the case may be. In no event shall such lienholder, ground lessor or any other successor to Landlord's interest in this Lease, as the case may be, be liable for any security deposit paid by Tenant to Landlord, unless and until such lienholder, ground lessor or other such successor, respectively, actually has been credited with or has received for its own account as landlord the amount of such security deposit or any portion thereof (in which event the liability of such lienholder, ground lessor or other such successor, as the case may be, shall be limited to the amount actually credited or received).

18.3.3 In no event shall the acquisition of title to the Building and the land upon which the Building is located or the Project or any part thereof which includes the Premises by a purchaser which, simultaneously therewith, leases back to the seller thereof the entire Building or the land upon which the Building is located or the Project or the entirety of that part thereof acquired by such purchaser, as the case may be, be treated as an assumption, by operation of law or otherwise, of Landlord's obligations under this Lease, but Tenant shall look solely to such seller-lessee, or to the successors to or assigns of such seller-lessee's estate, for performance of Landlord's obligations under this Lease. In any such event, this Lease shall be subject and subordinate to the lease to such seller-lessee, and Tenant covenants and agrees in the event the lease to such seller-lessee is terminated to attorn, without any deductions or set-offs whatsoever, to such purchaser-lessor, if so requested to do so by such purchaser-lessor, and to recognize such purchaser-lessor as the lessor under this Lease, provided such purchaser-lessor shall agree to accept this Lease and not disturb Tenant's occupancy, so long as Tenant timely pays the rent and observes and performs the terms, covenants and conditions of this Lease to be observed and performed by Tenant within applicable notice and cure periods expressly set forth in this Lease. For all purposes, such seller-lessee, or the successors to or assigns of such seller-lessee's estate, shall be the lessor under this Lease unless and until such seller-lessee's position shall have been assumed by such purchaser-lessor.

ARTICLE 19

DEFAULTS; REMEDIES

19.1 **Events of Default**. The occurrence of any of the following shall constitute a default of this Lease by Tenant:

19.1.1 Any failure by Tenant to pay any Rent or any other charge required to be paid under this Lease, or any part thereof, when due, which failure is not cured within five (5) days after written notice from Landlord that said amount was not paid when due, provided that if Tenant has previously received one (1) or more notices from Landlord during the immediately preceding twelve (12) month period stating that Tenant failed to pay any amount required to be paid by Tenant under this Lease when due, then Landlord shall not be required to deliver any notice to Tenant and a default shall immediately occur upon any failure by Tenant to pay any Rent or any other charge required to be paid under the Lease when due; or

19.1.2 Except where a specific time period is otherwise set forth for Tenant's performance in this Lease, in which event the failure to perform by Tenant within such time period shall be a default by Tenant under this Section 19.1.2, any failure by Tenant to observe or perform any other provision, covenant or condition of this Lease to be observed or performed by Tenant where such failure continues for thirty (30) days after written notice thereof from Landlord to Tenant; provided that if the nature of such default is such that the same cannot reasonably be cured within a thirty (30) day period, Tenant shall not be deemed to be in default if it diligently commences such cure within such period and thereafter diligently proceeds to rectify and cure such default; or

19.1.3 Abandonment of the Premises by Tenant; or

19.1.4 The failure by Tenant to observe or perform according to the provisions of Articles 5, 10, 14, 17 or 18 of this Lease, or any breach by Tenant of the representations and warranties set forth in Section 29.35 of this Lease, or the failure by Tenant to observe or perform any other provision, covenant or condition of this Lease which failure, because of the character of such provision, covenant or condition, would immediately jeopardize Landlord's interest, where such failure continues for more than two (2) business days after notice from Landlord.

The notice periods provided in this Section 19.1 are in lieu of, and not in addition to, any notice periods provided by law.

19.2 **Remedies Upon Default**. Upon the occurrence of any event of default by Tenant, Landlord shall have, in addition to any other remedies available to Landlord at law or in equity (all of which remedies shall be distinct, separate and cumulative), the option to pursue any one or more of the following remedies, each and all of which shall be cumulative and nonexclusive, without any notice or demand whatsoever.

19.2.1 Terminate this Lease, in which event Tenant shall immediately surrender the Premises to Landlord, and if Tenant fails to do so, Landlord may, without prejudice to any other remedy which it may have for possession or arrearages in rent, enter upon and take possession of the Premises and expel or remove Tenant and any other person who may be occupying the Premises or any part thereof, without being liable for prosecution or any claim or damages therefor; and Landlord may recover from Tenant the following:

(i) The worth at the time of award of any unpaid rent which has been earned at the time of such termination; plus

(ii) The worth at the time of award of the amount by which the unpaid rent which would have been earned after termination until the time of award exceeds the amount of such rental loss that Tenant proves could have been reasonably avoided; plus

(iii) The worth at the time of award of the amount by which the unpaid rent for the balance of the Lease Term after the time of award exceeds the amount of such rental loss that Tenant proves could have been reasonably avoided; plus

(iv) Any other amount necessary to compensate Landlord for all the detriment proximately caused by Tenant's failure to perform its obligations under this Lease or which in the ordinary course of things would be likely to result therefrom, specifically including but not limited to, brokerage commissions and advertising expenses incurred, expenses of remodeling the Premises or any portion thereof for a new tenant, whether for the same or a different use, and any special concessions made to obtain a new tenant; and

(v) At Landlord's election, such other amounts in addition to or in lieu of the foregoing as may be permitted from time to time by applicable law.

The term "rent" as used in this Section 19.2 shall be deemed to be and to mean all sums of every nature required to be paid by Tenant pursuant to the terms of this Lease, whether to Landlord or to others. As used in Sections 19.2.1(i) and 19.2.1(ii), above, the "worth at the time of award" shall be computed by allowing interest at the rate set forth in Article 25 of this Lease, but in no

case greater than the maximum amount of such interest permitted by law. As used in Section 19.2.1(iii) above, the "worth at the time of award" shall be computed by discounting such amount at the discount rate of the Federal Reserve Bank of San Francisco at the time of award plus one percent (1%).

19.2.2 Landlord shall have the remedy described in California Civil Code Section 1951.4 (lessor may continue lease in effect after lessee's breach and abandonment and recover rent as it becomes due, if lessee has the right to sublet or assign, subject only to reasonable limitations). Accordingly, if Landlord does not elect to terminate this Lease on account of any default by Tenant, Landlord may, from time to time, without terminating this Lease, enforce all of its rights and remedies under this Lease, including the right to recover all rent as it becomes due.

19.2.3 Landlord shall at all times have the rights and remedies (which shall be cumulative with each other and cumulative and in addition to those rights and remedies available under Sections 19.2.1 and 19.2.2, above, or any law or other provision of this Lease), without prior demand or notice except as required by applicable law, to seek any declaratory, injunctive or other equitable relief, and specifically enforce this Lease, or restrain or enjoin a violation or breach of any provision hereof.

19.3 **Subleases of Tenant**. If Landlord elects to terminate this Lease on account of any default by Tenant, as set forth in this Article 19, then Landlord shall have the right, at Landlord's option in its sole discretion, (i) to terminate any and all assignments, subleases, licenses, concessions or other consensual arrangements for possession entered into by Tenant and affecting the Premises, in which event Landlord shall have the right to repossess such affected portions of the Premises by any lawful means, or (ii) to succeed to Tenant's interest in any or all such assignments, subleases, licenses, concessions or arrangements, in which event Landlord may require any assignees, sublessees, licensees or other parties thereunder to attorn to and recognize Landlord as its assignor, sublessor, licensor, concessionaire or transferor thereunder. In the event of Landlord's election to succeed to Tenant's interest in any such assignments, subleases, licenses, concessions or arrangements, Tenant shall, as of the date of notice by Landlord of such election, have no further right to or interest in the rent or other consideration receivable thereunder.

19.4 **Efforts to Relet**. No re-entry or repossession, repairs, maintenance, changes, alterations and additions, reletting, appointment of a receiver to protect Landlord's interests hereunder, or any other action or omission by Landlord shall be construed as an election by Landlord to terminate this Lease or Tenant's right to possession, or to accept a surrender of the Premises, nor shall same operate to release Tenant in whole or in part from any of Tenant's obligations hereunder, unless express written notice of such intention is sent by Landlord to Tenant. Tenant hereby irrevocably waives any right otherwise available under any law to redeem or reinstate this Lease.

ARTICLE 20

COVENANT OF QUIET ENJOYMENT

Landlord covenants that Tenant, on paying the Rent, charges for services and other payments herein reserved and on keeping, observing and performing all the other terms, covenants,

conditions, provisions and agreements herein contained on the part of Tenant to be kept, observed and performed, shall, during the Lease Term, peaceably and quietly have, hold and enjoy the Premises subject to the terms, covenants, conditions, provisions and agreements hereof without interference by any persons lawfully claiming by or through Landlord. The foregoing covenant is in lieu of any other covenant express or implied.

ARTICLE 21

LETTER OF CREDIT

21.1 **Delivery of Letter of Credit**. Tenant shall deliver to Landlord concurrent with Tenant's execution of this Lease, as protection for the full and faithful performance by Tenant of all of its obligations under this Lease and for all losses and damages Landlord may suffer (or which Landlord reasonably estimates that it may suffer) as a result of any breach or default by Tenant under this Lease, an unconditional, clean, irrevocable negotiable standby letter of credit (the "**L-C**") in the amount set forth in Section 8 of the Summary (the "**L-C Amount**"), in the form attached hereto as **Exhibit H**, payable in the City of San Francisco, California, running in favor of Landlord, drawn on a bank (the "**Bank**") reasonably approved by Landlord and at a minimum having a long term issuer credit rating from Standard and Poor's Professional Rating Service of A or a comparable rating from Moody's Professional Rating Service (the "**Credit Rating Threshold**"), and otherwise conforming in all respects to the requirements of this Article 21, including, without limitation, all of the requirements of Section 21.2, below, all as set forth more particularly hereinbelow. Tenant shall pay all expenses, points and/or fees incurred by Tenant in obtaining and maintaining the L-C. In the event of an assignment by Tenant of its interest in the Lease (and irrespective of whether Landlord's consent is required for such assignment), the acceptance of any replacement or substitute letter of credit by Landlord from the assignee shall be subject to Landlord's prior written approval, in Landlord's reasonable discretion, and the attorney's fees incurred by Landlord in connection with such determination shall be payable by Tenant to Landlord within ten (10) days of billing. Tenant shall have no right to voluntarily replace the L-C without Landlord's prior written approval, in Landlord's sole and absolute discretion. Tenant shall be responsible for the payment of any and all costs incurred by Landlord relating to the review of any replacement L-C (including, without limitation, Landlord's reasonable attorneys' fees), which replacement is required pursuant to this Section or is otherwise requested by Tenant, and such attorneys' fees shall be payable by Tenant to Landlord within ten (10) days of billing. If Landlord approves any replacement or substitute letter of credit, Landlord shall return the L-C then held by Landlord within ninety-one (91) days following Landlord receipt of the replacement or substitute L-C tendered by Tenant.

21.2 **In General**. The L-C shall be "callable" at sight, permit partial draws and multiple presentations and drawings, and be otherwise subject to the Uniform Customs and Practices for Documentary Credits (1993-Rev), International Chamber of Commerce Publication #500, or the International Standby Practices-ISP 98, International Chamber of Commerce Publication #590. The L-C must provide that presentation of a drawing under the L-C may be made by hand delivery, courier service, overnight mail, or facsimile. Tenant further covenants and warrants as follows:

21.2.1 **Landlord Right to Transfer**. The L-C shall provide that Landlord, its successors and assigns, may, at any time and without notice to Tenant and without first obtaining

Tenant's consent thereto, transfer (one or more times) all or any portion of its interest in and to the L-C to another party, person or entity, regardless of whether or not such transfer is separate from or as a part of the assignment by Landlord of its rights and interests in and to this Lease. In the event of a transfer of Landlord's interest in the Building, Landlord shall transfer the L-C, in whole or in part, to the transferee and thereupon Landlord shall, without any further agreement between the parties, be released by Tenant from all liability therefor, and it is agreed that the provisions hereof shall apply to every transfer or assignment of the whole or any portion of said L-C to a new landlord. In connection with any such transfer of the L-C by Landlord, Tenant shall, at Tenant's sole cost and expense, execute and submit to the Bank such applications, documents and instruments as may be necessary to effectuate such transfer, and Tenant shall be responsible for paying the Bank's transfer and processing fees in connection therewith.

21.2.2 **No Assignment by Tenant**. Tenant shall neither assign nor encumber the L-C or any part thereof. Neither Landlord nor its successors or assigns will be bound by any assignment, encumbrance, attempted assignment or attempted encumbrance by Tenant in violation of this Section.

21.2.3 **Replenishment**. If, as a result of any drawing by Landlord on the L-C pursuant to its rights set forth in Section 21.3 below, the amount of the L-C shall be less than the L-C Amount, Tenant shall, within five (5) days thereafter, provide Landlord with (i) an amendment to the L-C restoring such L-C to the L-C Amount or (ii) additional L-Cs in an amount equal to the deficiency, which additional L-Cs shall comply with all of the provisions of this Article 21, and if Tenant fails to comply with the foregoing, notwithstanding anything to the contrary contained in Section 19.1 above, the same shall constitute an incurable default by Tenant under this Lease (without the need for any additional notice and/or cure period).

21.2.4 **Renewal; Replacement**. If the L-C expires earlier than the date (the "**LC Expiration Date**") that is ninety-one (91) days after the expiration of the Lease Term, Tenant shall deliver a new L-C or certificate of renewal or extension to Landlord at least sixty (60) days prior to the expiration of the L-C then held by Landlord, without any action whatsoever on the part of Landlord, which new L-C shall be irrevocable and automatically renewable through the LC Expiration Date upon the same terms as the expiring L-C or such other terms as may be acceptable to Landlord in its sole discretion. In furtherance of the foregoing, Landlord and Tenant agree that the L-C shall contain a so-called "evergreen provision," whereby the L-C will automatically be renewed unless at least thirty (30) days' prior written notice of non-renewal is provided by the issuer to Landlord; provided, however, that the final expiration date identified in the L-C, beyond which the L-C shall not automatically renew, shall not be earlier than the LC Expiration Date.

21.2.5 **Bank's Financial Condition**. If, at any time during the Lease Term, the Bank's long term credit rating is reduced below the Credit Rating Threshold, or if the financial condition of the Bank changes in any other materially adverse way (either, a "**Bank Credit Threat**"), then Landlord shall have the right to require that Tenant obtain from a different issuer a substitute L-C that complies in all respects with the requirements of this Article 21, and Tenant's failure to obtain such substitute L-C within ten (10) days following Landlord's written demand therefor (with no other notice or cure or grace period being applicable thereto, notwithstanding anything in this Lease to the contrary) shall entitle Landlord, or Landlord's then managing agent, to immediately draw upon the then existing L- C in whole or in part, without notice to Tenant, as

more specifically described in Section 21.3, below. Tenant shall be responsible for the payment of any and all costs incurred with the review of any replacement L-C (including without limitation Landlord's reasonable attorneys' fees), which replacement is required pursuant to this Section or is otherwise requested by Tenant.

21.3 **Application of Letter of Credit**. Tenant hereby acknowledges and agrees that Landlord is entering into this Lease in material reliance upon the ability of Landlord to draw upon the L-C as protection for the full and faithful performance by Tenant of all of its obligations under this Lease and for all losses and damages Landlord may suffer (or which Landlord reasonably estimates that it may suffer) as a result of any breach or default by Tenant under this Lease. Landlord, or its then managing agent, shall have the right to draw down an amount up to the face amount of the L-C if any of the following shall have occurred or be applicable: (A) such amount is due to Landlord under the terms and conditions of this Lease, or (B) Tenant has filed a voluntary petition under the U. S. Bankruptcy Code or any state bankruptcy code (collectively, "**Bankruptcy Code**"), or (C) an involuntary petition has been filed against Tenant under the Bankruptcy Code, or (D) the Bank has notified Landlord that the L-C will not be renewed or extended through the LC Expiration Date and Tenant has not provided Landlord with a replacement L-C that satisfies the requirements of this Article 21 within forty-five (45) days prior to the expiration thereof, or I a Bank Credit Threat or Receivership (as such term is defined in Section 21.6.1, below) has occurred and Tenant has failed to comply with the requirements of either Section 21.2.5, above, or Section 21.6, below, as applicable. If Tenant shall breach any provision of this Lease or otherwise be in default hereunder or if any of the foregoing events identified in Sections 21.3(B) through I shall have occurred, Landlord may, but without obligation to do so, and without notice to Tenant, draw upon the L-C, in part or in whole, and the proceeds may be applied by Landlord (i) to cure any breach or default of Tenant and/or to compensate Landlord for any and all damages of any kind or nature sustained or which Landlord reasonably estimates that it will sustain resulting from Tenant's breach or default, (ii) against any Rent payable by Tenant under this Lease that is not paid when due and/or (iii) to pay for all losses and damages that Landlord has suffered or that Landlord reasonably estimates that it will suffer as a result of any breach or default by Tenant under this Lease. The use, application or retention of the L-C, or any portion thereof, by Landlord shall not prevent Landlord from exercising any other right or remedy provided by this Lease or by any applicable law, it being intended that Landlord shall not first be required to proceed against the L-C, and shall not operate as a limitation on any recovery to which Landlord may otherwise be entitled. Tenant agrees not to interfere in any way with payment to Landlord of the proceeds of the L-C, either prior to or following a "draw" by Landlord of any portion of the L-C, regardless of whether any dispute exists between Tenant and Landlord as to Landlord's right to draw upon the L-C. No condition or term of this Lease shall be deemed to render the L-C conditional to justify the issuer of the L-C in failing to honor a drawing upon such L-C in a timely manner. Tenant agrees and acknowledges that (a) the L-C constitutes a separate and independent contract between Landlord and the Bank, (b) Tenant is not a third party beneficiary of such contract, (c) Tenant has no property interest whatsoever in the L-C or the proceeds thereof, and (d) in the event Tenant becomes a debtor under any chapter of the Bankruptcy Code, neither Tenant, any trustee, nor Tenant's bankruptcy estate shall have any right to restrict or limit Landlord's claim and/or rights to the L-C and/or the proceeds thereof by application of Section 502(b)(6) of the U. S. Bankruptcy Code or otherwise.

