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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 April 30, 2019 as Amendment No. 2 to the confidential submission dated January 17, 2019.
This draft registration statement has not been publicly filed with the Securities and Exchange Commission and all information herein remains confidential.

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
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.** **Laurie Burlingame, Esq.** **Goodwin Procter LLP** **100 Northern Avenue** **Boston, MA 02210** **(617) 570-1000**	**Jonathan Young** **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. o

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, 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	Proposed Maximum Aggregate Offering Price(1)(2)	Amount of Registration Fee
Common Stock, par value $0.0001 per share		

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.

(2) Includes the offering price of shares that the underwriters may purchase pursuant to an option to purchase additional shares.

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. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to Completion, dated , 2019

Preliminary prospectus

shares

akero

Common stock

This is an initial public offering of shares of common stock by Akero Therapeutics, Inc. We are offering shares of our common stock to be sold in the offering. The initial public offering price is expected to be between $ and $ per share.

Prior to this offering, there has been no public market for our common stock. We have applied for listing of our common stock on The Nasdaq Global Market under the symbol "AKRO."

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
Initial 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 9.

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 , 2019.

J.P. Morgan **Jefferies** **Evercore ISI**

Roth Capital Partners

, 2019

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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 , 2019 (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 information contained elsewhere in this prospectus and 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, including our consolidated financial statements and the related notes included elsewhere in this prospectus and the sections entitled "Risk factors" and "Management's discussion and analysis of financial condition and results of operations." 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 clinical-stage biotechnology company focused on developing and commercializing transformative treatments for serious metabolic diseases with high unmet medical need. Our initial focus is nonalcoholic steatohepatitis, or NASH, a disease without any approved therapies. 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. NASH is a leading cause for liver transplantation. Our lead product candidate, AKR-001, which we are developing as a potential treatment for patients with NASH, is an analog of fibroblast growth factor 21, or FGF21. FGF21 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. FGF21 analogs have shown evidence of therapeutic benefit in clinical trials of patients with NASH, many of whom are dyslipidemic and insulin resistant. In previous clinical trials in patients with type 2 diabetes, or T2D, administration of AKR-001 was associated with substantial improvements in lipid metabolism and insulin sensitivity. We believe these data demonstrate AKR-001's potential to serve as a cornerstone for the treatment of NASH. On April 24, 2019, we submitted to the U.S. Food and Drug Administration's Division of Gastroenterology and Inborn Errors Products an Investigational New Drug, or IND, application to permit patients with NASH to be treated with AKR-001. We plan to initiate a Phase 2a clinical trial for AKR-001 in NASH patients with fibrosis in the middle of 2019.

NASH is primarily driven by chronic excess caloric intake, which results in people becoming overweight and obese. Nearly half of NASH patients have T2D and nearly three-quarters have metabolic syndrome. The underlying insulin resistance among these patients contributes to accumulation of excess fat in the liver, which leads to stress on hepatocytes. This cellular stress triggers localized inflammation and can ultimately lead to fibrosis and scarring in the liver, or cirrhosis. As NASH progresses, cardiovascular-related morbidity and mortality also increase. The most frequent cause of death in patients with NASH is cardiovascular disease.

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. We believe the unmet medical need will remain high for this population despite investigational NASH therapies currently in late-stage clinical development, as many of these therapies have shown limited efficacy or may be limited by unwanted side effects.

Our lead product candidate, AKR-001

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 AKR-001 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 once-weekly dosing, while retaining the native biological activity of FGF21.

AKR-001 has been 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. In these clinical trials, it was also observed that administration of AKR-001 was associated with substantially improved markers of insulin sensitivity, including reductions of up to 37% in C-peptide and 55% in the homeostatic model assessment of insulin resistance. 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 and biomarkers of liver fibrosis were 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., which leveraged its deep protein engineering expertise to design and develop AKR-001. As of March 31, 2019, our patent portfolio relating to AKR-001 and other peptides included 111 issued patents and 41 pending patents worldwide, with expected patent exclusivity up to 2034 in the United States, including potential patent term extension. Since AKR-001 is a biologic, marketing approval would also provide twelve years of market exclusivity from the approval date of a Biologics License Application in the United States.

Our strategy

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

- Advance AKR-001 through clinical development in NASH;
- Scale our capabilities to support development and commercialization of AKR-001;
- Enhance our position as a leading metabolic disease company by leveraging our knowledge of FGF21 biology; and
- Develop, acquire or in-license product candidates that enhance our potential to become a leading metabolic disease company.

Our management team has extensive experience in drug discovery, development and commercialization, and has been involved in the approvals of more than 20 products. 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 Scientific Officer, Tim Rolph, DPhil, formerly Chief Scientific Officer of Pfizer's Cardiovascular & Metabolic Disease Research Unit, oversaw Pfizer's FGF21 program. We are also supported by our board of directors and a group of leading institutional investors. 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.

Risks associated with our business

Our ability to execute on our business strategy is subject to a number of risks, which are discussed more fully in the section of this prospectus entitled "Risk factors." You should carefully consider these risks before making an investment in our common stock. These risks include, among others, the following:

- We have incurred significant losses since our inception and we expect to incur losses for the foreseeable future.
- We currently have a limited operating history, have not generated any revenue to date, and may never become profitable.
- We currently have no products that are approved for commercial sale and our inability to obtain regulatory approval for AKR-001 or any future product candidate would substantially harm our business.
- We are heavily dependent on the success of AKR-001, our only product candidate.
- If we breach our license agreement with Amgen related to AKR-001, we could lose the ability to continue development and commercialization of AKR-001.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than us.
- Our success depends, in part, on our ability to obtain, maintain, protect and defend our intellectual property, which is difficult and costly, and we may not be able to ensure that we will be able to do so.
- 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.
- Our product candidate and any future product candidates must undergo rigorous clinical trials and regulatory approvals, and success in preclinical studies or earlier-stage clinical trials may not be indicative of results in future clinical trials.
- We are subject to many manufacturing risks, any of which could substantially increase our costs, delay clinical programs and limit supply of our products.

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 and a smaller reporting 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 this 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.

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 million measured on the last business day of our second fiscal quarter, or our annual revenues are more than $100 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is more than $700 million measured on the last business day of our second fiscal quarter.

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, assuming an initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated 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 development of our product candidate, AKR-001, including completion of our contemplated Phase 2a clinical trial and a subsequent Phase 2b clinical trial, for third-party drug substance and drug product manufacturing, as well as potential pipeline expansion and for 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.
Proposed Nasdaq Global Market symbol	"AKRO"

The number of shares of our common stock to be outstanding after this offering is based on 65,465,104 shares of our common stock outstanding as of March 31, 2019, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 64,730,410 shares of our common stock immediately prior to the completion of this offering, and excludes:

- 7,115,964 shares of common stock issuable upon the exercise of stock options outstanding as of March 31, 2019 under our 2018 Stock Option and Grant Plan, or the 2018 Plan, at a weighted-average exercise price of $0.58 per share (which excludes options to purchase an aggregate of 1,958,258 shares of common stock, at an exercise price of $2.28 per share, that were granted subsequent to March 31, 2019);
- 2,289,102 shares of common stock reserved for future issuance as of March 31, 2019 under the 2018 Plan, which will cease to be available for issuance at the time that our 2019 Stock Option and Grant Plan, or the 2019 Plan, becomes effective (which includes 1,958,258 shares of common stock subject to options that were granted subsequent to March 31, 2019);

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- shares of our common stock that will become available for future issuance under the 2019 Plan, which will become effective in connection with this offering; and
- shares of our common stock reserved for future issuance under our 2019 Employee Stock Purchase Plan which will become effective in connection with this offering.

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

- the filing and effectiveness of our fourth amended and restated certificate of incorporation and second amended and restated bylaws prior to the completion of this offering;
- a one-for- reverse stock split of our common stock effected on , 2019;
- the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of shares of our common stock immediately prior to the completion of this offering;
- 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.

Summary consolidated financial data

You should read the following summary consolidated financial data together with our consolidated financial statements and the related notes appearing elsewhere in this prospectus and the "Selected consolidated financial data" and "Management's discussion and analysis of financial condition and results of operations" sections of this prospectus. We have derived the consolidated statement of operations data for the period January 24, 2017 (inception) through December 31, 2017 and for the year ended December 31, 2018 from our audited consolidated financial statements appearing elsewhere in this prospectus. We have derived the consolidated statement of operations data for the three months ended March 31, 2018 and 2019 and the consolidated balance sheet data as of March 31, 2019 from our unaudited condensed consolidated financial statements appearing elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that should be expected in any future periods, and our results for any interim period are not necessarily indicative of results that should be expected for any full year.

(in thousands, except share and per share amounts)	For the period January 24, 2017 (Inception) through December 31, 2017	Year ended December 31, 2018	Three months ended March 31, 2018	Three months ended March 31, 2019
Consolidated Statement of Operation Data:				
Operating expenses:				
Research and development	$ 3,486	$ 11,882	$ 226	$ 4,063
General and administrative	1,078	1,896	195	1,449
Total operating expenses	4,564	13,778	421	5,512
Loss from operations	(4,564)	(13,778)	(421)	(5,512)
Other income (expense), net:				
Change in fair value of preferred stock tranche obligation	—	(62,150)	—	—
Change in fair value of anti-dilution right liability	—	(5,765)	—	—
Other income (expense), net		(21)	—	150
Total other income (expense)	—	(67,936)	—	150
Net loss	(4,564)	(81,714)	(421)	(5,362)
Accruing dividends on convertible preferred stock	(213)	—	—	—
Accretion of convertible preferred stock to redemption value		(520)	—	—
Net loss attributable to common stockholders	$ (4,777)	$ (82,234)	$ (421)	$ (5,362)
Net loss per share attributable to common stockholders—basic and diluted(1)		$ (258.68)	$ (3.39)	$ (10.38)
Weighted average common shares outstanding—basic and diluted(1)		317,894	124,163	516,711
Pro forma net loss per share attributable to common stockholders—basic and diluted (unaudited)(1)		$ (1.01)		$ (.08)
Pro forma weighted average common shares outstanding—basic and diluted (unaudited)(1)		19,295,870		65,247,121

(1) See Note 10 to our audited consolidated financial statements and Note 9 to our unaudited interim condensed consolidated financial statements appearing elsewhere in this prospectus for details on the calculation of basic and diluted net loss per share attributable to common stockholders and the calculation of basic and diluted pro forma net loss per share attributable to common stockholders.

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	As of March 31, 2019		
(in thousands)	**Actual**	**Pro forma(1)**	**Pro forma as adjusted(2)**
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$ 69,796	$ 69,796	$
Working capital(3)	68,295	68,295	
Total assets	72,066	72,066	
Convertible preferred stock	124,728	—	
Total stockholders' (deficit) equity	(55,066)	69,662	

(1) The pro forma consolidated balance sheet data gives effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 64,730,410 shares of common stock prior to the completion of this offering and (ii) the filing and effectiveness of our fourth amended and restated certificate of incorporation.

(2) The pro forma as adjusted consolidated balance sheet data gives effect to (i) the pro forma adjustments set forth in footnote (1) above and (ii) the issuance and sale of shares of our common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, working capital, total assets and total stockholders' (deficit) equity by $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase (decrease) of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, working capital, total assets and total stockholders' (deficit) equity by $ million, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(3) We define working capital as current assets less current liabilities.

Risk factors

Investment in our common stock involves a high degree of risk and uncertainty. You should carefully consider each of the risks and uncertainties described below before you decide to buy our common stock. You should also refer to the other information in this prospectus, including our consolidated financial statements and related notes. If any of the following risks and uncertainties materialize, our business, financial condition, liquidity and results of operations could be materially and adversely affected. This could cause the trading price of our common stock to decline, and you could lose all or part of your investment.

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 period from our inception through December 31, 2017 and the year ended December 31, 2018, we reported net losses of $4.6 million and $81.7 million, respectively. For the three months ended March 31, 2019, we reported a net loss of $5.4 million. The net loss for the year ended December 31, 2018 included non-cash charges of $62.2 million related to the change in fair value of our preferred stock tranche obligation and $5.8 million related to the change in fair value of our anti-dilution right liability. As of March 31, 2019, we had an accumulated deficit of $91.9 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidate. We anticipate that our expenses will increase substantially if, and as, we:

- conduct larger scale clinical trials for our product candidate, AKR-001, and any future product candidates;
- discover and develop new product candidates, and conduct nonclinical studies and clinical trials;
- manufacture, or have manufactured, clinical and commercial supplies of our product candidates;
- seek regulatory approvals for our product candidate or any future product candidates;
- commercialize AKR-001 or any future product candidates, if approved;
- attempt to transition from a company with a research 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 following the completion of this offering.

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

Though AKR-001 is ready for 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 collaborators', ability to:

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

- negotiate favorable terms in any collaboration, licensing or other arrangements into which we may enter in the future and performing our obligations in such collaborations;

- establish, maintain, protect and enforce our intellectual property rights; and

- attract, hire and retain qualified personnel.

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

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

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

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

As of March 31, 2019, we had $69.8 million of cash and cash equivalents. We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will fund our projected operating requirements through . Our 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. We have based this estimate on assumptions that 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;

- 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.

Further, all clinical development of AKR-001 to date has been conducted in patients with type 2 diabetes, or T2D. While we believe that the data from clinical trials of AKR-001 in patients with T2D supports development of AKR-001 for the treatment of patients with nonalcoholic steatohepatitis, or NASH, there is currently no available clinical data regarding the safety or efficacy of AKR-001 in patients with NASH. In addition, we did not control the majority of the nonclinical development or any of the clinical development thus far of AKR-001, 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 future clinical trials may not be able to replicate the results from Amgen's clinical trials. To the extent any of 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. As additional consideration for the license, we are required to pay Amgen aggregate milestone payments of up to $40.0 million upon the achievement of specified 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.

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Pursuant to 17 C.F.R. Section 200.83

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 our internal discovery 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. While we plan to initiate a Phase 2a clinical trial for AKR-001 for the treatment in patients with NASH, 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. We have no experience in conducting the clinical trials required to obtain regulatory approval. We may not be able to conduct clinical trials at preferred sites, enlist clinical investigators, enroll sufficient numbers of participants or begin or successfully complete clinical trials in a timely fashion, if at all. Our anticipated clinical trials may be insufficient to demonstrate that our potential products will be active, safe or

effective. Additional clinical trials may be required if clinical trial results are negative or inconclusive, which will require us to incur additional costs and significant delays.

Success in nonclinical studies and earlier-stage clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the effectiveness and safety of a product candidate. In addition, the design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. Because we have no experience designing clinical trials, we may be unable to design and execute a clinical trial to support regulatory approval. 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. Further, these risks may be elevated with respect to AKR-001 since all clinical development to date has been conducted in patients with T2D, rather than NASH.

From time to time, we may publish interim "top-line" or preliminary data from our clinical trials. Preliminary or interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or interim data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business and financial prospects.

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

To date, we have not manufactured a product candidate as a company. While we received a supply of AKR-001 drug substance from Amgen that we believe will be sufficient for use in our Phase 2a clinical trial, we have contracted with a third party manufacturer to make new drug substance to support future clinical trials and for commercial sale, if approved. Our contract manufacturer may not be able to adopt, adapt or scale up the manufacturing process as practiced by Amgen in a timely manner to support our future clinical trials. The process of manufacturing our product is complex, highly regulated and subject to several risks, including:

- the manufacturing process is susceptible to product loss due to contamination by adventitious microorganisms, equipment failure, improper installation or operation of equipment, vendor or operator error and improper storage conditions. Even minor deviations from normal manufacturing processes could result in reduced production yields and quality as well as other supply disruptions. If microbial, viral or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, the manufacturing facilities may need to be closed for an extended period of time to investigate and eliminate the contamination;

- the manufacturing facilities in which our products are made could be adversely affected by equipment failures, labor and raw material shortages, financial difficulties of our contract manufacturers, natural disasters, power failures, local political unrest and numerous other factors; and

- any adverse developments affecting manufacturing operations for our products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls or other interruptions in the supply of our products. We may also have to record inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more expensive manufacturing alternatives.

The manufacture of our product candidate requires significant expertise and capital investment, including the development of advanced manufacturing techniques and 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 process needed for pivotal clinical studies and commercial launch. These problems include failure to meet target production costs and yields, sub-par quality control testing, 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 filled drug product for use in clinical trials or commercialization. To a large extent, that makes us dependent on the goodwill of our contract manufacturing partners to quickly fix deviations that will inevitably occur during the manufacturing of our product. Any delay or interruption in the supply of clinical trial materials could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials altogether.

In addition, we plan to develop a new drug product formulation for late stage clinical trials and commercialization. Our current drug product is an Amgen early-stage platform formulation, which is stored as a frozen liquid and is therefore not well-suited to larger clinical trials or commercialization. We plan to enter into a contract with a formulation development company 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 subsequent Phase 2b clinical development. We also plan to begin development of a pen-type autoinjector for the new drug product formulation. There is no assurance that we will be successful in developing a new drug product formulation or an autoinjector on a timely basis or at all, which could impede our development and commercialization strategy for AKR-001. Further, the FDA or other similar foreign regulatory bodies could require nonclinical studies or clinical trials to support introduction of any new formulation and autoinjector, which could increase our development costs and delay or prevent us from proceeding with future clinical trials or commercialization of AKR-001, if approved.

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

As of March 31, 2019, we had 8 full-time employees. As we continue development and pursue the potential commercialization of our product candidate, as well as function as a public company, we will need to expand our financial, development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic collaborators, suppliers and other third parties. Our future financial performance and our ability to develop and commercialize our product

candidate and to compete effectively will depend, in part, on our ability to manage any future growth effectively.

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

We expect to incur significant additional costs as a result of being a public company, which may adversely affect our operating results and financial condition.

We expect to incur costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules implemented by the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, or the Dodd-Frank Act, the SEC and The Nasdaq Global Market. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations are expected to increase our accounting, legal and financial compliance costs and make some activities more time-consuming and costly. In addition, we will incur additional costs associated with our public company reporting requirements and we expect those costs to increase in the future. For example, we will be required to devote significant resources to complete the assessment and documentation of our internal control system and financial process under Section 404 of the Sarbanes-Oxley Act, or Section 404, including an assessment of the design of our information systems associated with our internal controls.

To date, we have never conducted a review of our internal control for the purpose of providing the reports required by these rules. During the course of our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we fail to remediate our existing material weakness in our internal control over financial reporting or if new material weaknesses are identified or arise in the future, we may not detect errors on a timely basis and our consolidated financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we will be required to timely file accurate quarterly and annual reports with the SEC under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from The Nasdaq Global Market or other adverse consequences. We will incur significant costs to remediate any material weaknesses we identify through these efforts. The increased costs will 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. We also expect these rules and regulations to make it more expensive for us to maintain directors' and officers' liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees, or as executive officers. We cannot predict or estimate the amount of additional costs we may incur or the timing of such costs.

New laws and regulations, as well as changes to existing laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act, the Dodd-Frank Act and rules adopted by the SEC and The Nasdaq Global Market, would likely result in increased costs to us as we respond to their requirements, which may adversely affect our operating results and financial condition.

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We have identified a material weakness in our internal control over financial reporting. If we do not remediate the material weakness in our internal control over financial reporting, or if we fail to establish and maintain effective internal control, we may not be able to accurately report our financial results or file our periodic reports in a timely manner, which may cause investors to lose confidence in our reported financial information and may lead to a decline in the market price of our stock.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports in a timely manner. In connection with the preparation of our consolidated financial statements for the period January 24, 2017 (inception) through December 31, 2017 and the year ended December 31, 2018, we concluded that there was a material weakness in our internal control over financial reporting. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim consolidated financial statements will not be prevented or detected on a timely basis. The material weakness that we identified related to the lack of segregation of duties. As of March 31, 2019, this material weakness remains unremediated.

While we have established certain procedures and control over our financial reporting processes, we cannot assure you that these efforts will remediate our material weakness and significant deficiencies in a timely manner, or at all, or prevent restatements of our consolidated financial statements in the future. If we are unable to successfully remediate our material weakness, or identify any future significant deficiencies or material weaknesses, 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, and the market price of our stock may decline as a result.

We are not currently required to comply with the SEC's rules that implement Section 404 of the Sarbanes-Oxley Act, and are therefore not yet required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. However, upon becoming a public company, we will be required to comply with certain of these rules, 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.

We are implementing measures designed to improve our internal control over financial reporting to remediate this material weakness, including formalizing our processes and internal control documentation and strengthening supervisory reviews by our financial management; hiring additional qualified accounting and finance personnel and engaging financial consultants to enable the implementation of internal control over financial reporting and segregating duties amongst accounting and finance personnel; and planning to implement certain accounting systems to automate manual processes, such as tracking and accounting for stock-based awards.

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. We expect to incur additional costs to remediate these control deficiencies, though there can be no assurance that our efforts will be successful or avoid potential future material weaknesses. 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 are unable to successfully remediate our existing or any future material weaknesses in our

internal control over financial reporting, or if we identify any additional material weaknesses, 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.

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.

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, including our President and Chief Executive Officer, Andrew Cheng, our Executive Vice President, Chief Financial Officer and Head of Corporate Development, William White, our Executive Vice President and Chief Operating Officer, Jonathan Young, our Chief Scientific Officer, Tim Rolph, and our Chief Development Officer, Kitty Yale. 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, and in Cambridge, Massachusetts, where we have a second office. 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 currently approved therapies. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. This could result in our own products being removed from the market or being less successful commercially.

We may also evaluate AKR-001 or any other future product candidates in combination with one or more other therapies that have not yet been approved for marketing by the FDA or similar regulatory authorities outside of the United States. We will not be able to market and sell AKR-001 or any product candidate we develop in combination with any such unapproved therapies that do not ultimately obtain marketing approval. If the FDA or similar regulatory authorities outside of the United States do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with, the drugs we choose to evaluate in combination with AKR-001 or any other product candidate we develop, we may be unable to obtain approval of or market AKR-001 or any other product candidate we develop.

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

Identifying and qualifying patients to participate in our clinical trials is critical to our success. We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials, and even once enrolled we may be unable to retain a sufficient number of patients to complete any of our 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 plan to enroll only patients with a biopsy-confirmed diagnosis of NASH in our planned Phase 2a clinical trial and subsequent clinical trials. We have engaged Summit Research Network, a third party investigator, to assist with patient enrollment for our Phase 2a clinical trial; however, there can be no assurance that we will be able to maintain our relationships with this third party or that this third party will be successful in helping us identify patients.

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

would 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. A number of pharmaceutical companies, including AbbVie, Inc., Allergan plc, AstraZeneca PLC/MedImmune LLC, Bayer AG, Bristol-Myers Squibb Company, Eisai, Inc., Eli Lilly and Company, GlaxoSmithKline plc, 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., Amgen, Cirius Therapeutics, Inc., Conatus Pharmaceuticals Inc., CymaBay Therapeutics, Inc., Enanta Pharmaceuticals, Inc., Galectin Therapeutics Inc., Galmed Pharmaceuticals Ltd., Genfit SA, Gilead Sciences, Inc., Intercept Pharmaceuticals, Inc., Inventiva Pharma SA, Madrigal Pharmaceuticals, Inc., MannKind Corporation, MediciNova, Inc., Metacrine, Inc., Nalpropion Pharmaceuticals, Inc., NGM Biopharmaceuticals, Inc., Terns Pharmaceuticals, Inc., Viking Therapeutics, Inc., Vivus, Inc. and Zafgen, 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 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.

Comprehensive tax reform legislation could adversely affect our business and financial condition.

The "Tax Cuts and Jobs Act," or the Tax Act, significantly revised the Internal Revenue Code of 1986, as amended, or the Code. The Tax Act, among other things, includes a reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, a limitation of the tax deduction for net interest expense to 30% of adjusted earnings (except for certain small businesses), a limitation of the deduction for net operating losses to 80% of current year taxable income and an elimination of net operating loss carrybacks, in each case, for losses generated after December 31, 2017 (though any such net operating losses may be carried forward indefinitely), and modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as "orphan drugs"). We continue to examine the impact this tax reform legislation may have on our business. We urge investors to consult with their legal and tax advisers regarding the implications of the Tax Act 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, 2018, we had federal and state net operating loss, or NOL, carryforwards of $10.6 million and $10.6 million, respectively, and federal and state research and development tax credit carryforwards of $0.2 million and $0.1 million, respectively. If not utilized, such NOL carryforwards (other than any federal NOL carryforwards arising in taxable years ending after December 31, 2017) and research and development credits will expire at various dates beginning in 2037 and 2032, respectively. We do not anticipate generating revenue from sales of products for the foreseeable future, if ever, and we may never achieve profitability. These NOL and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Act, NOL carryforwards generated in tax years ending after December 31, 2017 are not subject to expiration. However, utilization of NOL carryforwards generated in tax years beginning after December 31, 2017 are limited to a maximum of 80% of the taxable income for such year determined without regard to such NOL carryforwards. In addition, under Section 382 of the Code, the amount of benefits from our NOL carryforwards may be impaired or limited if we incur a cumulative ownership change of more than 50%, as interpreted by the U.S. Internal Revenue Service, over a three-year period. We may have experienced ownership changes in the past and may experience ownership changes in the future as a result of this offering and subsequent shifts in our stock ownership, some of which are outside our control. As a result, our use of federal NOL carryforwards could be limited. State NOL carryforwards may be similarly limited. Any such disallowances may result in greater tax

liabilities than we would incur in the absence of such a limitation and any increased liabilities could adversely affect our business, results of operations, financial position and cash flows.

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

Our research programs involve the use of hazardous materials and chemicals, which are currently only handled by third parties. We are subject to foreign, federal, state and local environmental and health and safety laws and regulations governing, among other matters, the use, manufacture, handling, storage and disposal of hazardous materials and waste products. We may incur significant costs to comply with these current or future environmental and health and safety laws and regulations. In addition, we cannot completely eliminate the risk of contamination or injury from hazardous materials and may incur material liability as a result of such contamination or injury. In the event of an accident, an injured party may seek to hold us liable for any damages that result. Any liability could exceed the limits or fall outside the coverage of our workers' compensation, property and business interruption insurance and we may not be able to maintain insurance on acceptable terms, if at all. We currently carry no insurance specifically covering environmental claims.

Risks related to government regulation

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

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

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

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

- changes in the approval policies or regulations that render our nonclinical and clinical data insufficient for approval.

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

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

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

- the FDA or comparable foreign regulatory authorities may not authorize us or our investigators to commence our planned clinical trials or any other clinical trials we may initiate, or may suspend our clinical trials, for example, through imposition of a clinical hold, and may request additional data to permit allowance of our investigational new drug, or IND;
- delays in filing or receiving allowance of additional IND applications that may be required;
- lack of adequate funding to continue our clinical trials and nonclinical studies;
- negative results from our ongoing nonclinical studies;
- delays in reaching or failing to reach agreement on acceptable terms with prospective CROs and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and study sites;
- inadequate quantity or quality of a product candidate or other materials necessary to conduct clinical trials, for example delays in the manufacturing of sufficient supply of finished drug product;
- difficulties obtaining ethics committee or Institutional Review Board, or IRB, approval to conduct a clinical study at a prospective site or sites;
- challenges in recruiting and enrolling subjects to participate in clinical trials, the proximity of subjects to study sites, eligibility criteria for the clinical study, the nature of the clinical study protocol, the availability of approved effective treatments for the relevant disease, and competition from other clinical study programs for similar indications;
- severe or unexpected drug-related side effects experienced by subjects in a clinical trial;
- we may decide, or regulatory authorities may require us, to conduct additional nonclinical or clinical trials or abandon product development programs;
- delays in validating, or inability to validate, any endpoints utilized in a clinical trial;

- the FDA or comparable foreign regulatory authorities may disagree with our clinical study design and our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials; and

- difficulties retaining subjects who have enrolled in a clinical trial but may be prone to withdraw due to rigors of the clinical trials, lack of efficacy, side effects, personal issues, or loss of interest.

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

- failure to conduct the clinical study in accordance with regulatory requirements or our clinical protocols;

- inspection of the clinical study operations or study sites by the FDA or other regulatory authorities that reveals deficiencies or violations that require us to undertake corrective action, including in response to the imposition of a clinical hold;

- unforeseen safety issues or safety signals, including any that could be identified in our ongoing nonclinical studies or clinical trials, adverse side effects or lack of effectiveness;

- changes in government regulations or administrative actions;

- problems with clinical supply materials; and

- lack of adequate funding to continue clinical trials.

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

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

As a company, 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.

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

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. Some of the provisions of the Affordable Care Act have yet to be implemented, and there have been judicial, congressional, and executive branch challenges to certain aspects of the Affordable Care Act. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. One Executive Order directs federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from, or delay the implementation of any provision of the Affordable Care Act that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the Affordable Care Act. Several state Attorneys General filed suit to stop the Trump administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. Further, on June 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in Affordable Care Act risk corridor payments to third-party payors who argued were owed to them. The effects of this gap in reimbursement on third-party payors, the viability of the Affordable Care Act marketplace, providers, and potentially our business, are not yet known.

Congress has also considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. The Tax Act included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain Affordable Care Act-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In July 2018, the Centers for Medicare and Medicaid Services, or CMS, published a final rule permitting further collections and payments to and from certain Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. Moreover, CMS issued a final rule in 2018 that will give states greater flexibility, starting in 2020, in setting benchmarks for insurers in the individual and small group marketplaces, which may have

the effect of relaxing the essential health benefits required under the Affordable Care Act for plans sold through such marketplaces. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or the Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the Affordable Care Act are invalid as well. While the Texas District Court Judge, as well as the Trump Administration and CMS, have stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act and 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 2027 under the BBA. 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 year 2019 contained further drug price control measures that could be enacted during the 2019 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 September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. On January 31, 2019, the HHS Office of Inspector General, proposed modifications to the federal Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. 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.

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. 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; 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 will come 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. 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.

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 submit INDs or similar applications for our preclinical programs 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 preclinical and clinical studies. For therapeutic applications, the FDA may require additional extensive preclinical and other studies. 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 testing and studies will ultimately support the further development of our programs As a result, there is no assurance that we will be able to submit INDs or similar applications on the timelines we expect, if at all, and we cannot be sure that submission of an IND or similar applications will result in the FDA or other regulatory authorities allowing a clinical trial design to begin.

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 (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 studies;
- 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 a U.S. subsidiary and 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, including beginning on December 22, 2018, 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, upon completion of this offering and in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Risks related to our intellectual property

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

Our success will depend in significant part on our and our current or future licensors', licensees' or collaborators' ability to establish and maintain adequate protection of our intellectual property covering the product candidates we plan to develop, and the ability to develop these product candidates and commercialize the products resulting therefrom, without infringing the intellectual property rights of others. We strive to protect and enhance the proprietary technologies that we believe are important to our business, including seeking patents intended to cover our products and compositions, their methods of use, and any other inventions that are important to the development of our business. In addition to taking other steps to protect our intellectual property, we have applied for, and intend to continue to apply for, patents with claims covering our technologies, processes and product candidates when and where we deem it appropriate to do so. Our in-licensed patents and patent applications in both United States and certain foreign jurisdictions relate to AKR-001 and related Fc-fusion polypeptides. There can be no assurance that the claims of our patents or any patent application that issues as a patent, will exclude others from

making, using or selling our product candidate or any future product candidates or products that are substantially similar to our product candidate or any future product candidates. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. In countries where we have not and do not seek patent protection, third parties may be able to manufacture and sell our product candidate or any future product candidates without our permission, and we may not be able to stop them from doing so.

With respect to patent rights, we do not know whether any of the pending patent applications for our product candidate or any future product candidates will result in the issuance of patents that effectively protect our technologies, processes and product candidates, or if any of our issued patents or our current or future licensors', licensees' or collaborators' issued patents will effectively prevent others from commercializing competitive technologies, processes and products. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all, until they are issued as a patent. Therefore, we cannot be certain that we or our current or future licensors, licensees or collaborators were the first to make or file on the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our current or future licensors, licensees or collaborators were the first to file for patent protection of such inventions. There is also no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which could be used by a third party to challenge the validity of our patents, should they issue, or prevent a patent from issuing from a pending patent application. Any of the foregoing could harm our competitive position, business, financial condition, results of operations, and prospects.

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

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

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

The patent positions of biotechnology and pharmaceutical companies, including our patent position, involve complex legal and factual questions, which in recent years have been the subject of much litigation, and, therefore, the issuance, scope, validity, enforceability, and commercial value of any patent claims that we have rights or may obtain cannot be predicted with certainty. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors', licensees' or collaborators' patent rights are highly uncertain. Our and our current or future licensors', licensees' or collaborators' pending and future patent applications may not result in patents being issued that protect our technology or product candidates, or products resulting therefrom, in whole or in part, or that effectively prevent others from commercializing competitive technologies and products. The patent examination process may require us or our current or future licensors, licensees or collaborators to narrow the scope of the claims of pending and future patent applications, which would limit the scope of patent protection that is obtained, if any. Our and our current or future licensors', licensees' or collaborators' patent applications cannot be enforced against third parties practicing the technology that is currently claimed in such applications unless and until a patent issues from such applications, and then only to the extent the claims that issue are broad enough to cover the technology being practiced by third parties.

