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Confidential Treatment Requested by Akero Therapeutics, Inc.
Pursuant to 17 C.F.R. Section 200.83

As confidentially submitted to the Securities and Exchange Commission on May 15, 2020.

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1

REGISTRATION STATEMENT
Under
The Securities Act of 1933

Akero Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**2836**	**81-5266573**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

170 Harbor Way, 3rd Floor
South San Francisco, CA 94080
(650) 487-6488
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Andrew Cheng, M.D., Ph.D.
President and Chief Executive Officer
170 Harbor Way, 3rd Floor
South San Francisco, CA 94080
(650) 487-6488
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Mitchell Bloom, Esq. **John Mutkoski, Esq.** **Sam Zucker, Esq.** Goodwin Procter LLP 100 Northern Avenue Boston, Massachusetts 02210 (617) 570-1000	**Jonathan Young, J.D., Ph.D.** Chief Operating Officer 170 Harbor Way, 3rd Floor South San Francisco, CA 94080 (650) 487-6488	**Divakar Gupta, Esq.** **Richard C. Segal, Esq.** **Charles S. Kim, Esq.** Cooley LLP 55 Hudson Yards New York, NY 10001 (212) 479-6000

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended, check the following box. ☒

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

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 o	Accelerated filer o	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 to Section 7(a)(2)(B) of the Securities Act. o

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be registered	Proposed maximum aggregate offering price per share	Proposed maximum aggregate offering price(1)	Amount of registration fee(2)
Common stock, par value $0.0001 per share		$	$	$

(1) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended. Includes the aggregate price of shares that the underwriters may purchase pursuant to an option to purchase additional shares.

(3) Calculated pursuant to Rule 457(o) under the Securities Act of 1933, as amended, based on an estimate of the proposed maximum aggregate offering price.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment that specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until this registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to completion, dated , 2020

Preliminary Prospectus

shares

Common stock

We are offering shares of our common stock to be sold in this offering. Our common stock is listed on The Nasdaq Global Select Market under the symbol "AKRO." The last reported sale price of our common stock on The Nasdaq Global Select Market on , 2020 was $ per share. The final public offering price will be determined through negotiation between us and the lead underwriters in this offering and the recent market price used throughout the prospectus may not be indicative of the actual offering price.

We are an "emerging growth company" as defined under the federal securities laws and, as such, have elected to comply with certain reduced public company reporting requirements.

	Per Share	Total
Public offering price	$	$
Underwriting discounts and commissions(1)	$	$
Proceeds to Akero Therapeutics, Inc., before expenses	$	$

(1) See "Underwriting" for a description of the compensation payable to the underwriters.

We have granted the underwriters an option for a period of 30 days to purchase up to additional shares of common stock.

Investing in our common stock involves a high degree of risk. See "Risk factors" beginning on page 7.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities, or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares to purchasers on or about , 2020.

The date of this prospectus is , 2020

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We incorporate by reference important information into this prospectus. You may obtain the information incorporated by reference without charge by following the instructions under "Where You Can Find More Information." You should carefully read this prospectus as well as additional information described under "Incorporation of Certain Information by Reference," before deciding to invest in our common stock

We are responsible for the information contained in this prospectus. We have not, and the underwriters have not, authorized anyone to provide you with any other information other than in this prospectus, and we take no responsibility for, and the underwriters have not taken responsibility for, any other information others may give you. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained in this prospectus is accurate as of any date other than its date.

Through and including , 2020 (the 25th day after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

For investors outside the United States: Neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus outside of the United States.

This prospectus contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or ^{TM} symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Prospectus summary

This summary highlights, and is qualified in its entirety by, the more detailed information included elsewhere in this prospectus or incorporated by reference. This summary does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should read the entire prospectus carefully, especially the "Risk factors" section of this prospectus." Except where the context otherwise requires or where otherwise indicated, the terms "Akero," "we," "us," "our," "our company," "the company," and "our business" refer to Akero Therapeutics, Inc., together with its subsidiary, as appropriate.

Overview

We are a cardio-metabolic nonalcoholic steatohepatitis, or NASH, company developing pioneering medicines designed to 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. We are currently conducting a Phase 2a randomized, double-blind, placebo-controlled clinical trial, the BALANCED study, which is evaluating AKR-001 in the treatment of NASH patients.

On March 31, 2020 we reported results for the primary and several secondary efficacy endpoints for the BALANCED study, all at week 12 of the 16-week dosing period. Each of the three AKR-001 dose groups met the primary endpoint as well as all reported secondary endpoints. These results included highly significant 12-14% absolute reductions in liver fat and 63-72% relative reductions in liver fat (in each case compared with 0% for placebo). Reductions in ALT of 24-32 U/L were observed (compared with 6 U/L for placebo). These robust efficacy results are expected to provide flexibility in dose selection for the next study. We propose, pending consultation with FDA, to progress two doses for further evaluation. These results are consistent with previous clinical trials in patients with type 2 diabetes, or T2D, in which 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.

The COVID-19 pandemic has not materially impacted data collection for the BALANCED study or preparations for our upcoming Phase 2b/3 trial. We have completed all data collection for the BALANCED study. A total of 50 subjects achieved at least a 30% relative reduction of liver fat at week 12 as measured by magnetic resonance imaging—proton density fat fraction (MRI-PDFF) and therefore were eligible for end-of-study biopsies. Forty-eight of the biopsy-eligible subjects were treated with AKR-001 compared with two subjects on placebo. End-of-study biopsies were collected for 42 (84%) of the 50 biopsy-eligible subjects. Toward the end of the second quarter, we expect to unblind the BALANCED study data and to report efficacy and safety data, including paired biopsy results. We expect to include results for the proportions of subjects who achieved at least a 2-point reduction in NAFLD activity score (NAS), a 1-point reversal in fibrosis score with no worsening of NASH, and NASH resolution with no worsening of fibrosis. Additional expected analyses include biomarkers of liver injury and fibrosis and other relevant measures for NASH studies, together with safety and tolerability.

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 59 patients with biopsy-confirmed NASH (F1-F3) for up to 16 weeks in the BALANCED study, an ongoing randomized, double-blind, placebo-controlled study. The primary endpoint (absolute reduction in liver fat as measured by MRI-PDFF) and several secondary endpoints (relative reduction in liver fat, the proportion of patients who achieved at least a 30% relative reduction in liver fat, and change from baseline in ALT) were measured at week 12.

Summary of Week 12 Efficacy Endpoints

		AKR-001 (once weekly dose)		
Measure (Mean)	**Placebo (N=21)**	**28 mg (N=19)**	**50 mg (N=20)**	**70 mg (N=20)**
Absolute reduction in liver fat (%)	–0.3	–12.3***	–13.4***	–14.1***
Relative reduction in liver fat (%)	0	–63***	–71***	–72***
[3]30% relative reduction in fat (%)	10	84***	85***	75***
Reduction in ALT (U/L)	–6	–24***	–30***	–32***

*** p<0.001, versus placebo

The blinded tolerability profile appears consistent with results from previous clinical trials evaluating AKR-001 in patients with Type 2 diabetes. The BALANCED study's Data Monitoring Committee was convened for a review of unblinded safety data following completion of treatment and recommended that an expansion cohort (Cohort C) in NASH patients who have compensated cirrhosis (F4), Child-Pugh Class A, proceed without any amendments to the protocol.

AKR-001 was previously 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. Because 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 liver disease, inflammation, oncology, and HIV 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.

Corporate information

We were incorporated in January 2017 under the laws of the State of Delaware under the name Pippin Pharmaceuticals, Inc. On May 16, 2018, we changed our name to Akero Therapeutics, Inc. Our principal executive offices are located at 170 Harbor Way, 3rd Floor, South San Francisco, CA 94080, and our telephone number is (650)-487-6488. Our website address is www.akerotx.com. The information contained in or accessible from our website is not incorporated into this prospectus, and you should not consider it part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

Implications of being an emerging growth company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced "Management's discussion and analysis of financial condition and results of operations" disclosure;
- reduced disclosure about our executive compensation arrangements;
- no non-binding advisory votes on executive compensation or golden parachute arrangements; and

- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of our initial public offering; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (iv) the last day of the fiscal year in which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission, or SEC, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th. We may choose to take advantage of some but not all of these exemptions. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock. We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements under the JOBS Act. Subject to certain conditions, as an emerging growth company, we may rely on certain of these exemptions, including without limitation, 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. We have elected to avail ourselves of this exemption and, therefore, while we are an emerging growth company we will not be subject to new or revised accounting standards at the same time that they become applicable to other public emerging growth companies that have not elected to avail themselves of this exemption.

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The offering

Common stock offered by us	Shares
Common stock to be outstanding immediately after this offering	shares (or shares if the underwriters exercise their option to purchase additional shares in full)
Option to purchase additional shares	We have granted the underwriters an option exercisable for a period of 30 days to purchase up to additional shares of our common stock.
Use of proceeds	We estimate that we will receive net proceeds from the sale of shares of our common stock in this offering of approximately $ million, or $ million if the underwriters exercise their option to purchase additional shares in full, based on an assumed public offering price of $ per share, which was the last reported sale price of our common stock on The Nasdaq Global Select Market on , 2020, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, for our ongoing Phase 2a clinical trial and a subsequent Phase 2b clinical trial of AKR-001, manufacturing to support future clinical trials, nonclinical studies and potential in-licensing to diversity our pipeline, and working capital and general corporate purposes. For a more complete description of our intended use of the proceeds from this offering, see "Use of proceeds."
Risk factors	You should carefully read the "Risk factors" section of this prospectus for a discussion of factors that you should consider before deciding to invest in our common stock.
The Nasdaq Global Select Market symbol	"AKRO"

The number of shares of our common stock to be outstanding after this offering is based on 28,671,222 shares of our common stock outstanding as of March 31, 2020, and excludes:

- 3,095,450 shares of common stock issuable upon the exercise of stock options outstanding as of March 31, 2020 at a weighted-average exercise price of $8.53 per share;
- 2,812,364 shares of common stock reserved for future issuance as of March 31, 2020 under our 2019 Stock Option and Incentive Plan, or the 2019 Plan; and
- 555,042 shares of our common stock reserved for future issuance under our 2019 Employee Stock Purchase Plan as of March 31, 2020.

Unless otherwise indicated, all information in this prospectus assumes or gives effect to the following:

- no exercise of the outstanding options referred to above; and
- no exercise by the underwriters of their option to purchase up to additional shares of our common stock in this offering.