21.4 **Letter of Credit not a Security Deposit**. Landlord and Tenant acknowledge and agree that in no event or circumstance shall the L-C or any renewal thereof or any proceeds thereof be (i) deemed to be or treated as a "security deposit" within the meaning of California Civil Code Section 1950.7, (ii) subject to the terms of such Section 1950.7, or (iii) intended to serve as a "security deposit" within the meaning of such Section 1950.7. The parties hereto (A) recite that the L-C is not intended to serve as a security deposit and such Section 1950.7 and any and all other laws, rules and regulations applicable to security deposits in the commercial context ("**Security Deposit Laws**") shall have no applicability or relevancy thereto and (B) waive any and all rights, duties and obligations either party may now or, in the future, will have relating to or arising from the Security Deposit Laws.

21.5 **Proceeds of Draw**. In the event Landlord draws down on the L-C pursuant to Sections 21.3(D) or I, above, the proceeds of the L-C may be held by Landlord and applied by Landlord against any Rent payable by Tenant under this Lease that is not paid when due and/or to pay for all losses and damages that Landlord has suffered or that Landlord reasonably estimates that it will suffer as a result of any breach or default by Tenant under this Lease. Any unused proceeds shall constitute the property of Landlord and need not be segregated from Landlord's other assets. Tenant hereby (i) agrees that (A) Tenant has no property interest whatsoever in the proceeds from any such draw, and (B) such proceeds shall not be deemed to be or treated as a "security deposit" under the Security Deposit Law, and (ii) waives all rights, duties and obligations either party may now or, in the future, will have relating to or arising from the Security Deposit Laws. Landlord agrees that the amount of any proceeds of the L-C received by Landlord, and not (a) applied against any Rent payable by Tenant under this Lease that was not paid when due, or (b) used to pay for any losses and/or damages suffered by Landlord (or reasonably estimated by Landlord that it will suffer) as a result of any breach or default by Tenant under this Lease (the "**Unused L-C Proceeds**"), shall be paid by Landlord to Tenant (x) upon receipt by Landlord of a replacement L-C in the full L-C Amount, which replacement L-C shall comply in all respects with the requirements of this Article 21, or (y) within thirty (30) days after the LC Expiration Date; provided, however, that if prior to the LC Expiration Date a voluntary petition is filed by Tenant, or an involuntary petition is filed against Tenant by any of Tenant's creditors, under the Bankruptcy Code, then Landlord shall not be obligated to make such payment in the amount of the Unused L-C Proceeds until either all preference issues relating to payments under this Lease have been resolved in such bankruptcy or reorganization case or such bankruptcy or reorganization case has been dismissed.

21.6 **Bank Placed Into Receivership**.

21.6.1 **Bank Placed Into Receivership**. In the event the Bank is placed into receivership or conservatorship (any such event, a "**Receivership**") by the Federal Deposit Insurance Corporation or any successor or similar entity (the "**FDIC**"), then, effective as of the date such Receivership occurs, the L-C shall be deemed to not meet the requirements of this Article 21, and, within ten (10) days following Landlord's notice to Tenant of such Receivership (the "**LC Replacement Notice**"), Tenant shall replace the L-C with a substitute L-C from a different issuer reasonably acceptable to Landlord and that complies in all respects with the requirements of this Article 21. If Tenant fails to replace such L-C with a substitute L-C from a different issuer pursuant to the terms and conditions of this Section 21.6.1, then, notwithstanding anything in this Lease to the contrary, Landlord shall have the right, at Landlord's option, to either

(i) declare Tenant in default of this Lease for which there shall be no notice or grace or cure periods being applicable thereto other than the aforesaid ten (10) day period), in which event, Landlord shall have the right to pursue any and all remedies available to it under this Lease and at law, including, without limitation, treating any Receivership as a Bank Credit Threat and exercising Landlord's remedies under Section 21.2.5, above, to the extent possible pursuant to then existing FDIC policy; or (ii) elect to increase the Base Rent due and owing under the terms of this Lease pursuant to the terms and conditions of Section 21.6.2 of this Lease, below. Tenant shall be responsible for the payment of any and all costs incurred with the review of any replacement L- C (including without limitation Landlord's reasonable attorneys' fees), which replacement is required pursuant to this Section or is otherwise requested by Tenant.

21.6.2 **FAILURE TO REPLACE L-C; LIQUIDATED DAMAGES**. IN THE EVENT THAT TENANT FAILS TO REPLACE THE L-C PURSUANT TO, AND WITHIN THE TIME PERIODS SET FORTH IN, SECTION 21.6.1 OF THIS LEASE, ABOVE, THEN TENANT'S MONTHLY INSTALLMENT OF BASE RENT SHALL BE INCREASED TO ONE HUNDRED TEN PERCENT (110%) OF ITS THEN EXISTING LEVEL DURING THE PERIOD COMMENCING ON THE DATE THAT OCCURS TEN (10) DAYS FOLLOWING THE DATE TENANT RECEIVES THE LC REPLACEMENT NOTICE AND ENDING ON THE EARLIER TO OCCUR OF (I) THE DATE SUCH REPLACEMENT L-C IS DELIVERED TO LANDLORD PURSUANT TO THE TERMS OF SECTION 21.6.1, OR (II) THE DATE WHICH IS NINETY (90) DAYS AFTER THE DATE OF SUCH LC REPLACEMENT NOTICE. IN THE EVENT THAT TENANT FAILS, DURING SUCH NINETY (90) DAY PERIOD FOLLOWING THE DATE OF THE LC REPLACEMENT NOTICE, TO CAUSE THE REPLACEMENT L-C TO BE DELIVERED TO LANDLORD PURSUANT TO THE TERMS OF SECTION 21.6.1, THEN TENANT'S MONTHLY INSTALLMENT OF BASE RENT SHALL BE INCREASED TO ONE HUNDRED TWENTY-FIVE PERCENT (125%) OF ITS THEN EXISTING LEVEL DURING THE PERIOD COMMENCING ON THE DATE WHICH IS NINETY (90) DAYS AFTER THE DATE OF SUCH LC REPLACEMENT NOTICE AND ENDING ON THE DATE SUCH REPLACEMENT L-C IS DELIVERED TO LANDLORD PURSUANT TO THE TERMS OF SECTION 21.6.1, PROVIDED, HOWEVER, THAT THE TOTAL AGGREGATE AMOUNT OF BASE RENT PAID BY TENANT IN EXCESS OF THE AMOUNT OF BASE RENT THAT TENANT WOULD HAVE PAID HAD SUCH L-C REPLACEMENT FAILURE NEVER OCCURRED SHALL IN NO EVENT EXCEED THE L-C AMOUNT. THE PARTIES AGREE THAT IT WOULD BE IMPRACTICABLE AND EXTREMELY DIFFICULT TO ASCERTAIN THE ACTUAL DAMAGES SUFFERED BY LANDLORD AS A RESULT OF TENANT'S FAILURE TO TIMELY REPLACE THE L-C FOLLOWING THE LC REPLACEMENT NOTICE AS REQUIRED IN SECTION 21.6.1, AND THAT UNDER THE CIRCUMSTANCES EXISTING AS OF THE DATE OF THIS LEASE, THE LIQUIDATED DAMAGES PROVIDED FOR IN THIS SECTION 21.6.2 REPRESENT A REASONABLE ESTIMATE OF THE DAMAGES WHICH LANDLORD WILL INCUR AS A RESULT OF SUCH FAILURE, PROVIDED, HOWEVER, THAT THIS PROVISION SHALL NOT WAIVE OR AFFECT LANDLORD'S RIGHTS AND TENANT'S INDEMNITY OBLIGATIONS UNDER OTHER SECTIONS OF THIS LEASE. THE PARTIES ACKNOWLEDGE THAT THE PAYMENT OF SUCH LIQUIDATED DAMAGES IS NOT INTENDED AS A FORFEITURE OR PENALTY WITHIN THE MEANING OF CALIFORNIA CIVIL CODE SECTION 3275 OR 3369, BUT IS INTENDED TO CONSTITUTE LIQUIDATED DAMAGES TO LANDLORD PURSUANT TO CALIFORNIA CIVIL CODE SECTION 1671.

ARTICLE 22

SUBSTITUTION OF OTHER PREMISES

Landlord shall have the right, not more than one time during the initial Lease Term (and not more than once during the Option Term, if applicable), to relocate Tenant to other space (the "**Relocation Space**") in the Project comparable to the Premises (e.g. comparable finishes and configuration, same number of offices and conference rooms, comparable ceiling treatment, doors and hardware), which Relocation Space shall be located on the third (3rd) floor or higher in the Project and all terms hereof shall apply to the Relocation Space with equal force and effect, except as otherwise provided in this Article 22. To the extent Tenant request any upgrades in the improvements located in such Relocation Space vis-à-vis the improvements then existing in the Premises (e.g., specialty finishes such as glass, ceiling treatments, specialty lighting, built-in or custom cabinetry), Tenant shall pay to Landlord, promptly upon billing therefor, all costs and expenses incurred by Landlord in connection with such upgraded improvements. In such event, Landlord shall give Tenant not less than ninety (90) days prior notice of Landlord's election to so relocate Tenant, and shall move Tenant's effects to the Relocation Space at Landlord's sole cost and expense at such time and in such manner as to inconvenience Tenant as little as reasonably practicable. Landlord shall reimburse Tenant for all actual out-of-pocket costs incurred by Tenant in connection with its move from the Premises to the Relocation Space, including, without limitation, the cost to install new communications and computer lines (to the extent not installed by Landlord as part of its installation of the tenant improvements in the Relocation Space), the cost to move and reconfigure Tenant's furniture from the Premises to the Relocation Space, and the cost of reasonable amounts of replacement stationery. Simultaneously with such relocation of the Premises, the parties shall immediately execute an amendment to this Lease (or, if the Relocation Space is in a building of the Project other than the Building, Tenant shall execute a new lease with the owner of such building, which shall be on substantially the same terms and conditions as this Lease, and Tenant and Landlord shall enter into a termination of this Lease) stating the relocation of the Premises, and amending those Sections of the Summary, and replacing **Exhibit A** to this Lease, as shall be necessary to accurately describe the Relocation Space (including, without limitation, the location and the rentable area of the Relocation Space). In the event Tenant is relocated in accordance with this Article 22, and the rentable area of the Relocation Space is not equal to the rentable area of the Premises, or if the Relocation Space is in a building of the Project other than the Building and the rentable area of such other building is not equal to the rentable area of the Building, all amounts, percentages and figures appearing or referred to in this Lease based upon such rentable area (including, without limitation, the amounts of the "Rent" and the "Security Deposit," as those terms are defined in Article 4 and Article 21 of this Lease, respectively, and "Tenant's Share," as that term is defined in Section 4.2.10 of this Lease) shall be modified accordingly; provided, however, that notwithstanding the foregoing, (i) in no event shall the rentable area of the Relocation Space be less than one hundred percent (100%) of the rentable area of the Premises; and (ii) none of Tenant's Base Rent, Tenant's Share, or the Security Deposit, shall increase as a result of such relocation during the initial Lease Term. Should Tenant refuse to permit Landlord to move Tenant to the Relocation Space, Landlord shall have the right to cancel and terminate this Lease effective sixty (60) days from the date of Landlord's election to relocate Tenant.

ARTICLE 23

SIGNS

23.1 **Full Floors**. Subject to Landlord's prior written approval, in its sole discretion, and provided all signs are in keeping with the quality, design and style of the Building and Project, Tenant, if the Premises comprise an entire floor of the Building, at its sole cost and expense, may install identification signage anywhere in the Premises including in the elevator lobby of the Premises, provided that such signs must not be visible from the exterior of the Building.

23.2 **Multi-Tenant Floors**. If other tenants can occupy space on the floor on which the Premises is located, Tenant's identifying suite entry sign and elevator lobby directory sign on the third (3rd) floor shall be provided by Landlord, at Tenant's cost, and such signage shall be comparable to that used by Landlord for other similar floors in the Building and shall comply with Landlord's then-current Building standard signage program.

23.3 **Prohibited Signage and Other Items**. Any signs, notices, logos, pictures, names or advertisements which are installed and that have not been separately approved by Landlord may be removed without notice by Landlord at the sole expense of Tenant. Tenant may not install any signs on the exterior or roof of the Project or the Common Areas. Any signs, window coverings, or blinds (even if the same are located behind the Landlord-approved window coverings for the Building), or other items visible from the exterior of the Premises or Building, shall be subject to the prior approval of Landlord, in its sole discretion.

23.4 **Building Directory**. Tenant shall have the right, at Tenant cost, to have Tenant's name entered into Landlord's directory in the lobby of the Building.

ARTICLE 24

COMPLIANCE WITH LAW

24.1 **In General**. Tenant shall not do anything or suffer its agents, employees or contractors to do anything in or about the Premises or the Project which will in any way conflict with any law, statute, ordinance or other governmental rule, regulation or requirement now in force or which may hereafter be enacted or promulgated, including any such governmental regulations related to disabled access (collectively, "**Applicable Laws**"). At its sole cost and expense, Tenant shall promptly comply with any Applicable Laws which relate to (i) Tenant's use of the Premises, (ii) any Alterations made by Tenant to the Premises, and any Tenant Improvements in the Premises, or (iii) the Base Building, but as to the Base Building, only to the extent such obligations are triggered by Alterations made by Tenant to the Premises to the extent such Alterations are not normal and customary business office improvements, or triggered by the Tenant Improvements to the extent such Tenant Improvements are not normal and customary business office improvements, or triggered by Tenant's use of the Premises for non-general office use (collectively, "**Tenant's Compliance with Laws Obligations**"). Tenant shall be responsible, at its sole cost and expense, to make all alterations to the Premises as are required to comply with Tenant's Compliance with Laws Obligations. The judgment of any court of competent jurisdiction or the admission of Tenant in any judicial action, regardless of whether Landlord is a party thereto, that Tenant has violated

any of said governmental measures, shall be conclusive of that fact as between Landlord and Tenant. Tenant shall promptly pay all fines, penalties and damages that may arise out of or be imposed because of its failure to comply with the provisions of this Article 24. Landlord shall comply with all Applicable Laws relating to the Base Building, provided that compliance with such Applicable Laws is not the responsibility of Tenant under this Lease, and provided further that Landlord's failure to comply therewith would prohibit Tenant from obtaining or maintaining a certificate of occupancy for the Premises, or would unreasonably and materially affect the safety of Tenant's employees or create a significant health hazard for Tenant's employees, or would otherwise materially and adversely affect Tenant's use of or access to the Premises. Landlord shall be permitted to include in Operating Expenses any costs or expenses incurred by Landlord under this Article 24 to the extent not prohibited by the terms of Article 4 of this Lease, above. Tenant hereby agrees to use reasonable efforts to notify Landlord if Tenant makes any Alterations or improvements to the Premises that might impact accessibility to the Premises or Building under access laws. Landlord hereby agrees to use reasonable efforts to notify Tenant if Landlord makes any alterations or improvements to the Premises that might impact accessibility to the Premises or Building under any disability access laws.

24.2 **Statutory Disclosure and Related Terms**. For purposes of Section 1938(a) of the California Civil Code, Landlord hereby discloses to Tenant, and Tenant hereby acknowledges, that to Landlord's actual knowledge, the Premises have not undergone inspection by a Certified Access Specialist (CASp). As required by Section 1938I of the California Civil Code, Landlord hereby states as follows: "A Certified Access Specialist (CASp) can inspect the subject premises and determine whether the subject premises comply with all of the applicable construction-related accessibility standards under state law. Although state law does not require a CASp inspection of the subject premises, the commercial property owner or lessor may not prohibit the lessee or tenant from obtaining a CASp inspection of the subject premises for the occupancy or potential occupancy of the lessee or tenant, if requested by the lessee or tenant. The parties shall mutually agree on the arrangements for the time and manner of the CASp inspection, the payment of the fee for the CASp inspection, and the cost of making any repairs necessary to correct violations of construction-related accessibility standards within the premises." In furtherance of the foregoing, Landlord and Tenant hereby agree as follows: (a) any CASp inspection requested by Tenant shall be conducted, at Tenant's sole cost and expense, by a CASp designated by Landlord, subject to Landlord's reasonable rules and requirements; (b) Tenant, at its sole cost and expense, shall be responsible for making any improvements or repairs within the Premises to correct violations of construction-related accessibility standards; and (c) if anything done by or for Tenant in its use or occupancy of the Premises shall require any improvements or repairs to the Building or Project (outside the Premises) to correct violations of construction-related accessibility standards, then Tenant shall reimburse Landlord upon demand, as Additional Rent, for the cost to Landlord of performing such improvements or repairs. The terms of this Section 24.2 do not amend or reduce the obligations of Landlord and Tenant set forth in this Lease regarding compliance with Applicable Laws and repair and maintenance of the Premises and the Project, but apply solely to the obligations of Landlord and Tenant in connection with Tenant's election to conduct a CASp inspection hereunder.