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

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

We are dependent on patents, know-how and proprietary technology in-licensed from Amgen. Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidate or any future product candidates and use our and our licensor's proprietary technologies without infringing the proprietary rights of third parties. Amgen may have the right to terminate the license

agreement in full in the event we materially breach or default in the performance of any of the obligations under the license agreement. A termination of the license agreement with Amgen could result in the loss of significant rights and could harm our ability to commercialize our product candidates.

Disputes may also arise between us and Amgen, as well as any future potential licensors, regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidate and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

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

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

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

Patent terms may be inadequate to protect our competitive position on our product candidate or any future product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Currently, our composition of matter patents expire in 2029 in the United States and in 2034, including potential patent term extensions, in other jurisdictions. Even if patents covering our product candidate or any future product candidate are obtained, once the patent life has expired, we may be open to competition from

competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidate or any future product candidate might expire before or shortly after we or our partners commercialize those candidates. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

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

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

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

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology. This could make it difficult for us and our licensor to stop the infringement of our and our licensor's patents or the marketing of competing products in violation of our and our licensor's proprietary rights, generally. Proceedings to enforce our and our licensor's patent rights in foreign jurisdictions could result in substantial costs and divert our and our licensor's efforts and attention from other aspects of our business, could put our and our licensor's patents at risk of being invalidated or interpreted narrowly, could place our and our licensor's patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensor. We or our licensor may not prevail in any

lawsuits that we or our licensor initiate and the damages or other remedies awarded, if any, may not be commercially meaningful.

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

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

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

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

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

Depending on what patent claims ultimately issue and how courts construe the issued patent claims, as well as depending on the ultimate formulation and method of use of our product candidate or any future product candidates, we may need to obtain a license under such patents. There can be no assurance that such licenses will be available on commercially reasonable terms, or at all. If a third party does not offer us a necessary license or offers a license only on terms that are unattractive or unacceptable to us, we might be unable to develop and commercialize one or more of our product candidate or any future product

candidates, which would have a material adverse effect on our business, financial condition and results of operations. Moreover, even if we obtain licenses to such intellectual property, but subsequently fail to meet our obligations under our license agreements, or such license agreements are terminated for any other reasons, we may lose our rights to in-licensed technologies.

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

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

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

invalidated, narrowed, held unenforceable or interpreted in such a manner that would not preclude third parties from entering the market with competing products.

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

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, many foreign jurisdictions have rules of discovery that are different than those in the United States and which may make defending or enforcing our or our licensor's patents extremely difficult. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock.

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

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

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

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

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

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

financial condition and prospects. Any of the foregoing would have a material adverse effect on our business, financial condition and operating results.

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

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

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

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

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

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make products that are similar to any product candidates we may develop or utilize similar technology but that are not covered by the claims of the patents that we license or may own in the future;
- we, or our current or future collaborators, might not have been the first to make the inventions covered by the issued patents and pending patent applications that we license or may own in the future;
- we, or our current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our pending patent applications or those that we may own in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

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

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

If we or our licensing partner initiate legal proceedings against a third party to enforce a patent covering our product candidate or any future product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. These types of mechanisms include *inter partes* review, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). These types of proceedings could result in revocation or amendment to our patents such that they no longer cover our product candidates. The outcome for any particular patent following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain

that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our product candidates. A loss of patent protection for our product candidates could have a material adverse impact on our ability to commercialize or license our technology and product candidates and, resultantly, on our business, financial condition, prospects and results of operations.

Likewise, our in-licensed U.S. patents directed to our proprietary technologies and our product candidates are expected to expire in 2034, including potential patent term extensions, without taking into account any possible patent term adjustments or extensions. Our earliest in-licensed patents 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. We in-license pending patent applications directed to proprietary technologies or our product candidates that, if issued as patents, are expected to expire from 2034, including potential patent term extensions, through 2036, without taking into account any possible patent term adjustments or extensions. However, we cannot be assured that the USPTO or relevant foreign patent offices will grant any of these patent applications.

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. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the filing and prosecution strategies associated with patent applications, including a change from a "first-to-invent" to a "first-inventor-to-file" patent system, and may also affect patent prosecution and litigation, such as by allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. The USPTO has developed regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act and, in particular, the "first-inventor-to-file" provisions, became effective in 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith

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

the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

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

If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to the failure (including by clinical sites or investigators) to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenues could be delayed significantly.

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

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

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

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

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

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

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

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

The processes involved in manufacturing our drug product candidates are complex, expensive, highly-regulated, and subject to multiple risks. Further, as product candidates are developed through nonclinical studies to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials.

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

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

We may pursue collaborations in order to develop and commercialize AKR-001 and any future product candidates. We face significant competition in seeking appropriate collaborators. Whether we reach a

definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products and the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborators may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

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

Risks related to commercialization

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

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

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors such as government health administration authorities, private health insurers and other organizations. Third-party payors determine which medications they will cover and establish reimbursement

levels. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval, if any. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which marketing approval is obtained, if any.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates third-party payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

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

We do not currently have an infrastructure for the sales, marketing, and distribution of pharmaceutical products. In order to market our product candidates, if approved by the FDA or any other regulatory body, we must build our sales, marketing, managerial, and other non-technical capabilities, or make arrangements with third parties to perform these services. There are risks involved with both establishing our own commercial capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force or reimbursement specialists is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing and other commercialization capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our commercialization personnel.

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

either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates if approved.

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

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

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

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

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

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

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

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

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

insurance coverage and our total assets. Claims against us, regardless of their merit or potential outcome, may also generate negative publicity or hurt our ability to obtain physician adoption of our product or expand our business.

Risks related to this offering and our common stock

We do not know whether an active, liquid and orderly trading market will develop for our common stock or what the market price of our common stock will be and, as a result, it may be difficult for you to sell your shares of our common stock and you may not be able to resell your shares at or above the initial public offering price.

Prior to this offering, no market for shares of our common stock existed and an active trading market for our shares may never develop or be sustained following this offering. We will determine the initial public offering price for our common stock through negotiations with the underwriters, and the negotiated price may not be indicative of the market price of our common stock after this offering. The market value of our common stock may decrease from the initial public offering price. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the initial public offering price. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. Furthermore, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies or products by using shares of our common stock as consideration.

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 following this offering is likely to be highly 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. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk factors" section, could have a dramatic and material adverse impact on the market price of our common stock.

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.

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

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Prior to this offering, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 79% of our voting stock as of March 31, 2019 and, upon completion of this offering, that same group will hold approximately % of our outstanding voting stock (no purchases of shares in this offering by any members of this group), in each case assuming the conversion of all outstanding shares of our convertible preferred stock into shares of our common stock in connection with the completion of this offering. After this offering, this group of stockholders will have the ability to control us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

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 this offering, (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 million measured on the last business day of our second fiscal quarter, or our annual revenues are more than $100 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is more than $700 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 company. 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.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. After this offering, we will have outstanding shares of common stock based on the number of shares outstanding as of March 31, 2019, assuming the conversion of all outstanding shares of our convertible preferred stock into shares of common stock upon the completion of this offering. This includes the shares that we sell in this offering, which may be resold in the public market immediately without restriction, unless purchased by our affiliates. Substantially all of the remaining shares of our common stock outstanding immediately after the completion of this offering will not be able to be sold immediately following this offering as a result of securities laws or lock-up agreements, but will be able to be sold after this offering as described in the section titled "Shares eligible for future sale." Moreover, after this offering, holders of an aggregate of shares of our common stock will have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also intend to register all shares of common stock that we

may issue under our equity compensation plans for resale under the Securities Act. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements.

The lock-up agreements pertaining to this offering will expire 180 days from the date of this prospectus, subject to earlier release of all or a portion of the shares subject to such agreements by J.P. Morgan Securities LLC, Jefferies LLC and Evercore Group L.L.C. in their sole discretion. After the lock-up agreements expire, based upon the number of shares of common stock, on an as-converted basis, outstanding as of , up to an additional shares of common stock will be eligible for sale in the public market. Approximately % of these additional shares are held by directors, executive officers and other affiliates and will be subject to certain limitations of Rule 144 under the Securities Act of 1933, as amended, or the Securities Act.

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

The initial public offering price is substantially higher than the pro forma as adjusted net tangible book value per share of our common stock as of March 31, 2019 after giving effect to this offering. Accordingly, investors purchasing common stock in this offering will pay a price per share that substantially exceeds the book value of our tangible assets after subtracting our liabilities. As a result, investors purchasing common stock in this offering will incur immediate dilution of $ per share, based on an assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Further, investors purchasing common stock in this offering will contribute approximately % of the total amount invested by stockholders since our inception, but will own only approximately % of the shares of common stock outstanding after this offering.

As of March 31, 2019, options to purchase 7,115,964 shares of our common stock at a weighted average exercise price of $0.58 per share were outstanding. The exercise of any of these options would result in additional 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 a liquidation.

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.

Upon completion of this offering, we will become subject to the periodic reporting requirements of the Exchange Act. 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, which are to become effective at or prior to the completion of this offering, 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 stockholders may only be called only by the chairman of the board of directors, the chief executive officer, or by a majority of the total number of authorized directors;
- 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 two-thirds ($^2/_3$) of all outstanding shares of our voting stock to amend any bylaws by stockholder action or 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 to be effective upon the effectiveness of this registration statement designate 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 will become effective prior to completion of this offering 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 arising out of or pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our second amended and restated bylaws or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein. This exclusive forum provision will not apply to any causes of action arising under the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. In addition, our second amended and restated bylaws will provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions. Additionally, the forum selection clause in our second amended and restated bylaws may limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

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

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

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

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

Special note regarding forward-looking statements

This prospectus contains forward-looking statements that are based on management's beliefs and assumptions and on information currently available to management. Some of the statements in the section captioned "Prospectus summary," "Risk factors," "Management's discussion and analysis of financial condition and results of operations," "Business" and elsewhere in this prospectus contain forward-looking statements. In some cases, you can identify forward-looking statements by the following words: "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words.

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. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. Forward-looking statements in this prospectus include, but are not limited to, statements about:

- the success, cost and timing of our product development activities and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs;
- our ability to advance any product candidate into or successfully complete any clinical trial;
- our ability or the potential to successfully manufacture our product candidates for clinical trials or for commercial use, if approved;
- the potential for our identified research priorities to advance our technologies;
- our ability to obtain and maintain regulatory approval, if obtained, of AKR-001 or any future product candidates, and any related restrictions, limitations and/or warnings in the label of an approved product candidate;
- the ability to license additional intellectual property relating to any future product candidates and to comply with our existing license agreements;
- 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.

In addition, you should refer to the "Risk factors" section of this prospectus for a discussion of other important factors that may cause actual results to differ materially from those expressed or implied by the forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this prospectus will prove to be accurate. Furthermore, if the forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. The forward-looking statements in this prospectus represent our views as of the date of this prospectus. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this prospectus. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

The market data and certain other statistical information used throughout this prospectus are based on independent industry publications, governmental publications, reports by market research firms or other independent sources that we believe to be reliable sources. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We are responsible for all of the disclosure contained in this prospectus, and we believe these industry publications and third-party research, surveys and studies are reliable. While we are not aware of any misstatements regarding any third-party information presented in this prospectus, their estimates, in particular, as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties, and are subject to change based on various factors, including those discussed under the section entitled "Risk factors" and elsewhere in this prospectus. Some data are also based on our good faith estimates.

Market, industry, and other data

This prospectus contains estimates, projections and other information concerning our industry, our business and the markets for our products, including data regarding the estimated size of those markets, their projected growth rates, the perceptions and preferences of patients and physicians regarding certain therapies and other patient data and reimbursement data, as well as market research, estimates and forecasts prepared by our management. We obtained the industry, market and other data throughout this prospectus from our own internal estimates and research, as well as from publicly available information, industry publications and research, surveys and studies conducted by third-parties, including governmental agencies.

Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information based on various factors, including those discussed in "Risk factors."

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Pursuant to 17 C.F.R. Section 200.83

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 upon an assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us from this offering by approximately $, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase (decrease) of 1,000,000 shares in the number of shares offered by us would increase (decrease) the net proceeds to us from this offering by approximately $, assuming that the assumed initial public offering price remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We do not expect that a change in the initial public offering price or the number of shares by these amounts would have a material effect on our uses of the proceeds from this offering, although it may accelerate the time at which we will need to seek additional capital.

We currently expect to use the net proceeds from this offering, together with our existing cash and cash equivalents as of March 31, 2019, as follows:

- approximately $ to complete our contemplated Phase 2a clinical trial and subsequent Phase 2b clinical trial of our lead product candidate, AKR-001, in patients with NASH;
- approximately $ for new AKR-001 drug substance and drug product manufactured by third parties;
- approximately $ 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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Capitalization

The following table sets forth our cash and cash equivalents and our capitalization as of March 31, 2019:

- on an actual basis;
- on a pro forma basis to give effect to the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 64,730,410 shares of common stock prior to the completion of this offering and the filing and effectiveness of our fourth amended and restated certificate of incorporation prior to the completion of this offering;
- on a pro forma as adjusted basis to give further effect to the issuance and sale of shares of common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma as adjusted information below is illustrative only, and our capitalization following the completion of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read the information in this table together with our consolidated financial statements and the related notes appearing elsewhere in this prospectus and the "Selected consolidated financial data" and "Management's discussion and analysis of financial condition and results of operations" sections of this prospectus.

	As of March 31, 2019		
(in thousands, except share and per share amounts)	**Actual**	**Pro forma**	**Pro forma as adjusted(1)**
Cash and cash equivalents	$ 69,796	$ 69,796	$
Redeemable convertible preferred stock (Series A and B), $0.0001 par value; 64,730,410 shares authorized, issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	124,728	—	
Stockholders' (deficit) equity:			
Preferred stock, $0.0001 par value; no shares authorized, issued or outstanding, actual; shares authorized and no shares issued or outstanding, pro forma and pro forma as adjusted	—		
Common stock, $0.0001 par value; 75,000,000 shares authorized, 734,694 shares issued and outstanding, actual; shares authorized, 65,465,104 shares issued and outstanding, pro forma; shares authorized, shares issued and outstanding, pro forma as adjusted	—	7	
Additional paid-in capital	36,861	161,582	
Accumulated deficit	(91,927)	(91,927)	
Total stockholders' (deficit) equity	(55,066)	69,662	
Total capitalization	$ 69,662	$ 69,662	$

(1) Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, total stockholders' (deficit) equity and total capitalization by $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase (decrease) of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, total stockholders' (deficit) equity and total capitalization by $ million, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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The number of shares of our common stock issued and outstanding actual, pro forma and pro forma as adjusted in the table above is based on 65,465,104 shares of our common stock outstanding as of March 31, 2019, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 64,730,410 shares of our common stock immediately prior to the completion of this offering, and excludes:

- 7,115,964 shares of common stock issuable upon the exercise of stock options outstanding as of March 31, 2019 under our 2018 Stock Option and Grant Plan, or the 2018 Plan, at a weighted-average exercise price of $0.58 per share (which excludes options to purchase an aggregate of 1,958,258 shares of common stock, at an exercise price of $2.28 per share, that were granted subsequent to March 31, 2019);

- 2,289,102 shares of common stock reserved for future issuance as of March 31, 2019 under the 2018 Plan, which will cease to be available for issuance at the time that our 2019 Stock Option and Grant Plan, or the 2019 Plan, becomes effective (which includes 1,958,258 shares of common stock subject to options granted subsequent to March 31, 2019);

- shares of our common stock that will become available for future issuance under the 2019 Plan in connection with the effectiveness of the registration statement of which this prospectus is a part; and

- shares of our common stock reserved for future issuance under our 2019 Employee Stock Purchase Plan which will become effective in connection with this offering.

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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 initial 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.

Our historical net tangible book value (deficit) as of March 31, 2019 was $(56.4) million, or $(76.76) per share of our common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets less our total liabilities and the carrying values of our convertible preferred stock, which is not included within stockholders' (deficit) equity. Our historical net tangible book value (deficit) per share represents historical net tangible book value (deficit) divided by the 734,694 shares of our common stock outstanding as March 31, 2019.

Our pro forma net tangible book value as of March 31, 2019 would have been $68.3 million, or $1.04 per share of our common stock. Pro forma net tangible book value represents the amount of our total tangible assets less our total liabilities, after giving effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 64,730,410 shares of common stock prior to the completion of this offering and (ii) the filing and effectiveness of our fourth amended and restated certificate of incorporation and second amended and restated bylaws prior to the completion of this offering. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares outstanding as of March 31, 2019, after giving effect to the pro forma adjustments described above.

After giving further effect to our issuance and sale of shares of our common stock in this offering at an assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of March 31, 2019 would have been $ million, or $ per share. This amount represents an immediate increase in pro forma as adjusted net tangible book value per share of $ to our existing stockholders and immediate dilution of $ in pro forma as adjusted net tangible book value per share to new investors purchasing common stock in this offering.

Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis (without giving effect to any exercise by the underwriters of their option to purchase additional shares):

Assumed initial public offering price per share		$
Historical net tangible book value (deficit) per share as of March 31, 2019	$ (76.76)	
Increase per share attributable to the pro forma adjustments described above	77.80	
Pro forma increase in historical net tangible book value per share as of March 31, 2019 attributable to the conversion of convertible preferred stock	1.04	
Increase in pro forma net tangible book value per share attributable to new investors participating in this offering		
Pro forma as adjusted net tangible book value per share after this offering		
Dilution per share to new investors purchasing common stock in this offering		$

Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) our

pro forma as adjusted net tangible book value per share after this offering by $ and dilution per share to new investors purchasing common stock in this offering by $, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase our pro forma as adjusted net tangible book value per share after this offering by $ and decrease dilution per share to new investors purchasing common stock in this offering by $, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. A decrease of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would decrease our pro forma as adjusted net tangible book value per share after this offering by $ and increase dilution per share to new investors purchasing common stock in this offering by $, assuming no change in the assumed initial public offering price and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise their option to purchase additional shares in full, our pro forma as adjusted net tangible book value per share after this offering would be $, representing an immediate increase in pro forma as adjusted net tangible book value per share of $ to existing stockholders and immediate dilution in pro forma as adjusted net tangible book value per share of $ to new investors purchasing common stock in this offering, based on the assumed initial public offering price of $ per share and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The following table summarizes on the pro forma as adjusted basis described above, the total number of shares of common stock purchased from us on an as converted to common stock basis, 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 an assumed initial public offering price of $ per share, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. As the table shows, new investors purchasing common stock in this offering will pay an average price per share substantially higher than our existing stockholders paid.

	Shares purchased		Total consideration		Average price per share
	Number	Percentage	Amount	Percentage	
Existing stockholders	65,465,104	%	$ 90,499,986	%	$ 1.38
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 65,465,104 shares of our common stock outstanding as of March 31, 2019, after giving effect to the

automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 64,730,410 shares of our common stock immediately prior to the completion of this offering, and excludes:

- 7,115,964 shares of common stock issuable upon the exercise of stock options outstanding as of March 31, 2019 under our 2018 Stock Option and Grant Plan, or the 2018 Plan, at a weighted-average exercise price of $0.58 per share (which excludes options to purchase an aggregate of 1,958,258 shares of common stock, at an exercise price of $2.28 per share, that were granted subsequent to March 31, 2019);

- 2,289,102 shares of common stock reserved for future issuance as of March 31, 2019 under the 2018 Plan, which will cease to be available for issuance at the time that our 2019 Stock Option and Grant Plan, or the 2019 Plan, becomes effective (which includes 1,958,258 shares of common stock subject to options granted subsequent to March 31, 2019);

- shares of our common stock that will become available for future issuance under the 2019 Plan in connection with the effectiveness of the registration statement of which this prospectus is a part; and

- shares of our common stock reserved for future issuance under our 2019 Employee Stock Purchase Plan which will become effective in connection with this offering.

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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Pursuant to 17 C.F.R. Section 200.83

Selected consolidated financial data

You should read the following selected consolidated financial data together with our consolidated financial statements and the related notes appearing elsewhere in this prospectus and the "Management's discussion and analysis of financial condition and results of operations" section of this prospectus. We have derived the consolidated statement of operations data for the period January 24, 2017 (inception) through December 31, 2017 and the year ended December 31, 2018 and the consolidated balance sheet data as of December 31, 2017 and 2018 from our audited consolidated financial statements appearing elsewhere in this prospectus. We have derived the consolidated statement of operations data for the three months ended March 31, 2018 and 2019 and the consolidated balance sheet data as of March 31, 2019 from our unaudited condensed consolidated financial statements appearing elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that should be expected in any future periods, and our results for any interim period are not necessarily indicative of results that should be expected for any full year.

(in thousands, except share and per share amounts)	For the period January 24, 2017 (inception) through December 31, 2017	Year ended December 31, 2018	Three months ended March 31, 2018	Three months ended March 31, 2019
Consolidated Statement of Operation Data:				
Operating expenses:				
Research and development	$ 3,486	$ 11,882	$ 226	$ 4,063
General and administrative	1,078	1,896	195	1,449
Total operating expenses	4,564	13,778	421	5,512
Loss from operations	(4,564)	(13,778)	(421)	(5,512)
Other income (expense), net:				
Change in fair value of preferred stock tranche obligation	—	(62,150)	—	—
Change in fair value of anti-dilution right liability	—	(5,765)	—	—
Other income (expense), net		(21)	—	150
Total other income (expense)	—	(67,936)	—	150
Net loss	(4,564)	(81,714)	(421)	(5,362)
Accruing dividends on convertible preferred stock	(213)	—	—	—
Accretion of convertible preferred stock to redemption value	—	(520)	—	—
Net loss attributable to common stockholders	$ (4,777)	$ (82,234)	$ (421)	$ (5,362)
Net loss per share attributable to common stockholders—basic and diluted(1)		$ (258.68)	$ (3.39)	$ (10.38)
Weighted average common shares outstanding—basic and diluted(1)		317,894	124,163	516,711
Pro forma net loss per share attributable to common stockholders—basic and diluted (unaudited)(1)		$ (1.01)		$ (0.08)
Pro forma weighted average common shares outstanding—basic and diluted (unaudited)(1)		19,295,870		65,247,121

(1) See Note 10 to our audited consolidated financial statements and Note 9 to our unaudited interim condensed consolidated financial statements appearing elsewhere in this prospectus for details on the calculation of basic and diluted net loss per share attributable to common stockholders and the calculation of basic and diluted pro forma net loss per share attributable to common stockholders.

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(in thousands)	2017	As of December 31, 2018	As of March 31, 2019
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$ 598	$ 75,975	$ 69,796
Working capital(1)	416	74,789	68,295
Total assets	658	77,151	72,066
Convertible preferred stock	5,000	124,728	124,728
Total stockholders' deficit	(4,564)	(49,919)	(55,066)

(1) We define working capital as current assets less current liabilities.

Management's discussion and analysis of financial condition and results of operations

You should read the following discussion and analysis of our financial condition and results of operations together with the "Selected consolidated financial data" section of this prospectus and our consolidated financial statements and the related notes appearing elsewhere in this prospectus. This discussion and other parts of this prospectus contain forward-looking statements that involve risks and uncertainties, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the "Risk factors" section of this prospectus.

Overview

We are a clinical-stage biotechnology company focused on developing and commercializing transformative treatments for serious metabolic diseases with high unmet medical need. Our initial focus is nonalcoholic steatohepatitis, or NASH, a disease without any approved therapies. 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. NASH is a leading cause for liver transplantation. Our lead product candidate, AKR-001, which we are developing as a potential treatment for patients with NASH, is an analog of fibroblast growth factor 21, or FGF21. FGF21 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. FGF21 analogs have shown evidence of therapeutic benefit in clinical trials of patients with NASH, many of whom are dyslipidemic and insulin resistant. In previous clinical trials in patients with type 2 diabetes, or T2D, administration of AKR-001 was associated with substantial improvements in lipid metabolism and insulin sensitivity. We believe these data demonstrate AKR-001's potential to serve as a cornerstone for the treatment of NASH. On April 24, 2019, we submitted to the U.S. Food and Drug Administration, or FDA, Division of Gastroenterology and Inborn Errors Products an Investigational New Drug, or IND, application to permit patients with NASH to be treated with AKR-001. We plan to initiate a Phase 2a clinical trial for AKR-001 in NASH patients with fibrosis in the middle of 2019.

We were incorporated in January 2017 and received initial seed funding in the amount of $5.0 million from Apple Tree Partners. Since our inception, we have devoted substantially all of our efforts to organizing and staffing our company, business planning, raising capital, in-licensing rights to AKR-001, research and development activities for AKR-001, building our intellectual property portfolio and providing general and administrative support for these operations. To date, we have principally raised capital through the issuance of convertible preferred stock. Through March 31, 2019, we had received gross proceeds of $90.5 million from sales of our convertible preferred stock.

We have incurred significant operating losses since inception. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of AKR-001 and any future product candidates. Our net losses were $4.6 million and $81.7 million for the period January 24, 2017 (inception) through December 31, 2017 and the year ended December 31, 2018, respectively, and $5.4 million for the three months ended March 31, 2019. The net loss for the year ended December 31, 2018 included non-cash charges of $62.2 million related to the change in fair value of our preferred stock tranche obligation and $5.8 million related to the change in fair value of our anti-dilution right liability. As of March 31, 2019, we had an accumulated deficit of $91.9 million. We

expect to continue to incur significant expenses for at least the next several years as we advance AKR-001 through later-stage clinical development, develop additional product candidates and seek regulatory approval of any product candidates that complete clinical development. In addition, if we obtain marketing approval for any product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. We may also incur expenses in connection with the in-licensing or acquisition of additional product candidates. Furthermore, upon the completion of this offering, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations, compliance and other expenses that we did not incur as a private company.

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

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

As of March 31, 2019, we had cash and cash equivalents of $69.8 million. We believe that the anticipated net proceeds from this offering, together with our existing cash and cash equivalents as of March 31, 2019, will enable us to fund our operating expenses and capital expenditure requirements through . We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See "Liquidity and capital resources."

Components of our results of operations

Revenue

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

Operating expenses

Research and development expenses

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

- employee-related expenses, including salaries, related benefits and stock-based compensation expense, for employees engaged in research and development functions;

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

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

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

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

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

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

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

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

General and administrative expenses

General and administrative expenses consist primarily of salaries and related costs for personnel in executive, finance, corporate and business development, and administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters; professional fees for accounting, auditing, tax and administrative consulting services; insurance costs; administrative travel expenses; marketing expenses and other operating costs.

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

Other expense

Change in fair value of preferred stock tranche obligation

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

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

Change in fair value of anti-dilution right

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

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

Income taxes

Since our inception, we have not recorded any income tax benefits for the net losses we have incurred in each period or for our earned research and development tax credits, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our net operating loss carryforwards and tax credits will not be realized. As of December 31, 2018, we had U.S. federal and state net operating loss carryforwards of $10.6 million and $10.6 million, respectively, which may be available to offset future income tax liabilities and expire at various dates beginning in 2037. The federal net operating loss carryforward includes $6.1 million that has a indefinite carryforward period. As of December 31, 2018, we also had U.S. federal and state research and development tax credit carryforwards of $0.2 million and $0.1 million, respectively, which may be available to offset future tax liabilities which expire at various dates beginning in 2032. We have recorded a full valuation allowance against our net deferred tax assets at each balance sheet date.

During 2017, we recorded tax charges to reflect the impact of the Tax Cuts and Jobs Act, or the Tax Act, using the current available information and technical guidance on the interpretations of the Tax Act. As permitted by SEC Staff Accounting Bulletin 118, *Income Tax Accounting Implications of the Tax Cuts and Jobs Act*, we recorded provisional estimates and have subsequently finalized our accounting analysis based on the guidance, interpretations, and data available as of December 31, 2018 with no material changes to our initial estimates.

Results of operations

Comparison of three months ended March 31, 2018 and 2019

The following table summarizes our results of operations for the three months ended March 31, 2018 and 2019:

	Three months ended March 31,	
(in thousands)	**2018**	**2019**
Operating expenses:		
Research and development	$ 226	$ 4,063
General and administrative	195	1,449
Total operating expenses	421	5,512
Loss from operations	(421)	(5,512)
Other income:		
Other income, net	—	150
Total other income	—	150
Net loss	$ (421)	$ (5,362)

Research and development expenses

(in thousands)	Three months ended March 31, 2018	2019	Change
Direct program expenses: AKR-001	$ 78	$ 3,538	$ 3,460
Personnel related	148	525	377
Total research and development expenses	$ 226	$ 4,063	$ 3,837

Research and development expenses were $0.2 million for the three months ended March 31, 2018, compared to $4.1 million for the three months ended March 31, 2019. The increase of $3.8 million was primarily due to a $3.5 million increase in direct costs related to our AKR-001 program and an increase of $0.4 million in personnel-related costs. Both increases were primarily a result of increased program activity in 2019 versus limited activities in the three months ended March 31, 2018 when we were in our formative stage. Specifically, the increase in direct costs related to our AKR-001 program was primarily due to increased costs incurred in connection with our external CROs, as well as clinical manufacturing costs, and the increase in personnel costs were a result of hiring additional personnel in our research and development department.

General and administrative expenses

(in thousands)	Three months ended March 31, 2018	2019	Change
Personnel related	$ 154	$ 783	$ 629
Legal and professional fees	39	552	513
Other	2	114	112
Total general and administrative expenses	$ 195	$ 1,449	$ 1,254

General and administrative expenses were $0.2 million for the three months ended March 31, 2018 compared to $1.5 million for the three months ended March 31, 2019. The increase in personnel related costs of $0.6 million was primarily due to hiring of additional personnel in our general and administrative functions. The increases in legal and professional fees and other expenses of $0.6 million were primarily due to $0.2 million increase in legal costs and a $0.4 million increase in accounting and tax fees during the three months ended March 31, 2019.

Other income

Other income was $0.2 million during the three months ended March 31, 2019. We did not record other income for the three months ended March 31, 2018. Other income in the three months ended March 31, 2019 was primarily related to interest income associated with our money market mutual fund investment account.

Comparison of the period January 24, 2017 (Inception) through December 31, 2017 and the year ended December 31, 2018

The following table summarizes our results of operations for the period January 24, 2017 (inception) through December 31, 2017 and the year ended December 31, 2018:

(in thousands)	For the period January 24, 2017 (inception) through December 31, 2017	Year ended December 31, 2018
Operating expenses:		
Research and development	$ 3,486	$ 11,882
General and administrative	1,078	1,896
Total operating expenses	4,564	13,778
Loss from operations	(4,564)	(13,778)
Other expense, net:		
Change in fair value of preferred stock tranche obligation	—	(62,150)
Change in fair value of anti-dilution right liability	—	(5,765)
Other expense, net	—	(21)
Total other expense	—	(67,936)
Net loss	$ (4,564)	$ (81,714)

Research and development expenses

(in thousands)	For the period January 24, 2017 (inception) through December 31, 2017	Year ended December 31, 2018	Change
Direct program expenses: AKR-001	$ 241	$ 10,894	$ 10,653
Personnel related	951	988	37
Discovery programs	2,294	—	(2,294)
Total research and development expenses	$ 3,486	$ 11,882	$ 8,396

Research and development expenses were $3.5 million for the period ended December 31, 2017, compared to $11.9 million for the year ended December 31, 2018. The increase of $8.4 million was primarily due to a $10.7 million increase in direct costs related to our AKR-001 program, partially offset by a $2.3 million decrease in costs related to our discovery programs. The increase in direct costs related to our AKR-001 program was primarily due to $8.0 million in expenses in connection with the Amgen Agreement. Pursuant to the agreement, we paid Amgen Inc., or Amgen, an upfront cash payment of $5.0 million and issued shares of Series A preferred stock to Amgen with a fair value of $1.4 million. Additionally, we recorded an expense of $1.6 million associated with our obligation to issue equity securities to Amgen in accordance with anti-dilution rights provided in the Amgen license agreement. The remaining increase in direct costs related to our AKR-001 program was primarily due to costs incurred with external CROs as well as toxicology, regulatory, and chemistry, manufacturing and controls, or CMC. The decrease in discovery programs of $2.3 million was primarily due to consulting fees associated with our prior discovery programs that were incurred in the period ended December 31, 2017 that were not repeated in the year ended December 31, 2018.

General and administrative expenses

(in thousands)	For the period January 24, 2017 (inception) through December 31, 2017	Year ended December 31, 2018	Change
Personnel related	$ 491	$ 1,076	$ 585
Legal and professional fees	276	707	431
Consulting fees	267	—	(267)
Other	44	113	69
Total general and administrative expenses	$ 1,078	$ 1,896	$ 818

General and administrative expenses were $1.1 million for the period ended December 31, 2017 compared to $1.9 million for the year ended December 31, 2018. The increase in personnel related costs of $0.6 million was primarily due to hiring of additional personnel in our general and administrative functions. The increases in legal and professional fees and other expenses of $0.5 million were primarily due to $0.3 million increase in legal costs associated with our financing activities and a $0.2 million increase in accounting and tax fees in the year ended December 31, 2018. These increases were partially offset by a decrease in consulting fees of $0.3 million as a result of costs incurred in the period ending December 31, 2017 associated with Apple Tree Partners for general and administrative activities during the Company's formation that were not repeated in the year ended December 31, 2018.