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Risk factors

Investing in our common stock involves a high degree of risk. You should consider carefully the following risks and uncertainties as well as the risks and uncertainties described in the section entitled "Risk Factors" contained in our Annual Report on Form 10-K for the year ended December 31, 2019, as filed with the Securities and Exchange Commission, or SEC, on March 16, 2020, as well as in our subsequent Quarterly and Annual Reports filed with the SEC, which descriptions are incorporated in this prospectus by reference in their entirety, as well as in any prospectus supplement hereto. These risks and uncertainties are not the only risks and uncertainties we face. Additional risks and uncertainties not currently known to us, or that we currently view as immaterial, may also impair our business. If any of the risks or uncertainties described in our SEC filings or any additional risks and uncertainties actually occur, our business, financial condition, results of operations and cash flow could be materially and adversely affected. In that case, the trading price of our common stock could decline and you might lose all or part of your investment. You should carefully consider the following information about risks, together with the other information contained in this prospectus, before making an investment in our common stock.

Risks related to this offering and 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 prospectus, 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, including very recently in connection with the ongoing COVID-19 pandemic, which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. Broad market and industry factors, including potentially worsening economic conditions and other adverse effects or developments relating to the ongoing COVID-19 pandemic, may significantly reduce 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.

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering, and you will be relying on the judgment of our management regarding the application of these proceeds. You will not have the opportunity, as part of your investment decision, to assess whether we are using the proceeds appropriately. Our management might not apply our net proceeds in ways that ultimately increase the value of your investment. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

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.

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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.

If you purchase our common stock in this offering, you may incur immediate and substantial dilution in the net tangible book value of your shares.

The offering price per share in this offering may exceed the net tangible book value per share of our common stock outstanding prior to this offering. Assuming that an aggregate of shares of our common stock are sold at a price of $ per share, the last reported sale price of our common stock on the Nasdaq Global Select Market on , 2020, for aggregate gross proceeds of $, and after deducting commissions and estimated offering expenses payable by us, you would experience immediate dilution of $ per share, representing the difference between our as adjusted net tangible book value per share as of March 31, 2020 after giving effect to this offering at the assumed offering price. The exercise of outstanding stock options and warrants would result in further dilution of your investment.

This dilution would be due to the substantially lower price paid by some of our investors who purchased shares prior to this offering as compared to the price offered to the public in this offering and the exercise of stock options granted to our employees, directors and consultants. In addition, we have a significant number of stock options outstanding. The exercise of any of these outstanding options would result in further dilution. As a result of the dilution to investors purchasing shares in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation. Further, because we expect we will need to raise additional capital to fund our future activities, we may in the future sell substantial amounts of common stock or securities convertible into or exchangeable for common stock.

Future issuances of common stock or common stock-related securities, together with the exercise of outstanding stock options, if any, may result in further dilution. For a further description of the dilution that you will experience immediately after this offering, see the section titled "Dilution."

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 may not publish an adequate amount of research on us, which may negatively impact the trading price for our stock. In addition, 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. Further, if our operating results fail to meet the forecasts of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us 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.

Risks related to our business, technology and industry

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 three months ended March 31, 2020 and 2019, we reported net losses of $11.9 million and $5.4 million, respectively. For the years ended December 31, 2019 and 2018, we reported net losses of $43.8 million and $81.7 million, respectively. As of March 31,

2020, we had an accumulated deficit of $142.2 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;
- incur setbacks or delays to the initiation or completion of preclinical and non-clinical studies, product development and/or clinical trials due to the COVID-19 pandemic;
- incur any disruption or delays to the supply of our product candidate due to the COVID-19 pandemic;
- 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.

Confidential Treatment Requested by Akero Therapeutics, Inc.
Pursuant to 17 C.F.R. Section 200.83

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.

Confidential Treatment Requested by Akero Therapeutics, Inc.
Pursuant to 17 C.F.R. Section 200.83

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 March 31, 2020, we had $125.3 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, including on account of any setbacks or delays due to the COVID-19 pandemic;
- the cost and timing of manufacturing our product candidate for use in clinical trials or, if approved by the FDA, for commercial use, including on account of any disruption or delays to the supply of our product candidate due to the COVID-19 pandemic;
- 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, such as on account of the COVID-19 pandemic, 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 released AKR-001 drug substance (active pharmaceutical ingredient, or API) that has been manufactured under GMP conditions for use in clinical trials. While we received a supply of AKR-001 drug substance from Amgen in 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 API manufacturing process to our third-party contract manufacturer has been completed successfully at both pilot scale and in an engineering run. We have also manufactured API under GMP conditions, which is being evaluated for release for clinical use. 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, including COVID-19, 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, pandemics, epidemics, or outbreaks of infectious disease, 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 AKR-001 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, including on account of the impact of the COVID-19 pandemic on our contract manufacturing partners, 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 specialist 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 delivery device for easy and convenient administration. There is no assurance that we will be successful in developing a new drug product formulation with preferred device convenience on a timely basis, including accounting for any impact of the COVID-19 pandemic, 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 device, 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 March 31, 2020, we had thirteen full-time employees and one part-time employee. 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 are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, which 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 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 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 additional cohorts for 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. Further, if patients are unwilling to enroll in our clinical trials because of the COVID-19 pandemic and restrictions on travel or healthcare institution policies or other impacts of the COVID-19 pandemic, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of our product candidate may be delayed.

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.

Our business could be adversely affected by the effects of health epidemics, including the recent COVID-19 pandemic, in regions where we, or third parties on which we rely, have significant manufacturing, analytical laboratory and transportation facilities, concentrations of clinical trial sites or other business operations. The COVID-19 pandemic could materially affect our operations, including at our headquarters in the San Francisco Bay Area, which is currently subject to a shelter-in-place order, and at our clinical trial sites, as well as the business or operations of our manufacturers, CROs or other third parties with whom we conduct business.

Our business could be adversely affected by health epidemics in regions where we have concentrations of clinical trial sites or other business operations, and could cause significant disruption in the operations of third-party manufacturers and CROs upon whom we rely. For example, in December 2019, a novel strain of coronavirus, SARS-CoV-2, causing a disease referred to as

COVID-19, was reported to have surfaced in Wuhan, China. Since then, COVID-19 has spread to multiple countries, including the United States and several European countries. In March 2020, the World Health Organization declared COVID-19 a pandemic, and the U.S. government-imposed travel restrictions on travel between the United States, Europe and certain other countries. Further, the President of the United States declared the COVID-19 pandemic a national emergency, invoking powers under the Stafford Act, the legislation that directs federal emergency disaster response. Similarly, the State of California declared a state of emergency related to the spread of COVID-19, and the San Francisco Department of Public Health announced aggressive recommendations to reduce the spread of the disease. On March 16, 2020, the health officers of six San Francisco Bay Area counties, including San Mateo County where our headquarters are located, issued shelter-in-place orders, which (i) direct all individuals living in those counties to shelter at their places of residence (subject to limited exceptions), (ii) direct all businesses and governmental agencies to cease non-essential operations at physical locations in those counties, (iii) prohibit all non-essential gatherings of any number of individuals, and (iv) order cessation of all non-essential travel. The shelter-in-place orders were subsequently revised and will continue until May 31, 2020, unless further extended. In addition, we have implemented work-from-home policies for our employees. The effects of the shelter-in-place order and our work-from-home policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

Quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases could impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain.

In addition, our clinical trials may be affected by the COVID-19 pandemic. Clinical site initiation and patient enrollment may be delayed due to government orders, site policies on account of the pandemic or prioritization of hospital resources toward the COVID-19 pandemic. Some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services or otherwise may be reluctant to enroll in clinical trials during the COVID-19 pandemic. For example, we have begun screening for Cohort C and expect to begin enrollment for Cohort C in the third quarter of 2020. As a result of the potential complications related to COVID-19, we will be adding an in-home nursing service as well as permitting remote visits via tele-medicine with sites. Though we expect the COVID-19 impact on our clinical trials to be minimal due to the type and location of our NASH sites, the future impact of the COVID-19 pandemic will depend on future developments, that are highly uncertain and cannot be predicted with confidence.

Such events may delay our ability to conduct preclinical and non-clinical studies and clinical trials or release clinical trial results and could delay our ability to obtain regulatory approval and commercialize our product candidate.

Business interruptions resulting from the coronavirus disease (COVID-19) outbreak or similar public health crises could cause a disruption of the development of our product candidates and adversely impact our business.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. In December 2019, a novel strain of a virus named SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), or coronavirus, which causes coronavirus disease, or COVID-19, surfaced in Wuhan, China and has reached multiple other regions and countries, including South San Francisco, California where our primary office space is located. The coronavirus pandemic is evolving, and to date has led to

the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures. The extent to which the coronavirus impacts our operations or those of our third party partners will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, new information that will emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others.

Additionally, timely enrollment in planned clinical trials is dependent upon clinical trial sites which will be adversely affected by global health matters, such as pandemics. We are conducting clinical trials for our product candidates in geographies which are currently being affected by the coronavirus. Some factors from the coronavirus outbreak that will delay or otherwise adversely affect enrollment in the clinical trials of our product candidates, as well as our business generally, include:

- the diversion of healthcare resources away from the conduct of clinical trials to focus on pandemic concerns, including the attention of physicians serving as our clinical trial investigators, hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our prospective clinical trials;

- limitations on travel that could interrupt key trial and business activities, such as clinical trial site initiations and monitoring, domestic and international travel by employees, contractors or patients to clinical trial sites, including any government-imposed travel restrictions or quarantines that will impact the ability or willingness of patients, employees or contractors to travel to our clinical trial sites or secure visas or entry permissions, a loss of face-to-face meetings and other interactions with potential partners, any of which could delay or adversely impact the conduct or progress of our prospective clinical trials;

- interruption in global shipping affecting the transport of clinical trial materials, such as patient samples, investigational drug product and conditioning drugs and other supplies used in our prospective clinical trials;

- business disruptions caused by potential workplace, laboratory and office closures and an increased reliance on employees working from home, disruptions to or delays in ongoing laboratory experiments and operations, product manufacturing and supply, staffing shortages, travel limitations or mass transit disruptions, any of which could adversely impact our business operations or delay necessary interactions with local regulators, ethics committees and other important agencies and contractors that enrolled participants will drop out before completion; and

- the FDA and other regulators have made COVID-19 a primary priority, which can result in delays for trials unrelated to the pandemic.

Moreover, COVID-19 may also severely affect employees of third-party contract research organizations located in affected geographies that we rely upon to carry out such enrollments and trials. Any negative impact COVID-19 has to patient enrollment or treatment could cause costly delays to clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses, and have a material adverse effect on our financial results.

These and other factors arising from the coronavirus could worsen in countries that are already afflicted with the coronavirus or could continue to spread to additional countries. Any of these factors, and other factors related to any such disruptions that are unforeseen, could have a material adverse effect on our business and our results of operation and financial condition. Further, uncertainty around these and related issues has severely harmed and is expected to continue to severely harm the economy of the United States, which could impact our ability to raise the necessary capital needed to develop and commercialize our product candidates.