ARTICLE 25

LATE CHARGES

If any installment of Rent or any other sum due from Tenant shall not be received by Landlord or Landlord's designee (i) within five (5) days after written notice from Landlord that said amount was not paid when due, or (ii) upon the date said amount is due, if Tenant has previously received one (1) or more notices from Landlord during the immediately preceding twelve (12) month period stating that Tenant failed to pay any amount required to be paid by Tenant under this Lease when due, then Tenant shall pay to Landlord a late charge equal to six percent (6%) of the overdue amount plus any attorneys' fees incurred by Landlord by reason of Tenant's failure to pay Rent and/or other charges when due hereunder. The late charge shall be deemed Additional Rent and the right to require it shall be in addition to all of Landlord's other rights and remedies hereunder or at law and shall not be construed as liquidated damages or as limiting Landlord's remedies in any manner. In addition to the late charge described above, any Rent or other amounts owing hereunder which are not paid (A) within five (5) days after written notice from Landlord that said amount was not paid when due, or (B) upon the date said amount is due, if Tenant has previously received one (1) or more notices from Landlord during the immediately preceding twelve (12) month period stating that Tenant failed to pay any amount required to be paid by Tenant under this Lease when due, shall bear interest from the date when due until paid at a rate per annum equal to the lesser of (x) the annual "**Bank Prime Loan**" rate cited in the Federal Reserve Statistical Release Publication H.15(519), published weekly (or such other comparable index as Landlord and Tenant shall reasonably agree upon if such rate ceases to be published) plus four (4) percentage points, and (y) the highest rate permitted by applicable law.

ARTICLE 26

LANDLORD'S RIGHT TO CURE DEFAULT; PAYMENTS BY TENANT

26.1 **Landlord's Cure**. All covenants and agreements to be kept or performed by Tenant under this Lease shall be performed by Tenant at Tenant's sole cost and expense and without any reduction of Rent, except to the extent, if any, otherwise expressly provided herein. If Tenant shall fail to perform any obligation under this Lease, and such failure shall continue in excess of the time allowed under Section 19.1.2, above, unless a specific time period is otherwise stated in this Lease, Landlord may, but shall not be obligated to, make any such payment or perform any such act on Tenant's part without waiving its rights based upon any default of Tenant and without releasing Tenant from any obligations hereunder.

26.2 **Tenant's Reimbursement**. Except as may be specifically provided to the contrary in this Lease, Tenant shall pay to Landlord the following sums (which sums shall bear interest from the date accrued by Landlord until paid by Tenant at a rate per annum equal to interest at the rate set forth in Article 25 of this Lease, but in no case greater than the maximum amount of such interest permitted by law), upon delivery by Landlord to Tenant of statements therefor: (i) sums equal to expenditures reasonably made and obligations incurred by Landlord in connection with the remedying by Landlord of Tenant's defaults pursuant to the provisions of Section 26.1; (ii) sums equal to all losses, costs, liabilities, damages and expenses referred to in Article 10 of this Lease; and (iii) subject to Section 29.21, sums equal to all expenditures reasonably made and

obligations incurred by Landlord in collecting or attempting to collect the Rent or in enforcing or attempting to enforce any rights of Landlord under this Lease or pursuant to law, including, without limitation, all reasonable legal fees and other amounts so expended. Tenant's obligations under this Section 26.2 shall survive the expiration or sooner termination of the Lease Term.

ARTICLE 27

ENTRY BY LANDLORD

Landlord reserves the right at all reasonable times and upon reasonable notice to Tenant (which notice, notwithstanding anything to the contrary contained in Article 28 of this Lease, may be oral, and which notice shall not be required in the case of an emergency) to enter the Premises to (i) inspect them; (ii) show the Premises to prospective purchasers or tenants, or to current or prospective mortgagees, ground or underlying lessors or insurers; (iii) post notices of nonresponsibility; or (iv) alter, improve or repair the Premises or the Building, or for structural alterations, repairs or improvements to the Building or the Building's systems and equipment. In connection with the foregoing entries described in (i)-(iv), (x) employees of Landlord will sign in and wear a badge provided by Tenant, and (y) Tenant shall be permitted the opportunity to cause a representative of Tenant to accompany Landlord during any such entry (except in the case of emergency), provided that such representative of Tenant does not unreasonably interfere with or delay Landlord exercising its rights or satisfying its obligations hereunder (collectively, the "**Access Requirements**"). Notwithstanding anything to the contrary contained in this Article 27, Landlord may enter the Premises at any reasonable time to (A) perform services required of Landlord, including janitorial service and access control personnel responding to calls/requests; (B) take possession due to any breach of this Lease in the manner provided herein; and (C) perform any covenants of Tenant which Tenant fails to perform. In connection with the foregoing entries described in (A)-(C), employees of Landlord shall not be required to comply with the Access Requirements. Landlord may make any such entries without the abatement of Rent and may take such reasonable steps as required to accomplish the stated purposes. Landlord shall use commercially reasonable efforts to minimize interference with the conduct of Tenant's business in connection with such entries into the Premises. Tenant hereby waives any claims for damages or for any injuries or inconvenience to or interference with Tenant's business, lost profits, any loss of occupancy or quiet enjoyment of the Premises, and any other loss occasioned thereby. For each of the above purposes, Landlord shall at all times have a key with which to unlock all the doors in the Premises, excluding Tenant's vaults, safes and special security areas designated in advance by Tenant. In an emergency, Landlord shall have the right to use any means that Landlord may deem proper to open the doors in and to the Premises. Any entry into the Premises by Landlord in the manner hereinbefore described shall not be deemed to be a forcible or unlawful entry into, or a detainer of, the Premises, or an actual or constructive eviction of Tenant from any portion of the Premises. No provision of this Lease shall be construed as obligating Landlord to perform any repairs, alterations or decorations except as otherwise expressly agreed to be performed by Landlord herein.

ARTICLE 28

NOTICES

All notices, demands, designations, approvals or other communications (collectively, "**Notices**") given or required to be given by either party to the other hereunder or by law shall be in writing, shall be (A) sent by United States certified or registered mail, postage prepaid, return receipt requested ("**Mail**"), (B) delivered by a nationally recognized overnight courier, or (C) delivered personally. Any Notice shall be sent, transmitted, or delivered, as the case may be, to Tenant at the appropriate address set forth in Section 9 of the Summary, or to such other place as Tenant may from time to time designate in a Notice to Landlord, or to Landlord at the addresses set forth below, or to such other places as Landlord may from time to time designate in a Notice to Tenant. Any Notice will be deemed given (i) three (3) days after the date it is posted if sent by Mail, (ii) the date the overnight courier delivery is made, or (iii) the date personal delivery is made. Any Notice given by an attorney on behalf of Landlord or by Landlord's managing agent shall be considered as given by Landlord and shall be fully effective. As of the date of this Lease, any Notices to Landlord must be sent, transmitted, or delivered, as the case may be, to the following addresses:

Boston Properties Limited Partnership
Four Embarcadero Center
Lobby Level, Suite One
San Francisco, California 94111
Attention: Mr. Bob Pester

and

Boston Properties, Inc.
Prudential Center Tower
800 Boylston Street, Suite 1900
Boston, Massachusetts 02199-8103
Attention: General Counsel

and

Boston Properties Limited Partnership
Four Embarcadero Center
Lobby Level, Suite One
San Francisco, California 94111
Attention: Regional Counsel

and

Allen Matkins Leck Gamble Mallory & Natsis LLP
1901 Avenue of the Stars, Suite 1800
Los Angeles, California 90067
Attention: Anton N. Natsis, Esq.

ARTICLE 29

MISCELLANEOUS PROVISIONS

29.1 **Terms; Captions**. The words "Landlord" and "Tenant" as used herein shall include the plural as well as the singular. The necessary grammatical changes required to make the provisions hereof apply either to corporations or partnerships or individuals, men or women, as the case may require, shall in all cases be assumed as though in each case fully expressed. The captions of Articles and Sections are for convenience only and shall not be deemed to limit, construe, affect or alter the meaning of such Articles and Sections.

29.2 **Binding Effect**. Subject to all other provisions of this Lease, each of the covenants, conditions and provisions of this Lease shall extend to and shall, as the case may require, bind or inure to the benefit not only of Landlord and of Tenant, but also of their respective heirs, personal representatives, successors or assigns, provided this clause shall not permit any assignment by Tenant contrary to the provisions of Article 14 of this Lease.

29.3 **No Light, Air or View Rights**. No rights to any view or to light or air over any property, whether belonging to Landlord or any other person, are granted to Tenant by this Lease. Under no circumstances whatsoever at any time during the Lease Term shall any temporary darkening of any windows of the Premises or any temporary obstruction of the light or view therefrom by reason of any repairs, improvements, maintenance or cleaning in or about the Project, or any diminution, impairment or obstruction (whether partial or total) of light, air or view by any structure which may be erected on any land comprising a part of, or located adjacent to or otherwise in the path of light, air or view to, the Project, in any way impose any liability upon Landlord or in any way reduce or diminish Tenant's obligations under this Lease.

29.4 **Modification of Lease**. Should any current or prospective mortgagee or ground lessor for the Building or Project require a modification of this Lease, which modification will not cause an increased cost or expense to Tenant or in any other way materially and adversely change the rights and obligations of Tenant hereunder or interfere with Tenant's use or operation of the Premises, then and in such event, Tenant agrees that this Lease may be so modified and agrees to execute whatever documents are reasonably required therefor and to deliver the same to Landlord within ten (10) days following a request therefor. At the request of Landlord or any mortgagee or ground lessor, Tenant agrees to execute a short form of Lease and deliver the same to Landlord within ten (10) days following the request therefor.

29.5 **Transfer of Landlord's Interest**. Tenant acknowledges that Landlord has the right to transfer all or any portion of its interest in the Project or Building and in this Lease, and Tenant agrees that in the event of any such transfer, provided the assignee assumes in writing all Landlord's obligations hereunder arising after the date of such transfer, Landlord shall automatically be released from all liability under this Lease accruing thereafter and Tenant agrees

to look solely to such transferee for the performance of Landlord's obligations hereunder after the date of transfer and such transferee shall be deemed to have fully assumed and be liable for all obligations of this Lease to be performed by Landlord, including the return of any Security Deposit, and Tenant shall attorn to such transferee.

29.6 **Prohibition Against Recording**. Except as provided in Section 29.4 of this Lease, neither this Lease, nor any memorandum, affidavit or other writing with respect thereto, shall be recorded by Tenant or by anyone acting through, under or on behalf of Tenant.

29.7 **Landlord's Title**. Landlord's title is and always shall be paramount to the title of Tenant. Nothing herein contained shall empower Tenant to do any act which can, shall or may encumber the title of Landlord.

29.8 **Relationship of Parties**. Nothing contained in this Lease shall be deemed or construed by the parties hereto or by any third party to create the relationship of principal and agent, partnership, joint enture or any association between Landlord and Tenant.

29.9 **Application of Payments**. If a default by Tenant exists beyond applicable notice and cure periods, Landlord shall have the right to apply payments received from Tenant pursuant to this Lease then due hereunder, regardless of Tenant's designation of such payments, to satisfy any obligations of Tenant hereunder, in such order and amounts as Landlord, in its sole discretion, may elect.

29.10 **Time of Essence**. Time is of the essence with respect to the performance of every provision of this Lease in which time of performance is a factor, including, without limitation, the giving of any Notice required to be given under this Lease or by law, the time periods for giving any such Notice and the taking of any action with respect to any such Notice.

29.11 **Partial Invalidity**. If any term, provision or condition contained in this Lease shall, to any extent, be invalid or unenforceable, the remainder of this Lease, or the application of such term, provision or condition to persons or circumstances other than those with respect to which it is invalid or unenforceable, shall not be affected thereby, and each and every other term, provision and condition of this Lease shall be valid and enforceable to the fullest extent possible permitted by law.

29.12 **No Warranty**. In executing and delivering this Lease, except as may be expressly set forth herein, Tenant has not relied on any representations, including, but not limited to, any representation as to the amount of any item comprising Additional Rent or the amount of the Additional Rent in the aggregate or that Landlord is furnishing the same services to other tenants, at all, on the same level or on the same basis, or any warranty or any statement of Landlord which is not set forth herein or in one or more of the exhibits attached hereto.

29.13 **Landlord Exculpation**. The liability of Landlord or the Landlord Parties to Tenant for any default by Landlord under this Lease or arising in connection herewith or with Landlord's operation, management, leasing, repair, renovation, alteration or any other matter relating to the Project or the Premises shall be limited solely and exclusively to an amount which is equal to the lesser of the amount of (a) the interest of Landlord in the Building or (b) the equity interest Landlord would have in the Building if the Building were encumbered by third-party debt in an

amount equal to eighty percent (80%) of the value of the Building (as such value is determined by Landlord), and any sales, rent or condemnation or insurance (to the extent not used to repair damage to the Building) proceeds received by Landlord or the Landlord Parties in connection with the Project, Building or Premises. Neither Landlord, nor any of the Landlord Parties shall have any personal liability therefor, and Tenant hereby expressly waives and releases such personal liability on behalf of itself and all persons claiming by, through or under Tenant. The limitations of liability contained in this Section 29.13 shall inure to the benefit of Landlord's and the Landlord Parties' present and future partners, beneficiaries, officers, directors, trustees, shareholders, agents and employees, and their respective partners, heirs, successors and assigns. Under no circumstances shall any present or future partner of Landlord (if Landlord is a partnership), or trustee or beneficiary (if Landlord or any partner of Landlord is a trust), have any liability for the performance of Landlord's obligations under this Lease. Notwithstanding any contrary provision herein, neither Landlord nor the Landlord Parties shall be liable under any circumstances for any indirect or consequential damages or any injury or damage to, or interference with, Tenant's business, including but not limited to, loss of profits, loss of rents or other revenues, loss of business opportunity, loss of goodwill or loss of use, in each case, however occurring.

29.14 **Entire Agreement**. It is understood and acknowledged that there are no oral agreements between the parties hereto affecting this Lease and this Lease constitutes the parties' entire agreement with respect to the leasing of the Premises and supersedes and cancels any and all previous negotiations, arrangements, brochures, agreements and understandings, if any, between the parties hereto or displayed by Landlord to Tenant with respect to the subject matter thereof, and none thereof shall be used to interpret or construe this Lease. None of the terms, covenants, conditions or provisions of this Lease can be modified, deleted or added to except in writing signed by the parties hereto.

29.15 **Right to Lease**. Landlord reserves the absolute right to effect such other tenancies in the Project as Landlord in the exercise of its sole business judgment shall determine to best promote the interests of the Building or Project. Tenant does not rely on the fact, nor does Landlord represent, that any specific tenant or type or number of tenants shall, during the Lease Term, occupy any space in the Building or Project.

29.16 **Force Majeure**. Any prevention, delay or stoppage due to strikes, lockouts, labor disputes, acts of God, inability to obtain services, labor, or materials or reasonable substitutes therefor, governmental actions, civil commotions, fire or other casualty, and other causes beyond the reasonable control of the party obligated to perform, except with respect to the obligations imposed with regard to Rent and other charges to be paid by Tenant pursuant to this Lease (collectively, a "**Force Majeure**"), notwithstanding anything to the contrary contained in this Lease, shall excuse the performance of such party for a period equal to any such prevention, delay or stoppage and, therefore, if this Lease specifies a time period for performance of an obligation of either party, that time period shall be extended by the period of any delay in such party's performance caused by a Force Majeure, but shall not delay any of Tenant's rent abatement or termination rights set forth herein.

29.17 **Waiver of Redemption by Tenant**. Tenant hereby waives, for Tenant and for all those claiming under Tenant, any and all rights now or hereafter existing to redeem by order or

judgment of any court or by any legal process or writ, Tenant's right of occupancy of the Premises after any termination of this Lease.

29.18 **Tenant Parking**. Tenant shall have the right to park up to twenty-two (22) automobiles (3.3 automobiles for every 1,000 rentable square feet in the Premises), free of charge, in the portions of the Common Areas designated by Landlord for vehicular parking. Such parking shall be on an as available "first-come, first-served" basis which shall be in common with all other tenants of the Project. Tenant's continued right to use the Common Areas designated by Landlord for vehicular parking is conditioned upon Tenant abiding by all reasonable rules and regulations which are prescribed from time to time for the orderly operation and use of the parking facility, including any sticker or other identification system established by Landlord, and Tenant's reasonable cooperation in seeing that Tenant's employees and visitors also comply with such rules and regulations. Landlord specifically reserves the right to change the size, configuration, design, layout and all other aspects of the Project parking facility at any time and Tenant acknowledges and agrees that Landlord may, without incurring any liability to Tenant and without any abatement of Rent under this Lease, from time to time, close-off or restrict access to the Project parking facility for purposes of permitting or facilitating any such construction, alteration or improvements. Landlord may delegate its responsibilities hereunder to a parking operator in which case such parking operator shall have all the rights of control attributed hereby to the Landlord. The parking rights granted to Tenant pursuant to this Section 29.18 are provided to Tenant solely for use by Tenant's own personnel and such passes may not be transferred, assigned, subleased or otherwise alienated by Tenant without Landlord's prior approval, except together with Transfers permitted under this Lease. Tenant may validate visitor parking by such method or methods as the Landlord may establish, at the validation rate from time to time generally applicable to visitor parking.

29.19 **Joint and Several**. If there is more than one Tenant, the obligations imposed upon Tenant under this Lease shall be joint and several.

29.20 **Authority**. Tenant hereby represents and warrants that Tenant is a duly formed and existing entity qualified to do business in California and that Tenant has full right and authority to execute and deliver this Lease and that each person signing on behalf of Tenant is authorized to do so. Concurrently with Tenant's delivery to Landlord of this Lease executed by Tenant, Tenant shall deliver to Landlord satisfactory evidence of such authority.

29.21 **Attorneys' Fees**. In the event that either Landlord or Tenant should bring suit for the possession of the Premises, for the recovery of any sum due under this Lease, or because of the breach of any provision of this Lease or for any other relief against the other, then all costs and expenses, including reasonable attorneys' fees, incurred by the prevailing party therein shall be paid by the other party, which obligation on the part of the other party shall be deemed to have accrued on the date of the commencement of such action and shall be enforceable whether or not the action is prosecuted to judgment.