Other expense

Other expense was $67.9 million during the year ended December 31, 2018. We did not record other expense for the period ended December 31, 2017. The increase is primarily due to $62.2 million and $5.8 million in losses related to the changes in fair value of the preferred stock tranche obligation and the fair value of the anti-dilution right liability, respectively.

Liquidity and capital resources

Since our inception, we have incurred significant operating losses. We have not yet commercialized any products and we do not expect to generate revenue from sales of products for several years, if at all. To date, we have funded our operations primarily with proceeds from the sale of our convertible preferred stock. Through March 31, 2019, we had received gross proceeds of $90.5 million from sales of our convertible preferred stock. As of March 31, 2019, we had cash and cash equivalents of $69.8 million.

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Cash flows

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

(in thousands)	For the period January 24, 2017 (inception) through December 31, 2017	Year ended December 31, 2018	Three months ended March 31, 2018	Three months ended March 31, 2019
Net cash used in operating activities	$ (4,382)	$ (4,625)	$ (338)	$ (5,444)
Net cash used in investing activities	—	(5,000)	—	—
Net cash provided by (used in) financing activities	5,000	85,007	—	(720)
Net increase in cash and cash equivalents and restricted cash	$ 618	$ 75,382	$ (338)	$ (6,164)

Operating activities

During the three months ended March 31, 2019, operating activities used $5.4 million of cash, resulting from our net loss of $5.4 million.

During the three months ended March 31, 2018, operating activities used $0.3 million of cash, resulting primarily from our net loss of $0.4 million.

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

During the period January 24, 2017 (inception) through December 31, 2017, operating activities used $4.4 million of cash, resulting from our net loss of $4.6 million, partially offset by changes in operating assets and liabilities of $0.2 million. Net cash provided by changes in our operating assets and liabilities primarily consisted of a $0.2 million increase in accrued expenses due to accrued compensation and accounting and tax fees.

Investing activities

There were no cash flows from investing activities during the three months ended March 31, 2018 and 2019.

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

We did not have any investing activities during the period from January 24, 2017 (inception) through December 31, 2017.

Financing activities

During the three months ended March 31, 2019, net cash used in financing activities was $0.7 million, which consisted of payments of legal and professional fees incurred in connection with our planned initial public offering.

There were no cash flows from financing activities during the three months ended March 31, 2018.

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

During the period January 24, 2017 (inception) through December 31, 2017, cash provided by financing activities was $5.0 million, consisting of proceeds from our issuance of Series A preferred stock.

Funding requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the later-stage clinical development of our product candidate. In addition, upon the completion of this offering, we expect to incur additional costs associated with operating as a public company. The timing and amount of our operating expenditures will depend largely on:

- the initiation, progress, timing, costs and results of nonclinical studies and clinical trials for our product candidate or any future product candidates we may develop;
- our ability to maintain our license to AKR-001 from Amgen;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more nonclinical studies or clinical trials than those that we currently expect or change their requirements on studies 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.

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We believe that the anticipated net proceeds from this offering, together with our existing cash and cash equivalents as of March 31, 2019, will enable us to fund our operating expenses and capital expenditure requirements through . We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. We expect that we will require additional funding to complete the clinical development of AKR-001, commercialize AKR-001, if we receive regulatory approval, and pursue in-licenses or acquisitions of other product candidates. If we receive regulatory approval for AKR-001 or other product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize AKR-001 ourselves.

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

Contractual obligations and commitments

The following table summarizes our contractual obligations as of December 31, 2018 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods:

		Payments due by period			
(in thousands)	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Third-party contract research and manufacturing commitments(1)	$ 553	$ 553	$ —	$ —	$ —
Operating lease commitments(2)	26	26	—	—	—
Total	$ 579	$ 579	$ —	$ —	$ —

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

(2) Amounts in the table reflect minimum payments due under our two leases for office space in Cambridge, Massachusetts and San Francisco, California at a monthly commitment fee of $1,000 and $5,000, respectively. The leases are both operating leases. The lease in Cambridge expires in May 2019 after which the agreement becomes cancelable by either party upon a 60-day written notice. The lease in San Francisco expires in April 2019 with the option to renew on a month to month basis thereafter. In March 2019, we amended our lease agreement associated with our office space in San Francisco, California. The amendment extended the term of the lease to March 2021 and expanded the square footage of the existing leased office space. Minimum payments due under the amendment of $0.2 million due in less than one year and $0.3 million due in 1-3 years are excluded from the table above.

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

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

Under the Amgen Agreement, we are obligated to make aggregate milestone payments of up to $40.0 million upon the achievement of specified clinical and regulatory milestones and aggregate milestone payments of up to $75.0 million upon the achievement of specified commercial milestones for all products licensed under the agreement. Commencing on the first commercial sale of licensed products, we are obligated to pay tiered royalties on escalating tiers of annual net sales of licensed products ranging from low to high single-digit percentages. See "Business—Exclusive license agreement with Amgen Inc."

Critical accounting policies and significant judgments and estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles, or GAAP, in the United States. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

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

Accrued research and development expenses

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

adjustments, if necessary. Examples of estimated accrued research and development expenses include fees paid to:

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

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

Stock-based compensation

We measure stock-based awards granted to employees, directors, and nonemployees based on their fair value on the date of the grant and recognize compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. For stock-based awards with service-based vesting conditions, we recognize compensation expense using the straight-line method. For stock-based awards with service-based vesting conditions, we recognize compensation expense using the graded-vesting method over the requisite service period, commencing when achievement of the performance condition becomes probable. The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model, which requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the option, the risk-free interest rate for a period that approximates the expected term of the option, and our expected dividend yield. The fair value of each restricted common stock award is estimated on the date of grant based on the fair value of our common stock on that same date.

Determination of the fair value of common stock

As there has been no public market for our common stock to date, the estimated fair value of our common stock has been determined by our board of directors as of the date of each option grant with input from management, considering our most recently available third-party valuations of common stock, and our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. Our common stock valuation was prepared using the option-pricing method, or OPM, which used a market approach to estimate our enterprise value. The third-party valuation resulted in a valuation of our common stock of $0.15 per share as of June 7, 2018, $0.38 as of September 8, 2018, $2.07 as of December 11, 2018 and $2.28 as of February 1, 2019.

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The assumptions underlying these valuations were highly complex and subjective and represented management's best estimates, which involved inherent uncertainties and the application of management's judgment. As a result, if we had used significantly different assumptions or estimates, the fair value of our common stock and our stock-based compensation expense could be materially different.

Once a public trading market for our common stock has been established in connection with the completion of this offering, it will no longer be necessary for our board of directors to estimate the fair value of our common stock in connection with our accounting for granted stock options and other such awards we may grant, as the fair value of our common stock will be determined based on the quoted market price of our common stock.

Options granted

The following table sets forth by grant date the number of shares subject to options granted between January 24, 2017 and March 31, 2019, the per share exercise price of the options, the fair value of common stock per share on each grant date, and the per share estimated fair value of the options:

Grant date	Number of shares subject options granted	Per share exercise price of options	Fair value per common share on grant date	Per share estimated fair value of options
July 30, 2018	875,598	$ 0.20	$ 0.15(1)	$ 0.09
September 8, 2018	1,341,666	$ 0.20	$ 0.38(1)	$ 0.29
September 8, 2018	60,000	$ 0.20	$ 0.38(1)	$ 0.28
September 27, 2018	331,666	$ 0.20	$ 0.38(1)	$ 0.29
October 18, 2018	3,179,979	$ 0.20	$ 0.38(1)	$ 0.29
January 16, 2019	587,419	$ 2.07	$ 2.07	$ 1.28
January 16, 2019	867,302	$ 2.07	$ 2.07	$ 1.29
January 16, 2019	5,000	$ 2.07	$ 2.07	$ 1.27

(1) For options granted on July 30, 2018 through October 18, 2018, our board of directors initially determined that the fair value of our common stock was $0.20 per share as of each respective grant date. However, as described below, the fair value of our common stock at the date of these grants was adjusted in connection with retrospective fair value assessments for accounting purposes.

In the course of preparing for this offering, in June 2018 and September 2018, we performed retrospective fair value assessments for accounting purposes. We applied the fair values of our common stock from our retrospective fair value assessments to determine the fair value of these awards and calculate stock-based compensation expense for accounting purposes. These reassessed values were based, in part, upon third-party valuations of our common stock prepared as of each grant date on a retrospective basis. The third-party valuations were prepared using the hybrid method and used market approaches to determine our enterprise value.

Valuation of preferred stock tranche obligation

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

comprehensive loss. Changes in the fair value of the preferred stock tranche obligation were recognized until the tranche obligations were fulfilled or otherwise extinguished in the fourth quarter of 2018.

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

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

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

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

Valuation of anti-dilution right

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

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

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

Emerging growth company status

Under Section 107(b) of the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, an "emerging growth company" can delay the adoption of new or revised accounting standards until such time as those standards would apply to private companies. We have elected this exemption to delay adopting new or revised accounting standards until such time as those standards apply to private companies. Where allowable we have early adopted certain standards as described in Note 2 of our consolidated financial statements. There are other exemptions and reduced reporting requirements provided by the JOBS Act that we are currently evaluating. For example, as an "emerging growth company," we are exempt from Sections 14A(a) and (b) of the Exchange Act which would otherwise require us to (1) submit certain executive compensation matters to shareholder advisory votes, such as "say-on-pay," "say-on-frequency," and "golden parachutes;" and (2) disclose certain executive compensation related items such as the correlation between executive compensation and performance and comparisons of our chief executive officer's compensation to our median employee compensation. We also intend to rely on an exemption from the rule requiring us to provide an auditor's attestation report on our internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act. We will continue to remain an "emerging growth company" until the earliest of the following: (1) the last day of the fiscal year following the fifth anniversary of the date of the completion of this offering; (2) the last day of the fiscal year in which our total annual gross revenue is equal to or more than $1.07 billion; (3) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (4) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

Off-balance sheet arrangements

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

Recently issued accounting pronouncements

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

Quantitative and qualitative disclosures about market risks

Our primary exposure to market risk relates to changes in interest rates. As of December 31, 2017 and 2018, we had cash of $0.6 million and $76.0 million, respectively. As of March 31, 2019, we had cash and cash equivalents of $69.8 million. As of December 31, 2017 and 2018 and March 31, 2019, we had no debt

outstanding and are therefore not exposed to interest rate risk with respect to debt. Our exposure to interest rate sensitivity is affected by changes in the general level of U.S. interest rates. If market interest rates were to increase immediately and uniformly by 100 basis points, or one percentage point, from levels at December 31, 2017 and 2018 and March 31, 2019, the net fair value of our interest sensitive marketable securities would not experience a material change in fair market value.

All of our employees and our operations are currently located in the United States. We have, from time to time, engaged in contracts with contractors or other vendors in a currency other than the U.S. dollar. To date, we have had minimal exposure to fluctuations in foreign currency exchange rates as the time period between the date that transactions are initiated, and the date of payment or receipt of payment is generally of short duration. Accordingly, we believe we do not have a material exposure to foreign currency risk.

Inflation generally affects us by increasing our cost of labor. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the period January 24, 2017 (inception) through December 31, 2017 or the year ended December 31, 2018 or the three months ended March 31, 2019.

Business

Overview

We are a clinical-stage biotechnology company focused on developing and commercializing transformative treatments for serious metabolic diseases with high unmet medical need. Our initial focus is on nonalcoholic steatohepatitis, or NASH, a disease without any approved therapies. 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. NASH is a leading cause for liver transplantation. Our lead product candidate, AKR-001, which we are developing as a potential treatment for patients with NASH, is an analog of fibroblast growth factor 21, or FGF21. FGF21 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. FGF21 analogs have shown evidence of therapeutic benefit in clinical trials of patients with NASH, many of whom are dyslipidemic and insulin resistant. In previous clinical trials in patients with type 2 diabetes, or T2D, administration of AKR-001 was associated with substantial improvements in lipid metabolism and insulin sensitivity. We believe these data demonstrate AKR-001's potential to serve as a cornerstone for the treatment of NASH. On April 24, 2019, we submitted to the U.S. Food and Drug Administration, or FDA, Division of Gastroenterology and Inborn Errors Products an Investigational New Drug, or IND, application to permit patients with NASH to be treated with AKR-001. We plan to initiate a Phase 2a clinical trial for AKR-001 in NASH patients with fibrosis in the middle of 2019.

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 once-weekly dosing, while retaining the native biological activity of FGF21.

AKR-001 has been 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. In these clinical trials, it was also observed that administration of AKR-001 was associated with

substantially improved markers of insulin sensitivity, including reductions of up to 37% in C-peptide and 55% in 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 and improvements in biomarkers of liver fibrosis were 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 March 31, 2019, our patent portfolio relating to AKR-001 and other peptides included 111 issued patents and 41 pending patents worldwide, with expected patent exclusivity up to 2034 in the United States, including potential patent term extension. Since AKR-001 is a biologic, marketing approval would also provide twelve years of market exclusivity from the approval date of a Biologics License Application, or BLA, in the United States.

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

Our strategy

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

- ***Advance AKR-001 through clinical development in NASH.*** We believe that AKR-001's differentiated profile as an FGF21 analog has the potential to result in a leading endocrine FGF analog, if approved, for the treatment of NASH. We submitted our IND application to the FDA on April 24, 2019, which included a Phase 2a clinical trial protocol. We plan to initiate a Phase 2a clinical trial in the middle of 2019, which will assess the efficacy and safety of AKR-001 in patients with NASH and inform dose selection for larger, longer-term trials. Consistent with recently-published draft guidance from the FDA on NASH development, we are committed to exploring ways to accelerate development of AKR-001 through innovative clinical trial designs.

- ***Scale our capabilities to support development and commercialization of AKR-001.*** We plan to scale our manufacturing and organizational capabilities to capitalize on our exclusive, global rights to market AKR-001 for all indications. We have contracted with a third-party manufacturer to support future clinical trials and the potential commercialization of AKR-001 with commercial-scale manufacturing. When appropriate, we intend to develop the commercial infrastructure required for bringing AKR-001 to

patients with NASH in the United States, if approved. We also plan to evaluate options for delivering AKR-001, if approved, to patients in other key markets, such as Europe, Japan and China, which may include strategic collaborations.

- ***Enhance our position as a leading metabolic disease company by leveraging our knowledge of FGF21 biology.*** Numerous publications have shown that increases in endogenous FGF21 expression occur in response to various types of metabolic and cellular stress arising from obesity, diabetes, mitochondrial diseases and cardiovascular disease, as well as NASH. AKR-001 has been engineered to reproduce the biological activity profile of native FGF21 while also addressing certain therapeutic limitations, such as a short half-life. We plan to explore opportunities to develop AKR-001 for additional indications where there is a compelling scientific rationale, strong clinical tractability and significant unmet medical need. Our strategy also includes evaluating the potential of novel oral therapeutic mechanisms to boost levels of endogenous FGF21, which may have utility in a broad population of NASH patients, including those with early-stage disease.

- ***Develop, acquire or in-license product candidates that enhance our potential to become a leading metabolic disease company.*** To supplement our own in-house research and development efforts, we are continually evaluating opportunities to build a robust pipeline of potential leading treatments for metabolic diseases. Our initial focus is on NASH, but we plan to evaluate programs outside of NASH that may provide compelling synergies with our development efforts. Additional NASH assets may be selected for their potential as stand-alone monotherapies or for eventual use in combination with other products.

NASH overview

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

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

Etiology of NASH

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

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

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

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

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

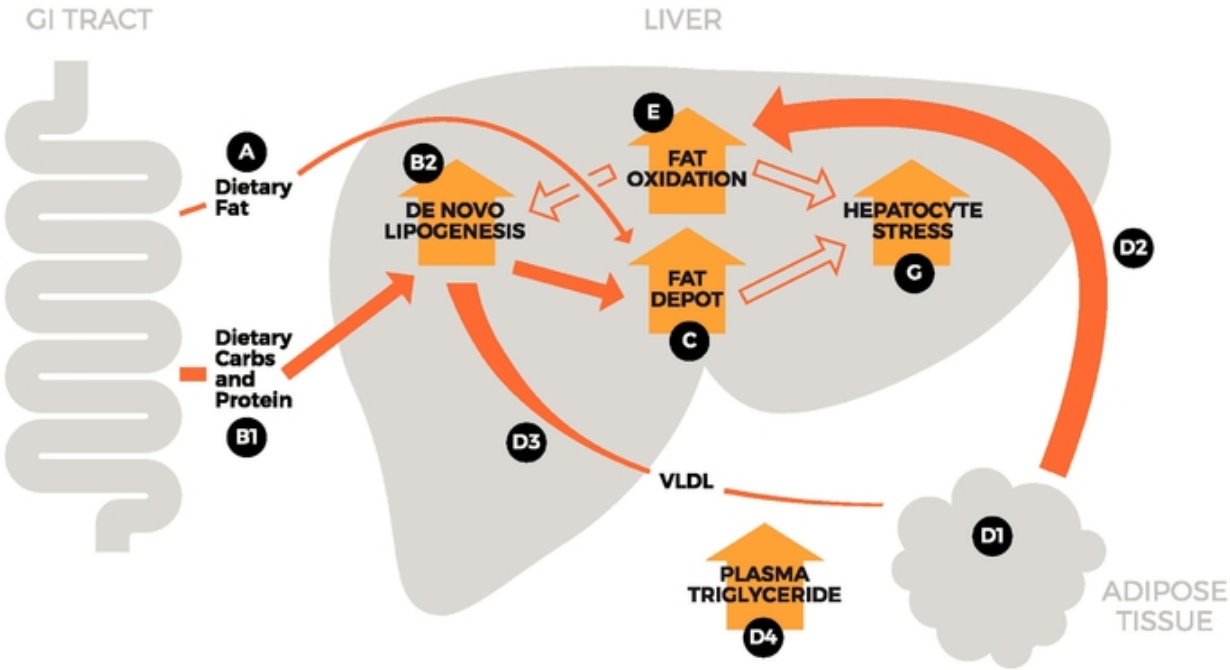
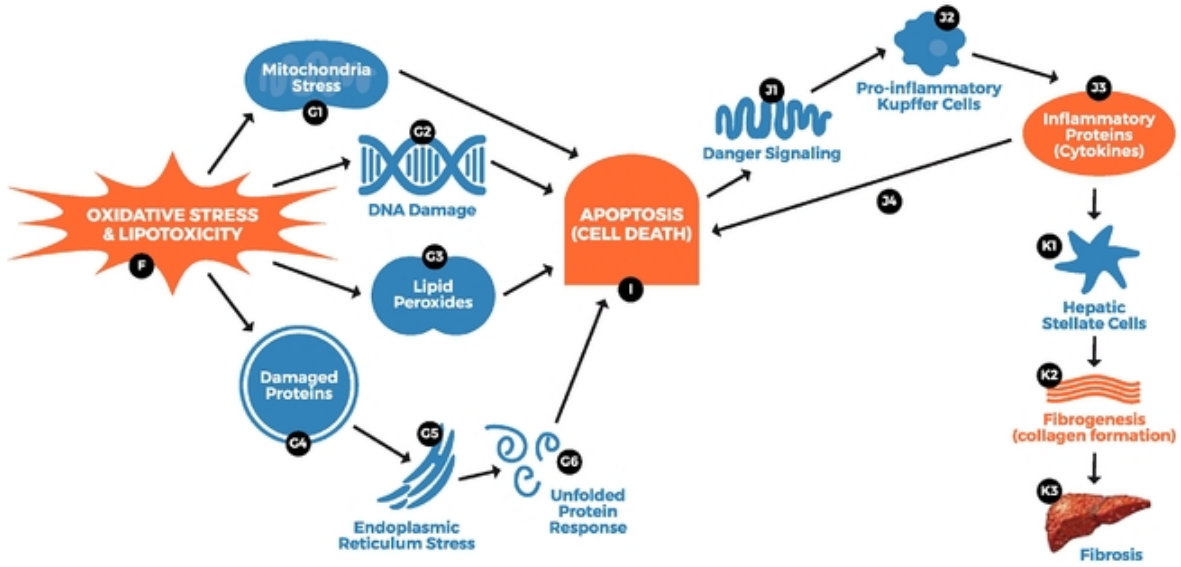


Figure 2—NASH pathogenesis: Oxidative stress and lipotoxicity induce hepatocyte death, local inflammation and fibrosis



Caloric overburdening of the liver

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

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

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

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

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

Hepatocyte stress, injury and death

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

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

Inflammatory response to hepatocyte stress and death

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

Fibrosis and cirrhosis

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

Disease diagnosis and disease burden

NASH is currently diagnosed only through liver biopsy and its severity is measured using scoring systems that assess the extent and severity of steatosis, lobular inflammation, hepatocellular ballooning and

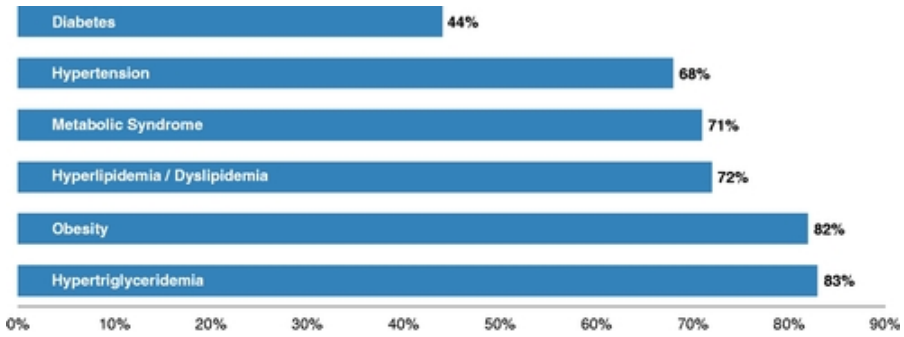
fibrosis. Some patients may be diagnosed with NASH after presenting with symptoms such as general fatigue and nondescript abdominal discomfort. However, NASH diagnosis more commonly follows detection of elevated liver enzymes on routine lab tests or detection of an enlarged steatotic liver by abdominal imaging. Although non-invasive methods, including a combination of imaging such as MRI-PDFF and plasma biomarkers of fibrosis, such as PRO-C3, are being evaluated as potential diagnostic tools, none have yet been validated for use in formal NASH diagnosis.

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

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

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

Figure 3—Prevalence of comorbidities among NASH patients



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

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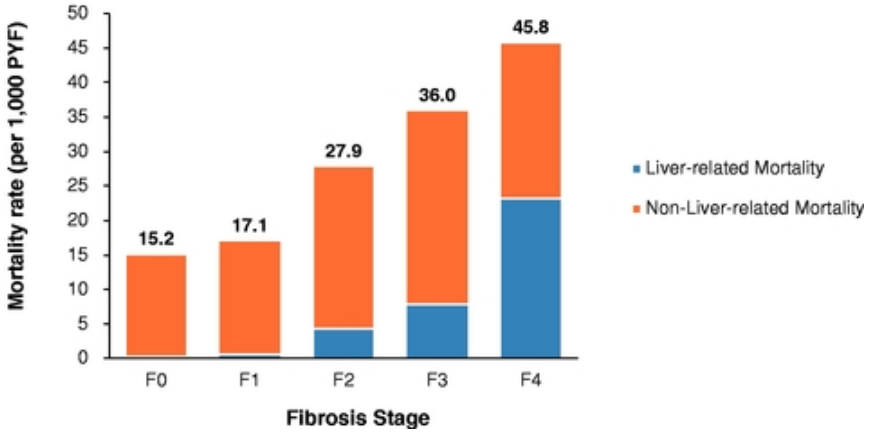
Figure 4—All-cause NASH mortality



Market size and trends

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

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

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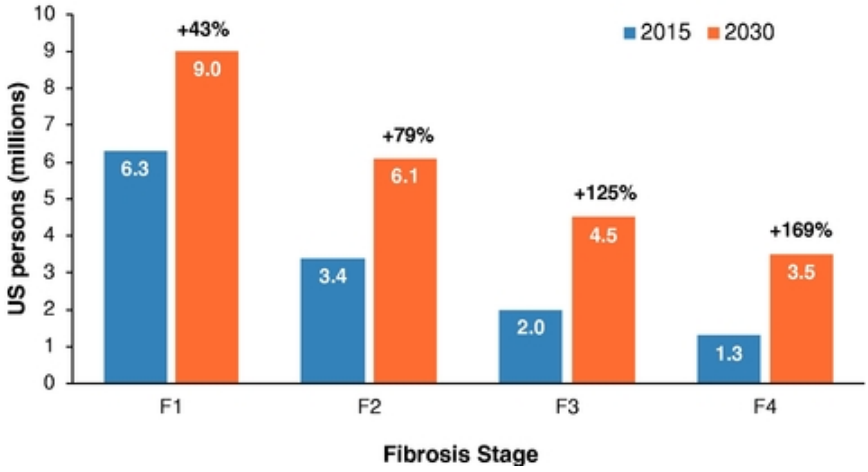
Figure 5—United States NASH prevalence by fibrosis stage



Emerging therapies in development

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

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

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

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

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

Figure 6—Selected NASH interventions under development

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

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

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

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

FGF21 is an endogenous hormone that has both local, or paracrine, effects on cells and systemic, or endocrine, effects on metabolic organs. FGF21's natural recruitment to alleviate many forms of cellular stress, and to regulate whole-body metabolism, make it a compelling therapeutic target. However, native FGF21 has several limitations that prevent it from being used effectively as a therapy, including a half-life estimated to be less than two hours, as found in published studies such as the *American Journal of Physiology, Endocrinology and Metabolism* (2009) and *Endocrinology* (2007). AKR-001 is a recombinantly-

engineered version of FGF21 designed to retain the native biological activity of FGF21 while enhancing its therapeutic utility. Specifically, AKR-001 features Fc-mediated half-life extension and substitution of specific amino acids within the protein sequence of FGF21. AKR-001 has a resulting half-life of three to four days in humans, which enables once-weekly subcutaneous administration. Pharmacology studies have shown AKR-001 reproduces the balanced potency of native FGF21, acting specifically on three cell-surface receptors. AKR-001 also reproduces native FGF21's weak potency as an agonist of another cell-surface receptor known to be associated with higher plasma LDL-C.

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

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

Overview of FGF21 biology

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

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

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

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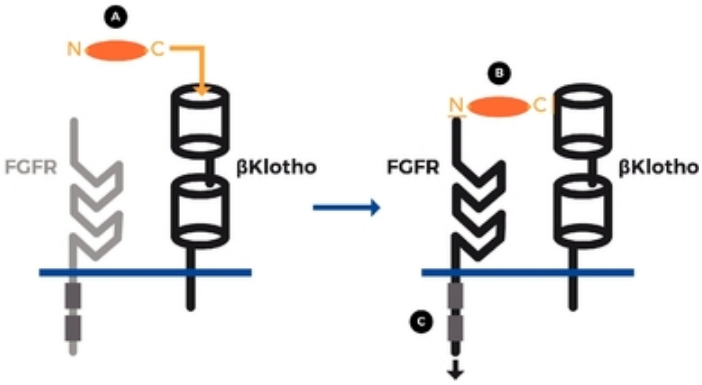
Figure 7—FGF21's two-step receptor binding with *b*Klotho and FGFRs



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

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

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

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

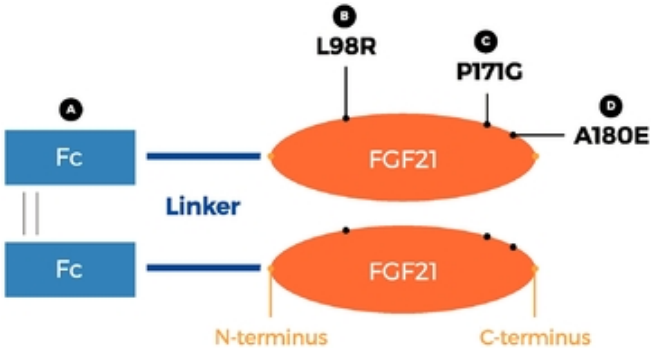
- **Recombinantly-expressed human FGF21, or rhFGF21, molecules are susceptible to aggregation when formulated into a solution suitable for injection into humans**. Aggregation can disrupt binding of rhFGF21 to its receptors, thereby causing it to lose its biological activity. Aggregates of rhFGF21 can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

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

AKR-001 has been engineered to: (1) protect against proteolysis and reduce renal clearance, (2) provide a half-life of three to four days in humans by protecting against proteolysis, (3) minimize potential for aggregation in solution and (4) improve binding affinity for *b*Klotho, while (5) retaining balanced agonism across FGFR1c, FGFR2c and FGFR3c. Figure 8 below illustrates the structural engineering of AKR-001, which

is also further described in the text that follows. We believe AKR-001's differentiated profile has the potential to result in a leading endocrine FGF analog, if approved, for treatment of NASH. This belief is based, in part, on AKR-001's observed effects on lipoproteins and markers of insulin sensitivity, when viewed in the context of similar measurements taken in clinical trials with other endocrine FGF analogs.

Figure 8—Protein engineering of AKR-001



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

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

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

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

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

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

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

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

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

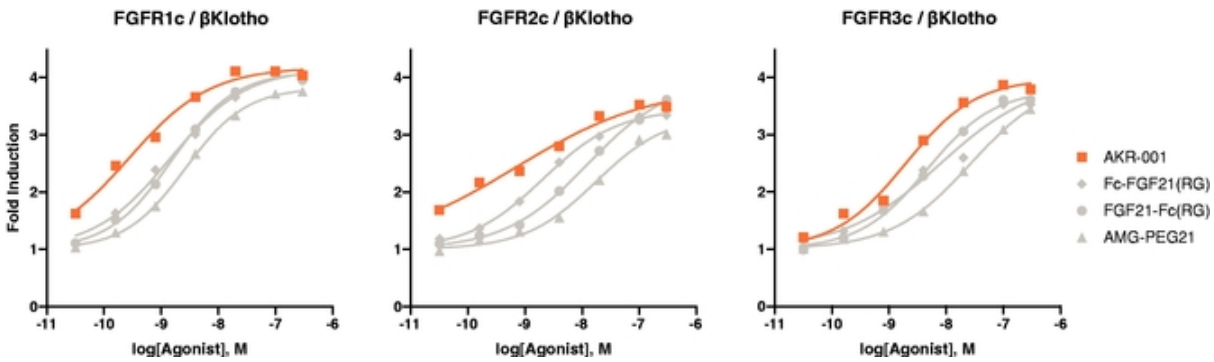


Figure 10—Comparison of AKR-001's agonism of FGF receptors with unmodified rhFGF19 and rhFGF21

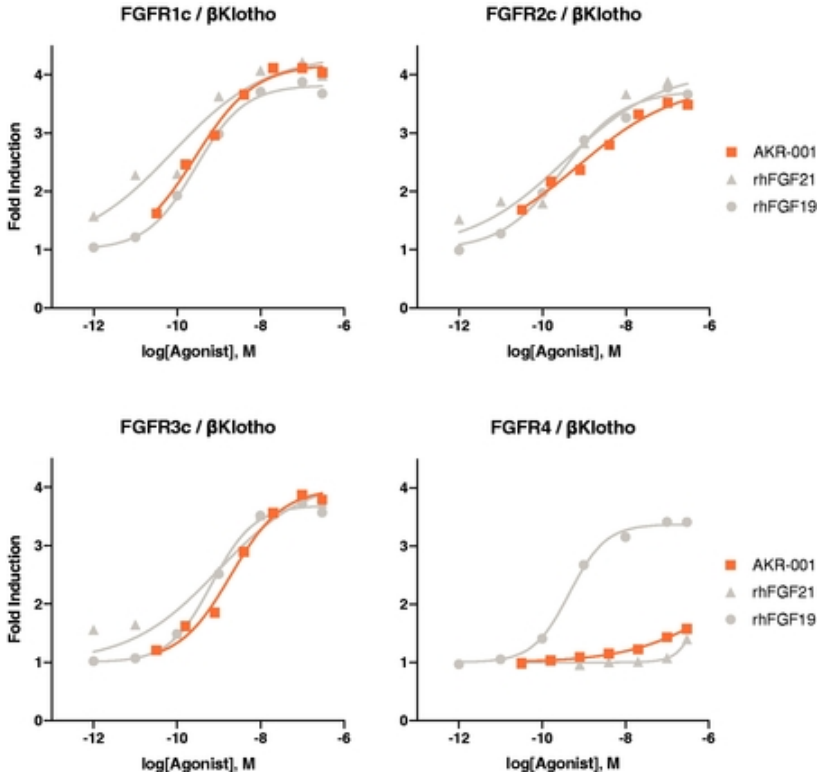


Figure 11—Relative potency of rhFGF21, AKR-001, rhFGF19 and other discovery candidates against FGF receptors

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

Clinical validation of endocrine FGF receptor agonism

Data from clinical trials evaluating three different FGF compounds acting on FGFR1c, FGFR2c and/or FGFR3c further validate the potential of FGF21 agonism as a NASH treatment. One compound is an FGF19 analog, which has been observed to substantially reduce liver fat and to reverse liver inflammation and fibrosis in patients with NASH, but also appears to increase LDL-C. Published nonclinical and clinical data suggest that

activation of FGFR4 increases LDL-C but does not meaningfully contribute to the pharmacodynamic effects of FGF19 on lipid metabolism in the liver. Consequently, we believe the optimal NASH therapeutic profile for an endocrine FGF analog is to have high, balanced potency for FGFR1c, 2c and 3c with minimal activity at FGFR4.