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, on March 27, 2020, the "Coronavirus Aid, Relief, and Economic Security Act" or the CARES Act was enacted, which included certain changes in tax law intended to stimulate the U.S. economy in light of the COVID-19 coronavirus outbreak, including temporary beneficial changes to the treatment of net operating losses, interest deductibility limitations and payroll tax matters. 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 U.S. 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 beginning 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 current law, federal NOL carryforwards generated in tax years beginning after December 31, 2017 are not subject to expiration. However, utilization of NOL carryforwards generated in tax years beginning after December 31, 2020 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.

Confidential Treatment Requested by Akero Therapeutics, Inc.
Pursuant to 17 C.F.R. Section 200.83

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.

Confidential Treatment Requested by Akero Therapeutics, Inc.
Pursuant to 17 C.F.R. Section 200.83

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;
- 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; and
- the impact of COVID-19 on the initiation or completion of preclinical studies or clinical trials or the reporting of results of our clinical trial and the supply of our product candidate.

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.

Confidential Treatment Requested by Akero Therapeutics, Inc.
Pursuant to 17 C.F.R. Section 200.83

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.

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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.

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Pursuant to 17 C.F.R. Section 200.83

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, such as due to the impacts of COVID-19, 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 due to the impact of COVID-19 or for other reasons 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, such as delays in performance due to COVID-19, 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.

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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;
- any impact to market health as a result of COVID-19;
- 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.

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Pursuant to 17 C.F.R. Section 200.83

Special note regarding forward-looking statements

This prospectus and the documents incorporated by reference contain 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 prospectus and in any relates prospectus supplement or free writing prospectus we may authorize for use in connection with this offering, 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 complete Cohort C in our ongoing Phase 2a clinical trial of AKR-001 in NASH patients, including the ability to complete patient enrollment and obtain data during the ongoing COVID-19 pandemic;
- our ability to manufacture drug product and submit an acceptable IND package to support our planned Phase 2b clinical trial during the ongoing COVID-19 pandemic;
- our ability to initiate and complete enrollment and collect sufficient data in our planned Phase 2b/3 clinical trial during the ongoing COVID-19 pandemic;
- the potential for COVID-19 or other pandemic, epidemic or outbreak of an infectious disease, including COVID-19, to disrupt our business plans, product development activities, ongoing clinical trials, including the timing and enrollment of patients, the health of our employees and the strength of our supply chain
- 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 prospectus, 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 prospectus 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.

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Use of proceeds

We estimate that the net proceeds to us from the sale of the shares of our common stock in this offering will be approximately $ million, or approximately $ million if the underwriters exercise their option to purchase additional shares in full, based on the assumed public offering price of $ per share, which was the last reported sale price of our common stock on The Nasdaq Global Select Market on , 2020, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

We currently expect to use the net proceeds from this offering, together with our existing cash and cash equivalents as of March 31, 2020, as follows:

- approximately $ million to complete our ongoing Phase 2a clinical trial and a subsequent Phase 2b clinical trial of our lead product candidate, AKR-001, in patients with NASH;
- approximately $ million for new AKR-001 drug substance and drug product manufactured by third parties to support a phase 3 extension program;
- approximately $ million for nonclinical studies, exploration of potential additional indications for AKR-001, internal discovery efforts and potential in-licensing to diversify our pipeline; and
- the remainder for working capital and general corporate purposes.

Based on our current plans, we believe our existing cash and cash equivalents, together with the net proceeds from this offering, will be sufficient to fund our operating expenses and capital expenditure requirements through , although there can be no assurance in that regard.

We may also use a portion of our net proceeds to co-develop, acquire or invest in products, technologies or businesses that are complementary to our business. However, we currently have no agreements or commitments to complete any such transaction.

We cannot specify with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering. Due to uncertainties inherent in the product development process, it is difficult to estimate the exact amounts of the net proceeds that will be used for any particular purpose. We may use our existing cash and cash equivalents and the future payments, if any, generated from any future collaboration agreements to fund our operations, either of which may alter the amount of net proceeds used for a particular purpose. In addition, the amount, allocation and timing of our actual expenditures will depend upon numerous factors, including the results of our research and development efforts, the timing and success of clinical trials and the timing of regulatory submissions. Accordingly, we will have broad discretion in using these proceeds.

Pending the uses described above, we plan to invest the net proceeds of this offering in short- and immediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

Dividend policy

We have never declared or paid any cash dividends on our common stock or any other securities. We anticipate that we will retain all available funds and any future earnings, if any, for use in the operation of our business and do not anticipate paying cash dividends in the foreseeable future. In addition, future debt instruments may materially restrict our ability to pay dividends on our common stock. Payment of future cash dividends, if any, will be at the discretion of the board of directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs, the requirements of then-existing debt instruments and other factors the board of directors deems relevant.

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Dilution

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the assumed public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

As of March 31, 2020 we had net tangible book value of approximately $118.3 million, or $4.13 per share of our common stock, based upon 28,671,222 shares of our common stock outstanding as of that date. Historical net tangible book value per share is the amount of our total tangible assets less our total liabilities. Dilution in net tangible book value per share represents the difference between the amount per share paid by purchasers of shares of common stock in this offering and the net tangible book value per share of our common stock immediately after this offering. Historical net tangible book value per common share is our historical net tangible book value divided by the number of shares of common stock outstanding as of March 31, 2020.

After giving further effect to our issuance and sale of shares of our common stock in this offering at the assumed offering price of $ per share, which was the last reported sale price of our common stock on The Nasdaq Global Select Market on , 2020, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of March 31, 2020 would have been approximately $ million, or approximately $ per share. This represents an immediate increase in as adjusted net tangible book value per share of $ to our existing stockholders and an immediate dilution in as adjusted net tangible book value per share of approximately $ to new investors purchasing common stock in this offering. Dilution per share to new investors purchasing common stock in this offering is determined by subtracting as adjusted net tangible book value per share after this offering from the assumed public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis:

Assumed public offering price per share		$
Historical net tangible book value per share as of March 31, 2020	$	
As adjusted net tangible book value per share after this offering		
Dilution per share to new investors purchasing common stock in this offering		$

If the underwriters exercise their option to purchase additional shares of common stock in this offering in full at the assumed public offering price of $ per share, which was the last reported sale price of our common stock on The Nasdaq Global Select Market on , 2020, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, the as adjusted net tangible book value per share after this offering would be $ per share, and the dilution in as adjusted net tangible book value per share to new investors purchasing common stock in this offering would be $ per share.

The following table summarizes on an as adjusted basis, the total number of shares of common stock purchased from us, the total consideration paid or to be paid, and the average price per share paid or to be paid by existing stockholders and by new investors in this offering at the assumed public offering price of $ per share, which was the last reported sale price of our common stock on

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The Nasdaq Global Select Market on , 2020, before deducting underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares purchased		Total consideration		Average price per share
	Number	Percentage	Amount	Percentage	
Existing stockholders		%	$	%	$
New investors		%		%	$
Total		100%	$	100%	

The table above assumes no exercise of the underwriters' option to purchase additional shares in this offering. If the underwriters' option to purchase additional shares is exercised in full, the number of shares of our common stock held by existing stockholders would be reduced to % of the total number of shares of our common stock outstanding after this offering, and the number of shares of common stock held by new investors purchasing common stock in this offering would be increased to % of the total number of shares of our common stock outstanding after this offering.

The discussion and tables (other than the historical net tangible book value calculation) above are based on 28,671,222 shares of our common stock outstanding as of March 31, 2020, and excludes:

- 3,095,450 shares of common stock issuable upon the exercise of stock options outstanding as of March 31, 2020 at a weighted-average exercise price of $8.53 per share;
- 2,812,364 shares of common stock reserved for future issuance as of March 31, 2020 under our 2019 Stock Option and Incentive Plan, or the 2019 Plan; and
- 555,042 shares of our common stock reserved for future issuance under our 2019 Employee Stock Purchase Plan as of March 31, 2020.

To the extent that new stock options are issued or any outstanding options are exercised, or we issue additional shares of common stock in the future, there will be further dilution to new investors. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

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Principal stockholders

The following table sets forth certain information known to us regarding beneficial ownership of our capital stock as of May 15, 2020, as adjusted to reflect the sale of common stock offered by us in this offering, for:

- each of our named executive officers;
- each of our directors;
- all of our executive officers and directors as a group; and
- each person or group of affiliated persons known by us to beneficially own more than 5% of our common stock.

Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Under those rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power, and includes securities that the individual or entity has the right to acquire, such as through the exercise of stock options, within 60 days of May 8, 2020. Except as noted by footnote, and subject to community property laws where applicable, we believe, based on the information provided to us, that the persons and entities named in the table below have sole voting and investment power with respect to all common stock shown as beneficially owned by them.

The percentage of beneficial ownership prior to this offering in the table below is based on 28,673,644 shares of common stock deemed to be outstanding as of May 8, 2020, and the percentage of beneficial ownership after this offering in the table below is based on shares of common stock assumed to be outstanding after the closing of the offering. The information in the table below assumes no exercise of the underwriters' option to purchase additional shares.

The following table does not reflect any such potential purchases by these stockholders or their affiliated entities. If any shares are purchased by these stockholders, the number of shares of common stock beneficially owned after this offering and the percentage of common stock beneficially owned after this offering would increase from that set forth in the table below.

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Except as otherwise noted below, the address for persons listed in the table is c/o Akero Therapeutics, Inc., 170 Harbor Way, 3rd Floor, South San Francisco, CA 94080.

	Shares beneficially owned	
Name and address of beneficial owner(1)	**Number**	**Percentage**
Greater-than-5% Stockholders:		
Amgen Inc.(2)	1,905,698	6.65%
Apple Tree Partners IV, L.P.(3)	5,415,203	18.89%
Entities affiliated with Atlas Venture(4)	3,110,491	10.85%
Entities affiliated with Janus Henderson(5)	2,409,533	8.40%
venBio Global Strategic Fund II, L.P.(6)	3,150,019	10.99%
Versant Venture Capital VI, L.P.(7)	3,029,698	10.57%
Named Executive Officers and Directors:		
Andrew Cheng, M.D., Ph.D.(8)	1,050,941	3.57%
William White(9)	141,033	*
Jonathan Young, J.D., Ph.D.(10)	303,740	1.06%
Timothy Rolph, DPhil(11)	303,073	1.05%
Kitty Yale(12)	265,574	*
Kevin Bitterman, Ph.D.(13)	5,055	*
Seth L. Harrison, M.D,(14)	5,055	*
Jane P. Henderson(15)	17,123	*
Mark Iwicki(16)	60,433	*
Graham Walmsley, M.D., Ph.D.(17)	5,055	*
All executive officers and directors as a group (12 persons)(18)	2,157,082	7.23%

* Represents beneficial ownership of less than one percent.

(1) Unless otherwise indicated, the address for each beneficial owner is c/o Akero Therapeutics, Inc., 170 Harbor Way, 3rd Floor, South San Francisco 94080.