29.22 **Governing Law; WAIVER OF TRIAL BY JURY**. This Lease shall be construed and enforced in accordance with the laws of the State of California. IN ANY ACTION OR PROCEEDING ARISING HEREFROM, LANDLORD AND TENANT HEREBY CONSENT TO (I) THE JURISDICTION OF ANY COMPETENT COURT WITHIN THE STATE OF

CALIFORNIA, (II) SERVICE OF PROCESS BY ANY MEANS AUTHORIZED BY CALIFORNIA LAW, AND (III) IN THE INTEREST OF SAVING TIME AND EXPENSE, TRIAL WITHOUT A JURY IN ANY ACTION, PROCEEDING OR COUNTERCLAIM BROUGHT BY EITHER OF THE PARTIES HERETO AGAINST THE OTHER OR THEIR SUCCESSORS IN RESPECT OF ANY MATTER ARISING OUT OF OR IN CONNECTION WITH THIS LEASE, THE RELATIONSHIP OF LANDLORD AND TENANT, TENANT'S USE OR OCCUPANCY OF THE PREMISES, AND/OR ANY CLAIM FOR INJURY OR DAMAGE, OR ANY EMERGENCY OR STATUTORY REMEDY. IN THE EVENT LANDLORD COMMENCES ANY SUMMARY PROCEEDINGS OR ACTION FOR NONPAYMENT OF BASE RENT OR ADDITIONAL RENT, TENANT SHALL NOT INTERPOSE ANY COUNTERCLAIM OF ANY NATURE OR DESCRIPTION (UNLESS SUCH COUNTERCLAIM SHALL BE MANDATORY) IN ANY SUCH PROCEEDING OR ACTION, BUT SHALL BE RELEGATED TO AN INDEPENDENT ACTION AT LAW.

29.23 **Submission of Lease**. Submission of this instrument for examination or signature by Tenant does not constitute a reservation of, option for or option to lease, and it is not effective as a lease or otherwise until execution and delivery by both Landlord and Tenant.

29.24 **Brokers**. Landlord and Tenant hereby warrant to each other that they have had no dealings with any real estate broker or agent in connection with the negotiation of this Lease, excepting only the real estate brokers or agents specified in Section 11 of the Summary (the "**Brokers**"), and that they know of no other real estate broker or agent who is entitled to a commission in connection with this Lease. Each party agrees to indemnify and defend the other party against and hold the other party harmless from any and all claims, demands, losses, liabilities, lawsuits, judgments, costs and expenses (including without limitation reasonable attorneys' fees) with respect to any leasing commission or equivalent compensation alleged to be owing on account of any dealings with any real estate broker or agent, other than the Brokers, occurring by, through, or under the indemnifying party.

29.25 **Independent Covenants**. This Lease shall be construed as though the covenants herein between Landlord and Tenant are independent and not dependent and Tenant hereby expressly waives the benefit of any statute to the contrary and agrees that if Landlord fails to perform its obligations set forth herein, Tenant shall not be entitled to make any repairs or perform any acts hereunder at Landlord's expense or to any setoff of the Rent or other amounts owing hereunder against Landlord.

29.26 **Project or Building Name and Signage**. Landlord shall have the right at any time to change the name of the Project or Building and to install, affix and maintain any and all signs on the exterior and on the interior of the Project or Building as Landlord may, in Landlord's sole discretion, desire. Tenant shall not use the words "**Gateway Center**" or the name of the Project or Building or use pictures or illustrations of the Project or Building in advertising or other publicity or for any purpose other than as the address of the business to be conducted by Tenant in the Premises, without the prior written consent of Landlord.

29.27 **Counterparts**. This Lease may be executed in counterparts with the same effect as if both parties hereto had executed the same document. Both counterparts shall be construed together and shall constitute a single lease.

29.28 **Intentionally Omitted**. Tenant acknowledges that the content of this Lease and any related documents are confidential information. Except as required by law, Tenant shall keep such confidential information strictly confidential and shall not disclose such confidential information to any person or entity other than Tenant's financial, legal, and space planning consultants.

29.29 **Development of the Project**.

29.29.1 **Subdivision**. Landlord reserves the right to further subdivide all or a portion of the Project provided the same does not unreasonably interfere with Tenant's use of or access to the Premises or materially increase the obligations or decrease the rights of Tenant under this Lease. Tenant agrees to execute and deliver, upon demand by Landlord and in the form reasonably requested by Landlord, any additional documents needed to conform this Lease to the circumstances resulting from such subdivision.

29.29.2 **The Other Improvements**. If portions of the Project or property adjacent to the Project (collectively, the "**Other Improvements**") are owned by an entity other than Landlord, Landlord, at its option, may enter into an agreement with the owner or owners of any or all of the Other Improvements to provide (i) for reciprocal rights of access and/or use of the Project and the Other Improvements, (ii) for the common management, operation, maintenance, improvement and/or repair of all or any portion of the Project and the Other Improvements, (iii) for the allocation of a portion of the Direct Expenses to the Other Improvements and the operating expenses and taxes for the Other Improvements to the Project, and (iv) for the use or improvement of the Other Improvements and/or the Project in connection with the improvement, construction, and/or excavation of the Other Improvements and/or the Project. Nothing contained herein shall be deemed or construed to limit or otherwise affect Landlord's right to convey all or any portion of the Project or any other of Landlord's rights described in this Lease.

29.29.3 **Construction of Project and Other Improvements**. Tenant acknowledges that portions of the Project and/or the Other Improvements may be under construction following Tenant's occupancy of the Premises, and that such construction may result in levels of noise, dust, odor, obstruction of access, etc. which are in excess of that present in a fully constructed project. Tenant hereby waives any and all rent offsets or claims of constructive eviction which may arise in connection with such construction. Landlord shall use commercially reasonable efforts to minimize interference with Tenant's use of or access to the Premises in connection with any such work or any Renovations.

29.30 **Building Renovations**. It is specifically understood and agreed that Landlord has no obligation and has made no promises to alter, remodel, improve, renovate, repair or decorate the Premises, Building, or any part thereof and that no representations respecting the condition of the Premises or the Building have been made by Landlord to Tenant except as specifically set forth herein or in the Tenant Work Letter. However, Tenant hereby acknowledges that Landlord is currently renovating or may during the Lease Term renovate, improve, alter, or modify (collectively, the "**Renovations**") the Project, the Building and/or the Premises. Tenant hereby agrees that such Renovations shall in no way constitute a constructive eviction of Tenant nor entitle Tenant to any abatement of Rent. Landlord shall have no responsibility and shall not be liable to Tenant for any injury to or interference with Tenant's business arising from the Renovations, nor

shall Tenant be entitled to any compensation or damages from Landlord for loss of the use of the whole or any part of the Premises or of Tenant's personal property or improvements resulting from the Renovations, or for any inconvenience or annoyance occasioned by such Renovations.

29.31 **No Violation**. Tenant hereby warrants and represents that neither its execution of nor performance under this Lease shall cause Tenant to be in violation of any agreement, instrument, contract, law, rule or regulation by which Tenant is bound, and Tenant shall protect, defend, indemnify and hold Landlord harmless against any claims, demands, losses, damages, liabilities, costs and expenses, including, without limitation, reasonable attorneys' fees and costs, arising from Tenant's breach of this warranty and representation.

29.32 **Communications and Computer Lines**. Tenant may install, maintain, replace, remove or use any electrical, communications or computer wires and cables (collectively, the "**Lines**") at the Project installed by or on behalf of Tenant in or serving solely the Premises, provided that (i) Tenant shall obtain Landlord's prior written consent, use an experienced and qualified contractor approved in writing by Landlord, and comply with all of the other provisions of Articles 7 and 8 of this Lease, (ii) an acceptable space for additional Lines shall be maintained for existing and future occupants of the Project, as determined in Landlord's reasonable opinion, (iii) the Lines therefor (including riser cables) shall be appropriately insulated to prevent excessive electromagnetic fields or radiation, and shall be surrounded by a protective conduit reasonably acceptable to Landlord, (iv) any new or existing Lines servicing the Premises shall comply with all applicable governmental laws and regulations, (v) as a condition to permitting the installation of new Lines, Landlord may require that Tenant remove existing unused Lines previously installed by or on behalf of Tenant and repair any damage in connection with such removal, and (vi) Tenant shall pay all costs in connection therewith. Landlord reserves the right to require that Tenant remove any Lines installed by or on behalf of Tenant and located in or serving the Premises which are installed in violation of these provisions, or which are at any time in violation of any laws or represent a dangerous or potentially dangerous condition. Landlord further reserves the right to require that Tenant remove any and all Lines installed by or on behalf of Tenant and located in or serving the Premises upon the expiration of the Lease Term or upon any earlier termination of this Lease.

29.33 **Landlord's Waiver of Security Interest in Tenant's Personal Property**. Landlord hereby acknowledges and agree that any and all of Tenant's movable furniture, furnishings, trade fixtures and equipment at the Premises ("**Tenant's Property**") may be financed by a third-party lender or lessor (an "**Equipment Lienor**"), and Landlord hereby (a) subordinates any rights of Landlord to Tenant's Property to such Equipment Lienor, and (b) agrees to recognize the rights of any such Equipment Lienor, subject to and in accordance with a commercially reasonable waiver agreement to be entered into by and between Landlord and the Equipment Lienor following request by Tenant. Tenant shall pay all fees and/or expenses imposed upon or otherwise paid by Landlord to the Equipment Lienor or otherwise expended by Landlord in connection with any such request (including, without limitation, reasonable attorney's fees).

29.34 **No Discrimination**. There shall be no discrimination against, or segregation of, any person or persons on account of sex, marital status, race, color, religion, creed, national origin or ancestry in the Transfer of the Premises, or any portion thereof, nor shall the Tenant itself, or any person claiming under or through it, establish or permit any such practice or practices of

discrimination or segregation with reference to the selection, location, number, use or occupancy of tenants, lessees, subtenants, sublessees, or vendees of the Premises, or any portion thereof.

29.35 **Patriot Act and Executive Order 13224**. As an inducement to Landlord to enter into this Lease, Tenant hereby represents and warrants that: (i) Tenant is not, nor is it owned or controlled directly or indirectly by, any person, group, entity or nation named on any list issued by the Office of Foreign Assets Control of the United States Department of the Treasury ("OFAC") pursuant to Executive Order 13224 or any similar list or any law, order, rule or regulation or any Executive Order of the President of the United States as a terrorist, "Specially Designated National and Blocked Person" or other banned or blocked person (any such person, group, entity or nation being hereinafter referred to as a "Prohibited Person"); (ii) Tenant is not (nor is it owned or controlled, directly or indirectly, by any person, group, entity or nation which is) acting directly or indirectly for or on behalf of any Prohibited Person; and (iii) neither Tenant (nor any person, group, entity or nation which owns or controls Tenant, directly or indirectly) has conducted or will conduct business or has engaged or will engage in any transaction or dealing with any Prohibited Person, including without limitation any assignment of this Lease or any subletting of all or any portion of the Premises or the making or receiving of any contribution of funds, goods or services to or for the benefit of a Prohibited Person. In connection with the foregoing, it is expressly understood and agreed that (x) any breach by Tenant of the foregoing representations and warranties shall be deemed a default by Tenant under Section 19.1.4 of this Lease and shall be covered by the indemnity provisions of Section 10.1 above, and (y) the representations and warranties contained in this subsection shall be continuing in nature and shall survive the expiration or earlier termination of this Lease.

[SIGNATURES ON NEXT PAGE]

IN WITNESS WHEREOF, Landlord and Tenant have caused this Lease to be executed the day and date first above written.

"Landlord":

601 & 651 GATEWAY CENTER LP,
a Delaware limited partnership

BY: GATEWAY CENTER GP LLC,,
a Delaware limited liability company,
its general partner

BY: GATEWAY PORTFOLIO MEMBER LLC,
a Delaware limited liability company,
its manager

BY: GATEWAY PORTFOLIO HOLDINGS LLC,
a Delaware limited liability company,
its manager

BY: ARE-SAN FRANCISCO NO. 83, LLC,
a Delaware limited liability company, its Managing Member

BY: ALEXANDRIA REAL ESTATE EQUITIES, L.P.,
A Delaware limited partnership, its Managing Member

By: ARE-QRS CORP.,
a Maryland corporation, its general partner

BY: /s/ Allison Grochola
Name: Allison Grochola
Title: Vice President, RE Legal Affairs

[signatures continue of following page]

"Tenant":

AKERO THERAPEUTICS, INC.,
a Delaware corporation

By: /s/ Andrew Cheng
Name: Andrew Cheng
Title: President and Chief Executive Officer

By: /s/ Jonathan Young
Name: Jonathan Young
Title: Chief Operating Officer

PLEASE NOTE: THIS LEASE MUST BE EXECUTED BY EITHER (I) BOTH (A) THE CHAIRMAN OF THE BOARD, THE PRESIDENT OR ANY VICE PRESIDENT OF TENANT, AND (B) THE SECRETARY, ANY ASSISTANT SECRETARY, THE CHIEF FINANCIAL OFFICER, OR ANY ASSISTANT TREASURER OF TENANT; OR (II) AN AUTHORIZED SIGNATORY OF TENANT PURSUANT TO A CERTIFIED CORPORATE RESOLUTION, A COPY OF WHICH SHOULD BE DELIVERED WITH THE EXECUTED ORIGINALS.

EXHIBIT A

601 GATEWAY BOULEVARD

OUTLINE OF PREMISES

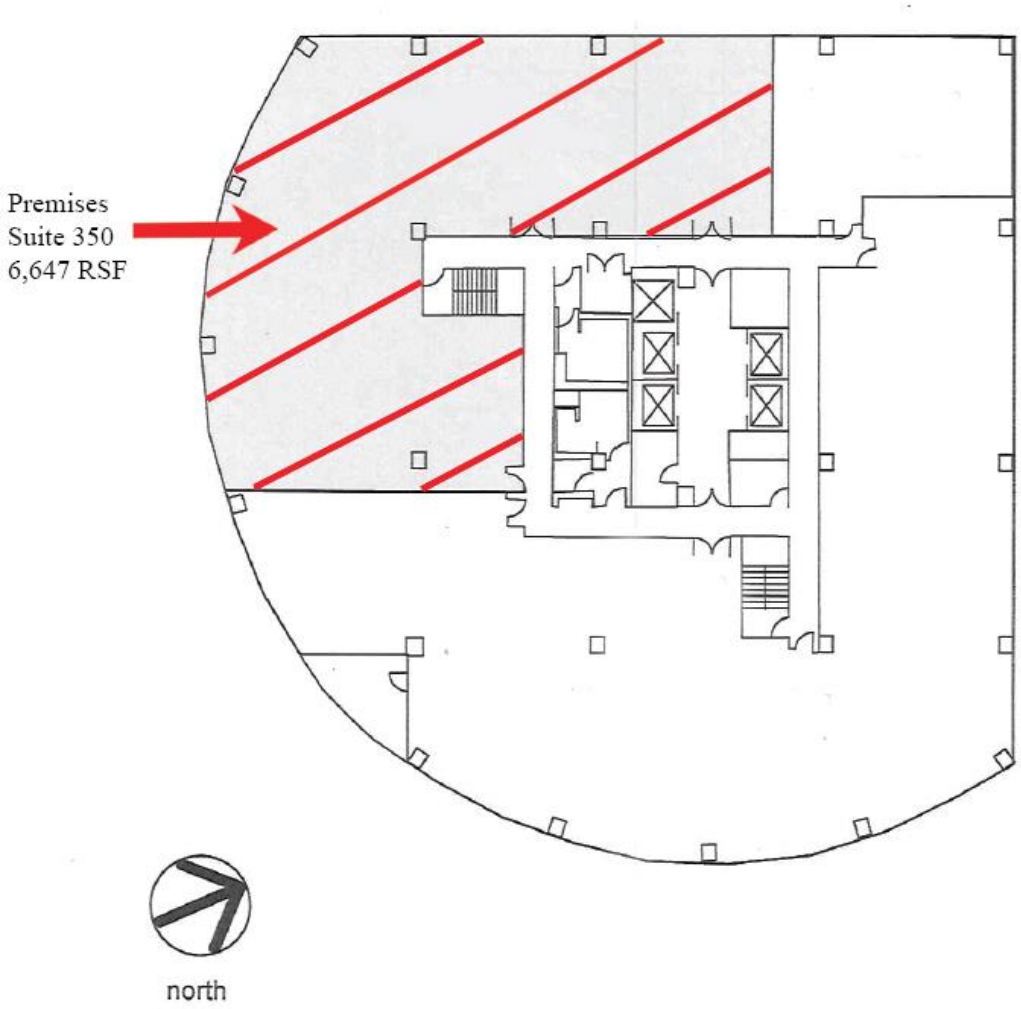


EXHIBIT B

601 GATEWAY BOULEVARD

TENANT WORK LETTER

This Tenant Work Letter shall set forth the terms and conditions relating to the construction of the tenant improvements in the Premises. This Tenant Work Letter is essentially organized chronologically and addresses the issues of the construction of the Premises, in sequence, as such issues will arise during the actual construction of the Premises. All references in this Tenant Work Letter to Articles or Sections of "this Lease" shall mean the relevant portion of Articles 1 through 29 of the Office Lease to which this Tenant Work Letter is attached as Exhibit B and of which this Tenant Work Letter forms a part, and all references in this Tenant Work Letter to Sections of "this Tenant Work Letter" shall mean the relevant portion of Sections 1 through 5 of this Tenant Work Letter.

SECTION 1

CONSTRUCTION DRAWINGS FOR THE PREMISES

1.1 Tenant Improvements. Landlord and Tenant have approved the space plan for the Premises prepared by Brown Reynolds Watford Architects, dated December 9, 2019, a copy of which is attached hereto as Schedule 1 (the "**Space Plan**"). Within five (5) days of request of Landlord, Tenant shall cooperate in good faith with Landlord's architects and engineers to supply such information necessary to allow the Landlord's architects and engineers to complete the architectural and engineering drawings for the Premises, and the final architectural working drawings in a form which is complete to allow subcontractors to bid on the work and to obtain all applicable permits and in a manner consistent with, and which are a logical extension of, the Space Plan (collectively, the "**Approved Working Drawings**"), which Approved Working Drawings shall include the Turnkey Scope of Work set forth on Schedule 1. Landlord shall construct the improvements in the Premises (the "**Tenant Improvements**") pursuant to the Approved Working Drawings. All such Tenant Improvements shall be completed to Landlord's "Building standard" condition in "Building standard" finishes to be designated by Tenant, subject to availability, within three (3) business days following demand by Landlord. Tenant shall make no changes or modifications to (i) the Space Plan or (ii) once completed, the Approved Working Drawings, without the prior written consent of Landlord, which consent may be withheld in Landlord's sole discretion if such change or modification would directly or indirectly delay the "Substantial Completion," as that term is defined in Section 4.1 of this Tenant Work Letter, of the Premises (unless Tenant agrees in writing that the terms of Section 4.2 apply thereto) or increase the cost of designing or constructing the Tenant Improvements.