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

A third compound is a monoclonal antibody, or mAb, designed to target only FGFR1c and its co-receptor, *b*Klotho. Consistent with nonclinical data, preliminary clinical data in patients with NASH suggest that administration of this FGFR1c-specific agonist was associated with substantial reductions in liver fat and improvements in lipoproteins, which may be attributable to lower rates of adipose tissue lipolysis.

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

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

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

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

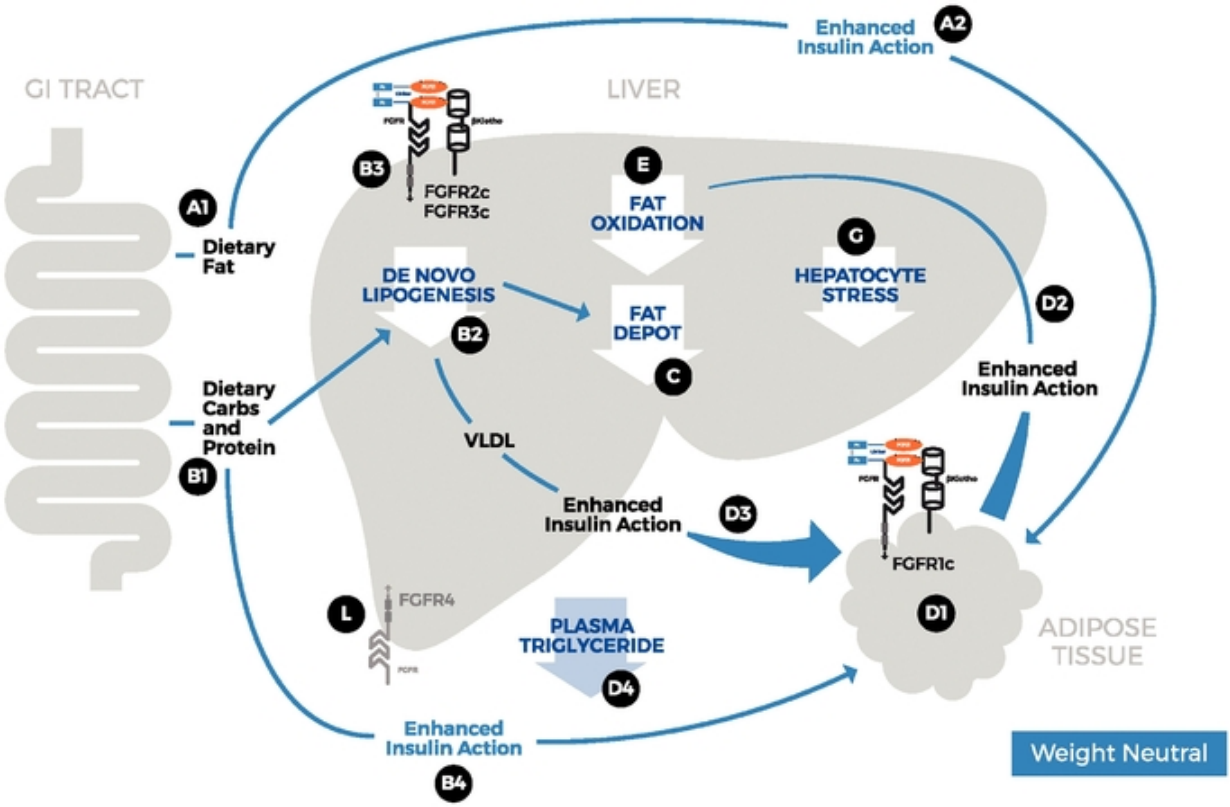
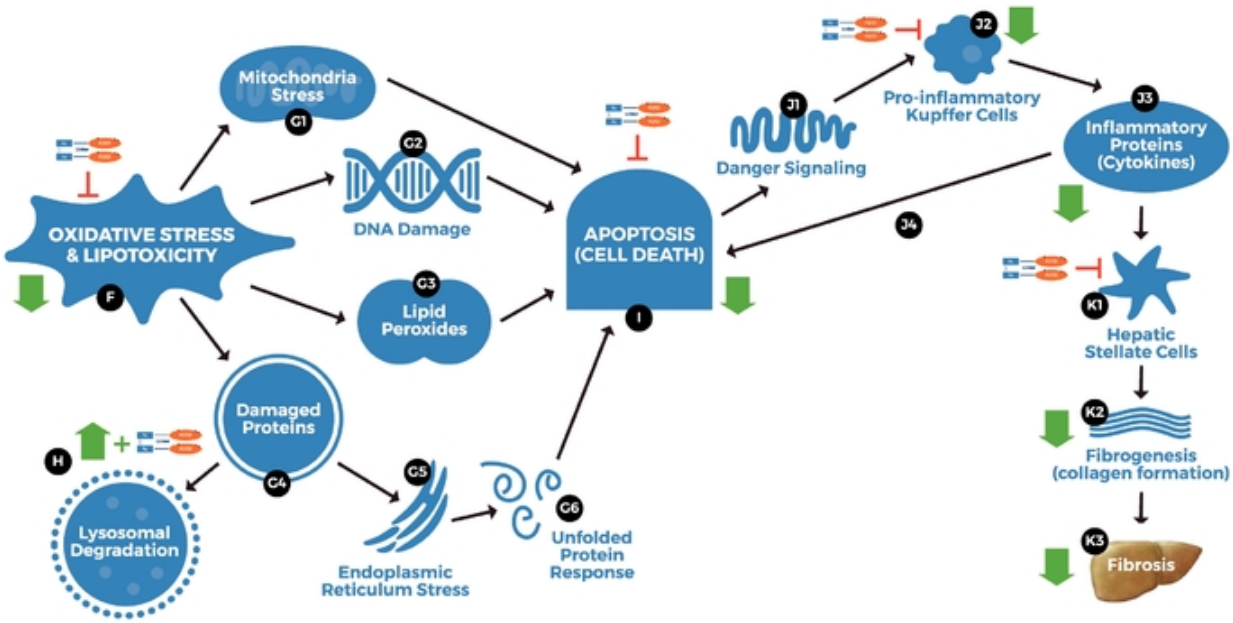


Figure 13—AKR-001's suppression of pathways leading to cell death reduces downstream liver inflammation and fibrosis



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

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

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

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

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

- reducing flow of fat from adipose tissue to liver by activating the FGFR1c receptor expressed in adipose tissue (D2), which leads to lower rates of fat oxidation (E);

- redirecting carbohydrates and protein absorbed from the GI tract away from the liver to adipose tissue (B1), thereby reducing DNL-dependent deposition of fat in the liver (B2 and C); and

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

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

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

Reducing liver cell stress, injury and death

A key driver of NASH progression is hepatocyte stress (G), which is triggered by increased oxidative stress as well as stress caused by lipotoxicity, or excessive amounts of certain lipids, in the liver (F). FGF21

inhibits oxidative stress and lipotoxicity in two ways. First, as described above, FGF21 leverages multiple body systems to reduce the flux of fat through the liver, which limits fat oxidation and thus oxidative stress, and reduces levels of lipotoxic species e.g. saturated long-chain fatty acids. Second, FGF21 directly alleviates oxidative stress through induction of TFs known as PGC1a and NRF2, which induce expression of anti-oxidant enzymes that protect against oxidative stress by neutralizing free radicals. PGC1a also improves mitochondrial function, which reduces oxidative stress.

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

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

Reducing inflammation and fibrosis

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

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

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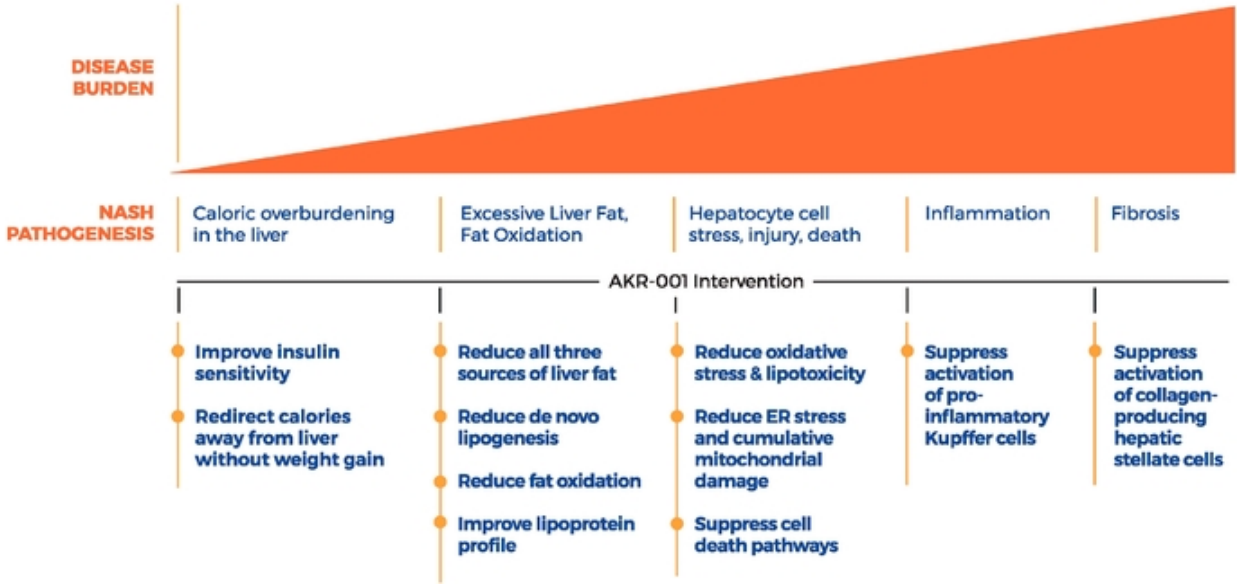
Figure 14—AKR-001's intervention in processes underlying NASH pathogenesis



AKR-001 clinical development

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

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

On April 24, 2019, we submitted to the FDA's Division of Gastroenterology and Inborn Errors Products an IND application to permit patients with NASH to be treated with AKR-001. The prior IND for AKR-001 permitted treatment of patients with T2D, having been approved by FDA's Division of Metabolism and Endocrinology Products. We plan to initiate a Phase 2a clinical trial to assess the efficacy and safety of AKR-001 in patients with NASH, which will help inform dose selection for larger, longer-term trials.

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

A Phase 1b clinical trial was conducted to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of AKR-001 in patients with T2D. This trial was a multicenter, randomized, double-blind, placebo-controlled, ascending multiple-dose clinical trial. Sixty-nine patients enrolled into one of eight cohorts were randomized to receive AKR-001 or placebo. Fifty-two patients received AKR-001 and 17

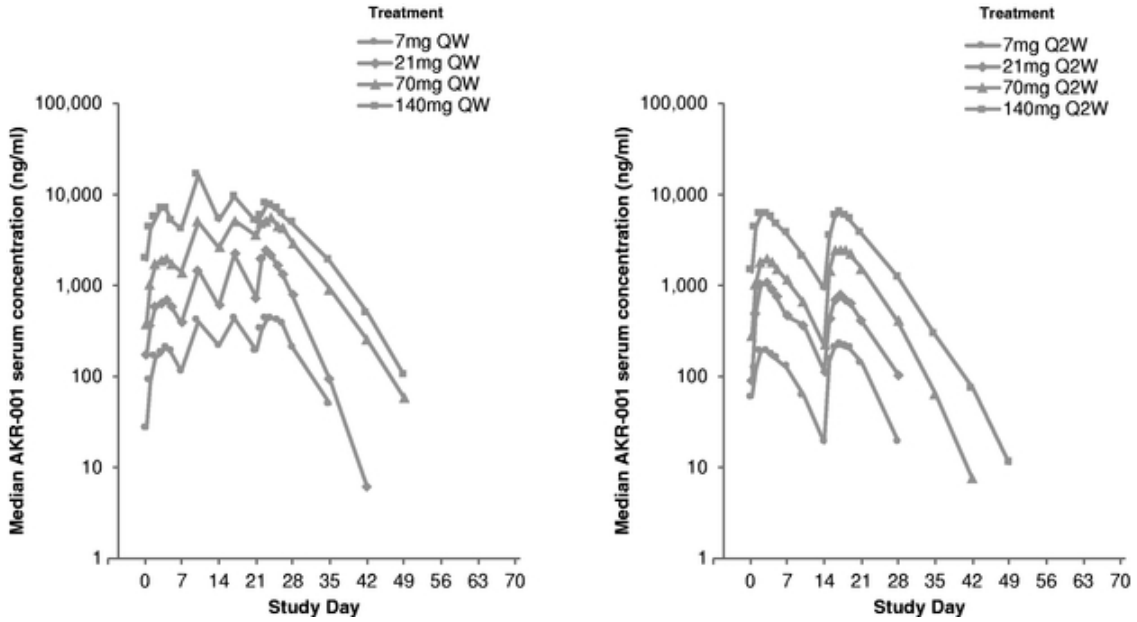
received placebo. Doses of 7mg, 21mg, 70mg and 140mg were administered subcutaneously either once every two weeks, or Q2W, or once weekly, or QW, over a 28-day treatment period. Patients in Q2W cohorts received doses of AKR-001 on Days 1 and 15, while subjects in QW cohorts received doses of AKR-001 on Days 1, 8, 15 and 22.

AKR-001 exhibited linear, dose-proportional pharmacokinetics

Linear, dose-proportional pharmacokinetics were observed across the range of AKR-001 doses tested. The observed median time of maximum serum concentration, or Tmax, ranged from two to 3.5 days. The observed half-life of the intact C-terminus of AKR-001 ranged from three to four days. By contrast, half-life of the intact C-terminus of other FGF21 analogs evaluated clinically has ranged from six to 24 hours.

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

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



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

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

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As shown in Figure 16 below, dose-related effects on pharmacodynamic measures were observed for the QW cohorts, with maximal or near-maximal effects achieved with the 70mg QW dose of AKR-001. Significant decreases in triglycerides and increases in HDL-C were observed for all dose groups, with additional significant decreases in non-HDL-C observed at doses greater than or equal to 70mg QW. Multiple markers of insulin sensitivity were also observed to be improved following treatment at a dose of 70mg QW. Significant decreases in C-peptide observed following the fourth dose of 21mg QW suggests that insulin sensitivity may be improved by longer-term treatment with doses lower than 70mg QW.

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

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

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

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

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

	Placebo adjusted change from baseline (%)			
	7mg QW (N=6)	21mg QW (N=6)	70mg QW (N=6)	140mg QW (N=6)
Glucose[a]	+4	+5	-19*	-18
Insulin[a]	-17	-29	-44**	-49**
C-peptide[a]	-21	-30**	-37***	-44***
HOMA-IR[a]	-13	-24	-55***	-58***
Adiponectin[b]	+42	+62	+94**	+143***
Triglycerides[a]	-39**	-55***	-69***	-64***
HDL-C[a]	+29***	+40***	+61***	+38***
Non-HDL-C[a]	-12	-11	-30***	-34***
LDL-C[a]	-6	+7	-15	-28*
ApoB[b]	0	-16	-37***	-18
Post-Meal FFA[a]	-2	+5	-29**	-30**
Body Weight[a]	0	0	-1	-2

[a] Day 25; [b] Day 29; * p<0.05; ** p<0.01; *** p<0.001

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

	Placebo adjusted change from baseline (%)			
	7mg Q2W (N=6)	21mg Q2W (N=6)	70mg Q2W (N=6)	140mg Q2W (N=6)
Glucose[a]	-5	+2	-7	-1
Insulin[a]	-6	-22	-14	-27
C-peptide[a]	+1	-13	-5	-26*
HOMA-IR[a]	-11	-22	-21	-29
Adiponectin[b]	+60	+73*	+65	+141***
Triglycerides[a]	-20	-29	-42**	-55***
HDL-C[a]	0	+28***	+23**	+40***
Non-HDL-C[a]	-10	-4	-11	-23**
LDL-C[a]	-3	+13	-1	-15
ApoB[b]	-12	-15	-11	ND
Post-Meal FFA[a]	-11	+10	+2	+21
Body Weight[a]	+1	0	-1	-2

[a] Day 18; [b] Day 29; * p<0.05; ** p<0.01; *** p<0.001

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

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

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

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

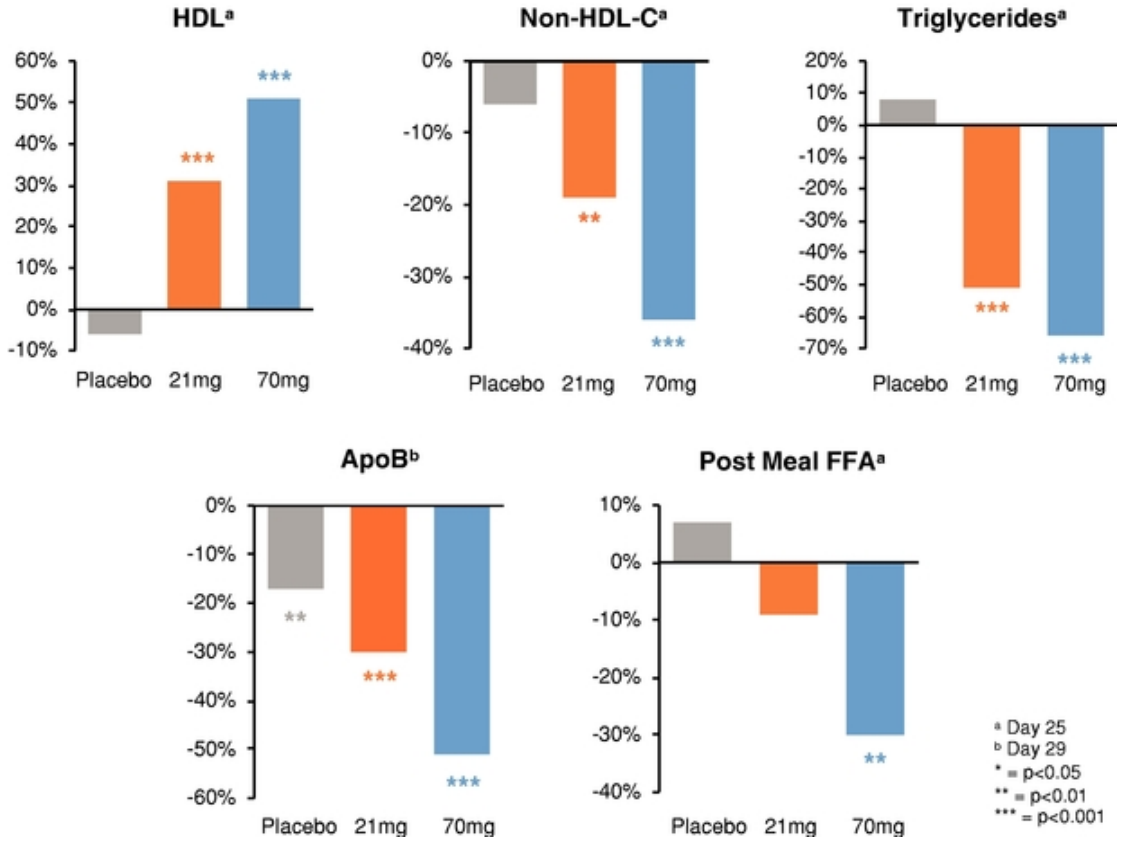

Figure 19: AKR-001 effects (percent change from baseline) on markers of insulin sensitivity: placebo, 21mg QW, and 70mg QW

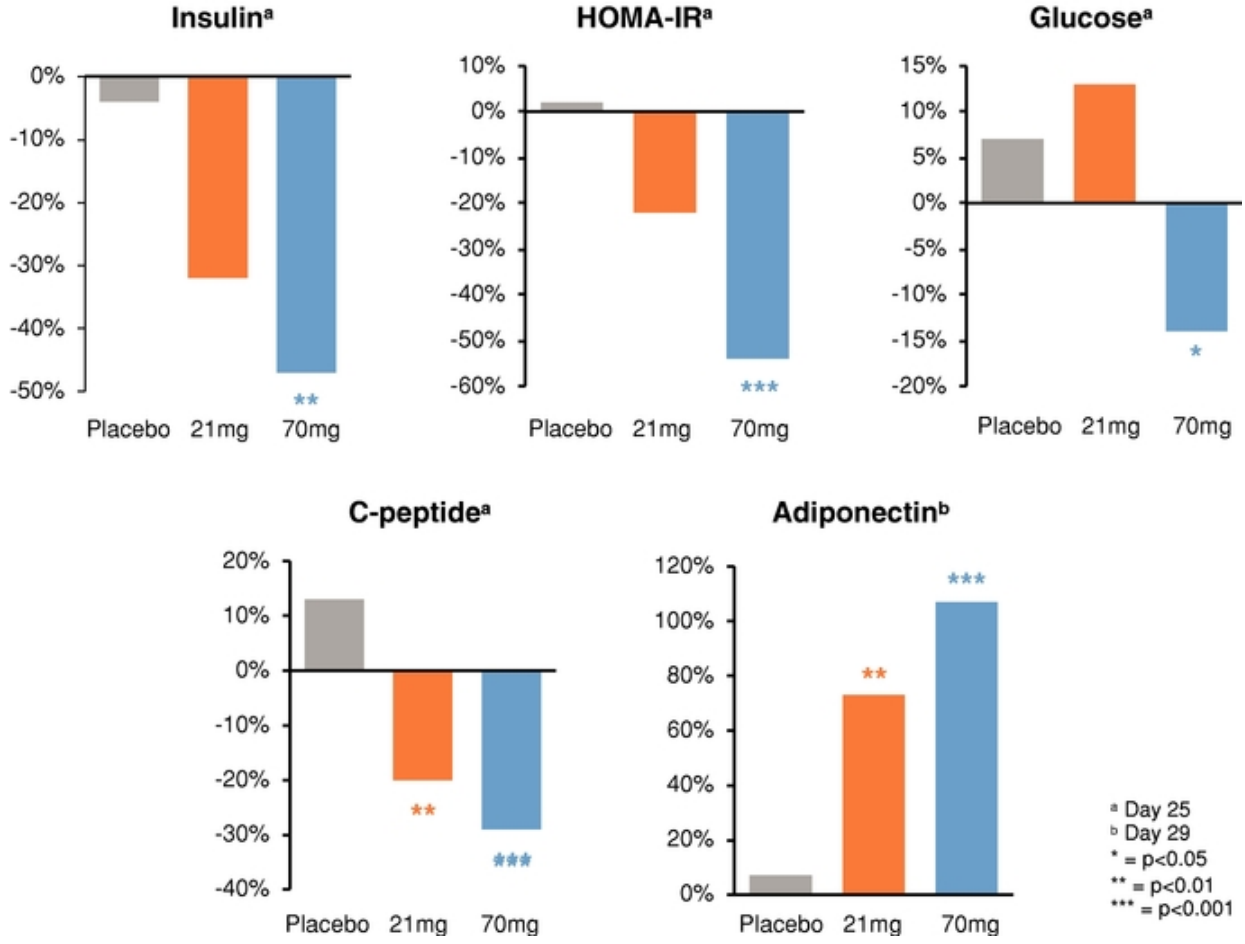

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Figure 20 below provides the data underlying Figures 18 and 19, shown in units of mg/dL.

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

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

[a] - D29

AKR-001 70mg QW showed rapid, durable effects

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

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

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

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

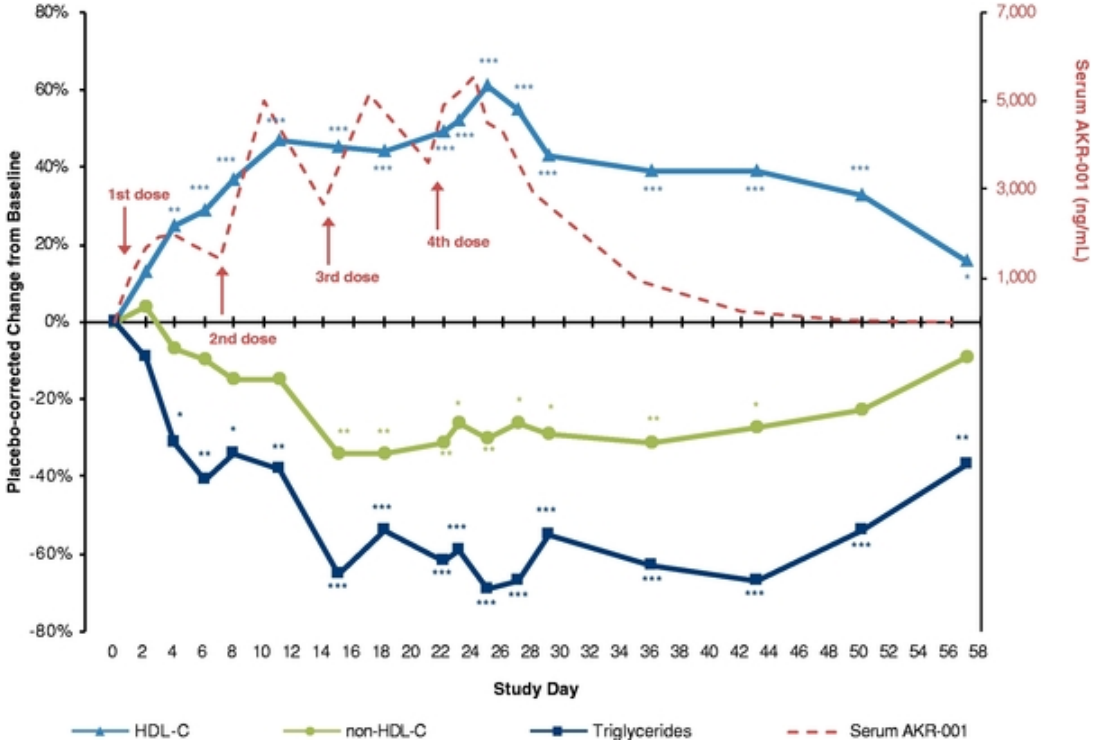

Figure 22: Time-course plots of AKR-001 70mg QW effects on markers of insulin sensitivity

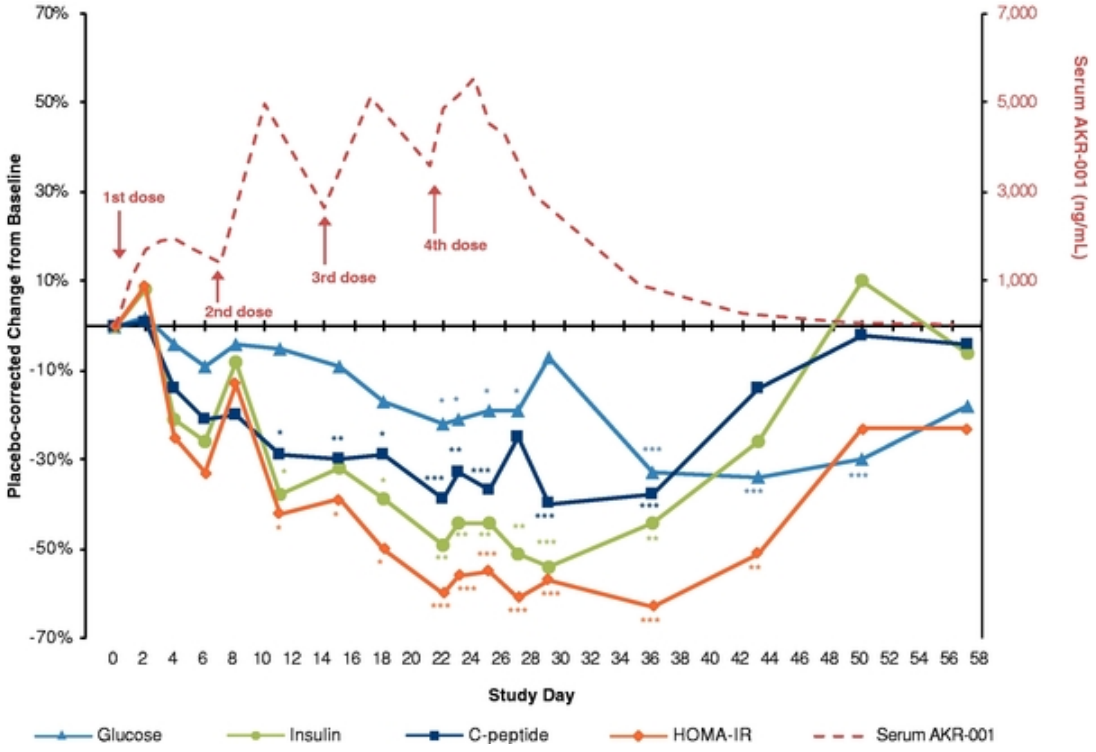

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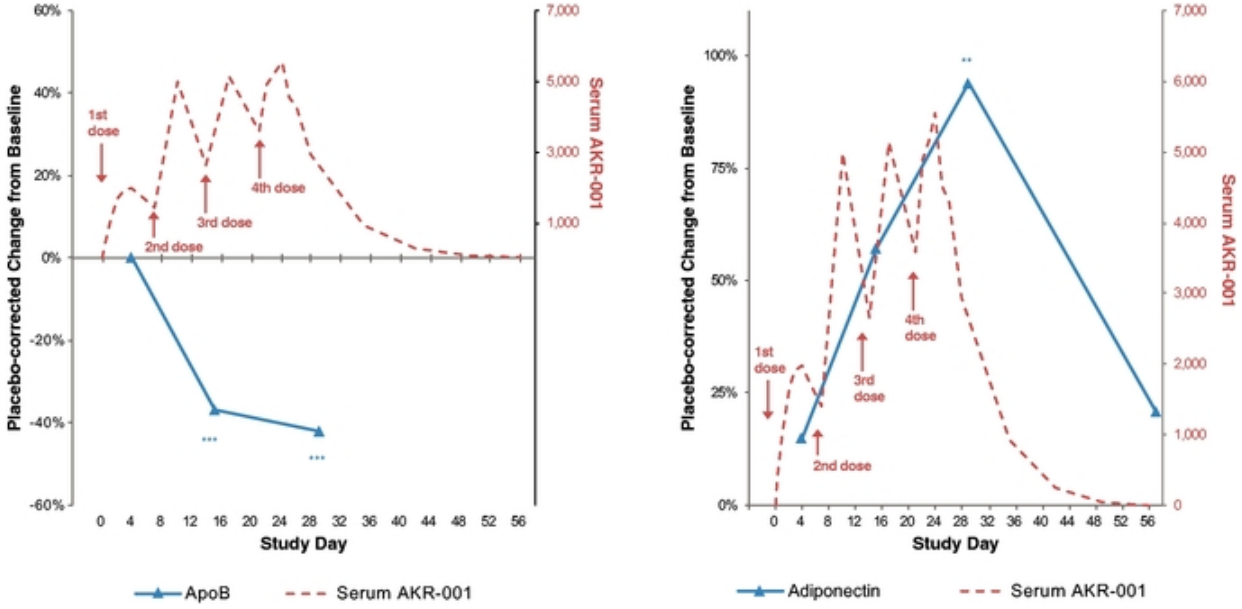
Figure 23: Time-course plots of AKR-001 70mg QW effects on apolipoprotein B and adiponectin



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

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

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

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

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

* - CTCAE toxicity grades
# - a single event of the following AEs was observed in the trial: dizziness (140 mg QW), dysgeusia (140 mg QW), musculoskeletal pain (7 mg Q2W), muscle spasms (140 mg QW), ventricular extrasystoles (140 mg QW), hyperhidrosis (140 mg QW), flushing (21 mg Q2W); all events Grade 1
† - includes increased appetite, decreased appetite, and hunger
‡ - includes constipation, dyspepsia, abdominal distension, abdominal pain, abdominal tenderness, and epigastric discomfort
§ - reason for withdrawals: nausea and tremor (1 subject), diarrhea (1 subject), nausea (1 subject), tremor (1 subject)

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

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

Phase 1a clinical trial in type 2 diabetic patients

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

At doses of 21mg SC and higher, significant increases were observed in HDL (up to 50% increase on Day 14 after a single 70mg SC dose, $p<0.001$) along with significant reductions in triglycerides (up to 50% reduction on Day 11 after a single 70mg SC dose, $p<0.001$), compared to placebo. No changes were noted in metabolic parameters of glucose, insulin, glucagon and free fatty acids under fasted conditions at doses

of 70mg SC or less. A significant reduction in body weight was observed by Day 5 in all dose groups at or above 21mg SC, with significant decreases in body weight following a single dose of 70mg SC observed on days 5 through 22, up to a maximum of a 2% decrease in weight.

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

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

There were no trends indicative of clinically important treatment-related laboratory abnormalities or clinically significant changes in vital signs or ECGs in subjects treated with AKR-001.