(2) Information herein is solely based on a Schedule 13G filed by Amgen Inc. with the SEC on February 10, 2020. Consists of 1,905,698 shares of common stock held by Amgen Inc. The mailing address of Amgen Inc. is One Amgen Center Drive, Thousand Oaks, CA 91320.

(3) Information herein is solely based on a Schedule 13F filed by Apple Tree Partners IV, L.P., ATP III GP, Ltd. and Seth L. Harrison with the SEC on February 3, 2020. Consists of 5,415,203 shares of common stock held by Apple Tree Partners IV, L.P. ("ATP"). ATP is managed by ATP III GP, Ltd., the sole director of which is Dr. Seth L. Harrison. Dr. Seth L. Harrison is also a member of our board of directors. Dr. Harrison disclaims beneficial ownership of the shares listed, except to the extent of his pecuniary interest therein. The mailing address of Apple Tree Partners IV, L.P. is 230 Park Avenue, Suite 2800, New York, NY 10169.

(4) Information herein is solely based on Form 4s filed with the SEC by (i) Atlas Venture Fund XI, L.P., a Delaware limited partnership ("Atlas XI") on January 2, 2020 and (ii) Atlas Venture Opportunity Fund I, L.P. ("AVO I") on February 10, 2020. Consists of (a) 2,706,412 shares of common stock held by Atlas XI and (b) 404,079 shares of common stock held by AVO I. Atlas Venture Associates XI, L.P. ("AVA XI LP") is the general partner of Atlas XI and Atlas Venture Associates XI, LLC ("AVA XI LLC" and together with Atlas XI and AVA XI LP, the "Fund XI Reporting Persons") is the general partner of AVA XI LP. Each of AVA XI LP and AVA XI LLC has voting and dispositive power over the shares held by Atlas XI. As such, each of the Fund XI Reporting Persons share voting and dispositive power with respect to the shares held by Atlas XI. Atlas Venture Associates Opportunity I, L.P. ("AVAO LP") is the general partner of AVO I and

Associates Opportunity I, LLC ("AVAO LLC" and together with AVO I and AVAO LP, the "Opportunity Fund Reporting Persons") is the general partner of AVAO LP. Each of AVAO LP and AVAO LLC has voting and dispositive power over the shares held by AVO I. As such, each of the Opportunity Fund Reporting Persons share voting and dispositive power with respect to the shares held by AVO I. Bruce Booth, Jean-Francois Formela, David Grayzel, Jason Rhodes, and Kevin Bitterman are the members of AVA IX LLC and AVAO LLC and collectively make investment decisions on behalf of Atlas Fund XI and Atlas Fund I. Kevin Bitterman is also a member of our board of directors. Mr. Bitterman disclaims beneficial ownership of the shares listed, except to the extent of his pecuniary interest therein. The mailing address of Atlas XI and AVO I is 400 Technology Square, 10th Floor, Cambridge, MA 02139.

(5) Information herein is solely based on a Schedule 13G filed by Janus Henderson Group plc with the SEC on February 14, 2020. Consists of 2,409,533 shares of common stock held by Janus Henderson Group plc ("Janus Henderspm"). Janus Henderson has an indirect 97% ownership stake in Intech Investment Management LLC ("Intech") and a 100% ownership stake in Janus Capital Management LLC ("JCM"), Perkins Investment Management LLC ("Perkins"),Geneva Capital Management LLC ("Geneva"), Henderson Global Investors Limited ("HGIL") and Janus Henderson Investors Australia Institutional Funds Management Limited ("JHIAIFML"), (each an "Asset Manager" and collectively as the "Asset Managers"). Due to the above ownership structure, holdings for the Asset Managers are aggregated for purposes of this filing. Each Asset Manager is an investment adviser registered or authorized in its relevant jurisdiction and each furnishing investment advice to various fund, individual and/or institutional clients (collectively referred to herein as "Managed Portfolios"). As a result of its role as investment adviser or sub-adviser to the Managed Portfolios, JCM may be deemed to be the beneficial owner of the shares held by such Managed Portfolios. However, JCM does not have the right to receive any dividends from, or the proceeds from the sale of, the securities held in the Managed Portfolios and disclaims any ownership associated with such rights. The mailing address for Janus Henderson Global Life Sciences Fund is 151 Detroit Street, Denver, CO 80206.

(6) Information herein is solely based on a Form 4 filed by venBio Global Strategic Fund II, L.P. (the "venBio Fund") with the SEC on March 6, 2020. Consists of 3,150,019 shares of common stock (the "Fund Shares") held by the venBio Fund. venBio Global Strategic GP II, L.P., (the "General Partner") is the sole general partner of the venBio Fund. venBio Global Strategic GP II, Ltd., ("GP Ltd.") is the sole general partner of the General Partner. Robert Adelman and Corey Goodman are directors of GP Ltd. As the sole general partner of the venBio Fund, the General Partner may be deemed to own beneficially the Fund Shares. As the sole general partner of the General Partner, the GP Ltd. likewise may be deemed to own beneficially the Fund Shares. As directors of the GP Ltd., each of the Directors likewise may be deemed to own beneficially the Fund Shares. The address for the Fund, the General Partner and GP Ltd. is c/o venBio Partners, LLC, 1700 Owens Street, Suite 595, San Francisco, CA 94158.

(7) Information herein is solely based on a Form 4 filed by Versant Venture Capital VI, L.P. with the SEC on January 21, 2020. Consists of 3,029,698 shares of common stock held by Versant Venture Capital VI, L.P. ("Versant VI"). Versant Ventures VI GP, L.P. ("Versant VI GP LP") is the sole general partner of Versant VI and Versant VI GP-GP, LLC is the sole general partner of Versant VI GP LP. Thomas Woiwode, Bradley Bolzon, Kirk Nielsen, Robin Praeger, and Jerel Davis, are the managing directors of Versant VI LLC and may be deemed to share voting and investment power over the shares held by Versant VI. The mailing address for Versant Venture Capital VI, L.P. is One Sansome, Suite 3630, San Francisco, CA 94104.

(8) Consists of: (i) 326,314 shares of common stock held by Dr. Cheng and (ii) 724,627 shares of common stock underlying options exercisable within 60 days of May 8, 2020.

(9) Consists of: (i) 1,025 shares of common stock held by Mr. White and (ii) 140,008 shares of common stock underlying options exercisable within 60 days of May 8, 2020.

(10) Consists of: (i) 183,600 shares of common stock held by Dr. Young, (ii) 20,000 shares of common stock held by the EA Irrevocable Trust of which Dr. Young's spouse is the trustee, (iii) 20,000 shares of common stock held by the CM Irrevocable Trust of which Dr. Young's spouse is the trustee, (iv) 20,000 shares of common stock held by JL Irrevocable Trust of which Dr. Young's spouse is the trustee and (v) 60,140 shares of common stock underlying options exercisable within 60 days of May 8, 2020. Dr. Young disclaims beneficial ownership of an additional 60,000 shares of common stock that are held in irrevocable trusts for the benefit of his children.

(11) Consists of: (i) 242,933 of common stock held by Dr. Rolph and (ii) 60,140 shares of common stock underlying options exercisable within 60 days of May 8, 2020.

(12) Consists of: (i) 163,669 shares of common stock held by Ms. Yale and (ii) 101,905 shares of common stock underlying options exercisable within 60 days of May 8, 2020.

(13) Consists of 5,055 shares of common stock underlying options exercisable within 60 days of May 8, 2020.

(14) Consists of 5,055 shares of common stock underlying options exercisable within 60 days of May 8, 2020.

(15) Consists of 17,123 shares of common stock underlying options exercisable within 60 days of May 8, 2020.

(16) Consists of 60,433 shares of common stock underlying options exercisable within 60 days of May 8, 2020.

(17) Consists of: (i) 2,168 shares of common stock held by Dr. Walmsley and (ii) 2,887 shares of common stock underlying options exercisable within 60 days of May 8, 2020.

(18) See notes 8 through 17 above. Consists of 919,709 shares of our common stock owned directly, and 1,177,373 shares of common stock subject to options exercisable within 60 days from May 8, 2020.

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Description of capital stock

The following descriptions are summaries of the material terms of our fourth amended and restated certificate of incorporation, second amended and restated bylaws. We refer in this section to our amended and restated certificate of incorporation as our certificate of incorporation, and we refer to our amended and restated bylaws as our bylaws.

General

Our authorized capital stock consists of 150,000,000 shares of common stock, par value $0.0001 per share, and 10,000,000 shares of convertible preferred stock, par value $0.0001 per share, all of which shares of convertible preferred stock are undesignated.

As of May 8, 2020, 28,673,644 shares of our common stock were outstanding and held by 11 stockholders of record.

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.

Preferred stock

Our board of directors has the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action. As of March 31, 2020, no shares of convertible preferred stock are currently outstanding, and we have no present plan to issue any shares of convertible preferred stock.

Options

As of March 31, 2020, options to purchase 3,095,450 shares of our common stock were outstanding, of which 264,176 were vested and exercisable as of that date, with a per share weighted-average price of $7.76 per share, under our 2018 Stock Option and Grant Plan and 2019 Stock Option and Incentive Plan.

Registration rights

Certain of our holders 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 investors' rights agreement between us and holders of our preferred stock, which was subsequently converted into common stock in

connection with our initial public offering. The 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 of our holders 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 our initial public offering or at such time 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

We are 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.

Nasdaq global select market listing

Our common stock is listed on The Nasdaq Global Select Market under the symbol "AKRO."

Transfer agent and registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. The transfer agent and registrar's address is 250 Royall Street, Canton, Massachusetts 02021, and its telephone number is (800) 962-4284.

Limitations of liability and indemnification matters

For a discussion of liability and indemnification, see "Executive compensation."

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Shares eligible for future sale

Future sales of our common stock, including shares issued upon the exercise of outstanding options or warrants, in the public market after this offering, or the perception that those sales may occur, could cause the prevailing market price for our common stock to fall or impair our ability to raise equity capital in the future. As described below, only a limited number of shares of our common stock will be available for sale in the public market for a period of days after consummation of this offering due to contractual and legal restrictions on resale described below. Future sales of our common stock in the public market either before (to the extent permitted) or after restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price of our common stock at such time and our ability to raise equity capital at a time and price we deem appropriate.

Sale of Restricted Shares

Based on the number of shares of our common stock outstanding as of March 31, 2020 and assuming (1) no exercise of the underwriters' option to purchase additional shares of common stock and (2) no exercise of any of our other outstanding options, we will have outstanding an aggregate of approximately shares of common stock following this offering. Of these shares, all of the shares of common stock to be sold in this offering, and any shares sold upon exercise of the underwriters' option to purchase additional shares, will be freely tradable in the public market without restriction or further registration under the Securities Act, unless the shares are held by any of our "affiliates" as such term is defined in Rule 144 of the Securities Act. Certain of the remaining shares of common stock held by existing stockholders immediately prior to the consummation of this offering will be "restricted securities" as such term is defined in Rule 144. These restricted securities were issued and sold by us, or will be issued and sold by us, in private transactions and are eligible for public sale only if registered under the Securities Act or if they qualify for an exemption from registration under the Securities Act, including the exemptions provided by Rule 144 or Rule 701, which rules are summarized below.