1.2 Common Areas. Notwithstanding anything set forth in this Tenant Work Letter to the contrary, Landlord shall, at Landlord's sole cost and expense, to the extent required in order to obtain a certificate of occupancy, or its legal equivalent, for the Premises for general office use assuming a normal and customary office occupancy density, cause the Building Common Areas (including the Base Building restrooms on the third (3rd) floor of the Building), to comply with applicable building codes and other governmental laws, ordinances and regulations, which were enacted and enforced as of the date of this Lease.

SECTION 2

TENANT CHANGES

In the event that after Tenant's execution of this Lease, any revisions, changes, or substitutions shall be made by Tenant to (i) the Space Plan, (ii) the Approved Working Drawings (once the same are completed), or (iii) the Tenant Improvements or in the event that Tenant requests revisions, changes, or substitutions which cause the Approved Working Drawings to not be a logical extension of the Space Plan, or if Tenant requests finishes that are not "Building standard," then Landlord shall cause the Contractor to prepare a change order for Tenant's approval specifying the anticipated increased cost and delay in Substantial Completion as a result thereof for Tenant's approval (the "**Change Order**") and any additional costs which arise in connection with such revisions, changes or substitutions shall be paid by Tenant to Landlord immediately upon Landlord's request.

SECTION 3

CONTRACTOR'S WARRANTIES AND GUARANTIES

Landlord hereby assigns to Tenant all warranties and guaranties by the contractor who constructs the Tenant Improvements (the "**Contractor**") relating to the Tenant Improvements, and Tenant hereby waives all claims against Landlord relating to, or arising out of the construction of, the Tenant Improvements; provided that prior to the expiration of such warranties and guaranties, Tenant's waiver shall only be to the extent covered by such warranties and guaranties.

SECTION 4

COMPLETION OF THE TENANT IMPROVEMENTS;

LEASE COMMENCEMENT DATE

4.1 Ready for Occupancy. The Premises shall be deemed "**Ready for Occupancy**" upon the Substantial Completion of the Tenant Improvements in the Premises and delivery of the Premises to Tenant in the condition required under Section 1.1.1 of the Lease. For purposes of this Lease, "**Substantial Completion**" of the Premises shall occur upon the completion of construction of the Tenant Improvements pursuant to the Approved Working Drawings, with the exception of any punch list items and any tenant fixtures, work-stations, built-in furniture, or equipment to be installed by Tenant or under the supervision of Contractor. Landlord and Tenant shall, promptly following completion of construction of the Tenant Improvements, jointly inspect the construction of the Tenant Improvements to develop a reasonable and mutually agreed upon punch list.

4.2 Delay of the Substantial Completion of the Premises. Except as provided in this Section 4.2, the Lease Commencement Date shall occur as set forth in the Lease and Section 4.1, above. If there shall be a delay or there are delays in the Substantial Completion of the Premises or in the occurrence of any of the other conditions precedent to the Commencement Date, as set forth in of the Lease, as a result of:

4.2.1 Tenant's failure to timely approve any matter requiring Tenant's approval;

4.2.2 A breach by Tenant of the terms of this Tenant Work Letter or the Lease;

4.2.3 Tenant's request for changes in the Approved Working Drawings;

4.2.4 Tenant's requirement for materials, components, finishes or improvements which are not available in a commercially reasonable time given the anticipated date of Substantial Completion of the Premises, as set forth in the Lease, or which are different from, or not included in, Landlord's standard improvement package items for the Building; or

4.2.5 Any other acts or omissions of Tenant, or its agents, or employees that continue for more than one (1) day after delivery of notice thereof from Landlord;

then, notwithstanding anything to the contrary set forth in the Lease or this Tenant Work Letter and regardless of the actual date of the Substantial Completion of the Premises, the date of Substantial Completion of the Premises shall be deemed to be the date the Substantial Completion of the Premises would have occurred if no Tenant delay or delays, as set forth above, had occurred.

SECTION 5

MISCELLANEOUS

5.1 Tenant's Entry Into the Premises Prior to Substantial Completion. Provided that Tenant and its agents do not interfere with Contractor's work in the Building and the Premises, Contractor shall allow Tenant access to the Premises at least seven (7) days prior to the Substantial Completion of the Premises for the purpose of Tenant installing furniture, equipment or fixtures (including Tenant's data and telephone equipment) in the Premises and any other purpose related to preparation for Tenant’s occupancy. Prior to Tenant's entry into the Premises as permitted by the terms of this Section 5.1, Tenant shall submit a schedule to Landlord and Contractor, for their approval, which schedule shall detail the timing and purpose of Tenant's entry. Tenant shall hold Landlord harmless from and indemnify, protect and defend Landlord against any loss or damage

to the Building or Premises and against injury to any persons caused by Tenant's actions pursuant to this Section 5.1, except to the extent due to the gross negligence, willful misconduct or violation of this Lease by Landlord. Such entry shall be on all the terms of this Lease except the obligations to pay Base Rent and Tenant Share of Direct Expenses and Capital Expenses.

5.2 Freight Elevators. Landlord shall, consistent with its obligations to other tenants of the Building, make the freight elevator reasonably available to Tenant in connection with initial decorating, furnishing and moving into the Premises.

5.3 Tenant's Representative. Tenant has designated Jonathan Young as its sole representative with respect to the matters set forth in this Tenant Work Letter, who, until further notice to Landlord, shall have full authority and responsibility to act on behalf of the Tenant as required in this Tenant Work Letter.

5.4 Landlord's Representative. Landlord has designated Pete Back as its sole representative with respect to the matters set forth in this Tenant Work Letter, who, until further notice to Tenant, shall have full authority and responsibility to act on behalf of the Landlord as required in this Tenant Work Letter.

5.5 Intentionally Omitted.

5.6 Time of the Essence in This Tenant Work Letter. Unless otherwise indicated, all references herein to a "number of days" shall mean and refer to calendar days. In all instances where Tenant is required to approve or deliver an item, if no written notice of approval is given or the item is not delivered within the stated time period, at Landlord's sole option, at the end of such period the item shall automatically be deemed approved or delivered by Tenant and the next succeeding time period shall commence.

5.7 Tenant's Lease Default. Notwithstanding any provision to the contrary contained in this Lease, if an event of default as described in the Lease, or a default by Tenant under this Tenant Work Letter, beyond any applicable notice and cure period expressly set forth in the Lease, has occurred at any time on or before the Substantial Completion of the Premises, then (i) in addition to all other rights and remedies granted to Landlord pursuant to the Lease, Landlord shall have the right to cause Contractor to cease the construction of the Premises (in which case, Tenant shall be responsible for any delay in the Substantial Completion of the Premises caused by such work stoppage as set forth in Section 4 of this Tenant Work Letter), and (ii) all other obligations of Landlord under the terms of this Tenant Work Letter shall be forgiven in each case until such time as such default is cured pursuant to the terms of the Lease.

SCHEDULE 1 TO EXHIBIT B

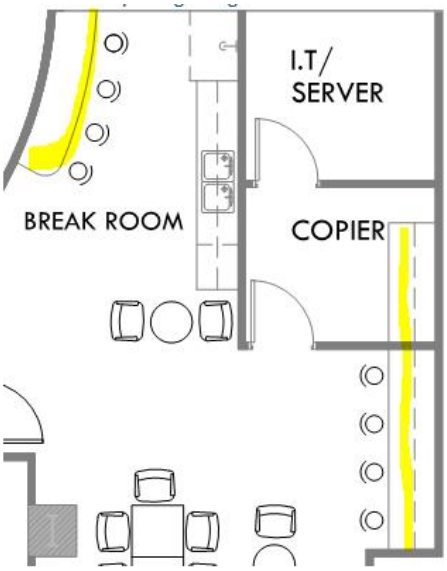
SPACE PLAN

[attached]

FLOOR 3
SUITE 350
KEYNOTES
bxp Boston Properties
AKERO THERAPEUTICS
601 GATEWAY 3rd Floor
SOUTH SAN FRANCISCO, CA
NORTH
SCALE: 1/8" = 1'-0"
BROWN REYNOLDS WATFORD ARCHITECTS
December 9, 2019

TURNKEY SCOPE OF WORK

- All millwork is excluded except for new lower cabinets at the break room (uppers priced as an alternate); existing rounded floating counter top to remain; millwork at copier and where new stools shown do not exist (lowers were removed; as set forth below with highlight of said area).



- New walls are priced at ceiling height, not full height.
- New carpet throughout and new VCT at breakroom priced at Building standard.
- Includes new building required flood stop, chronomite, and waterproofing.
- Assumes reuse of existing plumbing; no engineering included.
- Pricing assumes no new VAVs; pricing assumes redistributing existing for new layout.
- Operable partition to be Hufcor standard option and includes allowances for structural scope.

EXHIBIT C

601 GATEWAY BOULEVARD

NOTICE OF LEASE TERM DATES

Date: _____

To: _____
_____
_____
_____

Copy to: _____
_____
_____
_____

Re: Office Lease
Dated: _____
Between: 601 & 651 GATEWAY CENTER LP, a Delaware limited partnership, Lessor or Landlord, and _____, a _____, Lessee or Tenant

In accordance with the subject document we wish to advise you and/or confirm your tenancy of Suite _____ on the ____ floor of [APPROPRIATE BUILDING] Gateway Boulevard, South San Francisco, CA 94080, and that the following terms and conditions are accurate and in full force and effect:

Net rentable square feet _____ **Lease term** _____
Lease commencement date _____ **Lease expiration date** _____
Base rent schedule *From* _____ *To:* _____ *Monthly Rent:* $_____

Rent checks are

Payable to:	Mailed to:	All other inquiries to:
[APPROPRIATE ENTITY]	[APPROPRIATE ADDRESS]	Boston Properties Lobby Level, Suite One Four Embarcadero Center San Francisco, CA 94111 Telephone: 415-772-0700 Fax: 415-982-1780

If the Lease Commencement Date is other than the first day of the month, the first billing will contain a pro rata adjustment. Each billing thereafter, with the exception of the final billing, shall be for the full amount of the monthly installment as provided for in the Lease.

We request that you sign this letter where indicated below, confirming the information provided above, and return it to our representative below within ten (10) days of receipt. A return envelope is provided. Our failure to receive your executed Notice within such time period will indicate your acceptance that the information set forth is correct. A second letter is enclosed for your files.

Boston Properties, L.P.

Agreed to and Accepted:

By: Lease Administrator's name Date
Lease Administration

By: Date
Its:

copy: Property Manager, Property Accountant
via: Certified Mail

EXHIBIT D

601 GATEWAY BOULEVARD

RULES AND REGULATIONS

Tenant shall faithfully observe and comply with the following Rules and Regulations. Landlord shall not be responsible to Tenant for the nonperformance of any of said Rules and Regulations by or otherwise with respect to the acts or omissions of any other tenants or occupants of the Project; provided, however, that Landlord will exercise good faith efforts (without any obligation to place a tenant in default or commence litigation) to enforce the Rules and Regulations against other tenants and occupants of the Project in a nondiscriminatory manner. In the event of any conflict between the Rules and Regulations and the other provisions of this Lease, the latter shall control.

1. **Signs**. Except as specifically provided in this Lease to which these rules and regulations are attached, no sign, placard, picture, advertisement, name or notice shall be installed or displayed on any part of the outside or inside of the Building or on the Common Areas or other areas of the Project without Landlord's prior written consent. Landlord may remove, at Tenant's expense and without notice, any sign installed or displayed in violation of this rule. All signs or lettering on doors and walls must be approved by Landlord, and shall be printed, painted, affixed or inscribed or modified at Tenant's expense by a person approved by Landlord. Without Landlord's written consent, Tenant shall not use the name of the Building or the Project in connection with or in promoting or advertising the business of Tenant except as Tenant's address. Landlord hereby agrees to provide Tenant with the Building's standard graphics at the entrance to the Premises and in the elevator lobby.

2. **Window Treatments**. Tenant shall not place anything against or near glass partitions or doors or windows which may appear unsightly from outside the Premises. Tenant shall be held responsible for any damage to the glass coating within the Premises. If Landlord objects in writing to any curtains, blinds, shades, screens or hanging plants or other similar objects attached to or used in connection with any window or door of the Premises, or placed on any windowsill, which are visible from the exterior of the Premises, Tenant shall immediately discontinue such use.

3. **Common Areas**. The sidewalks, entrances, halls, corridors, elevators and stairways of the Building and the Project shall not be obstructed or used as a waiting or lounging place by Tenant and the Tenant's Parties. All entrance doors leading from the Premises to the hallways are to be kept closed at all times. The outside areas immediately adjoining the Premises shall be kept clear at all times by Tenant, and Tenant shall not place or permit any obstructions, garbage, refuse, merchandise or displays in such areas. The halls, passages, exits, entrances, elevators, escalators and stairways are not open to the general public, but are open, subject to reasonable regulations, to Tenant's Parties. Landlord shall, in all cases, retain the right to control and prevent access thereto of all persons whose presence in the judgment of Landlord would be prejudicial to the safety of the Project or any part thereof provided that nothing herein contained shall be construed to prevent such access to persons with whom any tenant normally deals in the

ordinary course of its business, unless such persons are engaged in illegal or unlawful activities. Neither Tenant nor any Tenant Parties shall go upon the roof of the Building.

4. **Directory**. The directory of the Building will be provided for the display of the name and location of tenants, and Landlord reserves the right to exclude any other names therefrom. Tenant shall be allocated its pro rata share of lines on the Building directory board in the main lobby.

5. **Cleanliness**. Tenant shall not exhibit carelessness or indifference to the good order and cleanliness of the Premises.

6. **Keys**. Landlord will furnish Tenant, free of charge, with two keys to each exterior door lock in the Premises. All duplicate keys shall be purchased only from Landlord. Landlord may charge a reasonable fee for any additional keys. Tenant shall not make or have made additional keys, and Tenant shall not alter any lock or install a new additional lock or bolt on any door of its Premises. Tenant, upon the termination of its tenancy, shall deliver to Landlord the keys to all doors and pay Landlord for any lost keys.

7. **Security Devices**. If Tenant requires telephonic, burglar alarm or similar services, it shall first obtain and comply with Landlord's instructions for their installation.

8. **Freight Elevators**. The Building service elevator shall be available for use by all tenants in the Building, subject to such reasonable scheduling by Landlord. No equipment, materials, furniture, packages, supplies, merchandise or other property will be received in the Building or carried in the elevators except between such hours and in such elevators as may be designated by Landlord. Tenant's initial move-in and subsequent deliveries of bulky items, such as furniture, safes and similar items shall be made after obtaining Landlord's written consent and shall be made during the hours of 12:00 a.m. to 5:00 a.m. and 6:00 p.m. to 11:59 p.m., Monday through Friday, or at any time on Saturday or Sunday, unless otherwise agreed in writing by Landlord. Deliveries during normal office hours shall be limited to normal office supplies and other small items. No deliveries shall be made which impede or interfere with other tenants or the operation of the Building.

9. **Floor Load**. Tenant shall not place a load upon any floor of the Premises which exceeds the load per square foot which such floor was designed to carry and which is allowed by law. Prior to delivery of any heavy object to the Building, Tenant shall notify Landlord of such object's specifications and contemplated location in order that Landlord may take action to prevent structural load damage to the Building. Landlord shall have the right to prescribe the weight, size and position of all equipment, materials, furniture or other property brought into the Building. Heavy objects shall, if considered necessary by Landlord, stand on such platforms as determined by Landlord to be necessary to properly distribute the weight, which platforms shall be provided at Tenant's sole cost and expense. Tenant shall be responsible for all structural engineering required to determine structural load. Business machines and mechanical equipment belonging to Tenant which cause noise or vibration that may be transmitted to the structure of the Building or to any space therein to such degree as to be objectionable to Landlord or to any tenants in the Building, shall be placed and maintained by Tenant, at Tenant's sole cost and expense, on vibration eliminators or other devices sufficient to eliminate noise or vibration. The persons

employed to move such equipment in or out of the Building must be acceptable to Landlord. Landlord will not be responsible for loss of, or damage to, any such equipment or other property from any cause, and all damage done to the Building by maintaining or moving such equipment or other property shall be repaired at the expense of Tenant.

10. **No Waste**. Tenant shall not use any method of heating and air conditioning other than that supplied by Landlord. Further, Tenant shall not waste electricity, water or air conditioning and agrees to cooperate fully with Landlord to assure the most effective operation of the Building's heating and air conditioning and to comply with any governmental energy-saving rules, laws or regulations of which Tenant has actual notice. Tenant shall keep corridor doors closed.

11. **Building Identification**. Landlord reserves the right, exercisable without notice and without liability to Tenant, to change the name and address of the Building and/or any other part of the Project.

12. **Building Access**. Landlord reserves the right to exclude from the Building between the hours of 12:00 a.m. to 7:00 a.m. and 6:00 p.m. to 11:59 p.m., Monday through Friday, and on Saturday, Sunday and holidays, any person not having a Building issue key and is not identified on the daily access list. Tenant shall be responsible for all persons for whom it requests passes and shall be liable to Landlord for all acts of such persons. Landlord may prevent access to the Project or any part thereof in case of invasion, mob, riot, public excitement or other commotion. Landlord may exclude or expel from the Project or any part thereof any person who, in Landlord's judgment, is intoxicated or under the influence of liquor or drugs or is in violation of any of the rules and regulations of the Project. Landlord shall not be liable for damages for any error with regard to the admission to or exclusion from the Project or any part thereof of any person.