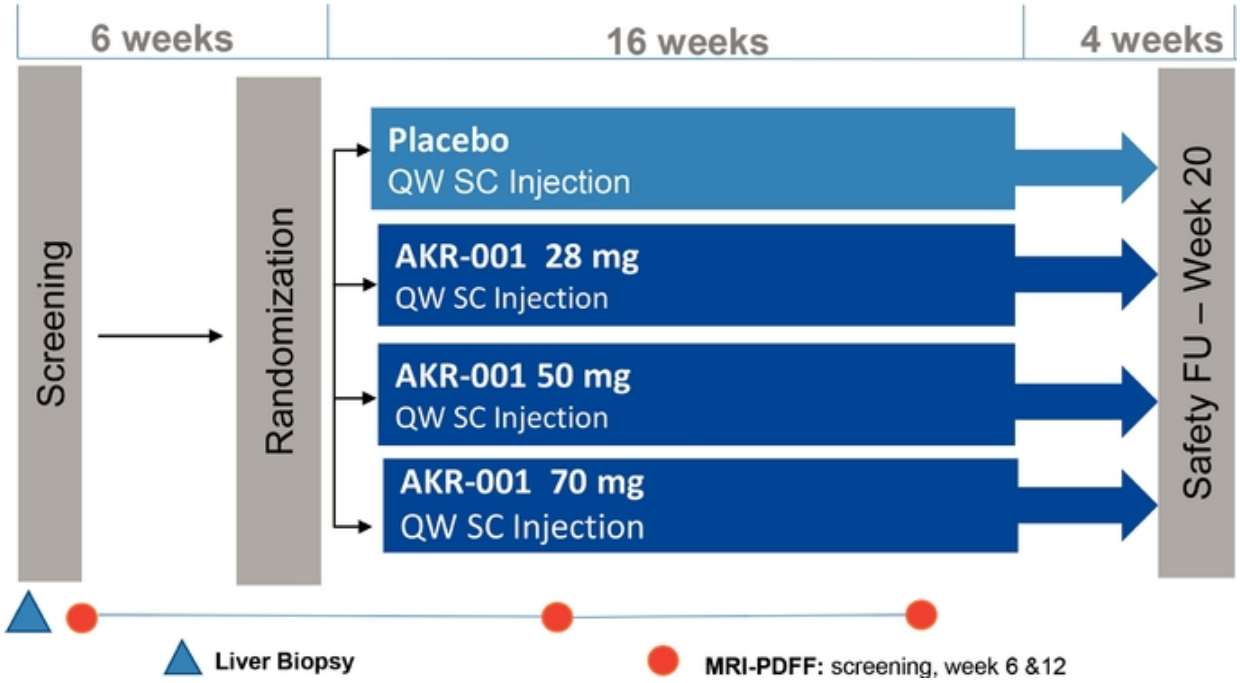
Anti-AKR-001 binding antibodies were detected in four of 31 subjects. In all instances the antibodies were non-neutralizing and did not appear to affect the tolerability profile profile or pharmacokinetics of AKR-001.

Planned Phase 2a clinical trial design

We submitted a Phase 2a clinical trial synopsis to the FDA in conjunction with a pre-IND meeting request and received comments from the FDA on January 23, 2019. The FDA supported the overall trial design and recommended several trial design elements, all of which have been incorporated into our draft protocol. We submitted our IND application to the FDA on April 24, 2019, which included a Phase 2a clinical trial protocol, audited draft reports for our 120-day toxicology studies in non-human primates and rodents, and stability data on drug product for use in the Phase 2a clinical trial. The FDA acknowledged receipt of the IND application on April 24, 2019.

As currently planned, our Phase 2a clinical trial will be a multicenter, randomized, double-blind, placebo-controlled, dose-ranging trial in biopsy-confirmed patients with NASH, with up to approximately 80 total patients randomized to receive weekly subcutaneous dosing of AKR-001 or placebo for up to 16 weeks. The three planned active treatment arms are doses of 28mg, 50mg and 70mg QW, all within the target dose range of 21mg to 70mg QW based on observed results from the Phase 1b clinical trial. The 70mg dose represents the highest tolerated dose in the Phase 1b clinical trial in T2D patients. Evaluating the highest-tolerated dose from Phase 1 clinical trials and testing multiple doses is consistent with FDA guidance. We have engaged Summit Research Network, a leading third party investigator with broad expertise in NASH patient enrollment, to assist with patient enrollment for our Phase 2a clinical trial.

Figure 25: Phase 2A Clinical Trial Design



The primary objective of the planned Phase 2a clinical trial is to evaluate absolute change from baseline in hepatic fat fraction assessed by Magnetic Resonance Imaging—Proton Density Fat Fraction, or MRI-PDFF, at Week 12.

The secondary objectives of the planned Phase 2a clinical trial are to:

- Evaluate percent change from baseline in hepatic fat fraction assessed by MRI-PDFF at Week 12;
- Evaluate the proportion of patients who achieve a clinically-meaningful reduction of at least 30% in relative liver fat content as measured by MRI-PDFF at Week 12; and
- Assess the safety and tolerability of AKR-001 in subjects with NASH, including analyses of treatment-emergent adverse events, clinical chemistry and hematology, vital signs, electrocardiogram, body weight, and incidence of anti-AKR-001 antibodies.

Planned exploratory objectives include:

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

Potential improvement of cardiovascular risk factors

We believe the effects observed following treatment with AKR-001 in clinical trials to date, particularly the 70mg QW dose level, indicate that AKR-001 has potential to have cardiovascular benefits when tested in patients with NASH, for whom cardiovascular disease is the leading cause of death. Figure 26 below

describes the extent of reduction in cardiovascular risk associated with improvement in individual lipoproteins, which are believed to be causal of cardiovascular disease. We believe these help to provide context for the changes in lipoproteins observed in the Phase 1b clinical trial of AKR-001. If the magnitude of improvement in lipoprotein profiles is reproduced in patients with NASH in larger, longer-term trials, AKR-001 could have the potential to improve cardiovascular outcomes.

Figure 26: Rationale for AKR-001's potential cardiovascular benefits

PD Measure	Evidence for Positive Impact	70mg QW AKR-001 (Pbo-adjusted %CFB) (post-4th dose)
Non-HDL Cholesterol	In a clinical trial of anacetrapib in combination with intensive atorvastatin therapy, an 18% decrease in non-HDL cholesterol was associated with a 9% reduction in cardiovascular risk.	**-30%**
Apolipoprotein B	In a global case-control analysis of lipoprotein levels in humans as markers of risk of myocardial infarction, an increase of 30% in ApoB was associated with a 30% increase in relative risk of a myocardial infarction.	**-37%**
Triglycerides and Apolipoprotein C-3	Carriers of mutations that disrupt ApoC3 function have 40% to 50% lower levels of both triglyceride and ApoC3, and a 40% lower risk of cardiovascular disease than non-carriers.	**-69%** (TG)

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

Additional clinical data supporting FGF21 in treatment of NASH

Other endocrine FGF analogs in development have shown encouraging signs of liver fat reduction, improved lipid profiles and reduced fibrosis in clinical trials in patients with NASH. Daily injections of an FGF19 analog were reported to be associated with a 67% relative reduction in liver fat as measured by MRI-PDFF on Day 85, as well as improvements in fibrosis as measured by liver biopsy. Daily and weekly injections of a PEGylated FGF21 analog were reported to be associated with 38% and 26% relative reductions in liver fat, respectively, compared with 6% for placebo, along with positive changes in Pro-C3, a marker of liver fibrosis. A single injection of a mAb developed to mimic FGF21's effects on FGFR1c and bKlotho, but with no activity on FGFR2c and 3c, was reported to be associated with a 37% relative reduction of liver fat as measured by MRI-PDFF on Day 36. The pattern and magnitude of changes in plasma lipoproteins varied across these three analogs. The FGF19 analog and FGF21 mAb both substantially reduced plasma triglyceride and increased HDL-C in comparison to the PEGylated FGF21 analog. Treatment with the FGF19 analog was associated with a placebo-corrected increase in LDL-C of 46 mg/dL, corresponding to about a 50% increase in fasting LDL-C. This increase in LDL-C is consistent with FGF19's potent agonism of FGFR4. Neither the FGF19 analog nor the PEGylated FGF21 analog were reported to result in significant reductions in insulin, glucose or C-peptide when evaluated in patients with T2D in earlier clinical trials.

Exclusive license agreement with Amgen Inc.

In June 2018, we entered into an exclusive license agreement with Amgen Inc., or Amgen, pursuant to which we have been granted an exclusive, royalty-bearing license to certain intellectual property rights owned or controlled by Amgen, to commercially develop, manufacture, use, distribute and sell therapeutic products, or Products. In particular, we have been granted licenses under patents filed in both the United States and foreign jurisdictions that are owned or controlled by Amgen, including an exclusive license

under certain patents claiming polypeptides comprised of an FGF21 portion with certain point mutations, a linker, and an Fc domain. Our exclusively licensed patents include, but are not limited to, the composition of AKR-001 and methods of using the same. In connection with the license, Amgen also licensed and transferred to us certain know-how related to the manufacture of AKR-001 as well as certain quantities of AKR-001 drug substance manufactured to GMP for clinical use, master cell bank, not-for-human use AKR-001 drug product suitable for nonclinical studies and critical reagents.

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

As initial consideration for the license, we paid Amgen an upfront payment of $5.0 million and also issued 2,653,333 shares of our Series A preferred stock to Amgen at the time of the initial closing in June 2018 with a subsequent 3,205,128 shares of our Series A preferred stock issued at the time of the second closing in November 2018, representing 10% of total shares outstanding at such times. As additional consideration for the license, we are required to pay Amgen up to $40.0 million upon the achievement of specified clinical and regulatory milestones and aggregate milestone payments of up to $75.0 million upon the achievement of specific commercial milestones. No development or commercial milestones have been achieved to date under the license agreement. We are also required to pay tiered royalties of low to high single-digit percentages on annual net sales of the products covered by the license. The royalty rate with respect to the net sales is subject to customary reductions, including in the event that the exploitation of a Product is not covered by a valid claim with the licensed patent rights. The royalty term will terminate on a country-by-country basis on the later of (i) the expiration date of the last valid claim within the licensed patent rights, (ii) the loss of regulatory exclusivity in such country, and (iii) the tenth anniversary of the first commercial sale of such product in such country.

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

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

Intellectual property

Our success depends in part upon our ability to protect our core technology and intellectual property. To protect our intellectual property rights, we rely on patents, trademarks, copyrights and trade secret laws, confidentiality procedures, and employee disclosure and invention assignment agreements. Our intellectual

property is critical to our business and we strive to protect it through a variety of approaches, including by obtaining and maintaining patent protection in the United States and internationally for our product candidates, novel biological discoveries, new targets and applications, and other inventions that are important to our business. For our product candidates, we generally intend to pursue patent protection covering compositions of matter, methods of making and methods of use, including combination therapies. As we continue the development of our product candidates, we intend to identify additional means of obtaining patent protection that would potentially enhance commercial success, including through claims covering additional methods of use and biomarkers and complementary diagnostic and/or companion diagnostic related claims. As of March 31, 2019, we have licensed from Amgen Inc. approximately 152 patents and pending patent applications in the U.S. and foreign jurisdictions, including 111 granted U.S. and foreign patents and 41 pending U.S. and foreign patent applications. There are currently no pending U.S. provisional patent applications.

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

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

Manufacturing and supply

We manage several external commercial manufacturing organizations, or CMOs, to develop and manufacture our product candidates.

AKR-001 drug substance is manufactured by fermentation of a recombinant strain of the bacterium *E. coli.* Product accumulates as insoluble particles (inclusion bodies) within the cells and is recovered by cell disruption, followed by solubilization of the inclusion bodies, protein refolding and several chromatographic separation steps to yield product with target quality attributes. We have an agreement with Boehringer Ingelheim Biopharmaceuticals GmbH to manufacture GMP drug substance for future clinical trials and plan to enter into a future agreement for commercial supply at the appropriate time.

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

We acquired approximately 475 grams of AKR-001 drug substance, or DS, as part of our license from Amgen, divided into 10 one-liter bottles and stored in frozen storage at –30 degrees Celsius. We used this DS, which was manufactured by Amgen in compliance with GMP, to support our planned Phase 2a trial. Approximately 100 grams of this material was used to dose two 120-day toxicity studies in rats and non-human primates. We converted the remaining drug substance, approximately 375 grams, to drug product, or DP. The new GMP DP was manufactured pursuant to a contract with Vetter Pharma International GmbH.

The new GMP DP is an Amgen early-stage platform formulation, which is stored as a frozen liquid. We have entered into a contract with a formulation development company to explore the potential for a new refrigerated liquid formulation and/or a freeze-dried, or lyophilized, formulation in parallel with the conduct of our planned Phase 2a clinical trial. Based on the results of these parallel efforts, we plan to select one approach to progress for use in subsequent Phase 2b clinical development. We also plan to begin development of a pen-type autoinjector for the new drug product formulation.

Sales and marketing

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

Competition

The biotechnology industry is intensely competitive and subject to rapid and significant technological change. Our competitors include multinational pharmaceutical companies, specialized biotechnology companies and universities and other research institutions. A number of pharmaceutical companies, including AbbVie, Inc., Allergan plc, AstraZeneca PLC/MedImmune LLC, Bayer AG, Bristol-Myers Squibb Company, Eisai, Inc., Eli Lilly and Company, GlaxoSmithKline plc, 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., Amgen Inc., Cirius Therapeutics, Inc., Conatus Pharmaceuticals Inc., CymaBay Therapeutics, Inc., Enanta Pharmaceuticals, Inc., Galectin Therapeutics Inc., Galmed Pharmaceuticals Ltd., Genfit SA, Gilead Sciences, Inc., Intercept Pharmaceuticals, Inc., Inventiva Pharma SA, Madrigal Pharmaceuticals, Inc., MannKind Corporation, MediciNova, Inc., Metacrine, Inc., Nalpropion Pharmaceuticals, Inc., NGM Biopharmaceuticals, Inc., Terns Pharmaceuticals, Inc., Viking Therapeutics, Inc., Vivus, Inc. and Zafgen, Inc., are pursuing the development or marketing of pharmaceuticals that target NASH. It is also probable that the number of companies seeking to develop products and therapies for the treatment of serious metabolic diseases, such as NASH, will increase. Many of our competitors have substantially greater financial, technical, human and other resources than we do and may be better equipped to develop, manufacture and market technologically superior products. In addition, many of these competitors have significantly greater experience than we have in undertaking nonclinical studies and human clinical trials of new pharmaceutical products and in obtaining regulatory approvals of human therapeutic products. Accordingly, our competitors may succeed in obtaining FDA approval for superior products. Many of our competitors have established distribution channels for the commercialization of their

products, whereas we have no such channel or capabilities. In addition, many competitors have greater name recognition and more extensive collaborative relationships. Smaller and earlier-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

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

Government regulation

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

U.S. biological product development

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

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

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

Nonclinical and clinical development

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

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

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

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

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

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

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

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

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

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

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events, any findings from

other studies, tests in laboratory animals or *in vitro* testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor, acting on its own or based on a recommendation from the sponsor's data safety monitoring board may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to patients.

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

BLA submission and review

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

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

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

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

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

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

Expedited development and review programs

The FDA has various programs, including Fast Track designation, breakthrough therapy designation, accelerated approval and priority review, that are intended to expedite or simplify the process for the

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

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

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

Additionally, a product may be eligible for accelerated approval (also referred to as Subpart E approval). Biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments, as demonstrated by a surrogate or intermediate clinical endpoint, may receive accelerated approval. Specifically, this means that they may be approved on the basis of clinical data establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on an intermediate clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a biological product receiving accelerated approval perform adequate and well-controlled post-marketing confirmatory clinical trials. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Pediatric information

Under the Pediatric Research Equity Act, a BLA or supplement to a BLA must contain data to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. A sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration must submit an initial Pediatric Study Plan, or PSP, within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 of Phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints, and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial

waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from nonclinical studies, early phase clinical trials, and/or other clinical development programs.

Post-Approval requirements

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

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

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the

FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

U.S. patent term restoration and marketing exclusivity

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

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

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

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

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

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

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

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

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

does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not meet the criteria for protection under a statutory exception or regulatory safe harbor.

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

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

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

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

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, as well as the California Consumer Privacy Act of 2018 (the "CCPA"), impose requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates, independent contractors, or agents of covered entities, which include certain healthcare providers, health plans, and healthcare clearinghouses, that receive or obtain protected health information in connection with providing a service on behalf of a

covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, many state laws govern the privacy and security of health information in specified circumstances. For example, in California the CCPA establishes a new privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. Many of the state laws differ from each other in significant ways and are often not pre-empted by HIPAA, and may have a more prohibitive effect than HIPAA, thus complicating compliance efforts.

We may develop products that, once approved, may be administered by a physician. Under currently applicable U.S. law, certain products not usually self-administered (including injectable drugs) may be eligible for coverage under Medicare through Medicare Part B. Medicare Part B is part of original Medicare, the federal health care program that provides health care benefits to the aged and disabled, and covers outpatient services and supplies, including certain pharmaceutical products, that are medically necessary to treat a beneficiary's health condition. As a condition of receiving Medicare Part B reimbursement for a manufacturer's eligible drugs, the manufacturer is required to participate in other government healthcare programs, including the Medicaid Drug Rebate Program and the 340B Drug Pricing Program. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of HHS as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. Under the 340B Drug Pricing Program, the manufacturer must extend discounts to entities that participate in the program.

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

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

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and

tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

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

Coverage, pricing and reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may obtain regulatory approval. In the United States and in foreign markets, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage and establish adequate reimbursement levels for such products. In the United States, third-party payors include federal and state healthcare programs, such as Medicare and Medicaid, private managed care providers, health insurers and other organizations. Adequate coverage and reimbursement from third-party payors are critical to new product acceptance.

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

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

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

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

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

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

Healthcare reform

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the

ability to profitably sell product candidates for which marketing approval is obtained. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, the Affordable Care Act has substantially changed healthcare financing and delivery by both governmental and private insurers. Among the Affordable Care Act provisions of importance to the pharmaceutical and biotechnology industries, in addition to those otherwise described above, are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs that began in 2011;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively, and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price, or AMP;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70%, the current discount owed as of January 1, 2019 pursuant to the Bipartisan Budget Act of 2018, or BBA) point-of-sale discounts, off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals beginning in 2014 and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the 340B Drug Discount Program;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- expansion of healthcare fraud and abuse laws, including the FCA and the federal Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected;
- requirements to report certain financial arrangements with physicians and teaching hospitals;
- a requirement to annually report certain information regarding drug samples that manufacturers and distributors provide to physicians;
- establishment of a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending; and

- a licensure framework for follow on biologic products.

Some of the provisions of the Affordable Care Act have yet to be implemented, and there have been legal and political challenges to certain aspects of the Affordable Care Act. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain Affordable Care Act-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In July 2018, CMS published a final rule permitting further collections and payments to and from certain Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or the Texas District Court Judge, ruled that the individual mandate is a critical and inserverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the Affordable Care Act are invalid as well. While the Texas District Court Judge, as well as the Trump Administration and CMS, have stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, 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 of at least $1.2 trillion for fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect beginning on April 1, 2013 and, due to legislation amendments to the statute, including the BBA, will stay in effect through 2027 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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

for fiscal year 2019 contained further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Further, the Trump administration released a "Blueprint", or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. HHS has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. On January 31, 2019, the HHS Office of Inspector General, proposed modifications to the federal Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. While a number of these and other proposed measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Further, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to request access to certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

The Foreign Corrupt Practices Act

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

Government regulations outside the United States

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing, among other things, research and development, clinical trials, testing, manufacturing, safety, efficacy, labeling, packaging, storage, record keeping, distribution, reporting,

advertising and other promotional practices involving biological products as well as authorization and approval of our products.

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

Regulation in the European Union

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

Pediatric development in the European Union

In the European Union, companies developing a new medicinal product must agree upon a Pediatric Investigation Plan, or PIP, with the EMA, and must conduct pediatric clinical trials in accordance with that PIP, unless a waiver applies, (e.g., because the relevant disease or condition occurs only in adults). The marketing authorization application for the product must include the results of pediatric clinical trials conducted in accordance with the PIP, unless a waiver applies, or a deferral has been granted, in which case the pediatric clinical trials must be completed at a later date. Products that are granted a marketing authorization on the basis of the pediatric clinical trials conducted in accordance with the PIP are eligible for a six month extension of the protection under a supplementary protection certificate (if any is in effect at the time of approval) or, in the case of orphan medicinal products, a two year extension of the orphan market exclusivity. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

Post-approval controls in the European Union

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

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

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

European data collection

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

European Union drug marketing

Much like the Anti Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order, or use of medicinal products is also prohibited in the European Union. The

provision of benefits or advantages to physicians is governed by the national anti bribery laws of European Union Member States. Infringement of these laws could result in substantial fines and imprisonment.

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

Rest of world regulation

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

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

Additional regulation

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

Employees

As of the date of this prospectus, we employed nine full-time employees and one part-time employee, including five with M.D. and/or Ph.D. degrees. Of these employees, five are in research and development and five are general and administrative. We have never had a work stoppage, and none of our employees is represented by a labor organization or under any collective-bargaining arrangements. We consider our employee relations to be good.

Facilities

We lease our office space, which consists of 3,691 square feet located at 170 Harbor Way, South San Francisco, California. Our lease expires on February 27, 2021, subject to automatic renewals for successive thirty (30) day periods. We believe our current office space is sufficient to meet our needs until the

expiration of our lease, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms, if required.

Legal proceedings

As of the date of this prospectus, we were not subject to any legal proceedings. From time to time, we may be involved in legal proceedings or subject to claims incident to the ordinary course of business. Regardless of the outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

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

Management

The following table sets forth the name and position of each of our executive officers and directors, and each such person's age as of March 31, 2019:

Name	Age	Position
Executive Officers		
Andrew Cheng, M.D., Ph.D.	52	President, Chief Executive Officer and Director
Jonathan Young, J.D., Ph.D.	49	Executive Vice President and Chief Operating Officer
William White, J.D.	46	Executive Vice President, Chief Financial Officer and Head of Corporate Development
Timothy Rolph, DPhil	65	Chief Scientific Officer
Kitty Yale	47	Chief Development Officer
Key Employee		
Arindam Bose, Ph.D.	66	Vice President, Process Development
Non-Employee Directors		
Kevin Bitterman, Ph.D.	42	Director
Seth L. Harrison, M.D.	58	Director
Jane P. Henderson	53	Director
Mark Iwicki	52	Director
Aaron Royston, M.D.	34	Director
Graham Walmsley, M.D., Ph.D.	32	Director

(1) Member of the Audit Committee

(2) Member of the Compensation Committee

(3) Member of the Nominating and Corporate Governance Committee

Executive team

Andrew Cheng, M.D., Ph.D. Dr. Cheng has served as our President and Chief Executive Officer since September 2018. Before joining the Company, Dr. Cheng was formerly at Gilead Sciences, Inc., a biotechnology company, as the Chief Medical Officer from March 2018 through September 2018, Executive Vice President from February 2015 through September 2018 and Senior Vice President from February 2009 through February 2015. During his nearly 20 year tenure, he was responsible for the clinical development for the HIV program resulting in 11 FDA/EMA approved products. His past responsibilities also included medical affairs and the creation of the development operations department (regulatory affairs, clinical operations, pharmacovigilance, project management, clinical pharmacology and biometrics) which covered clinical development support in multiple therapeutic areas including oncology, inflammation, respiratory, cardiovascular, HIV and liver diseases. Dr. Cheng has served on the board of directors of Syntimmune, Inc., a biotechnology company, which was acquired by Alexion. Dr. Cheng holds a B.A. in biology from the Johns Hopkins University and a M.D. and Ph.D. in cellular and molecular biology from Columbia University College of Physicians and Surgeons. He completed his internal medicine residency at UCLA and was board certified in internal medicine. We believe Dr. Cheng is qualified to serve as a member of our board of directors due to his extensive experience in clinical development across multiple therapeutic areas.

Jonathan Young, J.D., Ph.D. Dr. Young served as our co-founder, President and Chief Executive Officer from April 2017 to September 2018, and since September 2018 as our co-founder, Executive Vice President

and Chief Operating Officer. Before joining the Company, Dr. Young served as a Venture Partner at Apple Tree Partners, a venture capital firm, from October 2016 to September 2018. From August 2014 to October 2016, he served as Vice President of Policy/Advocacy and General Counsel at Braeburn Pharmaceuticals, Inc. From October 2006 through August 2014, Dr. Young served in positions of increasing responsibility at FoxKiser LLP, a legal services firm, ultimately as Partner and General Counsel. Dr. Young holds a B.A. in history from Messiah College, an M.A. and Ph.D. in American history from the University of North Carolina at Chapel Hill and a J.D. from Yale Law School.

William R. White. Mr. White has served as our Executive Vice President, Chief Financial Officer and Head of Corporate Development since April 2019. Before joining our company, Mr. White served as a Managing Director and Head of US Life Sciences Investment Banking at Deutsche Bank from September 2017 until March 2019. Prior to that position, Mr. White was a Managing Director in Healthcare Investment Banking at Citigroup from May 2006 until September 2017. Previously, he served as a Vice President in Healthcare Investment Banking at Goldman, Sachs & Co., from April 2004 to March 2006. Mr. White received an A.B. from Princeton University, an M.P.P. from Harvard University and a J.D. from Columbia University.

Timothy Rolph, DPhil. Dr. Rolph has served as our co-founder and Chief Scientific Officer since April 2017. Before joining our company, Dr. Rolph served as a Venture Partner at Apple Tree Partners, a venture capital firm, from October 2016 to September 2018. From March 1994 to October 2016, Dr. Rolph served in various roles at Pfizer Inc., a pharmaceutical company, most recently as Senior Vice President, Program Value Enhancement from July 2014 to October 2016 and as Chief Scientific Officer, Cardiovascular and Metabolic and Endocrine Disease from January 2009 to June 2014. During his tenure at Pfizer Inc., Dr. Rolph also oversaw the Company's FGF21 program. Dr. Rolph holds a B.Sc. in biochemistry from the University of London and a DPhil in muscle development from University of Oxford.

Kitty Yale. Ms. Yale has served as our Chief Development Officer since October 2018. Before joining the Company, Ms. Yale served in various roles at Gilead Sciences, Inc., a biotechnology company, from October 2001 to October 2018, where she held senior clinical research and operations roles and led global clinical operations and management of the Company's oncology, HIV, inflammation and liver disease trials. Most recently, Ms. Yale served as Vice President of Clinical Operations at Gilead Sciences, Inc. from July 2016 to October 2018. Ms. Yale holds a B.Sc. in applied biology from Glasgow Caledonian University.

Key employee

Arindam Bose, Ph.D. Dr. Bose has served as our Vice President, Process Development since January 2019. He also currently serves as an independent biotechnology and bioprocessing consultant for biotechnology companies. Previously, he served as Vice President, External Affairs & Biosimilars Strategy; Biotherapeutics Pharmaceutical Sciences at Pfizer Inc. from January 2010 to March 2016. Dr. Bose currently serves on the board of directors of Dyadic International Inc, a biotechnology company. Dr. Bose received a B.T. in chemical engineering from the Indian Institute of Technology in Kanpur, India, a Master's Degree in chemical engineering from the University of Michigan, College of Engineering and a Ph.D. in chemical engineering from Purdue University.

Non-executive directors

Kevin Bitterman, Ph.D. Dr. Bitterman has served as a member of our board of directors since June 2018. Dr. Bitterman currently serves as a partner at venture firm Atlas Venture, or Atlas, a venture capital firm, where he has been employed since June 2017 and where he focuses on investments in life science companies. Prior to joining Atlas in June 2017, Dr. Bitterman was a partner at Polaris Partners, an

investment firm, as a member of the healthcare team since July 2004. Dr. Bitterman was also the founding CEO at Editas Medicine Inc., a pharmaceutical company, Visterra Inc., a biotechnology company, and Morphic Rock, LLC, a biotechnology company. During the past five years, Dr. Bitterman has served on the board of directors of Editas Medicine, Inc., Kala Pharmaceuticals, Inc., a pharmaceutical company, Genocea Biosciences, Inc., a biosciences company, as well as on the board of directors of several private companies. Dr. Bitterman also serves as board chair of the New England Venture Capital Association. Dr. Bitterman received a B.A. in biology from Rutgers College and a Ph.D. in genetics from Harvard Medical School. We believe that Dr. Bitterman is qualified to serve on our board of directors due to his extensive experience investing in, guiding, and leading start-up and early phase companies, as well as his experience as a director of other companies.

Seth L. Harrison, M.D. Dr. Harrison has served as a member of our board of directors since April 2019 and previously from January 2017 to June 2018. Dr. Harrison has served as the managing partner of Apple Tree Partners, a series of venture capital funds investing in early-stage life sciences companies, since 1999. During the past five years, Dr. Harrison has served as a member of the board of directors of the following biotechnology companies: HeartWare International, Inc., Novus Therapeutics, Inc., and Cerecor, Inc. Dr. Harrison also currently serves as a member of the board directors of several private companies, including Elstar Therapeutics, Inc., Limelight Bio, Inc., Stoke Therapeutics, Inc., Apple Tree Life Sciences, Inc. and Braeburn Pharmaceuticals, Inc. Dr. Harrison also serves on the board of directors of the Harrison Atelier Foundation and Tortoise Foundation. From 2002 to 2010, he served on the board of the International Partnership for Microbicides, a Rockefeller Foundation/Gates Foundation sponsored public-private partnership engaged in the development of anti-HIV microbicides. Dr. Harrison received an A.B. from Princeton University, an M.D. and M.B.A. both from Columbia University, and completed a surgery internship at the Presbyterian Hospital in the City of New York. We believe that Dr. Harrison's extensive experience as a senior executive and service on the board of directors of other life science companies qualifies him to serve as a member of our board of directors.

Jane P. Henderson. Ms. Henderson has served as a member of our board of directors since April 2019. Ms. Henderson currently serves as the Chief Financial Officer of Turnstone Biologics, Inc., a viral immuno-oncology company, a position she has held since June 2018. Prior to joining Turnstone Biologics, Ms. Henderson served as Chief Financial Officer and Senior Vice President of Corporate Development of Voyager Therapeutics, Inc., a gene therapy company, since January 2017. She also served as the Senior Vice President, Chief Financial and Business Officer of Kolltan Pharmaceuticals, Inc., an oncology biopharmaceutical company, from February 2013 until November 2016, when Kolltan Pharmaceuticals was acquired by Celldex Therapeutics, Inc. Prior to Kolltan Pharmaceuticals, Ms. Henderson served in various financial and business development executive roles at biopharmaceutical companies after spending almost 20 years in health care investment banking. During the past five years, Ms. Henderson has served on the board of directors of Sesen Bio Inc., a biopharmaceutical company, and IVERIC Bio, Inc., a biopharmaceutical company. Ms. Henderson received a B.S. in psychology from Duke University. We believe that Ms. Henderson is qualified to serve on our board of directors due to her extensive financial leadership in the life sciences industry and in health care investment banking.

Mark Iwicki. Mr. Iwicki has served as a member of our board of directors since November 2018 and as the chairperson of our board of directors since April 2019. Mr. Iwicki currently serves as the Chairman and Chief Executive Officer of Kala Pharmaceuticals, Inc., a pharmaceutical company, where he has been employed since April 2015. From December 2012 to January 2014, Mr. Iwicki served as President and Chief Executive Officer and director at Blend Therapeutics, Inc., now known as Tarveda Therapeutics, Inc., a biotechnology company. From 2007 to June 2012, Mr. Iwicki served in several roles, including Chief

Commercial Officer, President and Chief Operating Officer and Director and Chief Executive Officer at Sunovion Pharmaceuticals, Inc., formerly Sepracor, Inc., a pharmaceutical company. From 1998 to 2007, Mr. Iwicki held executive positions, including Vice President and Business Unit Head, at Novartis Pharmaceuticals Corporation, a pharmaceutical company. Mr. Iwicki currently serves on the board of directors of Pulmatrix, Inc., a biopharmaceutical company, Aimmune Therapeutics, Inc., a biopharmaceutical company, Kala Pharmaceuticals, Inc. as well as on the board of directors of several private companies, including Nimbus Therapeutics, LLC, a biotechnology company, and Taris Biomedical, LLC, a pharmaceutical company. Mr. Iwicki received a B.A. in business administration from Ball State University and an M.B.A. from Loyola University. We believe that Mr. Iwicki is qualified to serve on our Board due to his executive management and operational experience in the life science industry.

Aaron Royston, M.D., M.B.A. Dr. Royston has served as a member of our board of directors since June 2018. Dr. Royston is a Partner at venBio, a life sciences investment firm, and has been with venBio since November 2015. Prior to joining venBio, Dr. Royston worked for Vivo Capital, a global life sciences investment firm from July 2014 to October 2015. Previously, he worked at Bain & Company from July 2013 to July 2014, where he advised biotechnology companies on a broad range of strategic and operational issues. Earlier in his career, Dr. Royston coordinated clinical research at Mount Sinai Medical Center, where his research has been published and presented in multiple medical journals and conferences. In 2011, Dr. Royston was recognized by the Obama Administration as a Champion of Change for his work in technology and innovation. Dr. Royston currently serves on the board of directors of Menlo Therapeutics, Inc., a biopharmaceutical company, as well as several private companies including Harmony Biosciences LLC, Impel Neuropharma, Inc. and Neurogastrx, Inc. Dr. Royston received a B.S. in biological sciences from Duke University, and an M.D. and M.B.A. from the University of Pennsylvania. We believe that Dr. Royston is qualified to serve on our board of directors due to his clinical and biotechnology industry experience.