Lock-up agreements

We, our directors and executive officers and holders of substantially all of our common stock have signed a lock-up agreement that prevent us and them from selling any of our common stock or any securities convertible into or exercisable or exchangeable for common stock for a period of not less than 180 days from the date of this prospectus without the prior written consent of , subject to certain exceptions. may waive these restrictions with respect to some or all of the subject securities in their sole discretion. See "Underwriting" appearing elsewhere in this prospectus for more information. Certain of our employees, including our executive officers, and/or directors may enter into written trading plans that are intended to comply with Rule 10b5-1 under the Exchange Act.

Following the lock-up periods set forth in the agreements described above, and assuming that the representatives of the underwriters do not release any parties from these agreements, all of the shares of our common stock that are restricted securities or are held by our affiliates as of the date of this prospectus will be eligible for sale in the public market in compliance with Rule 144 under the Securities Act.

Rule 144

In general, a person who has beneficially owned restricted stock for at least six months would be entitled to sell their securities provided that (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale and (ii) we are subject to the Securities Exchange Act of 1934, as amended, or the Exchange Act, periodic reporting

requirements for at least 90 days before the sale. Persons who have beneficially owned restricted shares for at least six months but who are our affiliates at the time of, or any time during the 90 days preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of either of the following:

- 1% of the number of shares then outstanding, which will equal approximately shares immediately after this offering, assuming no exercise of the underwriters' option to purchase additional shares or any of our other outstanding options, based on the number of shares outstanding as of March 31, 2020; or

- the average weekly trading volume of our common stock on The Nasdaq Global Select Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale;

provided, in each case, that we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Such sales both by affiliates and by non-affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144.

Rule 701

Rule 701 under the Securities Act, as in effect on the date of this prospectus, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Most of our employees, executive officers or directors who purchased shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling their shares.

However, substantially all Rule 701 shares are subject to lock-up agreements as described below and under "Underwriting" included elsewhere in this prospectus and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

Registration rights

Certain holders of our securities will be entitled to various rights with respect to registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration. See "Description of capital stock—Registration rights" appearing elsewhere in this prospectus for more information.

Confidential Treatment Requested by Akero Therapeutics, Inc.
Pursuant to 17 C.F.R. Section 200.83

Material U.S. federal income tax considerations for non-U.S. holders of common stock

The following discussion is a summary of the material U.S. federal income tax considerations applicable to non-U.S. holders (as defined below) with respect to their ownership and disposition of shares of our common stock issued pursuant to this offering. For purposes of this discussion, a non-U.S. holder means a beneficial owner of our common stock that is for U.S. federal income tax purposes:

- a non-resident alien individual;
- a foreign corporation or any other foreign organization taxable as a corporation for U.S. federal income tax purposes; or
- a foreign estate or trust, the income of which is not subject to U.S. federal income tax on a net income basis.

This discussion does not address the tax treatment of partnerships or other entities that are pass-through entities for U.S. federal income tax purposes or persons that hold their common stock through partnerships or other pass-through entities. A partner in a partnership or other pass-through entity that will hold our common stock should consult his, her or its tax advisor regarding the tax consequences of acquiring, holding and disposing of our common stock through a partnership or other pass-through entity, as applicable.

This discussion is based on current provisions of the U.S. Internal Revenue Code of 1986, as amended, which we refer to as the Code, existing and proposed U.S. Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, all as in effect as of the date of this prospectus and, all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any such change or differing interpretation could alter the tax consequences to non-U.S. holders described in this prospectus. There can be no assurance that the Internal Revenue Service, which we refer to as the IRS, will not challenge one or more of the tax consequences described herein. We assume in this discussion that a non-U.S. holder holds shares of our common stock as a capital asset within the meaning of Section 1221 of the Code, generally property held for investment.

This discussion does not address all aspects of U.S. federal income taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances nor does it address any U.S. state, local or non-U.S. taxes, the alternative minimum tax, the Medicare tax on net investment income, the rules regarding qualified small business stock within the meaning of Section 1202 of the Code, or any other aspect of any U.S. federal tax other than the income tax. This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address the special tax rules applicable to particular non-U.S. holders, such as:

- insurance companies;
- tax-exempt or governmental organizations;
- financial institutions;
- brokers or dealers in securities;
- regulated investment companies;
- pension plans;
- "controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;
- "qualified foreign pension funds," or entities wholly owned by a "qualified foreign pension fund";

- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment; and
- certain U.S. expatriates.

This discussion is for general information only and is not tax advice. Accordingly, all prospective non-U.S. holders of our common stock should consult their tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of the purchase, ownership and disposition of our common stock.

Distributions on our common stock

Distributions, if any, on our common stock will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, up to such holder's tax basis in the common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in "Gain on sale or other taxable disposition of our common stock." Any such distributions will also be subject to the discussions below under the sections titled "Backup withholding and information reporting" and "Withholding and information reporting requirements—FATCA."

Subject to the discussion in the following two paragraphs in this section, dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States, are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements. However, such U.S. effectively connected income, net of specified deductions and credits, is taxed at the same graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code). Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also, under certain circumstances, be subject to an additional "branch profits tax" at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E (or successor form) to the applicable withholding agent and satisfy applicable certification and other requirements. Non-U.S. holders are urged to consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty. A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing a U.S. tax return with the IRS.

Gain on sale or other taxable disposition of our common stock

Subject to the discussions below under "Backup withholding and information reporting" and "Withholding and information reporting requirements—FATCA," a non-U.S. holder generally will not

be subject to any U.S. federal income tax on any gain realized upon such holder's sale or other taxable disposition of shares of our common stock unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a U.S. trade or business and, if an applicable income tax treaty so provides, is attributable to a permanent establishment or a fixed-base maintained by such non-U.S. holder in the United States, in which case the non-U.S. holder generally will be taxed on a net income basis at the graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code) and, if the non-U.S. holder is a foreign corporation, the branch profits tax described above in "Distributions on our common stock" also may apply;

- the non-U.S. holder is a nonresident alien individual who is present in the United States for 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence) on the net gain derived from the disposition, which may be offset by certain U.S. source capital losses of the non-U.S. holder, if any (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses; or

- we are, or have been, at any time during the five-year period preceding such sale of other taxable disposition (or the non-U.S. holder's holding period, if shorter) a "U.S. real property holding corporation," unless our common stock is regularly traded on an established securities market and the non-U.S. holder holds no more than 5% of our outstanding common stock, directly or indirectly, actually or constructively, during the shorter of the 5-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. Generally, a corporation is a U.S. real property holding corporation only if the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we do not believe that we are, or have been, a U.S. real property holding corporation, or that we are likely to become one in the future. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above.

Backup withholding and information reporting

We must report annually to the IRS and to each non-U.S. holder the gross amount of the distributions on our common stock paid to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. holders may have to comply with specific certification procedures to establish that the holder is not a United States person (as defined in the Code) in order to avoid backup withholding at the applicable rate with respect to dividends on our common stock. Dividends paid to non-U.S. holders subject to withholding of U.S. federal income tax, as described above in "Distributions on our common stock," generally will be exempt from U.S. backup withholding.

Information reporting and backup withholding will generally apply to the proceeds of a disposition of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker.

Non-U.S. holders should consult their tax advisors regarding the application of the information reporting and backup withholding rules to them. Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement. Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder's U.S. federal income tax liability, if any, provided that an appropriate claim is filed with the IRS in a timely manner.

Withholding and information reporting requirements—FATCA

Provisions of the Code commonly referred to as the Foreign Account Tax Compliance Act, or FATCA, generally impose a U.S. federal withholding tax at a rate of 30% on payments of dividends on our common stock paid to a foreign entity unless (i) if the foreign entity is a "foreign financial institution," such foreign entity undertakes certain due diligence, reporting, withholding, and certification obligations, (ii) if the foreign entity is not a "foreign financial institution," such foreign entity identifies certain of its U.S. investors, if any, or (iii) the foreign entity is otherwise exempt under FATCA. Such withholding may also apply to payments of proceeds of sales or other dispositions of our common stock, although under recently proposed regulations (the preamble to which specifies that taxpayers are permitted to rely on them pending finalization), no withholding will apply to payments of gross proceeds. Under certain circumstances, a non-U.S. holder may be eligible for refunds or credits of this withholding tax. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph. Non-U.S. holders should consult their tax advisors regarding the possible implications of this legislation on their investment in our common stock and the entities through which they hold our common stock, including, without limitation, the process and deadlines for meeting the applicable requirements to prevent the imposition of the 30% withholding tax under FATCA.

Confidential Treatment Requested by Akero Therapeutics, Inc.
Pursuant to 17 C.F.R. Section 200.83

Underwriting

We are offering the shares of common stock described in this prospectus through a number of underwriters. are acting as joint book-running managers of the offering and as representatives of the underwriters. We have entered into an underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of shares of common stock listed next to its name in the following table:

Name	Number of shares
Total	

The underwriters are committed to purchase all the shares of common stock offered by us if they purchase any shares. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

The underwriters propose to offer the common stock directly to the public at the assumed public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of $ per share. After the offering of the shares to the public, if all of the shares of common stock are not sold at the public offering price, the underwriters may change the offering price and the other selling terms. Sales of shares made outside of the United States may be made by affiliates of the underwriters.

The underwriters have an option to buy up to additional shares of common stock from us to cover sales of shares by the underwriters which exceed the number of shares specified in the table above. The underwriters have 30 days from the date of this prospectus to exercise this option to purchase additional shares. If any shares are purchased with this option to purchase additional shares, the underwriters will purchase shares in approximately the same proportion as shown in the table above. If any additional shares of common stock are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

The underwriting fee is equal to the public offering price per share of common stock less the amount paid by the underwriters to us per share of common stock. The underwriting fee is $ per share. The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	Without option to purchase additional shares exercise	With full option to purchase additional shares exercise
Per Share	$	$
Total	$	$

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discount, will be

approximately $ million. We have agreed to reimburse the underwriters for expense relating to clearance of this offering with the Financial Industry Regulatory Authority up to $.

A prospectus in electronic format may be made available on the web sites maintained by one or more underwriters, or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make Internet distributions on the same basis as other allocations.

We have agreed that we will not (i) offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise dispose of, directly or indirectly, or file with the Securities and Exchange Commission a registration statement under the Securities Act relating to, any shares of our common stock or securities convertible into or exchangeable or exercisable for any shares of our common stock, or publicly disclose the intention to make any offer, sale, pledge, disposition or filing, or (ii) enter into any swap or other arrangement that transfers all or a portion of the economic consequences associated with the ownership of any shares of common stock or any such other securities (regardless of whether any of these transactions are to be settled by the delivery of shares of common stock or such other securities, in cash or otherwise), in each case without the prior written consent of the representatives for a period of 180 days after the date of this prospectus, subject to certain exceptions.