13. **Building Security**. Before Tenant and the Tenant Parties leave the Premises each day, Tenant shall (a) close and lock the doors of its Premises, and (b) shut off all water faucets and other utilities. Tenant shall be responsible for any damage or injuries sustained by other tenants or occupants of the Building or by Landlord for noncompliance with this rule.

14. **Outside Services**. Tenant shall not obtain for use on the Premises, towel or other similar services or accept barbering or bootblacking service upon the Premises, except as such hours and under such regulations as may be fixed by Landlord. Canvassing, soliciting and distribution of handbills or any other written material, and peddling in the Building are prohibited, and Tenant shall cooperate to prevent such activities.

15. **Lavatories**. The toilet rooms, toilets, urinals, wash bowls and other apparatus shall not be used for any purpose other than that for which they were constructed and no foreign substance of any kind whatsoever shall be thrown therein. The expense of any breakage, stoppage or damage resulting from the violation of this rule shall be borne by the tenant who, or whose Tenant Parties, shall have caused it.

16. **Solicitation**. Tenant shall not make any room-to-room solicitation of business from other tenants in the Project or any part thereof.

17. **Electronic Devices**. Tenant shall not install any radio or television antenna, loudspeaker or other devices on the roof or exterior walls of the Building. Tenant shall not interfere with radio or television broadcasting or reception from or in the Building or elsewhere.

18. **Trash Disposal**. Tenant shall store all its trash and garbage within the Premises or in other facilities provided by Landlord. Tenant shall not place in any trash box or receptacle any material which cannot be disposed of in the ordinary and customary manner of trash and garbage disposal. All garbage and refuse disposal shall be made in accordance with directions issued from time to time by Landlord.

19. **Prohibited Uses**. The Premises shall not be used for (a) the keeping of any bicycles, motorcycles or animals of any kind (except service animals to the extent access is required by Applicable Laws), or (b) lodging, or (c) for manufacturing of any kind; nor shall the Premises be used for any illegal purpose. No cooking or heating of food is permitted on the Premises, excepting therefrom microwave ovens and equipment for brewing coffee, tea, hot chocolate and similar beverages. Such cooking and heating devices and their use should be approved by Underwriters Laboratories in accordance with all applicable insurance regulations and federal, state, county and city laws, codes, ordinances, rules and regulations. Tenant shall not install, maintain or operate upon the Premises any vending machines without the written consent of Landlord, which consent shall not be unreasonably withheld.

20. **Prohibited Equipment**. Tenant shall not use in any space or in the public halls of the Project any hand truck except those equipped with rubber tires and side guards or such other material- handling equipment as Landlord may approve. Tenant shall not bring any other vehicles of any kind into the Building.

21. **Safety Procedures**. Tenant shall comply with all safety, fire protection and evacuation procedures and regulations established by Landlord or any governmental agency.

22. **Premises Security**. Tenant assumes full responsibility for protecting its space from theft, robbery and pilferage, which includes keeping doors locked and other means of entry to the Premises closed and secure. Landlord shall not in any way be responsible to Tenants or any Tenant Party, for any loss of property from the Premises or public areas or for any damage to any property thereon to the extent provided in the Lease.

23. **Building Management**. Tenant's requirements will be attended to only upon appropriate application to the Building management office by an authorized individual. Employees of Landlord shall not perform any work or do anything outside of their regular duties unless under special instructions from Landlord, and no employee of Landlord will admit any person (Tenant or otherwise) to any office without specific instructions from Landlord.

24. **Waiver**. Landlord may waive any one or more of these Rules and Regulations for the benefit of Tenant or any other tenant, but no such waiver by Landlord shall be construed as a waiver of such Rules and Regulations in favor of Tenant or any other tenant, nor prevent Landlord from thereafter enforcing any such Rules and Regulations against any or all of the tenants of the Building.

25. **Integration**. These Rules and Regulations are in addition to, and shall not be construed to in any way modify or amend, in whole or in part, the terms, covenants, agreements and conditions of the Lease.

26. **Additional Regulations**. Landlord reserves the right to make such other and reasonable rules and regulations as, in its judgment, may from time to time be needed for safety and security, for care and cleanliness of the Project of any part thereof and for the preservation of good order therein. Tenant agrees to abide by all such Rules and Regulations hereinabove stated and any additional rules and regulations which are adopted and delivered to Tenant in writing.

27. **Observance of Rules**. Tenant shall be responsible for the observance of all of the foregoing rules by Tenant's employees, agents, clients, customers, invitees, licensees and guests.

28. **Parking Facilities**. The following rules and regulations shall govern use of the parking facilities within the Common Areas appurtenant to the Project (such parking facilities being collectively referred to hereinafter as the "Parking Area").

28.1 Persons using the Parking Area shall obey all signs and shall park only in areas designated for vehicle parking within painted stall lines. Tenant's parking spaces shall be used only for parking vehicles no longer than full-sized passenger automobiles. Tenant shall not permit any vehicle that belongs to or is controlled by Tenant, its agents, employees, invitees, licensees and visitors, to be loaded, unloaded or parked in areas other than those designated by Landlord or its parking operator for such activities. No maintenance, washing, waxing or cleaning of vehicles shall be permitted in the Parking Area. Unless otherwise instructed, each person using the Parking Area shall park and lock his or her own vehicle. Neither Landlord nor its parking operator shall be liable for damage to any vehicle, injury to any person or loss of any property, all of which risks are assumed by the person using the Parking Area. Parking pursuant to this Lease is intended as a license only, and no bailment is intended or created hereby. Tenant shall abide by those rules promulgated by Landlord which provide for tandem parking. No overnight or extended term storage of any vehicles or other object shall be permitted.

28.2 Persons using the Parking Area shall comply with any parking identification system established by Landlord or its parking operator. Such a system may include the validation of visitor parking, at the validation rate applicable to visitor parking from time to time as set by Landlord or its parking operator. Parking stickers or other identification devices supplied by Landlord shall remain the property of Landlord. Such devices shall not be transferable, and any such device in the possession of an unauthorized holder may be retained by Landlord and declared void. Upon the loss or obliteration of a parking identification device, Tenant shall pay such reasonable replacement charge as may be established by Landlord or its parking operator. Upon the termination of parking privileges, all parking identification devices supplied by Landlord shall be returned to Landlord. Landlord may refuse the sale of monthly stickers or other parking identification devices to any tenant or person and/or his agents or representatives who willfully refuse to comply with these Rules and Regulations and all unposted city, state or federal ordinances, laws, or agreements. Loss or theft of parking identification devices from automobiles must be reported to the garage manager immediately, and a lost or stolen report must be filed by

the customer at that time. Landlord may exclude any car from the parking facilities that does not have an identification device. Any parking identification devices reported lost or stolen found on any unauthorized car will be confiscated and the illegal holder will be subject to prosecution. Lost or stolen devices found by the purchaser must be reported to the parking facility office immediately to avoid confusion.

28.3 The speed limit within all parking areas shall be five (5) miles per hour.

28.4 Landlord reserves the right to modify, redesign or redesignate uses permitted in the Parking Area or any portion thereof, to relocate parking spaces from floor to floor, from one portion of the Parking Area to another or to reasonably adjacent offsite locations, and to allocate parking spaces between compact and standard sizes from time to time, as long as the same comply with applicable laws and ordinances. Reserved parking spaces shall be clearly and prominently marked as such by Landlord. But neither Landlord nor its parking operator shall be liable or responsible for the failure of persons to observe such markings or to obey other rules and regulations, agreements, laws or ordinances applicable to the Parking Area. Without limiting the generality of the foregoing, Landlord shall not be obligated to tow any violator's vehicle, or to declare a default under or terminate the lease of any other tenant of the Building, on account of any such failure. If for any reason Landlord is unable to provide to Tenant all or any portion of its parking spaces or Tenant is unreasonably denied access thereto during the initial term of this Lease or any renewal or extension hereof, such fact shall not be a default by Landlord or permit Tenant to terminate this Lease, either in whole or in part, but Tenant's obligation to pay rental for any parking space which is not provided by Landlord shall be abated for so long as Tenant does not have the use of such parking space, in full settlement of all claims that Tenant might otherwise have against Landlord by reason of Landlord's failure or inability to provide Tenant with such parking space.

Tenant shall be responsible for the compliance with all of the foregoing rules and regulations by Tenant and Tenant Parties. Landlord may refuse to permit any person who violates any such rules and regulations to have access to the Project or any part thereof. Landlord reserves the right from time to time to modify the rules and regulations set forth herein, including, without limitation, to adopt and modify such rules and regulations applicable to the Parking Area, as it deems necessary for the proper operation.

EXHIBIT E

601 GATEWAY BOULEVARD

FORM OF TENANT'S ESTOPPEL CERTIFICATE

The undersigned, as Tenant under that certain Office Lease (the "Lease") made and entered into as of _____, 20 ___ by and between _____, as Landlord, and the undersigned, as Tenant, for Premises on the _____ floor(s) of the office building located at_____, certifies as follows:

1. Attached hereto as Exhibit A is a true and correct copy of the Lease and all amendments and modifications thereto. The documents contained in **Exhibit A** represent the entire agreement between the parties as to the Premises.

2. The undersigned currently occupies the Premises described in the Lease, the Lease Term commenced on _____, and the Lease Term expires on _____, and the undersigned has no option to terminate or cancel the Lease or to purchase all or any part of the Premises, the Building and/or the Project.

3. Base Rent became payable on _____.

4. The Lease is in full force and effect and has not been modified, supplemented or amended in any way except as provided in **Exhibit A**.

5. Tenant has not transferred, assigned, or sublet any portion of the Premises nor entered into any license or concession agreements with respect thereto except as follows:

6. All monthly installments of Base Rent, all Additional Rent and all monthly installments of estimated Additional Rent have been paid when due through _____. The current monthly installment of Base Rent is $_____.

7. To Tenant’s current actual knowledge, all conditions of the Lease to be performed by Landlord necessary to the enforceability of the Lease have been satisfied and Landlord is not in default thereunder. In addition, the undersigned has not delivered any notice to Landlord regarding a default by Landlord thereunder.

8. No rental has been paid more than thirty (30) days in advance and no security has been deposited with Landlord except the Security Deposit in the amount of $_____ as provided in the Lease.

9. To Tenant’s current actual knowledge, as of the date hereof, there are no existing defenses or offsets, or, to the undersigned's knowledge, claims or any basis for a claim, that the undersigned has against Landlord.

10. If Tenant is a corporation, limited liability company, partnership or limited liability partnership, Tenant hereby represents and warrants that Tenant is a duly formed and existing entity qualified to do business in California and that Tenant has full right and authority to execute and

deliver this Estoppel Certificate and that each person signing on behalf of Tenant is authorized to do so.

11. There are no actions pending against the undersigned under the bankruptcy or similar laws of the United States or any state.

12. Other than in compliance with all applicable laws and incidental to the ordinary course of the use of the Premises, the undersigned has not used or stored any hazardous substances in the Premises.

13. To Tenant's current actual knowledge, all tenant improvement work to be performed by Landlord under the Lease has been completed in accordance with the Lease and has been accepted by the undersigned and all reimbursements and allowances due to the undersigned under the Lease in connection with any tenant improvement work have been paid in full.

The undersigned acknowledges that this Estoppel Certificate may be delivered to Landlord or to a prospective mortgagee or prospective purchaser, and acknowledges that said prospective mortgagee or prospective purchaser will be relying upon the statements contained herein in making the loan or acquiring the property of which the Premises are a part and that receipt by it of this certificate is a condition of making such loan or acquiring such property.

Executed at _____ on the _____ day of _____, 20__.

"Tenant":

_____,
a _____

By:
Its: _____

By: _____
Its: _____

EXHIBIT F

601 GATEWAY BOULEVARD

STANDARDS FOR UTILITIES AND SERVICES

1. **Elevators**. Provide non-attended passenger elevators to and from the floor(s) on which the Premises are located. Landlord may limit the number of elevators operating outside normal business hours.

2. **HVAC**. On Monday through Friday, except holidays, from 7:00 a.m. to 6:00 p.m., ventilate the Premises and furnish air conditioning or heating on such days and hours, in temperatures and amounts which in Landlord's good faith judgment are reasonably required for comfortable occupancy of the Premises under normal business operations. If Tenant requires air conditioning during other hours, Landlord will furnish same through an access system provided to Tenant at the Premises, if available, or otherwise as specified in a written request of Tenant delivered to the Building management office before noon on the preceding business day. For this service Tenant will pay Landlord, upon receipt of Landlord's statement, the charge at an hourly rate reasonably and uniformly determined by Landlord from time to time, which is currently $266.97 for full HVAC and $126.92 for fans only per hour. Tenant agrees that neither Tenant nor any Tenant Party shall at any time enter mechanical installations or facilities of the Building or adjust, tamper with, touch or otherwise in any manner affect said installations or facilities. The cost of maintenance and service calls to adjust and regulate the air conditioning system shall be charged to Tenant if the need for maintenance work results from either Tenant's adjustment of room thermostats or Tenant's failure to comply with Landlord's rules governing the temperature within the Premises.

3. **Lighting**. Furnish electric lighting for all public areas and special service areas of the Building as Landlord determines in good faith to be reasonable and standard, including replacement of Building standard lights, bulbs and tubes.

4. **Electrical Service**. Subject to the limitation of this Paragraph 4, furnish electrical service to the Premises, including providing and installing all Building standard replacement lighting tubes. If Tenant uses more electrical power than Landlord in good faith considers reasonable or normal for office use, Tenant will pay Landlord on a monthly basis the cost of such excess power consumed by Tenant. Consumption will be determined, at Landlord's election, either (a) by a survey performed by a reputable consultant selected by Landlord, or (b) through separate meters or submeters installed, maintained and read by Landlord at Tenant's cost. For purposes of this Paragraph 4 only, "month" and "monthly" shall mean any billing period used by the utility or other power provider supplying electricity. All installations of electrical fixtures, appliances and equipment within the Premises other than normal office equipment shall be subject to Landlord's reasonable prior approval, and if they materially affect the temperature or humidity otherwise maintained, Landlord may, at Tenant's sole cost and expense (to be paid within (30) days after delivery of written demand supported by invoices or other reasonably satisfactory evidence), install supplemental air conditioning units. Tenant's use of electricity shall never exceed Tenant's share of the capacity of existing feeders to the Building or of the risers, wiring installations and transformers serving the floor(s) containing the Premises. Landlord shall provide

up to 3.5 watts per usable square foot (demand) of riser and floor panel electrical capacity averaged over the floor being serviced. Tenant shall be allocated an approximate 2.0 watts per usable square foot for power and 1.5 watts per usable square foot for lighting. Any risers or wiring necessary to meet Tenant's excess electrical requirements will be installed by Landlord on Tenant's request, at Tenant's sole cost and expense (to be paid in advance), but only if in Landlord's good faith belief, they are necessary and will not cause damage to the Building or a dangerous condition, entail excessive or unreasonable alterations, repairs or expense, or disturb other occupants.

5. **Water**. Provide toilet facilities, water for lavatory and toilet purposes, cold water for drinking and tepid water for lavatory purposes, all at points of supply provided for general use of tenants in the Building and in the Premises through fixtures installed by Landlord or by Tenant with Landlord's consent.

6. **Janitorial**. Provide janitorial service to the Premises on business days and other cleaning services as Landlord determines to be reasonably required. Tenant will pay Landlord the full cost attributable to any extraordinary janitorial or cleaning services which the Premises may require.

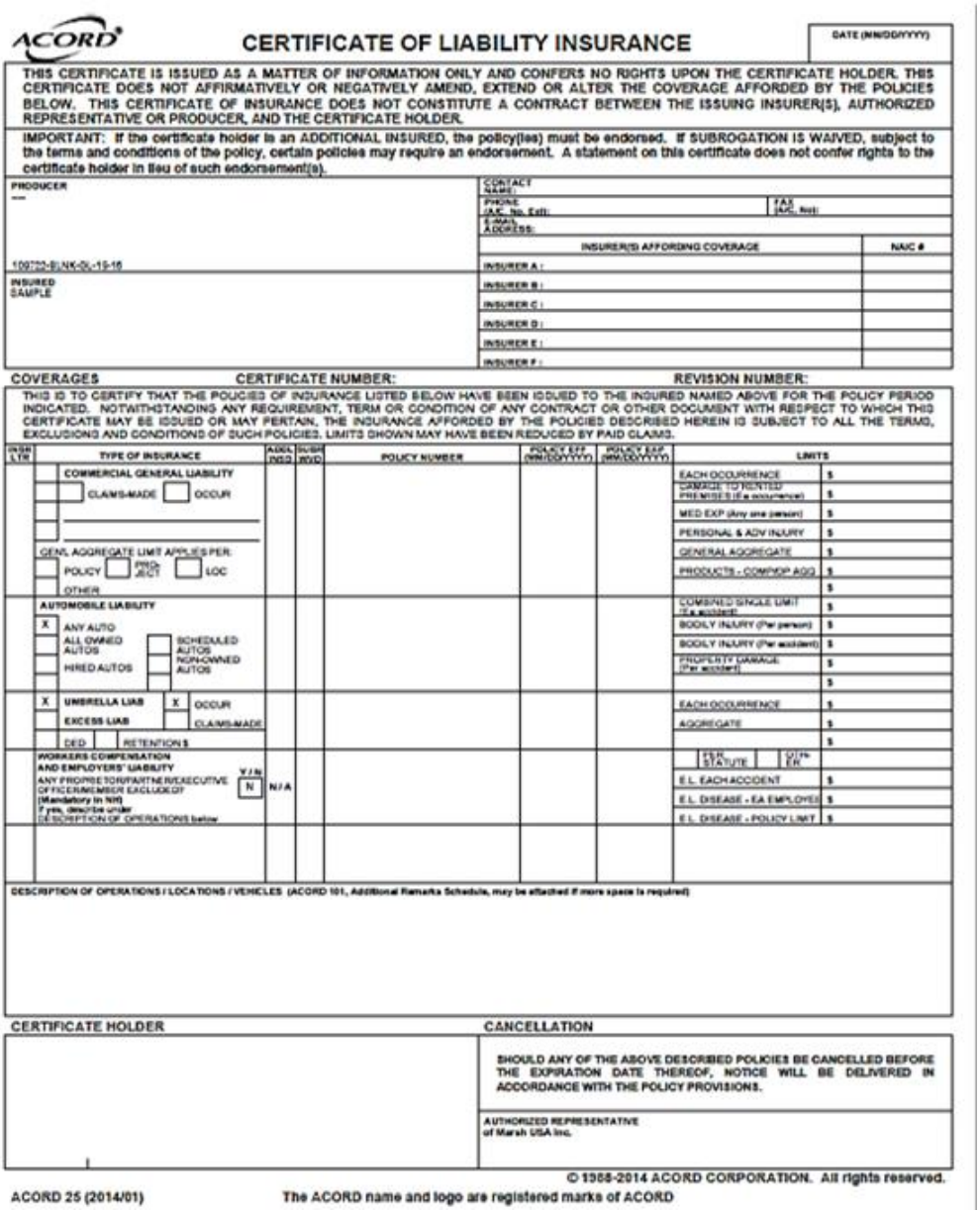
7. **Maintenance of Non-Building Standard Items**. Maintenance and service costs necessary for non-building standard items in the Premises shall be the responsibility of Tenant. As used in this paragraph, non-building standard items shall include, without limitation, heat pumps, condenser pumps, sinks and associated drain pipes, faucets, hot water heaters, garbage disposals, dishwashers, refrigerators, ice makers, air conditioning units, projection screens and associated wiring and switching, incandescent downlight or wallwash fixtures and lamps, floor electrical outlets and power poles.