Graham Walmsley, M.D., Ph.D. Dr. Walmsley has served as a member of our board of directors since June 2018. Dr. Walmsley currently serves as a Principal at Versant Ventures, where he has been employed since July 2016 after he received his Ph.D. from Stanford University School of Medicine and where he specializes in healthcare and biotechnology investments. At Versant, Dr. Walmsley has contributed to the deployment of capital into early and mid-stage private biotechnology companies across multiple funds. In addition, Dr. Walmsley served as Head of Business Development at Jecure Therapeutics, Inc., a biotechnology company, since June 2017 through its acquisition by Roche/Genentech in November 2018. Dr. Walmsley currently serves as a board observer for Turnstone Biologics Inc., an immuno-oncology company, BlueRock Therapeutics, LP, an engineered cell therapy company and Aligos Therapeutics, Inc., a biotechnology company. He was previously a board observer for CODA Biotherapeutics, Inc., a biopharmaceutical company. Dr. Walmsley received a B.A. in molecular and cell biology from the University of California, Berkeley and an M.D. and Ph.D. from Stanford University School of Medicine. We believe that Dr. Walmsley is qualified to serve on our board of directors due to his significant experience in the healthcare and biotechnology industry.

Family relationships

There are no family relationships among any of our directors or executive officers.

Composition of our board of directors

Our board of directors consists of six members, each of whom are members pursuant to the board composition provisions of our third amended and restated certificate of incorporation and agreements with

our stockholders. These board composition provisions will terminate upon the completion of this offering. Upon the termination of these provisions, there will be no further contractual obligations regarding the election of our directors. Our nominating and corporate governance committee and our board of directors may therefore consider a broad range of factors relating to the qualifications and background of nominees. Our nominating and corporate governance committee's and our board of directors' priority in selecting board members is the identification of persons who will further the interests of our stockholders through their established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business, understanding of the competitive landscape, and professional and personal experiences and expertise relevant to our growth strategy. Our directors hold office until their successors have been elected and qualified or until the earlier of their resignation or removal. Our fourth amended and restated certificate of incorporation that will become effective upon the completion of this offering and our second amended and restated bylaws that will become effective on the date on which the registration statement of which this prospectus is a part is declared effective by the SEC also provide that our directors may be removed only for cause by the affirmative vote of the holders of at least two-thirds of the votes that all our stockholders would be entitled to cast in an annual election of directors, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

We have no formal policy regarding board diversity. Our priority in selection of board members is identification of members who will further the interests of our stockholders through his or her established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business and understanding of the competitive landscape.

Director independence

Our board of directors has determined that all members of the board of directors, except Andrew Cheng, M.D., Ph.D., are independent directors, including for purposes of the rules of The Nasdaq Global Market and the Securities and Exchange Commission, or SEC. In making such independence determination, our board of directors considered the relationships that each non-employee director has with us and all other facts and circumstances that our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director. In considering the independence of the directors listed above, our board of directors considered the association of our directors with the holders of more than 5% of our common stock. Upon the completion of this offering, we expect that the composition and functioning of our board of directors and each of our committees will comply with all applicable requirements of The Nasdaq Global Market and the rules and regulations of the SEC. Andrew Cheng, M.D., Ph.D. is not an independent director under these rules because he is currently employed as the chief executive officer of our company.

Staggered board

In accordance with the terms of our fourth amended and restated certificate of incorporation that will become effective upon the completion of this offering and our second amended and restated bylaws that will become effective on the date on which the registration statement of which this prospectus is a part is declared effective by the SEC, our board of directors will be divided into three staggered classes of directors and each will be assigned to one of the three classes. At each annual meeting of the stockholders, a class of directors will be elected for a three-year term to succeed the directors of the same class whose terms are then expiring. The terms of the directors will expire upon the election and

qualification of successor directors at the annual meeting of stockholders to be held during the years 2020 for Class I directors, 2021 for Class II directors and 2022 for Class III directors.

- Our Class I directors will be . and ;
- Our Class II directors will be , and ; and
- Our Class III directors will be , and .

Our fourth amended and restated certificate of incorporation that will become effective upon the completion of this offering and our second amended and restated bylaws that will become effective on the date the registration statement of which this prospectus is a part is declared effective by the SEC will provide that the number of directors shall be fixed from time to time by a resolution of the majority of our board of directors.

The division of our board of directors into three classes with staggered three-year terms may delay or prevent stockholder efforts to effect a change of our management or a change in control.

Board leadership structure and board's role in risk oversight

Mark Iwicki is our current chairperson of our board of directors. We believe that separating the positions of Chief Executive Officer and chairperson of the board of directors allows our Chief Executive Officer to focus on our day-to-day business, while allowing a chairperson of the board to lead the board of directors in its fundamental role of providing advice to and independent oversight of management. Our board of directors recognizes the time, effort and energy that the Chief Executive Officer is required to devote to his position in the current business environment, as well as the commitment required to serve as our chairperson, particularly as the board of directors' oversight responsibilities continue to grow. While our amended and restated by-laws and corporate governance guidelines do not require that our chairperson and Chief Executive Officer positions be separate, our board of directors believes that having separate positions is the appropriate leadership structure for us at this time and demonstrates our commitment to good corporate governance.

Risk is inherent with every business, and how well a business manages risk can ultimately determine its success. We face a number of risks, including risks relating to our financial condition, development and commercialization activities, operations, strategic direction and intellectual property as more fully discussed in the section entitled "Risk factors" appearing elsewhere in this prospectus. Management is responsible for the day-to-day management of risks we face, while our board of directors, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, our board of directors has the responsibility to satisfy itself that the risk management processes designed and implemented by management are adequate and functioning as designed.

The role of the board of directors in overseeing the management of our risks is conducted primarily through committees of the board of directors, as disclosed in the descriptions of each of the committees below and in the charters of each of the committees. The full board of directors (or the appropriate board committee in the case of risks that are under the purview of a particular committee) discusses with management our major risk exposures, their potential impact on us, and the steps we take to manage them. When a board committee is responsible for evaluating and overseeing the management of a particular risk or risks, the chairman of the relevant committee reports on the discussion to the full board of directors during the committee reports portion of the next board meeting. This enables the board of directors and its committees to coordinate the risk oversight role, particularly with respect to risk interrelationships.

Committees of our board of directors

Our board of directors has established an audit committee, a compensation committee, and a nominating and corporate governance committee, each of which will operate pursuant to a charter adopted by our board of directors and will be effective upon the effectiveness of the registration statement of which this prospectus is a part. Upon the effectiveness of the registration statement of which this prospectus is a part, the composition and functioning of all of our committees will comply with all applicable requirements of the Sarbanes-Oxley Act of 2002, Nasdaq and SEC rules and regulations.

Audit committee

, and will serve on the audit committee, which will be chaired by . Our board of directors has determined that are "independent" for audit committee purposes as that term is defined in the rules of the SEC and the applicable Nasdaq rules, and each has sufficient knowledge in financial and auditing matters to serve on the audit committee. Our board of directors has designated as an "audit committee financial expert," as defined under the applicable rules of the SEC. The audit committee's responsibilities include:

- appointing, approving the compensation of, and assessing the independence of our independent registered public accounting firm;
- pre-approving auditing and permissible non-audit services, and the terms of such services, to be provided by our independent registered public accounting firm;
- reviewing the overall audit plan with our independent registered public accounting firm and members of management responsible for preparing our financial statements;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures as well as critical accounting policies and practices used by us;
- coordinating the oversight and reviewing the adequacy of our internal control over financial reporting;
- establishing policies and procedures for the receipt and retention of accounting-related complaints and concerns;
- recommending, based upon the audit committee's review and discussions with management and our independent registered public accounting firm, whether our audited financial statements shall be included in our Annual Report on Form 10-K;
- monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to our financial statements and accounting matters;
- preparing the audit committee report required by SEC rules to be included in our annual proxy statement;
- reviewing all related person transactions for potential conflict of interest situations and voting with respect to all such transactions; and
- reviewing quarterly earnings releases.

Compensation committee

, and will serve on the compensation committee, which will be chaired by . Our board of directors has determined that each member of the compensation committee is "independent" as defined in the applicable Nasdaq rules. The compensation committee's responsibilities include:

- annually reviewing and recommending to the board of directors the corporate goals and objectives relevant to the compensation of our principal executive officer;
- evaluating the performance of our principal executive officers in light of such corporate goals and objectives and based on such evaluation: (i) determining cash compensation of our principal executive officer; and (ii) reviewing and approving grants and awards to our principal executive officer under equity-based plans;
- reviewing and approving or recommending to the board of directors the cash compensation of our other executive officers;
- reviewing and establishing our overall management compensation, philosophy and policy;
- overseeing and administering our compensation and similar plans;
- evaluating and assessing potential and current compensation advisors in accordance with the independence standards identified in the applicable Nasdaq rules;
- reviewing and approving our policies and procedures for the grant of equity-based awards;
- reviewing and recommending to the board of directors the compensation of our directors;
- preparing the compensation committee report required by SEC rules, if and when required, to be included in our annual proxy statement; and
- reviewing and approving the retention, termination or compensation of any consulting firm or outside advisor to assist in the evaluation of compensation matters.

Nominating and corporate governance committee

, and will serve on the nominating and corporate governance committee, which will be chaired by . Our board of directors has determined that each member of the nominating and corporate governance committee is "independent" as defined in the applicable Nasdaq rules. The nominating and corporate governance committee's responsibilities include:

- developing and recommending to the board of directors criteria for board and committee membership;
- establishing procedures for identifying and evaluating board of director candidates, including nominees recommended by stockholders;
- reviewing the composition of the board of directors to ensure that it is composed of members containing the appropriate skills and expertise to advise us;
- identifying individuals qualified to become members of the board of directors;
- recommending to the board of directors the persons to be nominated for election as directors and to each of the board's committees;

- developing and recommending to the board of directors a code of business conduct and ethics and a set of corporate governance guidelines; and

- overseeing the evaluation of our board of directors and management.

Our board of directors may from time to time establish other committees.

Compensation committee interlocks and insider participation

None of the members of our compensation committee has at any time during the prior three years been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving on our board of directors or compensation committee.

Code of business conduct and ethics

We will have adopted a written code of business conduct and ethics, effective upon the effectiveness of the registration statement of which this prospectus is a part, that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. Following the effectiveness of the registration statement of which this prospectus is a part, a current copy of the code will be posted on the investor relations section of our website, which is located at www.akerotx.com. If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for any officer or director, we will disclose the nature of such amendment or waiver on our website or in a current report on Form 8-K.

Executive compensation

Executive compensation overview

Historically, our executive compensation program has reflected our growth and development-oriented corporate culture. To date, the compensation of our Chief Executive Officer and President and our other executive officers identified in the 2018 Summary Compensation Table below, who we refer to as the named executive officers, has consisted of a combination of base salary, bonuses and long-term incentive compensation in the form of restricted common stock awards and incentive stock options. Our named executive officers who are full-time employees, like all other full-time employees, are eligible to participate in our retirement and health and welfare benefit plans. As we transition from a private company to a publicly traded company, we will evaluate our compensation values and philosophy and compensation plans and arrangements as circumstances merit. At a minimum, we expect to review executive compensation annually with input from a compensation consultant. As part of this review process, we expect the board of directors and the compensation committee to apply our values and philosophy, while considering the compensation levels needed to ensure our executive compensation program remains competitive with our peers. In connection with our executive compensation program, we will also review whether we are meeting our retention objectives and the potential cost of replacing a key employee.

2018 Summary compensation table

The following table presents information regarding the total compensation awarded to, earned by, and paid to our named executive officers for services rendered to us in all capacities for the years indicated.

Name and principal position	Year	Salary ($)	Bonus ($)(1)	Option awards ($)(2)	All other compensation ($)(3)	Total ($)
Andrew Cheng, M.D., Ph.D., *Chief Executive Officer and President(4)*	2018	132,813	65,205	849,477	160	1,047,655
Jonathan Young, J.D., Ph.D., *Executive Vice President, Chief Operating Officer and former Chief Executive Officer(5)*	2018	400,000	100,000	159,073	454	659,527
Timothy Rolph, DPhil., *Chief Scientific Officer*	2018	400,000	100,000	159,073	454	659,527
Kitty Yale, *Chief Development Officer(6)*	2018	78,125	29,666	212,369	106	320,266

(1) The amounts in this column reflect discretionary cash bonuses paid for performance in 2018. The amounts reported for Dr. Cheng and Ms. Yale have been prorated to reflect their partial year of service.

(2) The amounts reported in the "Option Awards" column reflect the aggregate grant date fair value of share- based compensation awarded during the year computed in accordance with the provisions of Financial Accounting Standards Board Accounting Standards Codification, or ASC, Topic 718. See Note 7 to our consolidated financial statements appearing at the end of this prospectus regarding assumptions underlying the valuation of equity awards.

(3) Amounts in this column represent Company-paid life insurance premiums.

(4) The amount reported in the "Salary" column for Dr. Cheng represents his salary starting September 10, 2018, the date his employment with the Company commenced. His annual salary for 2018 was $425,000.

(5) Dr. Young served as our Chief Executive Officer until Dr. Cheng commenced employment on September 10, 2018.

(6) The amount reported in the "Salary" column for Ms. Yale represents her salary starting October 15, 2018, the date her employment with the Company commenced. Her annual salary was $375,000.

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Pursuant to 17 C.F.R. Section 200.83

Narrative to summary compensation table

Base salaries

We use base salaries to recognize the experience, skills, knowledge and responsibilities required of all our employees, including our named executive officers. Base salaries are reviewed annually, typically in connection with our annual performance review process, and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and experience. For the year ended December 31, 2018, the annual base salaries for each of Drs. Cheng, Young and Rolph and Ms. Yale were $425,000, $400,000, $400,000 and $375,000, respectively.

Bonuses

We pay discretionary cash bonuses to reward our executives for their performance over the fiscal year. For 2018, the target bonus for Dr. Cheng was equal to up to 40 percent of his base salary, the target bonus for each of Dr. Young and Dr. Rolph was up to 20 percent of his respective base salary, and the target bonus for Ms. Yale was equal to up to 30 percent of her base salary.

Equity compensation

Although we do not have a formal policy with respect to the grant of equity incentive awards to our executive officers, we believe that equity grants provide our executives with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and our stockholders. In addition, we believe that equity grants with a time-based vesting feature promote executive retention because this feature incentivizes our executive officers to remain in our employment during the vesting period. During the year ended December 31, 2018, we granted options to purchase shares of our common stock to each of the named executive officers, as described in more detail in the "Outstanding equity awards at 2018 fiscal year-end" table.

Employment arrangements with our named executive officers

Andrew Cheng, M.D., Ph.D.

On August 7, 2018, we entered into an employment agreement with Dr. Cheng, or the Cheng Employment Agreement, which sets forth the terms of his employment with us. Pursuant to the terms of the Cheng Employment Agreement, Dr. Cheng is employed as our CEO and president, and he serves as a member of our board of directors. As compensation for Dr. Cheng's services, we pay him a base salary of $425,000, and he is eligible to receive an annual bonus with a target of 40% of his base salary. Dr. Cheng is eligible to participate in our employee benefit plans available for executives, subject to the terms of those plans.

The Cheng Employment Agreement further provides that if Dr. Cheng's employment is terminated by us without Cause (as defined in the Cheng Employment Agreement) or Dr. Cheng resigns for Good Reason (as defined in the Cheng Employment Agreement), he will be entitled to receive as severance base salary continuation, plus payment by the Company of COBRA premiums if Dr. Cheng elects to extend our health care benefits through COBRA, each for a period of 12 months. Any such severance payment is conditioned upon execution by Dr. Cheng of a general release of claims in favor of the Company.

The Cheng Employment Agreement also granted Dr. Cheng an option to purchase a number of shares of our common stock equal to approximately 5% of our equity on a fully diluted basis, or the Initial Option. Twenty five percent of the Initial Option vests on the one-year anniversary of the Commencement Date (as defined in the Cheng Employment Agreement), and the remainder of the shares vest in equal monthly installments for a period of 36 months thereafter, provided Dr. Cheng remains employed with us as of

each such vesting date; provided, however, in the event that Dr. Cheng's service is terminated (i) by Dr. Cheng for Good Reason (as defined in the Cheng Employment Agreement); or (ii) due to Dr. Cheng's death or disability, 100% of the unvested Initial Option will vest and become exercisable, provided Dr. Cheng remained employed through the date of his termination. In addition, 100% of the unvested Initial Option will vest 6 months following a Sale Event (as defined in the Akero Therapeutics, Inc. 2018 Stock Option and Grant Plan (the "2018 Plan")) or sooner if Dr. Cheng terminated for any reason other than for Cause (as defined in the Cheng Employment Agreement) following such Sale Event. In addition, in the event that Dr. Cheng's service is terminated (i) by Dr. Cheng for Good Reason or (ii) by the Company without cause, then Dr. Cheng shall have 12 months following the termination of employment to exercise any vested options.

Jonathan Young, J.D., Ph.D.

On August 1, 2018, we entered into an amended and restated employment agreement with Dr. Young, or the Young Employment Agreement, which sets forth the terms of his employment with us. Dr. Young served as the President and CEO until we employed Dr. Cheng as the President and CEO on September 7, 2018, and at such time, Dr. Young's role transitioned to Executive Vice President and COO. As compensation for Dr. Young's services, we pay him a base salary of $400,000, and he is eligible to receive an annual bonus with a target of up to 20% of his base salary, subject to his employment on the date of payment. Dr. Young is eligible to participate in our employee benefit plans available for executives, subject to the terms of those plans.

The Young Employment Agreement further provides that if Dr. Young's employment is terminated by us without Cause (as defined in the Young Agreement) or Dr. Young resigns for Good Reason (as defined in the Young Employment Agreement), he will be entitled to receive as severance base salary continuation, plus payment of COBRA premiums by the Company if Dr. Young elects to extend our health care benefits through COBRA, each for a period of 9 months. Any such severance payment is conditioned upon execution by Dr. Young of a general release of claims in favor of the Company.

The Young Employment Agreement also grants Dr. Young an option to purchase a number of shares of our common stock equal to approximately 1.4% of our equity on a fully diluted basis, or the Initial Option. The number of shares underlying the Initial Option is equal to 1.4% of our fully diluted capitalization through tranche 1 of our series A financing as determined on the grant date. Twenty-five percent of the Initial Option vests on the date of grant, and the remainder of the shares will vest in equal monthly installments for a period of 36 months thereafter, provided Mr. Young remains engaged in a Service Relationship (as defined in the 2018 Plan) with the Company on each such vesting date. Any grants of an option to purchase shares of our common stock after the grant of the Initial Option, or the Subsequent Option, will vest in equal monthly installments and will vest in full 48 months following the date of grant, provided that Dr. Young remains employed on each such vesting date. In addition, 100% of the unvested Initial Option or any Subsequent Option will vest 6 months following a Sale Event (as defined in the 2018 Plan) or sooner if terminated for any reason other than for Cause following such Sale Event.

Timothy Rolph, DPhil.

On August 1, 2018, we entered into an amended and restated employment agreement with Dr. Rolph, or the Rolph Employment Agreement, which sets forth the terms of his employment with us. Pursuant to the terms of the Rolph Employment Agreement, Dr. Rolph is employed as our Chief Scientific Officer, and as compensation for Dr. Rolph's services, we pay him a base salary of $400,000. Dr. Rolph is eligible to receive an annual bonus with a target of up to 20% of his base salary. Dr. Rolph is eligible to participate in our employee benefit plans available for executives, subject to the terms of those plans.

The Rolph Employment Agreement further provides that if Dr. Rolph's employment is terminated by us without Cause (as defined in the Rolph Employment Agreement) or Dr. Rolph resigns for Good Reason (as defined in the Rolph Employment Agreement), he will be entitled to receive as severance base salary continuation, plus payment of COBRA premiums by the Company if Dr. Rolph elects to extend our health care benefits through COBRA, each for a period of 9 months. Any such severance payment is conditioned upon execution by Dr. Rolph of a general release of claims in favor of the Company.

The Rolph Employment Agreement grants Dr. Rolph an option to purchase a number of shares of our common stock equal to approximately 1.4% of our equity on a fully diluted basis, or the Initial Option. The number of shares underlying the Initial Option is equal to 1.4% of our fully diluted capitalization through tranche 1 of our series A financing as determined on the grant date. Twenty-five percent of the Initial Option vests on the date of grant, and the remainder of the shares vest in equal monthly installments for a period of 36 months thereafter, provided Dr. Rolph remains engaged in a Service Relationship (as defined in the 2018 Plan) with the Company on each such vesting date. Any grants of an option to purchase shares of our common stock after the grant of the Initial Option, or the Subsequent Option, will vest in equal monthly installments and will vest in full 48 months following the date of grant, provided that Dr. Rolph remains employed on each such vesting date. In addition, 100% of the unvested Initial Option or any Subsequent Option will vest 6 months following a Sale Event (as defined in the 2018 Plan) or sooner if terminated for any reason other than for Cause following such Sale Event.

Kitty Yale

On September 26, 2018, we entered into an employment agreement with Ms. Yale, or the Yale Employment Agreement, which sets forth the terms of her employment with us. Pursuant to the terms of the Yale Employment Agreement, Ms. Yale is employed as our Chief Development Officer, and as compensation for Ms. Yale's services, we pay her a base salary of $375,000. Ms. Yale is eligible to receive an annual bonus with a target of up to 30% of her base salary. Ms. Yale is eligible to participate in our employee benefit plans available for executives, subject to terms of those plans.

The Yale Employment Agreement further provides that if Ms. Yale's employment is terminated by us without Cause (as defined in the Yale Employment Agreement) or Ms. Yale resigns for Good Reason (as defined in the Yale Employment Agreement), she will be entitled to receive as severance base salary continuation, plus payment of COBRA premiums by the Company if Ms. Yale elects to extend our health care benefits through COBRA, each for a period of 9 months. Any such severance payment is conditioned upon execution by Ms. Yale of a general release of claims in favor of the Company.

The Yale Employment Agreement also grants Ms. Yale an option to purchase a number of shares of our common stock equal to approximately 1.25% of our equity on a fully diluted basis, or the Initial Option. Twenty-five percent of the Initial Option vests on the one-year anniversary of the Commencement Date (as defined in the Yale Employment Agreement), and the remainder of the shares vest in equal monthly installments for a period of 36 months thereafter, provided Ms. Yale remains employed with us as of each such vesting date. In addition, 100% of the unvested Initial Option will vest 6 months following a Sale Event (as defined in the 2018 Plan) or sooner if terminated for any reason other than for Cause following such Sale Event.

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Pursuant to 17 C.F.R. Section 200.83

Outstanding equity awards at 2018 fiscal year-end

The following table sets forth information concerning outstanding equity awards held by each of our named executive officers as of December 31, 2018. All equity awards set forth in the table below were granted under our 2018 Plan.

	Option awards(1)					Stock awards	
Name	Vesting commencement date	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Option exercise price ($)	Option expiration date	Number of shares or units of stock that have not vested (#)	Market value of shares or units of stock that have not vested ($)(2)
Andrew Cheng	9/1/2018	—	1,326,666	$ 0.20	9/07/2028	—	—
	10/1/2018	—	1,602,564	$ 0.20	10/17/2028	—	—
Jonathan Young	8/1/2018	123,823	247,643(3)	$ 0.20	8/01/2028	—	—
	10/1/2018	18,697	430,021(4)	$ 0.20	10/17/2028	—	—
	—	—	—	—	—	82,167(5)	
	—	—	—	—	—	41,083(6)	
Timothy Rolph	8/1/2018	123,823	247,643(3)	$ 0.20	8/01/2028	—	—
	10/18/2018	18,697	430,021(4)	$ 0.20	10/17/2028	—	—
	—	—	—	—	—	82,167(7)	
	—	—	—	—	—	41,083(6)	
Kitty Yale	10/1/2018	—	331,666	$ 0.20	9/26/2028	—	—
	10/1/2018	—	400,641	$ 0.20	10/17/2028	—	—

(1) Represents stock options granted to our named executive officers under our 2018 Plan. Unless otherwise noted, stock options vest over four years with 25% of the shares vesting on the first anniversary of the vesting commencement date, and the remaining shares vesting in 36 equal monthly installments thereafter, subject to continued service. Upon the earlier of the date that is six months following a sale event, or a termination of the executive's employment following such sale event other than for cause, the vesting of each stock option shall accelerate and vest in full.

(2) The market price of our common stock is based on the assumed initial public offering price of the common stock of $ per share, the midpoint of the price range on the cover page of this prospectus.

(3) This option vests over three years with 25% of the shares vesting on the vesting commencement date and the remaining shares vesting in 36 equal monthly installments thereafter, subject to continued service.

(4) This option vests in 48 equal monthly installments following the vesting commencement date, subject to continued service.

(5) Dr. Young purchased 232,000 shares of stock on March 16, 2017, and on March 29, 2018, amended the vesting terms applicable to such shares. 77,333 of such shares vested on March 29, 2018, 38,667 of the shares vested on May 1, 2018, and the remaining 116,000 shares vest in 24 equal monthly installments thereafter, subject to continued service. Any unvested shares will have their vesting accelerate in full upon a change in control, subject to Dr. Young's continued service through such date.

(6) Each of Mr. Young and Dr. Rolph purchased 116,000 shares of stock on March 29, 2018. 58,000 of such shares vested on May 1, 2018, and the remaining 58,000 shares vest in 24 equal monthly installments, subject to continued service through each such date. Any unvested shares will have their vesting accelerate in full upon a change in control, subject to the executive's continued service through such date.

(7) Dr. Rolph purchased 232,000 shares of stock on March 16, 2017, and on March 29, 2018, amended the vesting terms applicable to such shares. 77,333 of such shares vested on March 29, 2018, 38,667 of the shares vested on May 1, 2018, and the remaining 116,000 shares vest in 24 equal monthly installments thereafter, subject to continued service. Any unvested shares will have their vesting accelerate in full upon a change in control, subject to Dr. Rolph's continued service through such date.

Employee benefit and equity compensation plans

2019 Stock Option and Grant Plan

Our 2019 Stock Option and Grant Plan, or 2019 Plan, was adopted by our board of directors on , and approved by our stockholders on and will become effective as of the date immediately prior to the date of the effectiveness of the registration statement of which this prospectus is a part. The 2019 Plan allows the board of directors' compensation committee to make equity-based incentive awards to our officers, employees, directors and other key persons (including consultants).

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The 2019 Plan will replace our 2018 Plan. Our 2019 Plan provides flexibility to our compensation committee to use various equity-based incentive awards as compensation tools to motivate our workforce.

We have initially reserved shares of our common stock, or the Initial Limit, for the issuance of awards under the 2019 Plan, plus the number of shares of common stock remaining available for issuance under our 2018 Plan. The 2019 Plan provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2020, by % of the outstanding number of shares of our common stock on the immediately preceding December 31 or such lesser number of shares as determined by our compensation committee, or the Annual Increase. This number is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization.

The shares we issue under the 2019 Plan will be authorized but unissued shares or shares that we reacquire. The shares of common stock underlying any awards that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without any issuance of stock, expire or are otherwise terminated (other than by exercise) under each of the 2019 Plan and the 2018 Plan will be added back to the shares of common stock available for issuance under the 2019 Plan.

The maximum aggregate number of shares that may be issued in the form of incentive stock options shall not exceed the Initial Limit cumulatively increased on January 1, 2020 and on each January 1 thereafter by the lesser of the Annual Increase for such year or shares of common stock.

The 2019 Plan will be administered by our compensation committee. Our compensation committee has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to make any combination of awards to participants, and to determine the specific terms and conditions of each award, subject to the provisions of the 2019 Plan. Persons eligible to participate in the 2019 Plan will be those full or part-time officers, employees, non-employee directors and other key persons (including consultants) as selected from time to time by our compensation committee in its discretion.

The 2019 Plan permits the granting of both options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code and options that do not so qualify. The option exercise price of each option will be determined by our compensation committee but may not be less than 100% of the fair market value of our common stock on the date of grant. The term of each option will be fixed by our compensation committee and may not exceed 10 years from the date of grant. Our compensation committee will determine at what time or times each option may be exercised.

Our compensation committee may award stock appreciation rights subject to such conditions and restrictions as it may determine. Stock appreciation rights entitle the recipient to shares of common stock, or cash, equal to the value of the appreciation in our stock price over the exercise price. The exercise price of each stock appreciation right may not be less than 100% of the fair market value of the common stock on the date of grant.

Our compensation committee may award shares of restricted common stock and restricted stock units to participants subject to such conditions and restrictions as it may determine. These conditions and restrictions may include the achievement of certain performance goals and continued employment with us through a specified vesting period. Our compensation committee may also grant shares of common stock that are free from any restrictions under the 2019 Plan. Unrestricted stock may be granted to participants in recognition of past services or other valid consideration and may be issued in lieu of cash compensation due to such participant.

Our compensation committee may grant cash bonuses under the 2019 Plan to participants, subject to the achievement of certain performance goals.

The 2019 Plan provides that in the case of, and subject to, the consummation of a "sale event" as defined in the 2019 Plan, all outstanding awards may be assumed, substituted or otherwise continued by the successor entity. To the extent that the successor entity does not assume, substitute or otherwise continue such awards, then (i) all stock options and stock appreciation rights will automatically become fully exercisable and the restrictions and conditions on all other awards with time-based conditions will automatically be deemed waived, and awards with conditions and restrictions relating to the attainment of performance goals may become vested and non-forfeitable in connection with a sale event in the compensation committee's discretion and (ii) upon the effectiveness of the sale event, the 2019 Plan and all awards will automatically terminate. In the event of such termination, (i) individuals holding options and stock appreciation rights will be permitted to exercise such options and stock appreciation rights (to the extent exercisable) prior to the sale event; or (ii) we may make or provide for a cash payment to participants holding options and stock appreciation rights equal to the difference between the per share cash consideration payable to stockholders in the sale event and the exercise price of the options or stock appreciation rights (to the extent exercisable).

Our board of directors may amend or discontinue the 2019 Plan and our compensation committee may amend the exercise price of options and amend or cancel outstanding awards for purposes of satisfying changes in law or any other lawful purpose, but no such action may adversely affect rights under an award without the holder's consent. Certain amendments to the 2019 Plan require the approval of our stockholders.

No awards may be granted under the 2019 Plan after the date that is ten years from the date of stockholder approval. No awards under the 2019 Plan have been made prior to the date of this prospectus.

2018 Stock Option and Grant Plan

Our 2018 Stock Option and Grant Plan, or 2018 Plan, was approved and adopted by our board of directors and stockholders on June 7, 2018. Under the 2018 Plan, we have reserved for issuance an aggregate of 9,443,760 share of our common stock for the issuance of stock options and other equity awards under the 2018 Plan. This number of shares of common stock reserved for issuance is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization. As of March 31, 2019, options to purchase 7,115,964 shares of common stock were outstanding under the 2018 Plan. Our board of directors has determined not to make any further awards under the 2018 Plan following the completion of this offering, but all outstanding awards under the 2018 Plan will continue to be governed by their existing terms. The maximum number of shares that may be issued as incentive stock options may not exceed 80,000,000.

The shares of common stock underlying any awards that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without the issuance of stock, expire or are otherwise terminated (other than by exercise) under the 2018 Plan will be added back to the shares of common stock available for issuance under the 2018 Plan.

Our board of directors has acted as administrator of the 2018 Plan. The administrator has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to make any combination of awards to participants, and to determine the specific terms and conditions of each award, subject to the provisions of our 2018 Plan. Persons eligible to participate in our 2018 Plan will

be those full or part-time officers, employees, non-employee directors, and consultants as selected from time to time by the administrator in its discretion.

Our 2018 Plan permits the granting of both options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code and options that do not so qualify. The option exercise price of each option will be determined by our Committee but may not be less than 100% of the fair market value of our common stock on the date of grant, or in the case of an incentive stock option granted to a 10% owner, the exercise price shall not be less than 110% of the fair market value of our common stock on the date of grant. The term of each option will be fixed by our Committee and may not exceed ten years from the date of grant. Our Committee will determine at what time or times each option may be exercised.

Our Committee may award restricted shares of common stock and restricted stock units to participants subject to such conditions and restrictions as it may determine. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment with us through a specified vesting period.

Our Committee may also grant shares of common stock that are free from any restrictions under our 2018 Plan. Unrestricted stock may be granted to participants in recognition of past services or for other valid consideration and may be issued in lieu of cash compensation due to such participant.

Our 2018 Plan provides that upon the effectiveness of a Sale Event (as defined in our 2018 Plan) an acquirer or successor entity may assume, continue or substitute outstanding awards under our 2018 Plan. To the extent that awards granted under our 2018 Plan are not assumed or continued or substituted by the successor entity, except as may be otherwise provided in the relevant award certificate, all awards with time-based or performance-based vesting, conditions or restrictions shall be forfeited as of the effective time of the Sale Event.