Our directors and executive officers, and substantially all of our securityholders have entered into lock-up agreements with the underwriters prior to the commencement of this offering pursuant to which each of these persons or entities, with limited exceptions, for a period of 180 days after the date of this prospectus, may not, without the prior written consent of the representatives, (1) offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock (including, without limitation, common stock or such other securities which may be deemed to be beneficially owned by such directors, executive officers, managers and members in accordance with the rules and regulations of the SEC and securities which may be issued upon exercise of a stock option or warrant) or (2) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the common stock or such other securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of common stock or such other securities, in cash or otherwise, or (3) make any demand for or exercise any right with respect to the registration of any shares of our common stock or any security convertible into or exercisable or exchangeable for our common stock.

The restrictions described in the immediately preceding paragraph do not apply to, among other items:

1. the securities to be sold by the securityholder pursuant to the underwriting agreement,

2. sales or transfers of shares of common stock acquired in open market transactions after the consummation of this offering,

3. transfers of shares of common stock (i) as a bona fide gift or gifts, (ii) by will, other testamentary document or intestate succession to the legal representative, heir, beneficiary or a member of the immediate family of the securityholder in a transaction not involving a disposition for value or (iii) by operation of law, such as pursuant to a qualified domestic order or as required by a divorce settlement,

4. if the securityholder is an individual, transfers of shares of common stock or any security directly or indirectly convertible into common stock in a transaction not involving a disposition for value to any trust for the direct or indirect benefit of the securityholder or the immediate family of the securityholder, or limited partnerships the partners of which are the securityholder and/or the immediate family members of the securityholder, in each case for estate planning purposes,

5. if the securityholder is a trust, distributions of shares of common stock or any security directly or indirectly convertible into common stock to its beneficiaries in a transaction not involving a disposition for value,

6. if the securityholder is a corporation, limited liability company, partnership (whether general, limited or otherwise) or other entity, distribution of shares of common stock or any security directly or indirectly convertible into common stock to current or former members, stockholders, limited partners, general partners, subsidiaries or affiliates of the securityholder or to any investment fund or other entity that controls or manages the securityholder (including, for the avoidance of doubt, a fund managed by the same manager or managing member or general partner or management company or by an entity controlling, controlled by, or under common control with such manager or managing member or general partner or management company as the securityholder or who shares a common investment advisor with the securityholder) in a transaction not involving a disposition for value,

7. transfers of shares of common stock to our company in connection with the exercise of options, warrants or other rights to acquire common stock or any security convertible into or exercisable for our common stock by way of net exercise and/or to cover withholding tax obligations in connection with such exercise pursuant to an employee benefit plan, option, warrant or other right disclosed in this prospectus, provided that any such shares issued upon exercise of such option, warrant or other right shall be subject to the restrictions set forth herein; provided that no public report or filing required to be made under Section 16(a) of the Exchange Act or other public filing, report or announcement shall be required or shall be voluntarily made during the period beginning on the date hereof and continuing to and including the date that is 30 days after the date of this prospectus, or the "30 Day Period," and after such 30th day, if the securityholder is required to file a report under Section 16(a) of the Exchange Act during the restricted period, the securityholder shall clearly indicate in the footnotes thereto that such transfer is pursuant to the circumstances described in this clause (7), and provided, further that no other public announcement shall be made voluntarily in connection with such transfer, and

8. transfers of shares of common stock to a bona fide third party pursuant to a merger, consolidation, tender offer or other similar transaction made to all holders of common stock and involving a change of control of our company after this offering and approved by our board of directors, provided that in the event that such transaction is not completed, the shares of common stock held by the securityholder shall remain subject to the restrictions contained in the lockup agreement, and provided further that in the event any shares of common stock not transferred in the change of control shall remain subject to the restrictions contained in the lockup agreement.

provided that in the case of any transfer or distribution pursuant to clause (3), (4), (5), (6) or (7) each donee, transferee, heir, beneficiary or distributee shall execute and deliver to the representative a lockup agreement; and provided, further, that in the case of any transfer or distribution pursuant to clause (2), (3), (4), (5), or (6), no filing by any party (the securityholder, beneficiary, heir, donor, donee, transferor or transferee) under the Exchange Act or other public announcement shall be required or shall be made voluntarily in connection with such transfer or distribution (other than a

filing on a Form 5 and any required Schedule 13F, 13G or 13G/A, in each case made after the expiration of the restricted period referred to above). If the securityholder is an officer or director of our company, the securityholder further agrees that the foregoing provisions shall be equally applicable to any issuer-directed securities the securityholder may purchase in this offering.

In addition, notwithstanding anything to the contrary contained in the lockup agreement, the securityholder may (i) exercise options or warrants to purchase common stock (provided that any common stock received upon such exercise or exchange will be subject to the restrictions provided for in the lockup agreement) and (ii) enter into any plan designed to satisfy the requirements of Rule 10b5-1, or a "10b5-1 Plan," under the Exchange Act (other than the entry into such a plan in such a manner as to allow the sale of common stock within the restricted period); provided, however, that no sale of common stock may be made under such 10b5-1 Plan during the restricted period, and provided further that no filing by any party under the Exchange Act or other public announcement shall be required or shall be made voluntarily in connection with the establishment of such plan.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933.

Our common stock is listed on The Nasdaq Global Select Market under the symbol "AKRO."

In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling shares of common stock in the open market for the purpose of preventing or retarding a decline in the market price of the common stock while this offering is in progress. These stabilizing transactions may include making short sales of the common stock, which involves the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in this offering, and purchasing shares of common stock on the open market to cover positions created by short sales. Short sales may be "covered" shorts, which are short positions in an amount not greater than the underwriters' option to purchase additional shares referred to above, or may be "naked" shorts, which are short positions in excess of that amount. The underwriters may close out any covered short position either by exercising their option to purchase additional shares, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market compared to the price at which the underwriters may purchase shares through the option to purchase additional shares. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase shares in the open market to cover the position.

The underwriters have advised us that, pursuant to Regulation M of the Securities Act of 1933, they may also engage in other activities that stabilize, maintain or otherwise affect the price of the common stock, including the imposition of penalty bids. This means that if the representatives of the underwriters purchase common stock in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of the common stock or preventing or retarding a decline in the market price of the common stock, and, as a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on The Nasdaq Global Market, in the over-the-counter market or otherwise.

Other relationships

Certain of the underwriters and their affiliates have provided in the past to us and our affiliates and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and other services for us and such affiliates in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. In addition, from time to time, certain of the underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

Selling restrictions

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Notice to prospective investors in the European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a "Relevant Member State"), with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State, no offer of shares may be made to the public in that Relevant Member State other than:

a) to any legal entity which is a qualified investor as defined in the Prospectus Directive;

b) to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive), subject to obtaining the prior consent of the underwriters; or

c) in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of shares shall require the Company or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive and each person who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with each of the underwriters and the Company that it is a "qualified investor" within the meaning of the law in that Relevant Member State implementing Article 2(1)(e) of the Prospectus Directive.

In the case of any shares being offered to a financial intermediary as that term is used in Article 3(2) of the Prospectus Directive, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares to the public other than their offer or resale in a Relevant Member State to qualified investors as so defined or in circumstances in which the prior consent of the representatives has been obtained to each such proposed offer or resale.

For the purposes of this provision, the expression an "offer of shares to the public" in relation to any shares in any Relevant Member State means the communication in any form and by means of

sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase shares, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression "Prospectus Directive" means Directive 2003/71/EC (as amended, including by Directive 2010/73/EU), and includes any relevant implementing measure in the Relevant Member State.

Notice to prospective investors in the United Kingdom

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are "qualified investors" (as defined in the Prospectus Directive) (i) who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "Order") and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as "relevant persons") or otherwise in circumstances which have not resulted and will not result in an offer to the public of the shares in the United Kingdom within the meaning of the Financial Services and Markets Act 2000.

Any person in the United Kingdom that is not a relevant person should not act or rely on the information included in this document or use it as basis for taking any action. In the United Kingdom, any investment or investment activity that this document relates to may be made or taken exclusively by relevant persons.

Notice to prospective investors in Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Notice to prospective investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document does not constitute a prospectus within the meaning of, and has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Confidential Treatment Requested by Akero Therapeutics, Inc.
Pursuant to 17 C.F.R. Section 200.83

Neither this document nor any other offering or marketing material relating to the offering, the Company or the shares has been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA), and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

Notice to prospective investors in the Dubai International Financial Centre

This document relates to an Exempt Offer in accordance with the Markets Rules 2012 of the Dubai Financial Services Authority, or DFSA. This document is intended for distribution only to persons of a type specified in the Markets Rules 2012 of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus supplement nor taken steps to verify the information set forth herein and has no responsibility for this document. The securities to which this document relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the securities offered should conduct their own due diligence on the securities. If you do not understand the contents of this document you should consult an authorized financial advisor.

In relation to its use in the Dubai International Finance Centre, or DIFC, this document is strictly private and confidential and is being distributed to a limited number of investors and must not be provided to any person other than the original recipient, and may not be reproduced or used for any other purpose. The interests in the securities may not be offered or sold directly or indirectly to the public in the DIFC.

Notice to prospective investors in the United Arab Emirates

The shares have not been, and are not being, publicly offered, sold, promoted or advertised in the United Arab Emirates (including the Dubai International Financial Centre) other than in compliance with the laws of the United Arab Emirates (and the Dubai International Financial Centre) governing the issue, offering and sale of securities. Further, this prospectus does not constitute a public offer of securities in the United Arab Emirates (including the Dubai International Financial Centre) and is not intended to be a public offer. This prospectus has not been approved by or filed with the Central Bank of the United Arab Emirates, the Securities and Commodities Authority or the Dubai Financial Services Authority.

Notice to prospective investors in Australia

This prospectus:

- does not constitute a product disclosure document or a prospectus under Chapter 6D.2 of the Corporations Act 2001 (Cth), or the Corporations Act;
- has not been, and will not be, lodged with the Australian Securities and Investments Commission, or ASIC, as a disclosure document for the purposes of the Corporations Act and does not purport to include the information required of a disclosure document under Chapter 6D.2 of the Corporations Act;
- does not constitute or involve a recommendation to acquire, an offer or invitation for issue or sale, an offer or invitation to arrange the issue or sale, or an issue or sale, of interests to a "retail client" (as defined in section 761G of the Corporations Act and applicable regulations) in Australia; and

- may only be provided in Australia to select investors who are able to demonstrate that they fall within one or more of the categories of investors, or Exempt Investors, available under section 708 of the Corporations Act.