8. **Security Services.** Provide Building security personnel twenty-four (24) hours per day, seven (7) days per week, fifty-two (52) weeks per year and a card access system which allows access to individual office floors twenty-four (24) hours per day, seven (7) days per week, fifty-two (52) weeks per year, all of which shall be provided by Landlord in its sole and absolute discretion. Notwithstanding Landlord's providing security, Tenant waives any claim against Landlord with respect to any loss by theft or any other damage suffered or incurred by Tenant in connection with any entry into the Premises or any other breach of security with respect to the Premises or the Building, except due to the gross negligence or willful misconduct of Landlord or Landlord's violation of this Lease.

Landlord reserves the right to adopt reasonably, nondiscriminatory modifications and additions to these standards, which Landlord shall promptly deliver to Tenant in writing.

EXHIBIT G

ACCEPTABLE FORMS OF INSURANCE CERTIFICATE



ACORD

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
—

CONTACT NAME:
PHONE (A/C, No, Ext):
FAX (A/C, No):
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A :	
INSURER B :	
INSURER C :	
INSURER D :	
INSURER E :	
INSURER F :	

109722-BLNK-GL-19-16

INSURED
SAMPLE

COVERAGES CERTIFICATE NUMBER: REVISION NUMBER:

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS
	COMMERCIAL GENERAL LIABILITY CLAIMS-MADE OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: POLICY PRO-JECT LOC OTHER						EACH OCCURRENCE $ DAMAGE TO RENTED PREMISES (Ea occurrence) $ MED EXP (Any one person) $ PERSONAL & ADV INJURY $ GENERAL AGGREGATE $ PRODUCTS - COMP/OP AGG $ $
	AUTOMOBILE LIABILITY X ANY AUTO ALL OWNED AUTOS SCHEDULED AUTOS HIRED AUTOS NON-OWNED AUTOS						COMBINED SINGLE LIMIT (Ea accident) $ BODILY INJURY (Per person) $ BODILY INJURY (Per accident) $ PROPERTY DAMAGE (Per accident) $ $
	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED RETENTION $						EACH OCCURRENCE $ AGGREGATE $ $
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below Y / N: N N/A						PER STATUTE OTH-ER E.L. EACH ACCIDENT $ E.L. DISEASE - EA EMPLOYEE $ E.L. DISEASE - POLICY LIMIT $

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

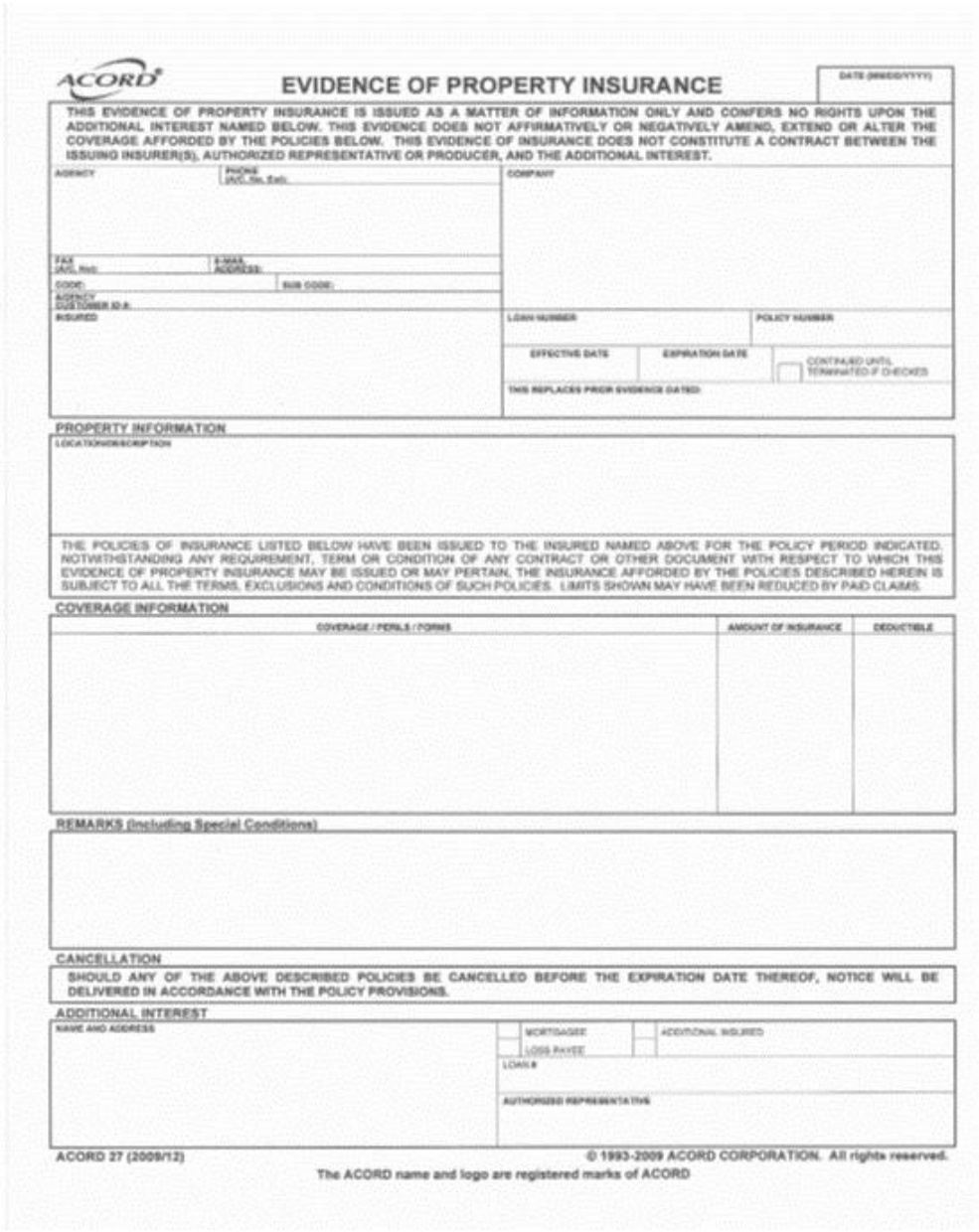
CERTIFICATE HOLDER

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
of Marsh USA Inc.

ACORD 25 (2014/01) The ACORD name and logo are registered marks of ACORD



ACORD

EVIDENCE OF PROPERTY INSURANCE

DATE (MM/DD/YYYY)

THIS EVIDENCE OF PROPERTY INSURANCE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE ADDITIONAL INTEREST NAMED BELOW. THIS EVIDENCE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS EVIDENCE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE ADDITIONAL INTEREST.

AGENCY | PHONE (A/C, No, Ext): | COMPANY

FAX (A/C, No): | E-MAIL ADDRESS:

CODE: | SUB CODE:

AGENCY CUSTOMER ID #:

INSURED | LOAN NUMBER | POLICY NUMBER

EFFECTIVE DATE | EXPIRATION DATE | ☐ CONTINUED UNTIL TERMINATED IF CHECKED

THIS REPLACES PRIOR EVIDENCE DATED:

PROPERTY INFORMATION

LOCATION/DESCRIPTION

THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS EVIDENCE OF PROPERTY INSURANCE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

COVERAGE INFORMATION

COVERAGE / PERILS / FORMS	AMOUNT OF INSURANCE	DEDUCTIBLE

REMARKS (Including Special Conditions)

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

ADDITIONAL INTEREST

NAME AND ADDRESS | ☐ MORTGAGEE ☐ LOSS PAYEE | ☐ ADDITIONAL INSURED

LOAN #

AUTHORIZED REPRESENTATIVE

ACORD 27 (2009/12)

EXHIBIT H

FORM OF LETTER OF CREDIT

IRREVOCABLE STANDBY LETTER OF CREDIT NUMBER _____

ISSUE DATE: _____

ISSUING BANK:
SILICON VALLEY BANK
3003 TASMAN DRIVE
2ND FLOOR, MAIL SORT HF210
SANTA CLARA, CALIFORNIA 95054

BENEFICIARY:
601 & 651 GATEWAY CENTER LP
C/O BOSTON PROPERTIES LIMITED PARTNERSHIP
FOUR EMBARCADRO CENTER
LOBBY LEVEL, SUITE ONE
SAN FRANCISCO, CA 94111
ATTENTION: MR. BOB PESTER

APPLICANT:
AKERO THERAPEUTICS, INC.
400 TECHNOLOGY SQUARE
10TH FLOOR
CAMBRIDGE, MA 02139

AMOUNT: US$107,953.86 (ONE HUNDRED SEVEN THOUSAND NINE HUNDRED FIFTY THREE AND 86/100 U.S. DOLLARS)

EXPIRATION DATE: FEBRUARY ___, 2021 (ONE YEAR FROM DATE THE LC IS ISSUED)

PLACE OF EXPIRATION: ISSUING BANK'S COUNTERS AT ITS ABOVE ADDRESS

DEAR SIR/MADAM:

[Type here]
ALL THE DETAILS SET FORTH HEREIN IN THIS LETTER OF CREDIT DRAFT IS APPROVED BY APPLICANT. IF THERE IS ANY DISCREPANCY BETWEEN THE DETAILS OF THIS LETTER OF CREDIT DRAFT AND THE LETTER OF CREDIT APPLICATION, BETWEEN APPLICANT AND SILICON VALLEY BANK, THE DETAILS HEREOF SHALL PREVAIL.

_____ _____
Applicant's Authorized Signature DATE

WE HEREBY ESTABLISH OUR IRREVOCABLE STANDBY LETTER OF CREDIT NO. SVBS_____ IN YOUR FAVOR FOR THE ACCOUNT OF THE APPLICANT EFFECTIVE IMMEDIATELY, FOR THE SUM NOT EXCEEDING ONE HUNDRED SEVEN THOUSAND NINE HUNDRED FIFTY THREE AND 86/100 U.S. DOLLARS ($107,953.86) WHICH EXPIRES ON _____ AT OUR OFFICE AND AVAILABLE BY YOUR DRAFT(S) DRAWN ON US AT SIGHT IN THE FORM OF EXHIBIT "A" ATTACHED AND ACCOMPANIED BY THE FOLLOWING DOCUMENTS:

1. THE ORIGINAL OF THIS LETTER OF CREDIT AND ALL AMENDMENT(S), IF ANY.

2. BENEFICIARY'S DATED AND SIGNED STATEMENT, STATING ANY ONE OF THE FOLLOWING WITH INSTRUCTIONS IN BRACKETS THEREIN COMPLETED:

"THE UNDERSIGNED HEREBY CERTIFIES THAT BENEFICIARY, EITHER (A) UNDER THE LEASE (DEFINED BELOW), OR (B) AS A RESULT OF THE TERMINATION OF SUCH LEASE, HAS THE RIGHT TO DRAW DOWN THE AMOUNT OF USD(INSERT) IN ACCORDANCE WITH THE TERMS OF THAT CERTAIN OFFICE LEASE DATED FEBRUARY____, 2020 BY AND BETWEEN BENEFICIARY AND APPLICANT (OR THE SUCCESSOR-IN-INTEREST TO THE ORIGINAL TENANT OF SUCH OFFICE LEASE), AS THE SAME MAY HAVE BEEN AMENDED (COLLECTIVELY, THE "LEASE"), OR SUCH AMOUNT CONSTITUTES DAMAGES OWING BY THE TENANT TO BENEFICIARY RESULTING FROM THE BREACH OF SUCH LEASE BY THE TENANT THEREUNDER, OR THE TERMINATION OF SUCH LEASE, AND SUCH AMOUNT REMAINS UNPAID AT THE TIME OF THIS DRAWING."

OR

"THE UNDERSIGNED HEREBY CERTIFIES THAT BENEFICIARY HAS RECEIVED A WRITTEN NOTICE OF SILICON VALLEY BANK'S ELECTION NOT TO EXTEND ITS STANDBY LETTER OF CREDIT NO. SVBSF(INSERT) AND LESS THAN FORTY-FIVE (45) DAYS REMAIN PRIOR TO THE EXPIRATION OF SUCH LETTER OF CREDIT."

OR

"THE UNDERSIGNED HEREBY CERTIFIES THAT BENEFICIARY IS ENTITLED TO DRAW DOWN THE FULL AMOUNT OF LETTER OF CREDIT NO. SVBSF(INSERT) AS THE RESULT OF THE FILING OF A VOLUNTARY PETITION UNDER THE U.S. BANKRUPTCY CODE OR A STATE BANKRUPTCY CODE BY THE TENANT UNDER THAT CERTAIN OFFICE LEASE DATED FEBRUARY___, 2020 BY AND BETWEEN BENEFICIARY AND APPLICANT (OR THE SUCCESSOR-IN-INTEREST TO THE

ALL THE DETAILS SET FORTH HEREIN IN THIS LETTER OF CREDIT DRAFT IS APPROVED BY APPLICANT. IF THERE IS ANY DISCREPANCY BETWEEN THE DETAILS OF THIS LETTER OF CREDIT DRAFT AND THE LETTER OF CREDIT APPLICATION, BETWEEN APPLICANT AND SILICON VALLEY BANK, THE DETAILS HEREOF SHALL PREVAIL.

_____ _____

Applicant's Authorized Signature DATE

ORIGINAL TENANT OF SUCH OFFICE LEASE), AS THE SAME MAY HAVE BEEN AMENDED (COLLECTIVELY, THE "LEASE"), WHICH FILING HAS NOT BEEN DISMISSED AT THE TIME OF THIS DRAWING."

OR

"THE UNDERSIGNED HEREBY CERTIFIES THAT BENEFICIARY IS ENTITLED TO DRAW DOWN THE FULL AMOUNT OF LETTER OF CREDIT NO. SVBSF(INSERT) AS THE RESULT OF AN INVOLUNTARY PETITION HAVING BEEN FILED UNDER THE U.S. BANKRUPTCY CODE OR A STATE BANKRUPTCY CODE AGAINST THE TENANT UNDER THAT CERTAIN OFFICE LEASE DATED FEBRUARY____, 2020 BY AND BETWEEN BENEFICIARY AND APPLICANT (OR THE SUCCESSOR-IN-INTEREST TO THE ORIGINAL TENANT OF SUCH OFFICE LEASE), AS THE SAME MAY HAVE BEEN AMENDED (COLLECTIVELY, THE "LEASE"), WHICH FILING HAS NOT BEEN DISMISSED AT THE TIME OF THIS DRAWING."

OR

"THE UNDERSIGNED HEREBY CERTIFIES THAT BENEFICIARY IS ENTITLED TO DRAW DOWN THE FULL AMOUNT OF LETTER OF CREDIT NO. SVBSF(INSERT) AS THE RESULT OF THE REJECTION, OR DEEMED REJECTION, OF THAT CERTAIN OFFICE LEASE DATED FEBRUARY____, 2020 BY AND BETWEEN BENEFICIARY AND APPLICANT(OR THE SUCCESSOR-IN-INTEREST TO THE ORIGINAL TENANT OF SUCH OFFICE LEASE), AS THE SAME MAY HAVE BEEN AMENDED, UNDER SECTION 365 OF THE U.S. BANKRUPTCY CODE."

PARTIAL DRAWINGS AND MULTIPLE PRESENTATIONS ARE ALLOWED.

NOTWITHSTANDING THE EXPIRATION DATE IDENTIFIED ABOVE IN THIS LETTER OF CREDIT, THIS LETTER OF CREDIT SHALL BE AUTOMATICALLY EXTENDED FOR AN ADDITIONAL PERIOD OF ONE YEAR, WITHOUT AMENDMENT, FROM THE PRESENT OR EACH FUTURE EXPIRATION DATE UNLESS AT LEAST 60 DAYS PRIOR TO THE THEN CURRENT EXPIRATION DATE WE SEND YOU A NOTICE BY REGISTERED OR CERTIFIED MAIL OR OVERNIGHT COURIER SERVICE AT THE ABOVE ADDRESS THAT THIS LETTER OF CREDIT WILL NOT BE EXTENDED BEYOND THE THEN CURRENT EXPIRATION DATE. IN NO EVENT SHALL THIS LETTER OF CREDIT BE AUTOMATICALLY EXTENDED BEYOND SEPTEMBER 1, 2027. IN THE EVENT WE SEND SUCH NOTICE OF NON-EXTENSION, YOU MAY DRAW HEREUNDER BY YOUR PRESENTATION TO US OF YOUR SIGNED AND DATED STATEMENT STATING THAT YOU HAVE RECEIVED A NON-EXTENSION NOTICE FROM SILICON VALLEY BANK IN RESPECT OF LETTER OF CREDIT NO. SVBSF _____, YOU

ALL THE DETAILS SET FORTH HEREIN IN THIS LETTER OF CREDIT DRAFT IS APPROVED BY APPLICANT. IF THERE IS ANY DISCREPANCY BETWEEN THE DETAILS OF THIS LETTER OF CREDIT DRAFT AND THE LETTER OF CREDIT APPLICATION, BETWEEN APPLICANT AND SILICON VALLEY BANK, THE DETAILS HEREOF SHALL PREVAIL.