Upon the effective time of the sale event, all outstanding awards granted under our 2018 Plan and our 2018 Plan shall terminate. In the event of such termination, individuals holding options will be permitted to exercise such options within a specified period of time prior to the Sale Event. In addition, in connection with the termination of our 2018 Plan upon a Sale Event, we may make or provide for a payment, in cash or in kind, to participants holding vested and exercisable options equal to the difference between the per share cash consideration payable to stockholders in the Sale Event and the exercise price of the options. Our board of directors may amend or discontinue our 2018 Plan and our Committee may amend or cancel outstanding awards for purposes of satisfying changes in law or any other lawful purpose, but no such action may adversely affect rights under an award without the holder's consent. Certain amendments to our 2018 Plan require the approval of our stockholders.

No awards may be granted under our 2018 Plan after the date that is ten years from the effective date of our 2018 Plan.

Employee stock purchase plan

On , our board of directors adopted the Employee Stock Purchase Plan, or the ESPP, and on , our stockholders approved the ESPP. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423(b) of the Code. The ESPP initially reserves and authorizes the issuance of up to a total of shares of common stock to participating employees. The ESPP provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2020 and each January 1 thereafter through January 1, 2029, by

the least of (i) % of the outstanding number of shares of our common stock on the immediately preceding December 31, (ii) shares or (iii) such number of shares as determined by the ESPP administrator. The number of shares reserved under the ESPP is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization.

All employees whose customary employment is for more than 20 hours per week and have completed at least months of employment are eligible to participate in the ESPP. However, any participating employee who would own 5% or more of the total combined voting power or value of all classes of stock after an option were granted under the ESPP would not be eligible to purchase shares under the ESPP.

We will make one or more offerings each year to our employees to purchase shares under the ESPP. Offerings will usually begin on each January 1 and July 1 and will continue for six-month periods, referred to as offering periods. Each eligible employee may elect to participate in any offering by submitting an enrollment form at least 15 business days before the relevant offering date.

Each employee who is a participant in the ESPP may purchase shares by authorizing payroll deductions of up to % of his or her base compensation during an offering period. Unless the participating employee has previously withdrawn from the offering, his or her accumulated payroll deductions will be used to purchase shares on the last business day of the offering period at a price equal to 85% of the fair market value of the shares on the first business day or the last business day of the offering period, whichever is lower. Under applicable tax rules, an employee may purchase no more than $25,000 worth of shares of common stock, valued at the start of the purchase period, under the ESPP in any calendar year.

The accumulated payroll deductions of any employee who is not a participant on the last day of an offering period will be refunded. An employee's rights under the ESPP terminate upon voluntary withdrawal from the plan or when the employee ceases employment with us for any reason.

Senior executive cash incentive bonus plan

In , our board of directors adopted the Senior Executive Cash Incentive Bonus Plan, or the Bonus Plan. The Bonus Plan provides for cash bonus payments based upon the attainment of performance targets established by our compensation committee.

The payment targets will be related to financial and operational measures or objectives with respect to our company, or corporate performance goals, as well as individual performance objectives. Our compensation committee may select corporate performance goals from among the following: achievement of specified research and development, publication, clinical and/or regulatory milestones, adjusted billings, earnings before interest, taxes, depreciation and amortization, net income (loss) (either before or after interest, taxes, depreciation and/or amortization), changes in the market price of our common stock, economic value-added, funds from operations or similar measure, sales or revenue, acquisitions or strategic transactions, operating income (loss), cash flow (including, but not limited to, operating cash flow and free cash flow), return on capital, assets, equity, or investment, stockholder returns, return on sales, gross or net profit levels, productivity, efficiency, margins, operating efficiency, customer satisfaction, working capital, earnings (loss) per share of stock, bookings, new bookings or renewals, sales or market shares; number of customers number of new customers or customer references; operating income and/or net annual recurring revenue, any of which may be measured in absolute terms, as compared to any incremental increase, in terms of growth, or as compared to results of a peer group, against the market as a whole, compared to applicable market indices and/or measured on a pre-tax or post-tax basis.

Each executive officer who is selected to participate in the Bonus Plan will have a target bonus opportunity set for each performance period. The bonus formulas will be adopted in each performance period by the compensation committee and communicated to each executive. The corporate performance goals will be measured at the end of each performance period after our financial reports have been published or such other appropriate time as the compensation committee determines. If the corporate performance goals and individual performance objectives are met, payments will be made as soon as practicable following the end of each performance period. Subject to the rights contained in any agreement between the executive officer and us, an executive officer must be employed by us on the bonus payment date to be eligible to receive a bonus payment. The Bonus Plan also permits the compensation committee to adjust or approve additional bonuses to executive officers in its sole discretion.

401(k) Plan

We maintain a tax-qualified retirement plan, or the 401(k) Plan, that provides eligible U.S. employees with an opportunity to save for retirement on a tax advantaged basis. Eligible employees are able to defer eligible compensation subject to applicable annual Code limits. Employees' pre-tax or Roth contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. Employees are immediately and fully vested in their contributions. Our 401(k) Plan is intended to be qualified under Section 401(a) of the Code with our 401(k) Plan's related trust intended to be tax exempt under Section 501(a) of the Code. As a tax-qualified retirement plan, contributions to our 401(k) Plan and earnings on those contributions are not taxable to the employees until distributed from our 401(k) Plan.

Director compensation

The following table presents the total compensation for each person who served as a non-employee member of our board of directors and received compensation for such service during the fiscal year ended December 31, 2018. Other than as set forth in the table and described more fully below, we did not pay any compensation, make any equity awards to, or pay any other compensation to any of the non-employee members of our board of directors in 2018. Andrew Cheng, our President and Chief Executive Officer, did not receive any compensation for his service as a member of our board of directors during 2018. Dr. Cheng's compensation for service as an employee for fiscal year 2018 is presented in "Executive compensation—2018 Summary compensation table." We reimburse non-employee members of our board of directors for reasonable travel expenses.

Director compensation table—2018

Name	Fees earned or paid in cash ($)	Option awards ($)(1)	Total ($)
Kevin Bitterman Ph.D.	—	—	—
Mark Iwicki(2)	6,250(3)	67,958	74,208
Aaron Kantoff	—	—	—
Aaron Royston M.D., M.B.A.	—	—	—
Graham Walmsley M.D., Ph.D.	—	—	—

(1) The amounts reported in the "Option Awards" column reflect the aggregate grant date fair value of share- based compensation awarded during the year computed in accordance with the provisions of Financial Accounting Standards Board Accounting Standards Codification, or ASC, Topic 718. See Note 7 to our consolidated financial statements appearing at the end of this prospectus regarding assumptions underlying the valuation of equity awards.

(2) As of December 31, 2018, Mr. Iwicki held an unexercised option to purchase 234,338 shares of our common stock.

(3) Mr. Iwicki serves as the Lead Director of our Board of Directors. We pay Mr. Iwicki a $25,000 fee for his services, which fee was prorated for the 2018 calendar year based on his start date.

Non-Employee director compensation policy

Our board of directors will adopt a non-employee director compensation policy, effective upon effectiveness of the registration statement of which this prospectus forms a part that is designed to enable us to attract and retain, on a long-term basis, highly qualified non-employee directors. Under the policy, each director who is not an employee will be paid cash compensation from and after the completion of this offering, as set forth below:

	Member annual fee ($)	Chairman additional annual fee ($)
Board of Directors		
Audit Committee		
Compensation Committee		
Nominating and Corporate Governance Committee		

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In addition, each non-employee director serving on our board of directors upon completion of this offering and each non-employee director elected or appointed to our board of directors following the completion of this offering will be granted a one-time equity award of shares on the date of such director's election or appointment to the board of directors, which will vest annually over three years, subject to continued service through such vesting dates. On the date of each annual meeting of stockholders of our company, each non-employee director will be granted an annual equity award of shares, which will vest in full of the earlier to occur of the first anniversary of the date of grant or the next annual meeting, subject to continued service as a director through such vesting date.

Certain relationships and related party transactions

The following includes a summary of transactions since our inception on January 24, 2017 to which we have been a party in which the amount involved exceeded or will exceed $120,000 (or, if less, 1% of the average of our total asset amounts as of December 31, 2017 and 2018), and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under "Executive compensation" and "Director compensation." We also describe below certain other transactions with our directors, executive officers and stockholders.

Sales of securities

Common stock

In March 2017, we issued 232,000 shares of our common stock to Jonathan Young, our co-founder and Chief Operating Officer, and 232,000 shares of our common stock to Timothy Rolph, our Chief Scientific Officer, each with a $0.0001 purchase price per share for total proceeds of $23.20, respectively. In March 2018, we issued 116,000 shares of our common stock to Jonathan Young and 116,000 shares of our common stock to Timothy Rolph, each with a $0.0001 purchase price per share for total proceeds of $11.60, respectively.

Series A convertible preferred stock financing

In June 2018, with a subsequent closing in November 2018, we issued an aggregate of 50,858,462 shares of our Series A convertible preferred stock at a purchase price of $1.00 per share pursuant to agreements entered into with investors, for an aggregate purchase price of approximately $45.0 million. Each share of our Series A convertible Preferred Stock will automatically convert into one share of our common stock immediately prior to the completion of this offering. All purchasers of our convertible preferred stock are entitled to specified registration rights. See "Description of capital stock—Registration rights" for more information regarding these registration rights. The following table summarizes purchases of our Series A convertible preferred stock by related persons:

Participant	Shares of series A convertible preferred stock		Total purchase price
Apple Tree Partners IV, L.P.(1)	13,000,000	$	13,000,000
venBio Global Strategic Fund II, L.P.(2)	10,666,667	$	10,666,667
Versant Venture Capital VI, L.P.(3)	10,666,667	$	10,666,667
Atlas Venture Fund XI, L.P.(4)	10,666,667	$	10,666,667
Amgen Inc.(5)	5,858,461	$	0(6)

(1) Apple Tree Partners IV, L.P., or ATP, is a holder of five percent or more of our capital stock. Seth L. Harrison, M.D. is the founder and managing partner of ATP and a member of our board of directors.

(2) venBio Global Strategic Fund II, L.P., or venBio, is a holder of five percent or more of our capital stock. Aaron Royston, M.D., M.B.A., is a partner at venBio and a member of our board of directors.

(3) Versant Venture Capital VI, L.P., or Versant, is a holder of five percent or more of our capital stock. Graham Walmsley M.D., Ph.D., is a principal at Versant and a member of our board of directors.

(4) Atlas Venture Fund XI, L.P., or Atlas Fund XI, together with its affiliate fund Atlas Venture Opportunity Fund I, L.P., or Atlas Fund I, is a holder of five percent or more of our capital stock. Kevin Bitterman, Ph.D., is a partner at Atlas Fund XI, Atlas Fund I and a member of our board of directors.

(5) Amgen Inc., or Amgen, is a holder of five percent or more of our capital stock.

(6) The shares of Series A convertible preferred stock issued to Amgen were partial consideration for the exclusive license agreement entered into simultaneously with the sale and issuance of the Series A convertible preferred stock.

Series B convertible preferred stock financing

In December 2018, we sold an aggregate of 13,871,948 shares of our Series B convertible preferred stock at a purchase price of $3.28 per share pursuant to agreements entered into with investors, for an aggregate purchase price of approximately $45.5 million. Each share of our Series B convertible preferred stock will automatically convert into one share of our common stock immediately prior to the completion of this offering. All purchasers of our convertible preferred stock are entitled to specified registration rights. See "Description of capital stock—Registration rights" for more information regarding these registration rights. The following table summarizes purchases of our Series B convertible preferred stock by related persons:

Participant	Shares of series B convertible preferred stock		Total purchase price
Apple Tree Partners IV, L.P.(1)	880,568	$	2,888,263.04
Atlas Venture Opportunity Fund I, L.P.(2)	722,737	$	2,370,577.36
venBio Global Strategic Fund II, L.P.(3)	722,737	$	2,370,577.36
Versant Venture Capital VI, L.P.(4)	722,737	$	2,370,577.36
Entities affiliated with Janus Henderson(5)	4,268,292	$	13,999,997.76

(1) Apple Tree Partners IV, L.P., or ATP is a holder of five percent or more of our capital stock. Seth L. Harrison, M.D. is the founder and managing partner of ATP and a member of our board of directors.

(2) Atlas Venture Opportunity Fund I, L.P., or Atlas Fund I, together with its affiliate fund Atlas Venture Fund XI, L.P., or Atlas Fund XI, is a holder of five percent or more of our capital stock. Kevin Bitterman, Ph.D., is a partner at Atlas Fund I, Atlas Fund XI and a member of our board of directors.

(3) venBio Global Strategic Fund II, L.P., or venBio, is a holder of five percent or more of our capital stock. Aaron Royston, M.D., M.B.A., is a partner at venBio and a member of our board of directors.

(4) Versant Venture Capital VI, L.P., or Versant, is a holder of five percent or more of our capital stock. Graham Walmsley M.D., Ph.D., is a principal at Versant and a member of our board of directors.

(5) Consists of: (i) 2,642,075 shares of Series B convertible preferred stock purchased and received by Janus Henderson Global Life Sciences Fund, (ii) 1,610,974 shares of Series B convertible preferred stock purchased and received by Janus Henderson Capital Funds PLC, and (iii) 15,243 shares of Series B convertible preferred stock purchased and received by Janus Henderson Horizon Fund—Biotechnology Fund.

Services agreement

On June 7, 2017, we entered into a services agreement with Apple Tree Life Sciences, Inc., or ATLS, an affiliate of Apple Tree Partners IV, L.P., under which ATLS provided us with personnel, advisory and consulting services relating to potential investment and/or acquisition, development and implementation of a plan to obtain regulatory approval of any acquired candidates, general scientific leadership, and management of research and development. The services agreement was terminated in December 2018. From June 2017 to January 2019, we paid ATLS an aggregate of $2.1 million for services provided under the services agreement, inclusive of the services provided by Jonathan Young, Tim Rolph and Paul DaSilva-Jardine. Paul DaSilva-Jardine served as our Chief Discovery Officer from March 2017 until October 2017. Jonathan Young and Tim Rolph have served as executive officers since March 2017. Seth L. Harrison, who

currently serves on our board of directors since April 2019 and previously served as a member of our board of directors from January 2017 to June 2018, is the President and director of ATLS, as well as the director of the general partner of Apple Tree Partners IV, L.P. For more information see the "Principal stockholders" section below.

License agreement

On June 7, 2018, we entered into an exclusive license agreement with Amgen. Amgen granted us an exclusive license to certain patents and a non-exclusive license to certain related know-how to commercially develop, manufacture, use and distribute throughout the world therapeutic products that incorporate such patents and related know-how. We paid Amgen an upfront fee of $5.0 million and issued to Amgen an aggregate of 5,858,461 shares of Series A convertible preferred stock. We will also make certain milestone payments to Amgen and royalty payments on future sales of licensed products. For more information regarding the license agreement see "Business—Exclusive license agreement with Amgen Inc."

Amended and restated investors' rights agreement

We are a party to an investors' rights agreement, effective as of December 10, 2018, with holders of our convertible preferred stock, including our 5% stockholder and entities affiliated with our directors. The investor rights agreement provides these holders the right, following the completion of this offering, to demand that we file a registration statement or request that their shares be covered by a registration statement that we are otherwise filing. The investor rights agreement also provides a right of first refusal to purchase future securities sold by us, which such right shall terminate immediately prior to the consummation of this offering. See "Description of capital stock—Registration rights" for additional information regarding these registration rights.

Amended and restated voting agreement

We are party to a voting agreement, effective as of December 10, 2018, with certain of our stockholders. Each of Apple Tree, Atlas, venBio, and Versant have appointed representatives to our Board of Directors. The voting agreement will terminate upon the completion of this offering, and members previously elected to our board of directors pursuant to this agreement will continue to serve as directors until they resign, are removed or their successors are duly elected by the holders of our common stock. The composition of our board of directors after this offering is described in more detail under "Management—Board composition and election of directors."

Amended and restated right of first refusal and co-sale agreement

We are a party to an amended and restated right of first refusal and co-sale agreement, effective as of December 10, 2018, with holders of our convertible preferred stock, including some of our 5% stockholders and entities affiliated with our directors. The right of first refusal and co-sale agreement provides the key holders the right to purchase all or any portion of transfer stock, as well as the right of co-sale and participation in any proposed transfers. The agreement will terminate upon completion of this offering.

Employment agreements

We have entered into employment agreements with our named executive officers. For more information regarding the agreements with our named executive officers, see "Executive compensation—Employment agreements."

Director compensation

See "Director compensation" for information regarding compensation of our directors.

Indemnification agreements

In connection with this offering, we intend to enter into agreements to indemnify our directors and executive officers. These agreements will, among other things, require us to indemnify these individuals for certain expenses (including attorneys' fees), judgments, fines and settlement amounts reasonably incurred by such person in any action or proceeding, including any action by or in our right, on account of any services undertaken by such person on behalf of our company or that person's status as a member of our board of directors to the maximum extent allowed under Delaware law.

Stock option grants to executive officers and directors

We have granted stock options to our executive officers and certain of our directors as more fully described in the sections entitled "Executive compensation" and "Director compensation."

Policies for approval of related party transactions

Our board of directors reviews and approves transactions with directors, officers and holders of five percent or more of our voting securities and their affiliates, each a related party. Prior to this offering, the material facts as to the related party's relationship or interest in the transaction are disclosed to our board of directors prior to their consideration of such transaction, and the transaction is not considered approved by our board of directors unless a majority of the directors who are not interested in the transaction approve the transaction. Further, when stockholders are entitled to vote on a transaction with a related party, the material facts of the related party's relationship or interest in the transaction are disclosed to the stockholders, who must approve the transaction in good faith.

In connection with this offering, we expect to adopt a written related party transactions policy that such transactions must be approved by our audit committee. This policy will become effective on the date on which the registration statement of which this prospectus is a part is declared effective by the SEC. Pursuant to this policy, the audit committee has the primary responsibility for reviewing and approving or disapproving "related party transactions," which are transactions between us and related persons in which the aggregate amount involved exceeds or may be expected to exceed $120,000 and in which a related person has or will have a direct or indirect material interest. For purposes of this policy, a related person will be defined as a director, executive officer, nominee for director, or greater than 5% beneficial owner of our common stock, in each case since the beginning of the most recently completed year, and their immediate family members.

Principal stockholders

The following table sets forth certain information known to us regarding beneficial ownership of our capital stock as of March 31, 2019, 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 March 31, 2019. 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 65,465,104 shares of common stock deemed to be outstanding as of March 31, 2019, assuming the conversion of all outstanding shares of our convertible preferred stock upon the completion of this offering into an aggregate of shares of common stock upon the completion of this offering, and the percentage of beneficial ownership at 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.

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

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.

Name and address of beneficial owner	Number of shares beneficially owned	Percentage of shares beneficially owned	
		Before offering	After offering
5% or Greater Stockholders:			
Amgen Inc.(1)	5,858,461	7.8%	%
Apple Tree Partner IV, L.P.(2)	13,880,568	18.5%	%
Entities affiliated with Atlas Venture(3)	11,389,404	15.2%	%
Entities affiliated with Janus Henderson(4)	4,268,292	5.7%	%
venBio Global Strategic Fund II, L.P.(5)	11,389,404	15.2%	%
Versant Venture Capital VI, L.P.(6)	11,389,404	15.2%	%
Named Executive Officers and Directors:			
Andrew Cheng, M.D., Ph.D.	—	—	%
Jonathan Young, J.D., Ph.D.(7)	594,601	*%	%
Timothy Rolph, DPhil(8)	594,601	*%	%
Kitty Yale	—	—	%
Kevin Bitterman, Ph.D.	—	—	%
Seth L. Harrison, M.D.	—	—	%
Jane P. Henderson	—	—	%
Mark Iwicki	—	—	%
Aaron Royston, M.D., M.B.A	—	—	%
Graham Walmsley, M.D., Ph.D.	—	—	%
All Executive Officers and Directors as a group (11 persons)(9)	1,189,202	1.58%	

* Represents beneficial ownership of less than one percent.

(1) Consists of 5,858,461 shares of Series A convertible preferred stock issued to Amgen Inc. in connection with a license agreement. The mailing address of Amgen Inc. is One Amgen Center Drive, Thousand Oaks, CA 91320.

(2) Consists of (a) 13,000,000 shares of Series A convertible preferred stock purchased and received by Apple Tree Partners IV, L.P., or ATP, and (b) 880,568 shares of Series B convertible preferred stock purchased and received by ATP. ATP is managed by ATP III GP, Ltd., the sole director of which is Dr. Seth L. Harrison The mailing address of Apple Tree Partners IV, L.P. is 230 Park Avenue, Suite 2800, New York, NY 10169.

(3) Consists of (a) 10,666,667 shares of Series A convertible preferred stock purchased and received by Atlas Venture Fund XI, L.P., or Atlas Fund XI and (b) 722,737 shares of Series B convertible preferred stock purchased and received by Atlas Venture Opportunity Fund I, L.P., or Atlas Fund I. Atlas Fund XI is managed by Atlas Venture Associates XI, LLC, or AVA XI LLC. Atlas Fund I is managed by Atlas Venture Associates Opportunity I, L.P., which is managed by Atlas Venture Associates Opportunity I, LLC, AVAO LLC. 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 Fund XI and Atlas Fund I is 400 Technology Square, 10th Floor, Cambridge, MA 02139.

(4) Consists of (a) 2,642,075 shares of Series B convertible preferred stock purchased and received by Janus Henderson Global Life Sciences Fund, (b) 1,610,927 shares of Series B convertible preferred stock purchased and received by Janus Henderson Capital Funds PLC, and (c) 15,243 shares of Series B convertible preferred stock purchased and received by Janus Henderson Horizon Fund Biotechnology Fund. The mailing address for Janus Henderson Global Life Sciences Fund is 151 Detroit Street, Denver, CO 80206.

(5) Consists of (a) 10,666,667 shares of Series A convertible preferred stock purchased and received by venBio Global Strategic Fund II, L.P., or venBio L and (b) 722,737 shares of Series B convertible preferred stock purchased and received by venBio. venBio Global Strategic GP II, L.P., or the General Partner, is the sole general partner of venBio Global Strategic Fund II LP, or venBio. venBio Global Strategic GP II, Ltd., or GP Ltd., is the sole general partner of the General Partner. Robert Adelman and Corey Goodman are directors of the GP Ltd. As the sole general partner of the Fund, the General Partner may be deemed to own beneficially the venBio Shares. As the sole general partner of the General Partner, the GP Ltd. likewise may be deemed to own beneficially the venBio Shares. As directors of the GP Ltd.,

each of the Directors likewise may be deemed to own beneficially the venBio Shares. The address for venBio, the General Partner and GP Ltd. is c/o venBio Partners, LLC, 1700 Owens Street, Suite 595, San Francisco, CA 94158.

(6) Consists of (a) 10,666,667 shares of Series A convertible preferred stock purchased and received by Versant Venture Capital VI, L.P., or Versant VI LP and (b) 722,737 shares of Series B convertible preferred stock purchased and received by Versant VI LP. Versant Ventures VI GP-GP, LLC, or Versant VI LLC is the ultimate general partner of Versant VI 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 LP. The mailing address for Versant Venture Capital VI, L.P. is One Sansome, Suite 3630, San Francisco, CA 94104.

(7) Consists of (a) 348,000 shares of restricted common stock and (b) 246,601 shares of common stock underlying options exercisable within 60 days of March 31, 2019.

(8) Consists of (a) 348,000 shares of restricted common stock and (b) 246,601 shares of common stock underlying options exercisable within 60 days of March 31, 2019.

(9) See notes (8) and (9) above; also includes William White, J.D., who is an executive officer, but not a named executive officer for the fiscal year ended December 31, 2018.

Description of capital stock

The following descriptions are summaries of the material terms of our fourth amended and restated certificate of incorporation, which will be effective upon the completion of this offering and fourth amended and restated bylaws, which will be effective on the date of the effectiveness of the registration statement of which this prospectus is a part. The descriptions of the common stock and convertible preferred stock give effect to changes to our capital structure that will occur immediately prior to the completion of this offering. We refer in this section to our fourth amended and restated certificate of incorporation as our certificate of incorporation, and we refer to our second amended and restated bylaws as our bylaws.

General

Upon completion of this offering, our authorized capital stock will consist of shares of common stock, par value $0.0001 per share, and shares of convertible preferred stock, par value $0.0001 per share, all of which shares of convertible preferred stock will be undesignated.

As of March 31, 2019, 734,694 shares of our common stock and 64,730,410 shares of convertible preferred stock were outstanding and held by 25 stockholders of record. This amount does not take into account the conversion of all outstanding shares of our convertible preferred stock into common stock upon the completion of this offering.

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. The shares to be issued by us in this offering will be, when issued and paid for, validly issued, fully paid and non-assessable.

Preferred stock

Upon the completion of this offering, all outstanding shares of our convertible preferred stock will be converted into shares of our common stock. Upon the consummation of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to 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. Immediately after consummation

of this offering, no shares of convertible preferred stock will be outstanding, and we have no present plan to issue any shares of convertible preferred stock.

Options

As of March 31, 2019, options to purchase 7,115,964 shares of our common stock were outstanding, of which 428,700 were vested and exercisable as of that date. For additional information regarding the terms of this plan, see "Executive compensation—Employee benefit and equity compensation plans—2018 Stock Option and Grant Plan."

Registration rights

Upon the completion of this offering, the holders of shares of our common stock, including those issuable upon the conversion of convertible preferred stock will be entitled to rights with respect to the registration of these securities under the Securities Act. These rights are provided under the terms of an amended and restated investors' rights agreement between us and holders of our convertible preferred stock. The amended and restated investors' rights agreement includes demand registration rights, short-form registration rights and piggyback registration rights. All fees, costs and expenses of underwritten registrations under this agreement will be borne by us and all selling expenses, including underwriting discounts and selling commissions, will be borne by the holders of the shares being registered.

Demand registration rights

Beginning 180 days after the effective date of this registration statement, the holders of shares of our common stock, including those issuable upon the conversion of convertible preferred stock upon completion of this offering, are entitled to demand registration rights. Under the terms of the amended and restated investors' rights agreement, we will be required, upon the written request of a majority of the holders of convertible preferred stock, to file a registration statement and use best efforts to effect the registration of all or a portion of these shares for public resale at an aggregate price of at least $10.0 million. We are required to effect only one registration pursuant to this provision of the amended and restated investors' rights agreement.

Short-Form registration rights

Pursuant to the amended and restated investors' rights agreement, if we are eligible to file a registration statement on Form S-3, upon the written request of at least 20% of these holders to sell registrable securities at an aggregate price of at least $5.0 million, we will be required to use commercially reasonable efforts to effect a registration of such shares. We are required to effect only one registration in any twelve-month period pursuant to this provision of the investors' rights agreement. The right to have such shares registered on Form S-3 is further subject to other specified conditions and limitations.

Piggyback registration rights

Pursuant to the amended and restated investors' rights agreement, if we register any of our securities either for our own account or for the account of other security holders, the holders of these shares are entitled to include their shares in the registration. Subject to certain exceptions contained in the amended and restated investors' rights agreement, we and the underwriters may terminate or withdraw any registration initiated before the effective date of such registration in our sole discretion.

Indemnification

Our amended and restated investors' rights agreement contains customary cross-indemnification provisions, under which we are obligated to indemnify holders of registrable securities in the event of material misstatements or omissions in the registration statement attributable to us, and they are obligated to indemnify us for material misstatements or omissions attributable to them.

Expiration of registration rights

The demand registration rights and short form registration rights granted under the investors' rights agreement will terminate on the third anniversary of the completion of this offering or at such time after this offering when the holders' shares may be sold without restriction pursuant to Rule 144 within a three-month period.

Anti-Takeover effects of our certificate of incorporation and bylaws and delaware law

Our certificate of incorporation and bylaws include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Board composition and filling vacancies

Our certificate of incorporation provides for the division of our board of directors into three classes serving staggered three-year terms, with one class being elected each year. Our certificate of incorporation also provides that directors may be removed only for cause and then only by the affirmative vote of the holders of two-thirds or more of the shares then entitled to vote at an election of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum. The classification of directors, together with the limitations on removal of directors and treatment of vacancies, has the effect of making it more difficult for stockholders to change the composition of our board of directors.

No written consent of stockholders

Our certificate of incorporation provides that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our bylaws or removal of directors by our stockholders without holding a meeting of stockholders.

Meetings of stockholders

Our certificate of incorporation and bylaws provide that only a majority of the members of our board of directors then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance notice requirements

Our bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our bylaws specify the requirements as to form and content of all stockholders' notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

Amendment to certificate of incorporation and bylaws

Any amendment of our certificate of incorporation must first be approved by a majority of our board of directors, and if required by law or our certificate of incorporation, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to stockholder action, board composition, limitation of liability and the amendment of our bylaws 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 at least two-thirds of the outstanding shares entitled to vote on the amendment, or, if our board of directors recommends that the stockholders approve the amendment, by the affirmative vote of the majority of the outstanding shares entitled to vote on the amendment, in each case voting together as a single class.

Undesignated preferred stock

Our certificate of incorporation provides for 5,000,000 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 certificate of incorporation provides 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 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; (4) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws; or (5) any action asserting a claim 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 certificate of incorporation 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 certificate of incorporation is inapplicable or unenforceable if it is challenged in a proceeding or otherwise.

In addition, our bylaws provide that, unless we consent in writing to the selection of an alternative forum, the United States District Court for the Southern District of New York will be the exclusive forum for any private action asserting violations by us or any of our directors or officers of the Securities Act or the Exchange Act, or the rules and regulations promulgated thereunder, and of all suits in equity and actions at law brought to enforce any liability or duty created by those statutes or the rules and regulations under such statutes. If any action the subject matter of which is within the scope of the preceding sentence is filed in a court other than the United States District Court for the Southern District of New York, the plaintiff or plaintiffs shall be deemed by this provision of the bylaws (i) to have consented to removal of the action by us to the United States District Court for the Southern District of New York, in the case of an action filed in a state court, and (ii) to have consented to transfer of the action to the United States District Court for the Southern District of New York.

Section 203 of the Delaware general corporation law

Upon completion of this offering, we will be subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or
- at or after the time the stockholder became interested, the business combination was approved by our board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;

- any sale, transfer, lease, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.
- In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Nasdaq global market listing

We have applied for listing of our common stock on The Nasdaq Global Market under the symbol "AKRO."

Transfer agent and registrar

The transfer agent and registrar for our common stock will be . The transfer agent and registrar's address is .

Limitations of liability and indemnification matters

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

Shares eligible for future sale

Prior to this offering, there has been no public market for our commons stock. Future sales of our common stock in the public market, or the availability of such shares for sale in the public market, could adversely affect market prices prevailing from time to time. As described below, only a limited number of shares will be available for sale shortly after this offering due to contractual and legal restrictions on resale. Nevertheless, sales of our common stock in the public market after such restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price at such time and our ability to raise equity capital in the future.

Based on the number of shares outstanding as of March 31, 2019, upon the completion of this offering, shares of our common stock will be outstanding. Of the outstanding shares, all of the shares sold in this offering will be freely tradable, except that any shares held by our affiliates, as that term is defined in Rule 144 under the Securities Act, may only be sold in compliance with the limitations described below. All remaining shares of common stock held by existing stockholders immediately prior to the completion 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, summarized below.

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, based on the number of shares outstanding as of March 31, 2019; or

- the average weekly trading volume of our common stock on The Nasdaq Global 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.

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 J.P. Morgan Securities LLC, Jefferies LLC and Evercore Group L.L.C., subject to certain exceptions. J.P. Morgan Securities LLC, Jefferies LLC and Evercore Group L.L.C. 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.

Rule 10b5-1 trading plans

Following the completion of this offering, certain of our officers, directors and significant stockholders may adopt written plans, known as Rule 10b5-1 trading plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis to diversify their assets and investments. Under these 10b5-1 trading plans, a broker may execute trades pursuant to parameters established by the officer, director or stockholder when entering into the plan, without further direction from such officer, director or stockholder. Such sales would not commence until the expiration of the applicable lock-up agreements entered into by such officer, director or stockholder in connection with this offering.

Registration rights

Upon completion of this offering, 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.

Equity incentive plans

We intend to file one or more registration statements on Form S-8 under the Securities Act to register our shares issued or reserved for issuance under our equity incentive plans. The first such registration statement is expected to be filed soon after the date of this prospectus and will automatically become effective upon filing with the SEC. Accordingly, shares registered under such registration statement will be available for sale in the open market, unless such shares are subject to vesting restrictions with us or the lock-up restrictions described above. As of March 31, 2019, we estimate that such registration statement on Form S-8 will cover approximately shares.

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. J.P. Morgan Securities LLC, Jefferies LLC and Evercore Group L.L.C. 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
J.P. Morgan Securities LLC	
Jefferies LLC	
Evercore Group L.L.C.	
Roth Capital Partners, LLC	
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 initial 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. Any such dealers may resell shares to certain other brokers or dealers at a discount of up to $ per share from the initial public offering price. After the initial offering of the shares to the public, if all of the shares of common stock are not sold at the initial 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 discounts and commissions, will be approximately $. We have agreed to reimburse the underwriters for expenses relating to the clearance of this offering with the Financial Industry Regulatory Authority, Inc. in an amount 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.

We have applied for listing of our common stock on The Nasdaq Global 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.