The shares may not be directly or indirectly offered for subscription or purchased or sold, and no invitations to subscribe for or buy the shares may be issued, and no draft or definitive offering memorandum, advertisement or other offering material relating to any shares may be distributed in Australia, except where disclosure to investors is not required under Chapter 6D of the Corporations Act or is otherwise in compliance with all applicable Australian laws and regulations. By submitting an application for the shares, you represent and warrant to us that you are an Exempt Investor.

As any offer of shares under this document will be made without disclosure in Australia under Chapter 6D.2 of the Corporations Act, the offer of those securities for resale in Australia within 12 months may, under section 707 of the Corporations Act, require disclosure to investors under Chapter 6D.2 if none of the exemptions in section 708 applies to that resale. By applying for the shares you undertake to us that you will not, for a period of 12 months from the date of issue of the shares, offer, transfer, assign or otherwise alienate those securities to investors in Australia except in circumstances where disclosure to investors is not required under Chapter 6D.2 of the Corporations Act or where a compliant disclosure document is prepared and lodged with ASIC.

Notice to prospective investors in Japan

The shares have not been and will not be registered pursuant to Article 4, Paragraph 1 of the Financial Instruments and Exchange Act. Accordingly, none of the shares nor any interest therein may be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any "resident" of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to or for the benefit of a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Act and any other applicable laws, regulations and ministerial guidelines of Japan in effect at the relevant time.

Notice to prospective investors in Hong Kong

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (b) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

Notice to prospective investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether

directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA"), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

a) to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

b) where no consideration is or will be given for the transfer;

c) where the transfer is by operation of law;

d) as specified in Section 276(7) of the SFA; or

e) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

Solely for the purposes of its obligations pursuant to Section 309B of the SFA, we have determined, and hereby notify all relevant persons (as defined in the CMP Regulations 2018), that the shares are "prescribed capital markets products" (as defined in the CMP Regulations 2018) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).

Notice to prospective investors in Bermuda

Shares may be offered or sold in Bermuda only in compliance with the provisions of the Investment Business Act of 2003 of Bermuda which regulates the sale of securities in Bermuda. Additionally, non-Bermudian persons (including companies) may not carry on or engage in any trade or business in Bermuda unless such persons are permitted to do so under applicable Bermuda legislation.

Notice to prospective investors in Saudi Arabia

This document may not be distributed in the Kingdom of Saudi Arabia except to such persons as are permitted under the Offers of Securities Regulations as issued by the board of the Saudi Arabian Capital Market Authority, or CMA, pursuant to resolution number 2-11-2004 dated 4 October 2004 as amended by resolution number 1-28-2008, as amended (the "CMA Regulations"). The CMA does not make any representation as to the accuracy or completeness of this document and expressly disclaims any liability whatsoever for any loss arising from, or incurred in reliance upon, any part of this document. Prospective purchasers of the securities offered hereby should conduct their own due

diligence on the accuracy of the information relating to the securities. If you do not understand the contents of this document, you should consult an authorized financial adviser.

Notice to prospective investors in the British Virgin Islands

The shares are not being, and may not be offered to the public or to any person in the British Virgin Islands for purchase or subscription by or on behalf of the Company. The Company may be offered to companies incorporated under the BVI Business Companies Act, 2004 (British Virgin Islands), or BVI Companies, but only where the offer will be made to, and received by, the relevant BVI Company entirely outside of the British Virgin Islands. This prospectus has not been, and will not be, registered with the Financial Services Commission of the British Virgin Islands. No registered prospectus has been or will be prepared in respect of the shares for the purposes of the Securities and Investment Business Act, 2010, or SIBA, or the Public Issuers Code of the British Virgin Islands.

Notice to prospective investors in China

This prospectus does not constitute a public offer of shares, whether by sale or subscription, in the People's Republic of China, the PRC. The shares are not being offered or sold directly or indirectly in the PRC to or for the benefit of, legal or natural persons of the PRC.

Further, no legal or natural persons of the PRC may directly or indirectly purchase any of the shares or any beneficial interest therein without obtaining all prior PRC's governmental approvals that are required, whether statutorily or otherwise. Persons who come into possession of this document are required by the issuer and its representatives to observe these restrictions.

Notice to prospective investors in Korea

The shares have not been and will not be registered under the Financial Investments Services and Capital Markets Act of Korea and the decrees and regulations thereunder (the "FSCMA"), and the shares have been and will be offered in Korea as a private placement under the FSCMA. None of the shares may be offered, sold or delivered directly or indirectly, or offered or sold to any person for re-offering or resale, directly or indirectly, in Korea or to any resident of Korea except pursuant to the applicable laws and regulations of Korea, including the FSCMA and the Foreign Exchange Transaction Law of Korea and the decrees and regulations thereunder (the "FETL"). Furthermore, the purchaser of the shares shall comply with all applicable regulatory requirements (including but not limited to requirements under the FETL) in connection with the purchase of the shares. By the purchase of the shares, the relevant holder thereof will be deemed to represent and warrant that if it is in Korea or is a resident of Korea, it purchased the shares pursuant to the applicable laws and regulations of Korea.

Notice to prospective investors in Malaysia

No prospectus or other offering material or document in connection with the offer and sale of the shares has been or will be registered with the Securities Commission of Malaysia, or the Commission, for the Commission's approval pursuant to the Capital Markets and Services Act 2007. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Malaysia other than (i) a closed end fund approved by the Commission; (ii) a holder of a Capital Markets Services Licence; (iii) a person who acquires the shares, as principal, if the offer is on terms that the shares may only be acquired at a consideration of not less than RM250,000 (or its equivalent in foreign currencies) for each transaction; (iv) an individual whose total net personal assets or total net joint assets with his or her spouse exceeds RM3 million (or its equivalent in foreign currencies), excluding the value of the primary residence of the individual; (v) an

individual who has a gross annual income exceeding RM300,000 (or its equivalent in foreign currencies) per annum in the preceding twelve months; (vi) an individual who, jointly with his or her spouse, has a gross annual income of RM400,000 (or its equivalent in foreign currencies), per annum in the preceding twelve months; (vii) a corporation with total net assets exceeding RM10 million (or its equivalent in a foreign currencies) based on the last audited accounts; (viii) a partnership with total net assets exceeding RM10 million (or its equivalent in foreign currencies); (ix) a bank licensee or insurance licensee as defined in the Labuan Financial Services and Securities Act 2010; (x) an Islamic bank licensee or takaful licensee as defined in the Labuan Financial Services and Securities Act 2010; and (xi) any other person as may be specified by the Commission; provided that, in the each of the preceding categories (i) to (xi), the distribution of the shares is made by a holder of a Capital Markets Services Licence who carries on the business of dealing in securities. The distribution in Malaysia of this prospectus is subject to Malaysian laws. This prospectus does not constitute and may not be used for the purpose of public offering or an issue, offer for subscription or purchase, invitation to subscribe for or purchase any securities requiring the registration of a prospectus with the Commission under the Capital Markets and Services Act 2007.

Notice to prospective investors in Taiwan

The shares have not been and will not be registered with the Financial Supervisory Commission of Taiwan pursuant to relevant securities laws and regulations and may not be sold, issued or offered within Taiwan through a public offering or in circumstances which constitutes an offer within the meaning of the Securities and Exchange Act of Taiwan that requires a registration or approval of the Financial Supervisory Commission of Taiwan. No person or entity in Taiwan has been authorized to offer, sell, give advice regarding or otherwise intermediate the offering and sale of the shares in Taiwan.

Notice to prospective investors in South Africa

Due to restrictions under the securities laws of South Africa, the shares are not offered, and the offer shall not be transferred, sold, renounced or delivered, in South Africa or to a person with an address in South Africa, unless one or other of the following exemptions applies:

a) the offer, transfer, sale, renunciation or delivery is to:

i) persons whose ordinary business is to deal in securities, as principal or agent;

ii) the South African Public Investment Corporation;

iii) persons or entities regulated by the Reserve Bank of South Africa;

iv) authorised financial service providers under South African law;

v) financial institutions recognised as such under South African law;

vi) a wholly-owned subsidiary of any person or entity contemplated in (c), (d) or (e), acting as agent in the capacity of an authorised portfolio manager for a pension fund or collective investment scheme (in each case duly registered as such under South African law); or

vii) any combination of the person in (a) to (f); or

b) the total contemplated acquisition cost of the securities, for any single addressee acting as principal is equal to or greater than ZAR1,000,000.

No "offer to the public" (as such term is defined in the South African Companies Act, No. 71 of 2008 (as amended or re-enacted) (the "South African Companies Act")) in South Africa is being made in connection with the issue of the shares. Accordingly, this document does not, nor is it intended to, constitute a "registered prospectus" (as that term is defined in the South African Companies Act)

prepared and registered under the South African Companies Act and has not been approved by, and/or filed with, the South African Companies and Intellectual Property Commission or any other regulatory authority in South Africa. Any issue or offering of the shares in South Africa constitutes an offer of the shares in South Africa for subscription or sale in South Africa only to persons who fall within the exemption from "offers to the public" set out in section 96(1)(a) of the South African Companies Act. Accordingly, this document must not be acted on or relied on by persons in South Africa who do not fall within section 96(1)(a) of the South African Companies Act (such persons being referred to as "SA Relevant Persons"). Any investment or investment activity to which this document relates is available in South Africa only to SA Relevant Persons and will be engaged in South Africa only with SA relevant persons.

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Legal matters

The validity of the shares of common stock offered by this prospectus will be passed upon for us by Goodwin Procter LLP, Boston, Massachusetts. Certain legal matters related to this offering will be passed upon for the underwriters by Cooley LLP, New York, New York.

Experts

The financial statements incorporated in this Prospectus by reference from the Company's Annual Report on Form 10-K for the year ended December 31, 2019 have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report, which is incorporated herein by reference. Such financial statements have been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

Where you can find more information

We have filed with the SEC a registration statement on Form S-1 under the Securities Act, with respect to the securities being offered by this prospectus. This prospectus does not contain all of the information in the registration statement and its exhibits. For further information with respect to us and the securities offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

We are subject to the information and periodic reporting requirements of the Exchange Act, and we file periodic reports, proxy statements and other information with the SEC. You can read our SEC filings, including the registration statement, over the Internet at the SEC's website at www.sec.gov. You may also request a copy of these filings, at no cost, by writing us at Akero Therapeutics. Inc., 170 Harbor Way, 3rd Floor, South San Francisco, CA 94080 We also maintain a website at www.bionanogenomics.com, at which you may access these materials free of charge after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not incorporated by reference in, and is not part of, this prospectus.

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INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to "incorporate by reference" information from other documents that we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus.