_____ _____

Applicant's Authorized Signature DATE

ARE DRAWING ON SUCH LETTER OF CREDIT FOR US$_____, LESS THAN SIXTY (60) DAYS REMAIN PRIOR TO THE EXPIRATION OF THIS LETTER OF CREDIT AND YOU HAVE NOT RECEIVED A REPLACEMENT LETTER OF CREDIT ACCEPTABLE TO YOU.

ALL DEMANDS FOR PAYMENT SHALL BE MADE BY PRESENTATION OF THE REQUIRED DOCUMENTS ON A BUSINESS DAY AT OUR OFFICE (THE "BANK'S OFFICE") AT: SILICON VALLEY BANK, 3003 TASMAN DRIVE, MAIL SORT HF 210, SANTA CLARA, CA 95054, ATTENTION: GLOBAL TRADE FINANCE. AS USED IN THIS LETTER OF CREDIT, "BUSINESS DAY" SHALL MEAN ANY DAY OTHER THAN A SATURDAY, SUNDAY OR A DAY ON WHICH BANKING INSTITUTIONS IN THE STATE OF CALIFORNIA ARE AUTHORIZED OR REQUIRED BY LAW TO CLOSE. NOTWITHSTANDING ANY PROVISION TO THE CONTRARY IN THE ISP98 (AS HEREINAFTER DEFINED), IF THE EXPIRATION DATE OR THE FINAL EXPIRATION DATE IS NOT A BUSINESS Day THEN SUCH DATE SHALL BE AUTOMATICALLY EXTENDED TO THE NEXT SUCCEEDING DATE WHICH IS A BUSINESS DAY.

FACSIMILE PRESENTATIONS ARE ALSO PERMITTED. EACH FACSIMILE TRANSMISSION SHALL BE MADE AT: (408) 496-2418 OR (408) 969-6510; AND UNDER CONTEMPORANEOUS TELEPHONE ADVICE TO: (408) 450-5001 OR (408) 654-7176, ATTENTION: GLOBAL TRADE FINANCE. ABSENCE OF THE AFORESAID TELEPHONE ADVICE SHALL NOT AFFECT OUR OBLIGATION TO HONOR ANY DRAW REQUEST.

THIS LETTER OF CREDIT IS TRANSFERABLE IN WHOLE BUT NOT IN PART ONE OR MORE TIMES, BUT IN EACH INSTANCE ONLY TO A SINGLE BENEFICIARY AS TRANSFEREE AND FOR THE THEN AVAILABLE AMOUNT, ASSUMING SUCH TRANSFER TO SUCH TRANSFEREE WOULD BE IN COMPLIANCE WITH THEN APPLICABLE LAW AND REGULATION, INCLUDING BUT NOT LIMITED TO THE REGULATIONS OF THE U.S. DEPARTMENT OF TREASURY AND U.S. DEPARTMENT OF COMMERCE. AT THE TIME OF TRANSFER, THE ORIGINAL LETTER OF CREDIT AND ORIGINALS OR COPIES OF ALL AMENDMENTS, IF ANY, TO THIS LETTER OF CREDIT MUST BE SURRENDERED TO US AT OUR ADDRESS INDICATED IN THIS LETTER OF CREDIT TOGETHER WITH OUR TRANSFER FORM ATTACHED HERETO AS EXHIBIT "B" DULY EXECUTED. APPLICANT SHALL PAY OUR TRANSFER FEE OF ¼ OF 1% OF THE TRANSFER AMOUNT (MINIMUM US$250.00) UNDER THIS LETTER OF CREDIT BUT SUCH PAYMENT BY APPLICANT SHALL NOT BE A CONDITION TO TRANSFER. EACH TRANSFER SHALL BE EVIDENCED BY EITHER (1) OUR ENDORSEMENT ON THE REVERSE OF THE LETTER OF CREDIT AND WE SHALL FORWARD THE ORIGINAL OF THE LETTER OF CREDIT SO ENDORSED TO THE TRANSFEREE OR (2) OUR ISSUING A REPLACEMENT LETTER OF CREDIT TO THE TRANSFEREE ON SUBSTANTIALLY THE SAME TERMS AND CONDITIONS AS THE

ALL THE DETAILS SET FORTH HEREIN IN THIS LETTER OF CREDIT DRAFT IS APPROVED BY APPLICANT. IF THERE IS ANY DISCREPANCY BETWEEN THE DETAILS OF THIS LETTER OF CREDIT DRAFT AND THE LETTER OF CREDIT APPLICATION, BETWEEN APPLICANT AND SILICON VALLEY BANK, THE DETAILS HEREOF SHALL PREVAIL.

_____ _____

Applicant's Authorized Signature DATE

TRANSFERRED LETTER OF CREDIT (IN WHICH EVENT THE TRANSFERRED LETTER OF CREDIT SHALL HAVE NO FURTHER EFFECT).

IF DEMAND FOR PAYMENT IS PRESENTED BY 10 A.M. CALIFORNIA TIME AND CONFORMS TO THE TERMS AND CONDITIONS OF THIS LETTER OF CREDIT, PAYMENT SHALL BE MADE BY ISSUING BANK TO YOU OF THE AMOUNT SPECIFIED, IN IMMEDIATELY AVAILABLE FUNDS NO LATER THAN THE NEXT FOLLOWING BUSINESS DAY AFTER THE DATE OF PRESENTMENT. IF DEMAND FOR PAYMENT IS PRESENTED BY YOU HEREUNDER AFTER THE TIME SPECIFIED ABOVE, AND CONFORMS TO THE TERMS AND CONDITIONS OF THIS LETTER OF CREDIT, PAYMENT SHALL BE MADE TO YOU, OF THE AMOUNT OF SPECIFIED, IN IMMEDIATELY AVAILABLE FUNDS NO LATER THAN THE SECOND BUSINESS DAY AFTER THE DATE OF PRESENTMENT.

WE HEREBY AGREE WITH THE BENEFICIARY THAT THE DRAFTS DRAWN UNDER AND IN ACCORDANCE WITH THE TERMS AND CONDITIONS OF THIS LETTER OF CREDIT SHALL BE DULY HONORED UPON PRESENTATION TO US ON OR BEFORE THE EXPIRATION DATE OF THIS LETTER OF CREDIT OR ANY AUTOMATICALLY EXTENDED EXPIRATION DATE.

IF THE ORIGINAL AND/OR ANY AMENDMENTS THERETO OF THIS STANDBY LETTER OF CREDIT NO. SVBSF____ ARE LOST, STOLEN OR DESTROYED, WE WILL ISSUE YOU A "CERTIFIED TRUE COPY" OF THIS STANDBY LETTER OF CREDIT NO. SVBSF_____ UPON OUR RECEIPT OF YOUR INDEMNITY LETTER. IF THE ORIGINAL OF THIS STANDBY LETTER OF CREDIT IS MUTILATED, WE WILL ISSUE YOU A REPLACEMENT STANDBY LETTER OF CREDIT WITH THE SAME NUMBER, DATE AND TERMS AS THE ORIGINAL UPON OUR RECEIPT OF THE MUTILATED STANDBY LETTER OF CREDIT.

IF ANY INSTRUCTIONS ACCOMPANYING A DRAWING UNDER THIS LETTER OF CREDIT REQUEST THAT PAYMENT IS TO BE MADE BY TRANSFER TO YOUR ACCOUNT WITH ANOTHER BANK, WE WILL ONLY EFFECT SUCH PAYMENT BY FED WIRE TO A U.S. REGULATED BANK, AND WE AND/OR SUCH OTHER BANK MAY RELY ON AN ACCOUNT NUMBER SPECIFIED IN SUCH INSTRUCTIONS EVEN IF THE NUMBER IDENTIFIES A PERSON OR ENTITY DIFFERENT FROM THE INTENDED PAYEE.

THIS LETTER OF CREDIT IS SUBJECT TO THE INTERNATIONAL STANDBY PRACTICES (ISP98), INTERNATIONAL CHAMBER OF COMMERCE, PUBLICATION NO. 590.

[Type here]

ALL THE DETAILS SET FORTH HEREIN IN THIS LETTER OF CREDIT DRAFT IS APPROVED BY APPLICANT. IF THERE IS ANY DISCREPANCY BETWEEN THE DETAILS OF THIS LETTER OF CREDIT DRAFT AND THE LETTER OF CREDIT APPLICATION, BETWEEN APPLICANT AND SILICON VALLEY BANK, THE DETAILS HEREOF SHALL PREVAIL.

_____ _____

Applicant's Authorized Signature DATE

SILICON VALLEY BANK,

AUTHORIZED SIGNATURE

AUTHORIZED SIGNATURE

[Type here]

ALL THE DETAILS SET FORTH HEREIN IN THIS LETTER OF CREDIT DRAFT IS APPROVED BY APPLICANT. IF THERE IS ANY DISCREPANCY BETWEEN THE DETAILS OF THIS LETTER OF CREDIT DRAFT AND THE LETTER OF CREDIT APPLICATION, BETWEEN APPLICANT AND SILICON VALLEY BANK, THE DETAILS HEREOF SHALL PREVAIL.

Applicant's Authorized Signature

DATE

EXHIBIT "A"
SIGHT DRAFT

DATE: _____ REF. NO. _____

AT SIGHT OF THIS DRAFT
PAY TO THE ORDER OF US$ _____

USDOLLARS _____

DRAWN UNDER SILICON VALLEY BANK, SANTA CLARA, CALIFORNIA, STANDBY
LETTER OF CREDIT NUMBER NO. DATED _____

TO: SILICON VALLEY BANK
3003 TASMAN DRIVE
SANTA CLARA, CA 95054

_____
(BENEFICIARY'S NAME)

_____
Authorized Signature

GUIDELINES TO PREPARE THE DRAFT

[Type here]
ALL THE DETAILS SET FORTH HEREIN IN THIS LETTER OF CREDIT DRAFT IS APPROVED BY APPLICANT. IF THERE IS ANY DISCREPANCY BETWEEN THE DETAILS OF THIS LETTER OF CREDIT DRAFT AND THE LETTER OF CREDIT APPLICATION, BETWEEN APPLICANT AND SILICON VALLEY BANK, THE DETAILS HEREOF SHALL PREVAIL.

_____ _____
Applicant's Authorized Signature DATE

1. DATE: ISSUANCE DATE OF DRAFT.
2. REF. NO.: BENEFICIARY'S REFERENCE NUMBER, IF ANY.
3. PAY TO THE ORDER OF: NAME OF BENEFICIARY AS INDICATED IN THE L/C (MAKE SURE BENEFICIARY ENDORSES IT ON THE REVERSE SIDE).
4. US$: AMOUNT OF DRAWING IN FIGURES.
5. USDOLLARS: AMOUNT OF DRAWING IN WORDS.
6. LETTER OF CREDIT NUMBER: SILICON VALLEY BANK'S STANDBY L/C NUMBER THAT PERTAINS TO THE DRAWING.
7. DATED: ISSUANCE DATE OF THE STANDBY L/C.
8. BENEFICIARY'S NAME: NAME OF BENEFICIARY AS INDICATED IN THE L/C.
9. AUTHORIZED SIGNATURE: SIGNED BY AN AUTHORIZED SIGNER OF BENEFICIARY.

IF YOU NEED FURTHER ASSISTANCE IN COMPLETING THIS DRAFT, PLEASE CALL OUR L/C PAYMENT SECTION AT 408-654-6274 OR 408-654-7716.

IRREVOCABLE STANDBY LETTER OF CREDIT NUMBER _____

[Type here]

ALL THE DETAILS SET FORTH HEREIN IN THIS LETTER OF CREDIT DRAFT IS APPROVED BY APPLICANT. IF THERE IS ANY DISCREPANCY BETWEEN THE DETAILS OF THIS LETTER OF CREDIT DRAFT AND THE LETTER OF CREDIT APPLICATION, BETWEEN APPLICANT AND SILICON VALLEY BANK, THE DETAILS HEREOF SHALL PREVAIL.

_____ _____

Applicant’s Authorized Signature DATE

EXHIBIT "B"
FORM OF TRANSFER FORM

DATE:

TO: SILICON VALLEY BANK
3003 TASMAN DRIVE
SANTA CLARA, CA 95054
ATTN: GLOBAL TRADE FINANCE
STANDBY LETTERS OF CREDIT

RE: IRREVOCABLE STANDBY LETTER OF CREDIT
NO. _____ ISSUED BY
SILICON VALLEY BANK, SANTA CLARA
L/C AMOUNT: _____

GENTLEMEN:

FOR VALUE RECEIVED, THE UNDERSIGNED BENEFICIARY HEREBY IRREVOCABLY TRANSFERS TO:

_____
(NAME OF TRANSFEREE)

_____
(ADDRESS)

ALL RIGHTS OF THE UNDERSIGNED BENEFICIARY TO DRAW UNDER THE ABOVE LETTER OF CREDIT UP TO ITS AVAILABLE AMOUNT AS SHOWN ABOVE AS OF THE DATE OF THIS TRANSFER.

BY THIS TRANSFER, ALL RIGHTS OF THE UNDERSIGNED BENEFICIARY IN SUCH LETTER OF CREDIT ARE TRANSFERRED TO THE TRANSFEREE. TRANSFEREE SHALL HAVE THE SOLE RIGHTS AS BENEFICIARY THEREOF, INCLUDING SOLE RIGHTS RELATING TO ANY AMENDMENTS, WHETHER INCREASES OR EXTENSIONS OR OTHER AMENDMENTS, AND WHETHER NOW EXISTING OR HEREAFTER MADE. ALL AMENDMENTS ARE TO BE ADVISED DIRECTLY TO THE TRANSFEREE WITHOUT NECESSITY OF ANY CONSENT OF OR NOTICE TO THE UNDERSIGNED BENEFICIARY.

THE ORIGINAL OF SUCH LETTER OF CREDIT IS RETURNED HEREWITH, AND WE ASK YOU TO EITHER (1) ENDORSE THE TRANSFER ON THE REVERSE THEREOF, AND FORWARD IT DIRECTLY TO THE TRANSFEREE WITH YOUR CUSTOMARY NOTICE OF TRANSFER, OR (2) ISSUE A REPLACEMENT LETTER OF CREDIT TO THE TRANSFEREE ON SUBSTANTIALLY THE SAME TERMS AND CONDITIONS AS THE TRANSFERRED LETTER OF CREDIT (IN WHICH EVENT THE TRANSFERRED LETTER OF CREDIT SHALL HAVE NO FURTHER EFFECT).

SINCERELY,

_____
(BENEFICIARY'S NAME)

_____
(SIGNATURE OF BENEFICIARY)

_____
(NAME AND TITLE)

SIGNATURE AUTHENTICATED
The name(s), title(s), and signature(s) conform to that/those on file with us for the company and the signature(s) is/are authorized to execute this instrument.
(Name of Bank)
(Address of Bank)
(City, State, ZIP Code)
(Authorized Name and Title)
(Authorized Signature)
(Telephone number)

[Type here]
ALL THE DETAILS SET FORTH HEREIN IN THIS LETTER OF CREDIT DRAFT IS APPROVED BY APPLICANT. IF THERE IS ANY DISCREPANCY BETWEEN THE DETAILS OF THIS LETTER OF CREDIT DRAFT AND THE LETTER OF CREDIT APPLICATION, BETWEEN APPLICANT AND SILICON VALLEY BANK, THE DETAILS HEREOF SHALL PREVAIL.

_____ _____
Applicant's Authorized Signature DATE

OFFICE LEASE

601 GATEWAY BOULEVARD

601 & 651 GATEWAY CENTER LP,
a Delaware limited partnership,

as Landlord,

and

AKERO THERAPEUTICS, INC.,
a Delaware corporation,

as Tenant.

TABLE OF CONTENTS

INDEX

Exhibit 21.1

SUBSIDIARIES

Subsidiary	Jurisdiction of Incorporation
Akero Securities Corporation	Massachusetts

Exhibit Ex 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-232234 on Form S-8 of our report dated March 16, 2020 relating to the consolidated financial statements of Akero Therapeutics, Inc. appearing in this Annual Report on Form 10-K for the year ended December 31, 2019.

/s/ Deloitte & Touche LLP

Parsippany, NJ

March 16, 2020

EXHIBIT 31.1

CERTIFICATION

I, Andrew Cheng, certify that:

1. I have reviewed this annual report on Form 10-K of Akero 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

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

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

5. The registrant's other certifying officer(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 16, 2020

/s/ ANDREW CHENG

Andrew Cheng, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, William White, certify that:

1. I have reviewed this annual report on Form 10-K of Akero Therapuetics, 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

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

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

5. The registrant's other certifying officer(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 16, 2020

/s/ WILLIAM WHITE
William White
Executive Vice President, Chief Financial Officer and Head of Corporate Development
(Principal Financial and Accounting Officer)

EXHIBIT 32.1*

Certification of Principal Executive Officer and Principal Financial Officer
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 Akero Therapeutics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2019 (the "Report"), the undersigned hereby certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of their knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, 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.

Dated: March 16, 2020

/s/ ANDREW CHENG
Andrew Cheng, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Dated: March 16, 2020

/s/ WILLIAM WHITE
William White
Executive Vice President, Chief Financial Officer and Head of Corporate Development
(Principal Financial and Accounting Officer)

* This certification shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that section, nor shall it be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934.