We incorporate by reference into this prospectus and the registration statement of which this prospectus form a part the information or documents listed below that we have filed with the SEC, and any future filings we will make with the SEC under Sections 13(a), 13(c), 14, or 15(d) of the Exchange Act after the date of the initial filing of the registration statement of which this prospectus is a part and prior to effectiveness of such registration statement, and until the termination of the offering of the shares covered by this prospectus (other than information furnished under Item 2.02 or Item 7.01 of Form 8-K):

- our Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on March 16, 2020;
- our Quarterly Report on Form 10-Q for the quarter ended March 31, 2020 filed with the SEC on May 13, 2020;
- the portions of our definitive proxy statement on Schedule 14A filed with the SEC on April 27, 2020 that are deemed "filed" under the Exchange Act;
- our Current Reports on Form 8-K (other than information furnished rather than filed) filed with the SEC on January 13, 2020, and March 31, 2020; and
- the description our common stock which is registered under Section 12 of the Exchange Act, in our registration statement on Form 8-A, filed on June 17, 2019, including any amendment or reports filed for the purposes of updating this description.

Any statement contained in this prospectus or in a document incorporated or deemed to be incorporated by reference into this prospectus will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or any other subsequently filed document that is deemed to be incorporated by reference into this prospectus modifies or supersedes the statement. Any statements so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

We will furnish without charge to you, on written or oral request, a copy of any or all of the documents incorporated by reference in this prospectus, including exhibits to these documents. You should direct any requests for documents to Akero Therapeutics, Inc., 170 Harbor Way, 3rd Floor, South San Francisco, CA 94080; telephone: (650) 487-6488.

You also may access these filings on our website at www.akerotx.com. We do not incorporate the information on our website into this prospectus or any supplement to this prospectus and you should not consider any information on, or that can be accessed through, our website as part of this prospectus or any supplement to this prospectus (other than those filings with the SEC that we specifically incorporate by reference into this prospectus).

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Part II

Information not required in prospectus

Item 13. Other expenses of issuance and distribution.

The following table sets forth the fees and expenses, other than underwriting discounts and commissions, payable in connection with the registration of the common stock hereunder. All amounts are estimates except the SEC registration fee and the FINRA filing fee.

	Amount to be paid
SEC registration fee	*
FINRA filing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer agent and registrar fees and expenses	*
Miscellaneous	*
Total	$ *

* To be filed by amendment.

Item 14. Indemnification of directors and officers.

Section 145 of the Delaware General Corporation Law (the "DGCL") authorizes a corporation to indemnify its directors and officers against liabilities arising out of actions, suits and proceedings to which they are made or threatened to be made a party by reason of the fact that they have served or are currently serving as a director or officer to a corporation. The indemnity may cover expenses (including attorneys' fees) judgments, fines and amounts paid in settlement actually and reasonably incurred by the director or officer in connection with any such action, suit or proceeding. Section 145 permits corporations to pay expenses (including attorneys' fees) incurred by directors and officers in advance of the final disposition of such action, suit or proceeding. In addition, Section 145 provides that a corporation has the power to purchase and maintain insurance on behalf of its directors and officers against any liability asserted against them and incurred by them in their capacity as a director or officer, or arising out of their status as such, whether or not the corporation would have the power to indemnify the director or officer against such liability under Section 145.

We have adopted provisions in our certificate of incorporation to be in effect upon the completion of this offering and bylaws to be in effect upon the effectiveness of this registration statement that limit or eliminate the personal liability of our directors to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any unlawful payments related to dividends or unlawful stock purchases, redemptions or other distributions; or
- any transaction from which the director derived an improper personal benefit.

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These limitations of liability do not alter director liability under the federal securities laws and do not affect the availability of equitable remedies such as an injunction or rescission.

In addition, our bylaws provide that:

- we will indemnify our directors, officers and, in the discretion of our board of directors, certain employees to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended; and

- we will advance reasonable expenses, including attorneys' fees, to our directors and, in the discretion of our board of directors, to our officers and certain employees, in connection with legal proceedings relating to their service for or on behalf of us, subject to limited exceptions.

We have entered into indemnification agreements with each of our directors and intend to enter into such agreements with our executive officers. These agreements provide that we will indemnify each of our directors, our executive officers and, at times, their affiliates to the fullest extent permitted by Delaware law. We will advance expenses, including attorneys' fees (but excluding judgments, fines and settlement amounts), to each indemnified director, executive officer or affiliate in connection with any proceeding in which indemnification is available and we will indemnify our directors and officers for any action or proceeding arising out of that person's services as a director or officer brought on behalf of us or in furtherance of our rights. Additionally, certain of our directors or officers may have certain rights to indemnification, advancement of expenses or insurance provided by their affiliates or other third parties, which indemnification relates to and might apply to the same proceedings arising out of such director's or officer's services as a director referenced herein. Nonetheless, we have agreed in the indemnification agreements that our obligations to those same directors or officers are primary and any obligation of such affiliates or other third parties to advance expenses or to provide indemnification for the expenses or liabilities incurred by those directors are secondary.

We also maintain general liability insurance which covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act of 1933, as amended (the "Securities Act").

The underwriting agreement filed as Exhibit 1.1 to this registration statement provides for indemnification of us and our directors and officers by the underwriters against certain liabilities under the Securities Act and the Securities Exchange Act of 1934.

Item 15. Recent sales of unregistered securities.

Since our inception on Set forth below is information regarding shares of our common stock and shares of our preferred stock, and stock options granted, by us within the past three years 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 rule of the SEC, under which exemption from registration was claimed.

(a) Issuances of capital stock

In June 2018, with subsequent filings in November 2018, we issued and sold an aggregate of 50,858,462 Series A preferred shares at a price per share of $1.00 for aggregate cash consideration of approximately $45.0 million; including an aggregate of 5,858,461 shares of Series A preferred shares to an accredited investor in connection with the Amgen Agreement.

In December 2018, we issued and sold an aggregate of 13,871,948 Series B preferred shares at a price per share of $3.28 for aggregate cash consideration of approximately $45.5 million.

No underwriters were involved in the foregoing sales of securities. Unless otherwise stated, the sales of securities described above were deemed to be exempt from registration pursuant to

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Section 4(a)(2) of the Securities Act, including Regulation D and Rule 506 promulgated thereunder, as transactions by an issuer not involving a public offering. All of the purchasers in these transactions represented to us in connection with their purchase that they were acquiring the securities for investment and not distribution, that they could bear the risks of the investment and could hold the securities for an indefinite period of time. Such purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration or an available exemption from such registration. All of the foregoing securities are deemed restricted securities for the purposes of the Securities Act.

(b) Grants and exercises of stock options

Since January 24, 2017, we granted stock options under our 2018 Stock Option and Grant Plan, as amended, our 2019 Stock Option and Incentive Plan and our 2019 Employee Stock Purchase Plan, to purchase an aggregate of 3,898,919 shares of our common stock, with exercise prices ranging from $0.62 to $23.20 per share to certain directors, officers, employees and consultants.

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 for purposes of the Securities Act.

All certificates representing the securities issued in the transactions described in this Item 15 included appropriate legends setting forth that the securities had not been offered or sold pursuant to a registration statement and describing the applicable restrictions on transfer of the securities. There were no underwriters employed in connection with any of the transactions set forth in this Item 15.

Item 16. Exhibits and financial statement schedules.

(a) Exhibits

Exhibit number	Description
1.1*	Form of Underwriting Agreement
3.1	Amended and Restated Certificate of Incorporation of Registrant, as currently in effect, (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 (incorporated by reference to Exhibit 4.3 of the Registrant's Annual Report on Form 10-K (File No. 001-38944) filed on March 16, 2020).
5.1*	Opinion of Goodwin Procter LLP.
10.1#	2018 Stock Option and Grant Plan, amendments thereto, 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).

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Exhibit number	Description
10.2#	2019 Stock Option and Incentive 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#	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).
10.5#	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).
10.6#	Amended and Restated Non-Employee Director Compensation Policy incorporated by reference to Exhibit 10.11 of the Registrant's Annual report on Form 10-K (File No. 001-38944) filed on March 16, 2020).
10.7	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)
10.8#	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)
10.9#	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).
10.10#	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).
10.11†	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).
10.12	Office Lease between Gateway Center LP and the Registrant, dated as of February 14, 2020 (incorporated by reference to Exhibit 21.1 of the Registrant's Annual Report on Form 10-K (File No. 001-38944) filed on March 16, 2020).
21.1	List of Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 of the Registrant's Annual Report on Form 10-K (File No. 001-38944 filed on March 16, 2020).
23.1*	Consent of Deloitte & Touche LLP, independent registered public accounting firm.
23.2	Consent of Goodwin Procter LLP (included in Exhibit 5.1).
24.1*	Power of Attorney

* To be filed by amendment.

† Confidential treatment has been granted to certain confidential information in this exhibit. Omitted material for which confidential treatment has been granted has been filed separately with the Securities and Exchange Commission.

# Indicates a management contract or any compensatory plan, contract or arrangement.

Confidential Treatment Requested by Akero Therapeutics, Inc.
Pursuant to 17 C.F.R. Section 200.83

Item 17. Undertakings.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, or the Act, may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is therefore unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

The Registrant hereby undertakes that:

(a) The Registrant will provide to the underwriter at the closing as specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

(b) For purposes of determining any liability under the Securities Act of 1933, as amended, the information omitted from a form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in the form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act of 1933, as amended, shall be deemed to be part of this registration statement as of the time it was declared effective.

(c) For the purpose of determining any liability under the Securities Act of 1933, as amended, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof

Confidential Treatment Requested by Akero Therapeutics, Inc.
Pursuant to 17 C.F.R. Section 200.83

Signatures

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of San Francisco, California, on , 2020.

AKERO THERAPEUTICS, INC.

By: _____

Andrew Cheng, M.D., Ph.D.
President and Chief Executive Officer

Power of Attorney

Each individual whose signature appears below hereby constitutes and appoints Andrew Cheng, Jonathan Young, and William White as such person's true and lawful attorney-in-fact and agent with full power of substitution and resubstitution, for such person in such person's name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Registration Statement (or any Registration Statement for the same offering that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933), and to file the same, with all exhibits thereto, and all documents in connection therewith, with the Securities and Exchange Commission granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that any said attorney-in-fact and agent, or any substitute or substitutes of any of them, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement and Power of Attorney has been signed by the following person in the capacities and on the date indicated.

Name	Title	Date
_____ Andrew Cheng, M.D., Ph.D.	Director, President, and Chief Executive Officer (Principal Executive Officer)	
_____ William White, J.D.	Executive Vice President, Chief Financial Officer and Head of Corporate Development (Principal Financial Officer and Principal Accounting Officer)	
_____ Kevin Bitterman, Ph.D.	Director	

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Pursuant to 17 C.F.R. Section 200.83

Name	Title	Date
Seth L. Harrison, M.D.	Director	
Jane P. Henderson	Director	
Mark Iwicki	Director, Chairperson	
Graham Walmsley, M.D., Ph.D.	Director	