Prior to this offering, there has been no public market for our common stock. The initial public offering price will be determined by negotiations between us and the representatives of the underwriters. In determining the initial public offering price, we and the representatives of the underwriters expect to consider a number of factors including:

the information set forth in this prospectus and otherwise available to the representatives;

our prospects and the history and prospects for the industry in which we compete;

an assessment of our management;

our prospects for future earnings;

the general condition of the securities markets at the time of this offering;

the recent market prices of, and demand for, publicly traded common stock of generally comparable companies; and

other factors deemed relevant by the underwriters and us.

Neither we nor the underwriters can assure investors that an active trading market will develop for our common shares, or that the shares will trade in the public market at or above the initial public offering price.

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.

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

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.

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 authorised 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 authorised 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.

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 consolidated financial statements as of December 31, 2018 and 2017, and for the year ended December 31, 2018, and for the period January 24, 2017 (inception) to December 31, 2017 included in this Prospectus, have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report appearing herein. Such consolidated financial statements are included 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 common stock we are offering by this prospectus. This prospectus does not contain all of the information included in the registration statement. For further information pertaining to us and our common stock, you should refer to the registration statement and to its exhibits. Whenever we make reference in this prospectus to any of our contracts, agreements or other documents, the references are not necessarily complete, and you should refer to the exhibits attached to the registration statement for copies of the actual contract, agreement or other document.

Upon the completion of the offering, we will be subject to the informational requirements of the Exchange Act and will file annual, quarterly and current reports, proxy statements and other information with the SEC. You can read our SEC filings, including the registration statement, at the SEC's website at www.sec.gov. We also maintain a website at 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.

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

Akero Therapeutics, Inc.
Index to consolidated financial statements as of December 31, 2017 and 2018, the period January 24, 2017 (inception) through December 31, 2017 and the year ended December 31, 2018

Index to unaudited interim condensed consolidated financial statements as of March 31, 2019 and for the three month periods ended March 31, 2018 and 2019

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

Report of independent registered public accounting firm

To the stockholders and the Board of Directors of Akero Therapeutics, Inc.

Opinion on the financial statements

We have audited the accompanying consolidated balance sheets of Akero Therapeutics, Inc. (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' deficit, and cash flows, for the year ended December 31, 2018, and for the period January 24, 2017 (inception) to December 31, 2017, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for the year ended December 31, 2018, and for the period January 24, 2017 (inception) to December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

Basis for opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Deloitte & Touche LLP

Parsippany, NJ
March 19, 2019

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

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

Akero Therapeutics, Inc.
Consolidated balance sheets
(In thousands, except share and per share amounts)

	As of December 31,	
	2017	2018
Assets		
Current assets:		
Cash	$ 598	$ 75,975
Prepaid expenses and other current assets	40	1,156
Total current assets	638	77,131
Restricted cash	20	20
Total assets	$ 658	$ 77,151
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 60	$ 1,373
Accrued expenses	162	969
Total current liabilities	222	2,342
Commitments and contingencies (Note 11)		
Redeemable convertible preferred stock (Series A and B), $0.0001 par value; 5,000,000 shares and 64,730,410 shares authorized, issued and outstanding as of December 31, 2017 and 2018, respectively; aggregate liquidation preference of $5,213 and $96,358 as of December 31, 2017 and 2018, respectively	5,000	124,728
Stockholders' deficit:		
Common stock, $0.0001 par value, 7,000,000 shares and 75,000,000 shares authorized as of December 31, 2017 and 2018 respectively; 696,000 shares and 734,694 shares issued and outstanding as of December 31, 2017 and 2018, respectively	—	—
Additional paid-in capital	—	36,646
Accumulated deficit	(4,564)	(86,565)
Total stockholders' deficit	(4,564)	(49,919)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 658	$ 77,151

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

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

Akero Therapeutics, Inc.
Consolidated statements of operations and comprehensive loss
(In thousands, except share and per share amounts)

	For the period January 24, 2017 (inception) through December 31, 2017	Year ended December 31, 2018
Operating expenses:		
Research and development	$ 3,486	$ 11,882
General and administrative	1,078	1,896
Total operating expenses	4,564	13,778
Loss from operations	(4,564)	(13,778)
Other expense, net:		
Change in fair value of preferred stock tranche obligation	—	(62,150)
Change in fair value of anti-dilution right liability	—	(5,765)
Other expense, net	—	(21)
Total other expense	—	(67,936)
Net loss and comprehensive loss	(4,564)	(81,714)
Accruing dividends on redeemable convertible preferred stock	(213)	—
Accretion of redeemable convertible preferred stock to redemption value	—	(520)
Net loss attributable to common stockholders	$ (4,777)	$ (82,234)
Net loss per share attributable to common stockholders—basic and diluted		$ (258.68)
Weighted average common shares outstanding—basic and diluted		317,894
Pro forma net loss per share attributable to common stockholders—basic and diluted (unaudited)		$ (1.01)
Pro forma weighted average common shares outstanding—basic and diluted (unaudited)		19,295,870

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

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

Akero Therapeutics, Inc.
Consolidated statements of redeemable convertible preferred stock and stockholders' deficit
(In thousands, except share amounts)

	Redeemable convertible preferred stock		Common stock		Treasury stock		Additional paid-in capital	Accumulated deficit	Total stockholders' deficit
	Shares	Amount	Shares	Amount	Shares	Amount			
Balances at January 24, 2017 (inception)	—	$ —	—	$—	—	$—	$ —	$ —	$ —
Issuance of founders' common stock	—	—	696,000	—	—	—	—	—	—
Issuance of Series A redeemable convertible preferred stock	5,000,000	5,000	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	(4,564)	(4,564)
Balances at December 31, 2017	5,000,000	5,000	696,000	—	—	—	—	(4,564)	(4,564)
Repurchase of founders' common stock	—	—	(232,000)	—	232,000	—	—	—	—
Issuance of treasury stock as founders' common stock	—	—	232,000	—	(232,000)	—	—	—	—
Issuance of Series A redeemable convertible preferred stock, net of issuance costs of $216	17,653,333	8,787	—	—	—	—	—	—	—
Issuance of Series A redeemable convertible preferred stock in connection with Second Tranche Closing, net of issuance costs of $4	25,000,001	24,996	—	—	—	—	—	—	—
Settlement of future purchase obligation	—	32,750	—	—	—	—	—	—	—
Issuance of Series A redeemable convertible preferred stock, in settlement of anti-dilution right liability	3,205,128	7,404	—	—	—	—	—	—	—
Issuance of Series B redeemable convertible preferred stock, net of issuance costs of $229	13,871,948	45,271	—	—	—	—	—	—	—
Extinguishment of call option liability	—	—	—	—	—	—	36,750	—	36,750
Exercise of stock	—	—	38,694	—	—	—	8	—	8

options									
Stock-based compensation expense	—	—	—	—	—	—	121	—	121
Accretion of redeemable convertible preferred stock to redemption value	—	520	—	—	—	—	(233)	(287)	(520)
Net loss	—	—	—	—	—	—	—	(81,714)	(81,714)
Balances at December 31, 2018	64,730,410	$124,728	734,694	$—	—	$—	$ 36,646	$(86,565)	$(49,919)

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

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

Akero Therapeutics, Inc.
Consolidated statements of cash flows
(In thousands)

	For the period January 24, 2017 (inception) through December 31, 2017	Year ended December 31, 2018
Cash flows from operating activities:		
Net loss	$ (4,564)	$ (81,714)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	—	121
Shares issued in connection with Amgen Agreement	—	1,353
Acquisition of technology in connection with Amgen Agreement	—	5,000
Issuance date fair value of anti-dilution right liability	—	1,639
Change in fair value of preferred stock tranche obligation	—	62,150
Change in fair value of anti-dilution right liability	—	5,765
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(40)	(1,059)
Accounts payable	60	1,313
Accrued expenses	162	807
Net cash used in operating activities	(4,382)	(4,625)
Cash flows from investing activities:		
Acquisition of technology in connection with Amgen Agreement	—	(5,000)
Net cash used in investing activities	—	(5,000)
Cash flows from financing activities:		
Proceeds from issuance of Series A redeemable convertible preferred stock	5,000	40,000
Proceeds from issuance of Series B redeemable convertible preferred stock		45,500
Proceeds from exercise of stock options		8
Payment of initial public offering costs	—	(52)
Payment of preferred stock issuance costs	—	(449)
Net cash provided by financing activities	5,000	85,007
Net increase in cash and restricted cash	618	75,382
Cash and restricted cash at beginning of period	—	618
Cash and restricted cash at end of period	$ 618	$ 76,000
Supplemental disclosure of non-cash investing and financing activities:		
Accretion of redeemable convertible preferred stock to redemption value	$ —	$ 520
Issuance date fair value of preferred stock tranche obligation	$ —	$ 7,350
Deferred offering costs included in accounts payable and accrued expenses	$ —	$ 309
Shares issued in connection with Amgen Agreement	$ —	$ 1,353
Settlement of future purchase obligation	$ —	$ 32,750
Issuance of Series A redeemable convertible preferred stock in settlement of anti-dilution right liability	$ —	$ 7,404
Extinguishment of call option liability	$	$ 36,750

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

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

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

1. Nature of the business and basis of presentation

Akero Therapeutics, Inc. ("Akero" or the "Company") is a clinical-stage biotechnology company focused on developing and commercializing transformative treatments for patients with serious metabolic diseases. Akero's initial focus is on nonalcoholic steatohepatitis ("NASH"), a disease without any approved therapies. NASH is a severe form of nonalcoholic fatty liver disease ("NAFLD"), characterized by inflammation and fibrosis in the liver that can progress to cirrhosis, failure, cancer of the liver, and death. We are developing AKR-001, an analog of fibroblast growth factor 21 ("FGF21"), for NASH and plan to initiate a Phase 2a clinical trial for AKR-001 in NASH patients with fibrosis in the middle of 2019.

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

In December 2018, the Company entered into a subscription agreement with Akero Securities Corporation ("Akero Securities") and acquired all of the outstanding shares of Akero Securities common stock for an immaterial amount, which resulted in Akero Securities becoming a wholly owned subsidiary of the Company. Akero Securities is incorporated under the laws of Massachusetts. The principal activities of this company is to engage exclusively in buying, selling, dealing in or holding securities on its own behalf.

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

Going concern

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

Since its inception, the Company has funded its operations primarily with proceeds from sales of redeemable convertible preferred stock. The Company has incurred recurring losses since its inception, including net losses of $4,564 for the period from January 24, 2017 (inception) through December 31, 2017 and $81,714 for the year ended December 31, 2018. In addition, as of December 31, 2018, the Company had an accumulated deficit of $86,565. The Company expects to continue to generate operating losses for the

foreseeable future. As of March 19, 2019, the issuance date of these consolidated financial statements, the Company expects that its existing cash of $75,975 as of December 31, 2018, will be sufficient to fund its operating expenses and capital expenditure requirements for at least 12 months from the issuance date of these consolidated financial statements. The future viability of the Company beyond that point is dependent on its ability to raise additional capital to finance its operations.

The Company is seeking to complete an initial public offering ("IPO") of its common stock. In the event the Company does not complete an IPO, the Company expects to seek additional funding through private equity financings, debt financings or other capital sources, including collaborations with other companies or other strategic transactions. The Company may not be able to obtain financing on acceptable terms, or at all. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders.

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

2. Summary of significant accounting policies

Use of estimates

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

Unaudited pro forma information

In the accompanying consolidated statements of operations, the unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2018 have been prepared assuming the automatic conversion of all outstanding shares of redeemable convertible preferred stock into shares of common stock upon an IPO, as if the proposed IPO had occurred on the later of January 1, 2018 the issuance date of the redeemable convertible preferred stock.

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

Restricted cash

As of December 31, 2017 and 2018, the Company was required to maintain a separate cash balance of $20 to collateralize corporate credit cards with a bank, which was classified as restricted cash (non-current) on its consolidated balance sheets.

As of December 31, 2018, the Company was required to maintain a separate cash balance of $5 for the benefit of the landlord in connection with one of the Company's office space lease, which was classified as other current assets on its consolidated balance sheets.

Concentrations of credit risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash. Periodically, the Company maintains deposits in accredited financial institutions in excess of federally insured limits. The Company deposits its cash in financial institutions that it believes have high credit quality and has not experienced any losses on such accounts and does not believe it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships. At December 31, 2017 and 2018, all of the Company's cash was held at one accredited financial institution.

Deferred offering costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process preferred stock or common equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded as a reduction to the carrying value of redeemable convertible preferred stock or in stockholders' equity (deficit) as a reduction of additional paid-in capital generated as a result of such offering. Should an in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statements of operations and comprehensive loss. As of December 31, 2017, the Company did not have any deferred offering costs. As of December 31, 2018, the Company recorded deferred offering costs of $361 in the accompanying consolidated balance sheets.

Fair value measurements

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

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

- Level 3—Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's preferred stock tranche obligation and anti-dilution right liability are carried at fair value, determined according to Level 3 inputs in the fair value hierarchy described above (See Note 3). In November 2018, in connection with the Company's issuance and sale of Series A Preferred Stock at the Second Tranche Closing (as defined below), the Company satisfied its obligation to issue additional shares under the Second Tranche Closing (See Note 5) and accordingly reclassified the carrying value of the preferred stock tranche obligation associated with the future purchase obligation, equal to the then current fair value, to the carrying value of the Series A Preferred Stock. Also, in November 2018, in connection with the Company's issuance and sale of Series A Preferred Stock, the Company satisfied its anti-dilution obligation under the Amgen Agreement (as defined below) (see Notes 5 and 8). In December 2018, in connection with the Company's issuance and sale of Series B Preferred Stock, the Company terminated the option to purchase Series A Preferred Stock provided under the 2018 Series A Agreement (as defined below) (see Note 5). The carrying values of the Company's prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities.

Segment information

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

Research and development costs

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

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

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

Research contract costs and accruals

The Company has entered into various research and development and other agreements with commercial firms, researchers, universities and others for provisions of goods and services. These agreements are generally cancelable, and the related costs are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research and development costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or clinical trials, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ materially from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Patent costs

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

Stock-based compensation

The Company measures all stock-based awards granted to employees and nonemployees based on the fair value on the date of the grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. The Company accounts for forfeitures as they occur. For stock-based awards with service-based vesting conditions, the Company recognizes compensation expense using the straight-line method.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model, which requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the option, the risk-free interest rate for a period that approximates the expected term of the option, and the Company's expected dividend yield. The Company historically has been a private company and lacks company-specific historical and implied volatility information for its shares. Therefore, it estimates its expected share price volatility based on the historical volatility of publicly traded peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded share price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future. The fair value of each restricted common stock award is estimated on the date of grant based on the fair value of the Company's common stock on that same date.

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

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

Preferred stock tranche obligation

The Company classified the preferred stock tranche obligation for the future purchase, and option to purchase, Series A Preferred Stock (see Note 5) as a liability on its consolidated balance sheets as the preferred stock tranche obligation was a freestanding financial instrument that required the Company to transfer equity instruments upon future closings of the Series A Preferred Stock. The preferred stock tranche obligation was initially recorded at fair value upon the date of issuance and was subsequently remeasured to fair value at each reporting date. Changes in the fair value of the preferred stock tranche obligation were recognized as a component of other expense in the consolidated statements of operations and comprehensive loss. Changes in the fair value of the preferred stock tranche obligation were recognized until the tranche obligations were fulfilled or otherwise extinguished in the fourth quarter of 2018.

In November 2018, in connection with the Company's issuance and sale of Series A Preferred Stock, the Company satisfied its obligation to issue additional shares under the Second Tranche Closing. In December 2018, in connection with the Company's issuance and sale of Series B Preferred Stock, the Company terminated the option to purchase Series A Preferred Stock provided under the 2018 Series A Agreement (see Notes 3 and 5).

Anti-dilution right liability

The Company classified the anti-dilution right under its license agreement with Amgen Inc. ("Amgen") (see Note 8) as a derivative liability on its consolidated balance sheets as the anti-dilution right represented a freestanding financial instrument that required the Company to transfer equity instruments upon future equity closings. The anti-dilution right liability was initially recorded at fair value upon the date of issuance and was subsequently remeasured to fair value at each reporting date. The issuance date fair value of the anti-dilution right liability was recognized as a research and development expense upon entering into the agreement with Amgen. Changes in the fair value of the anti-dilution right liability were recognized as a component of other expense in the consolidated statements of operations and comprehensive loss. Changes in the fair value of the anti-dilution right liability were recognized until the anti-dilution right was satisfied in the fourth quarter of 2018.

In November 2018, in connection with the Company's issuance and sale of Series A Preferred Stock, the Company satisfied its anti-dilution right under the Amgen Agreement (see Notes 5 and 8).

Classification and accretion of redeemable convertible preferred stock

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

Stock that allowed the holders, at their option, to elect to redeem their shares at a specified date. Accordingly, the Company ceased accreting the net carrying value of the Series A redeemable convertible preferred stock to the redemption value.

Comprehensive loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders. There was no difference between net loss and comprehensive loss for each of the periods presented in the accompanying consolidated financial statements.

Income taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined based on the difference between the consolidated financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

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

Net income (loss) per share

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

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

The Company's redeemable convertible preferred stock contractually entitles the holders of such shares to participate in dividends but does not contractually require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss attributable to common stockholders, such losses are not allocated to such participating securities. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss attributable to common stockholders for the period January 24, 2017 (inception) through December 31, 2017 and the year ended December 31, 2018, respectively.

Emerging growth company

The Company is an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, as amended (the "JOBS Act"). Under the JOBS Act, companies have extended transition periods available for complying with new or revised accounting standards. The Company has elected this exemption to delay adopting new or revised accounting standards until such time as those standards apply to private companies. Where allowable, we have early adopted certain standards as described in Note 2.

Recently adopted accounting pronouncements

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2014-09"), which supersedes existing revenue recognition guidance under GAAP. This standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The standard defines a five-step process to achieve this principle and will require companies to use more judgment and make more estimates than under the current guidance. The Company expects that these judgments and estimates will include identifying performance obligations in the customer contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts. In August 2015, the FASB issued ASU No. 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, which delayed the effective date of ASU 2014-09 such that the standard is effective for non-public entities for annual periods beginning after December 15, 2018 and for interim periods beginning after December 15, 2019. The FASB subsequently issued amendments to ASU 2014-09 that have the same effective date and transition date. The Company

early adopted ASU 2014-09 as of January 1, 2018 and the adoption had no impact on the Company's financial position, results of operations or cash flows as the Company does not currently have any revenue-generating arrangements.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments (Topic 230)* ("ASU 2016-15"), to address diversity in practice in how certain cash receipts and cash payments are presented in the statement of cash flows. For non-public entities, ASU 2016-15 is effective for annual reporting periods beginning after December 15, 2018, including interim periods within those fiscal years. The adoption of ASU 2016-15 is required to be applied retrospectively. The Company early adopted ASU 2016-15 as of January 1, 2018, and its adoption had no impact on the Company's financial position, results of operations or cash flows.

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business* ("ASU 2017-01"), which clarifies the definition of a business and provides a screen to determine when an integrated set of assets and activities is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the asset is not a business. For non-public entities, ASU 2017-01 is effective for annual reporting periods beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. The Company early adopted ASU 2017-01 as of January 1, 2018, and its adoption had no impact on the Company's financial position, results of operations or cash flows.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting* ("ASU 2017-09"). The amendments in ASU 2017-09 clarifies that modification accounting is required only if the fair value, the vesting conditions or the classification of the awards (as equity or liability) changes as a result of the change in terms or conditions. For non-public entities, ASU 2017-09 is effective for annual reporting periods beginning after December 15, 2017, including interim periods within those fiscal years. The Company adopted ASU 2017-09 as of January 1, 2018. The adoption of ASU 2017-09 did not have a material impact on the Company's financial position, results of operations or cash flows, but will impact the accounting for modifications of stock-based awards, if any, after the date of adoption.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"). These amendments expand the scope of *Topic 718, Compensation—Stock Compensation* (which currently only includes stock-based payments to employees) to include stock-based payments issued to nonemployees for goods or services. Consequently, the accounting for stock-based payments to nonemployees and employees will be substantially aligned. The ASU *supersedes Subtopic 505-50, Equity—Equity-Based Payments to Non-Employees*. This standard is effective for non-public companies for annual periods beginning after December 15, 2019, including interim periods within those fiscal years, with early adoption permitted as long as ASU 2014-09 has been adopted by the Company. The Company early adopted this guidance as of January 1, 2018.

**Akero Therapeutics, Inc.
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Recently issued accounting pronouncements

In February 2016, the FASB issued ASU No. 2016-02*, Leases (Topic 842)* ("ASU 2016-02"), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less may be accounted for similar to existing guidance for operating leases today. For non-public entities, ASU 2016-02 is effective for annual reporting periods beginning after December 15, 2019, including interim periods within those fiscal years, and early adoption is permitted. The Company is in the process of completing its review of its existing lease agreements under ASC 842 and does not expect the adoption of ASU 2016-02 to have a material impact on its financial position, results of operations or cash flows.

In July 2017, the FASB issued ASU No. 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815) (Part I) Accounting for Certain Financial Instruments with Down Round Features (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception* ("ASU 2017-11"). Part I applies to entities that issue financial instruments such as warrants, convertible debt or convertible preferred stock that contain down-round features. Part II replaces the indefinite deferral for certain mandatorily redeemable noncontrolling interests and mandatorily redeemable financial instruments of non-public entities contained within Accounting Standards Codification ("ASC") Topic 480 with a scope exception and does not impact the accounting for these mandatorily redeemable instruments. For non-public entities, ASU 2017-11 is effective for annual reporting periods beginning after December 15, 2019, including interim periods within those fiscal years. The Company is currently evaluating the impact that the adoption of ASU 2017-11 will have on its consolidated financial statements.

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

3. Fair value of financial assets and liabilities

At December 31, 2018, the Company did not have any financial assets or liabilities measured at fair value on a recurring basis. In November 2018, in connection with the Company's issuance and sale of Series A Preferred Stock under the Second Tranche Closing, the Company satisfied its obligation to issue additional shares at the Second Tranche Closing and accordingly reclassified the carrying value of the preferred stock tranche obligation associated with the future purchase obligation, equal to the then current fair value of $32,750, to the carrying value of the Series A Preferred Stock.

Akero Therapeutics, Inc.
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In November 2018, in connection with the Company's Second Tranche Closing, the Company issued 3,205,128 shares of Series A Preferred Stock to Amgen for a total value of $7,404 satisfying its anti-dilution obligation under the Amgen Agreement. The Company reclassified the carrying value of the anti-dilution right liability, equal to the then current fair value of $7,404, to the carrying value of the Series A Preferred Stock.

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

During the period January 24, 2017 (inception) through December 31, 2017 and the year ended December 31, 2018, there were no transfers between Level 1, Level 2 and Level 3.

Valuation of preferred stock tranche obligation

The fair value of the preferred stock tranche obligation recognized in connection with the Company's issuance of Series A Preferred Stock in June 2018 (see Note 5) was determined based on significant inputs not observable in the market, which represented a Level 3 measurement within the fair value hierarchy. The fair value of the liability was estimated based on results of a third-party valuation performed in connection with the June 2018 Series A issuance. The Company determined that this valuation represented the fair value of the liability at the reporting date. The liability included (i) an obligation to issue shares in a second tranche of Series A Preferred Stock and (ii) an obligation to issue shares under the call option to purchase Series A Preferred Stock following the Second Tranche Closing.

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

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

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

Valuation of anti-dilution right liability

The fair value of the anti-dilution right liability recognized in connection with the anti-dilution provisions set forth in the Company's license agreement with Amgen (see Note 8) was determined based on significant inputs not observable in the market, which represented a Level 3 measurement within the fair value hierarchy.

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

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

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

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4. Accrued expenses

Accrued expenses consisted of the following:

	December 31,	
	2017	2018
Accrued employee compensation and benefits	$ 160	$ 304
Accrued external research and development expenses	—	430
Accrued legal and professional fees	—	106
Other accrued expenses	2	129
	$ 162	$ 969

5. Redeemable convertible preferred stock

As of December 31, 2017 and 2018, the Company's certificate of incorporation, as amended and restated (the "Amended and Restated Certificate of Incorporation"), authorized the Company to issue 5,000,000 shares and 64,730,410 shares, respectively, of Preferred Stock, par value $0.0001 per share. The Preferred Stock is classified outside of stockholders' equity (deficit) because the shares contain redemption features that are not solely within the control of the Company.

The Company has issued Series A Preferred Stock and Series B Preferred Stock. The Series A Preferred Stock and Series B Preferred Stock are collectively referred to as Preferred Stock.

During 2017, the Company issued and sold 5,000,000 shares of Series A Preferred Stock to Apple Tree Partner IV, L.P. ("Apple Tree") at a price of $1.00 ("Series A Original Issue Price") per share for aggregate proceeds of $5,000.

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

In June 2018, the Company completed its First Tranche Closing, and issued and sold 15,000,000 shares of Series A Preferred Stock at a price of $1.00 ("2018 Series A Agreement Purchase Price") per share for aggregate proceeds of $14,784, net of issuance costs of $216. Upon the execution of the Company's license agreement with Amgen (see Note 8), the Company issued an additional 2,653,333 shares of Series A Preferred Stock to Amgen in June 2018 for a total value of $1,353.

The Second Tranche Closing was contingent upon the achievement of the Second Tranche Closing Milestone Event ("Milestone Event"), as reasonably determined by a majority of the Company's board of directors, prior to December 31, 2019 or waiver of the Milestone Event through written elections by a majority of the purchasers of shares of Series A Preferred Stock, subject to the provisions included in the Amended and Restated Certificate of Incorporation ("Special Mandatory Conversion" as defined below). The Milestone Event is defined as the earlier of (a) a successful completion of a 90 or 120 day chronic toxicity animal studies, and (b) identification of sufficient therapeutic index for a Phase 2 clinical trial. Upon achievement

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or waiver of the Milestone Event, Amgen would be issued a number of additional shares for no consideration provided that Amgen's total holdings equal ten percent (10%) of the total outstanding and issued common stock of the Company on a fully diluted and as converted basis of the Second Tranche Closing, provided that the percentage shall only be based on the First Tranche Closing and a maximum of 25,000,000 shares of Series A Preferred Stock issued in the Second Tranche Closing. An additional 25,000,000 shares of Series A Preferred Stock will be issued upon the Second Tranche Closing at a price equal to the 2018 Series A Agreement Purchase Price.

Additionally, the 2018 Series A Agreement contains a call option such that, following the Second Tranche Closing, the stockholders of Series A Preferred Stock have the right, but not the obligation, to purchase up to $20,000 of additional shares of Series A Preferred Stock at any time prior to January 14, 2022 at a price equal to the 2018 Series A Agreement Purchase Price, upon the written election of the Requisite Preferred (as defined below). Each of the four Series A stockholders, other than Amgen, will be allocated the right to purchase 22.5% of the Series A Preferred Stock ("Call Amount") and Amgen will be allocated the right to purchase 10% of Series A Preferred Stock ("Amgen Call Amount"), with participating investors having the option to purchase any shares not purchased by other investors on a pro rata basis. If Amgen elects not to participate in the Amgen Call Amount, Apple Tree shall have the right to purchase 70% of the Amgen Call Amount and the remaining Series A stockholders will be allocated the remaining 30% on a pro rata basis.

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

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

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

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

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Preferred Stock, the preferred stock tranche obligation associated with the future purchase obligation of $32,750, equal to then current fair value, was reclassified to the carrying value of the Series A Preferred Stock.

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

In December 2018, the Company issued and sold 13,871,948 shares of Series B Preferred Stock, at an issuance price of $3.28 per share, for proceeds of approximately $45,500 before issuance costs of $229. In connection with the Company's issuance and sale of Series B Preferred Stock, the Company terminated the option to purchase Series A Preferred Stock provided under the 2018 Series A Agreement (see Note 3).

As of each balance sheet date, the Preferred Stock consisted of the following:

	December 31, 2017				
	Preferred stock authorized	Preferred stock issued and outstanding	Carrying value	Liquidation preference	Common stock issuable upon conversion
Series A Preferred Stock	5,000,000	5,000,000	$ 5,000	$ 5,213	5,000,000
	5,000,000	5,000,000	$ 5,000	$ 5,213	5,000,000

	December 31, 2018				
	Preferred stock authorized	Preferred stock issued and outstanding	Carrying value	Liquidation preference	Common stock issuable upon conversion
Series A Preferred Stock	50,858,462	50,858,462	$ 79,457	$ 50,858	50,858,462
Series B Preferred Stock	13,871,948	13,871,948	$ 45,271	$ 45,500	13,871,948
	64,730,410	64,730,410	$ 124,728	$ 96,358	64,730,410

The holders of the Preferred Stock have the following rights and preferences:

Voting

The holders of Preferred Stock are entitled to vote, together with the holders of common stock as a single class, on all matters submitted to stockholders for a vote and have the right to vote the number of shares equal to the number of shares of common stock into which each share of Preferred Stock could convert on the record date for determination of stockholders entitled to vote.

The holders of Series B Preferred Stock, voting exclusively and as a separate class, are entitled to elect four directors of the Company.

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

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Conversion

Each share of Preferred Stock is convertible, at the option of the holder, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and non-assessable shares of common stock as is determined by dividing the Original Issue Price by the applicable Preferred Stock Conversion Price (as defined below) in effect at the time of conversion. The Series A Original Issue Price and Series A Conversion Price were equal to $1.00 as of December 31, 2017 and 2018. The Series B Original Issue Price and Series B Conversion Price were equal to $3.28 as of December 31, 2018. Such Series A Original Issue Price, Series B Original Issue Price, Series A Conversion Price and Series B Conversion Price, and the rate at which each series of Preferred Stock may be converted into common stock, are subject to adjustment from time to time to reflect future share dividends, splits, combinations, recapitalizations and similar events. The Preferred Stock Conversion Price is also subject to adjustments based on weighted-average anti-dilution provisions set forth in the Amended and Restated Certificate of Incorporation in the event that additional options or convertible securities are issued at a purchase price less than the applicable Preferred Stock Conversion Price then in effect. As of December 31, 2017 and 2018, each share of Preferred Stock was convertible into one share of common stock.

Upon either (a) the closing of the sale of shares of common stock to the public at a price of at least $5.00 per share (subject to appropriate adjustment in the event of any share dividend, share split, combination or other similar recapitalization with respect to the applicable class of common stock) in an initial public offering resulting in at least $60,000 of gross proceeds to the Company or (b) the date and time, or the occurrence of an event, specified by vote or written consent of the holders of a majority of the outstanding shares of Series B Preferred Stock voting as a separate class on an as converted basis and the vote or written consent of the holders of a majority of the outstanding shares of Preferred Stock voting together as a single class on an as converted basis ("Requisite Preferred"), all outstanding shares of Preferred Stock shall automatically be converted into shares of common stock at the then effective conversion rate.

Dividends

The holders of Preferred Stock are entitled to receive noncumulative dividends when, as and if declared by the board of directors. Dividends accrue on Series A Preferred Stock at a rate of $0.08 per share, or 8%, dividends accrue on Series B Preferred Stock at a rate of $0.26 per share, or 26%, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Preferred Stock; however, such dividends are only payable in any calendar year when and as if declared by the board of directors or, as applicable in the case of a liquidation, dissolution, or winding up of the Company or Deemed Liquidation Event (as defined below).

The Company may not declare, pay or set aside any dividends on shares of any other class or series of capital stock of the Company, other than dividends on shares of common stock payable in shares of common stock, unless the holders of the Preferred Stock then outstanding shall first receive, or simultaneously receive, a dividend on each outstanding share of Preferred Stock in an amount at least equal to the greater of (i) the amount of the dividend for such share of Preferred Stock not previously paid during the applicable fiscal year of the Company and (ii) (A) in the case of a dividend on common stock or any class or series that is convertible into common stock, that dividend per share of such series of Preferred Stock as would equal the product of (1) the dividend payable on each share of such class or

series determined, if applicable, as if all shares of such class or series had been converted into common stock and (2) the number of shares of common stock issuable upon conversion of a share of such series of Preferred Stock, in each case calculated on the record date for determination of holders entitled to receive such dividend or (B) in the case of a dividend on any class or series that is not convertible into common stock, at a rate per share of each series Preferred Stock determined by (1) dividing the amount of the dividend payable on each share of such class or series of capital stock by the original issuance price of such class or series of capital stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to such class or series) and (2) multiplying such fraction by an amount equal to the applicable Original Issue Price; provided that if the Company declares, pays or sets aside, on the same date, a dividend on shares of more than one class or series of capital stock of the Company, the dividend payable to the holders of Preferred Stock shall be calculated based upon the dividend on the class or series of capital stock that would result in the highest Preferred Stock dividend.

Prior to the 2018 Series A Agreement, the holders of Series A Preferred Stock were entitled to cumulative dividends of $0.08 per share, or 8%. As part of the Amended and Restated Certificate of Incorporation in connection with the 2018 Series A Agreement in June 2018, the rights of the holders of Preferred Stock were amended. For the computation of net loss per share attributable to common stockholders, accruing undeclared dividends on Series A Preferred Stock increased the net loss attributable to common stockholders for the period January 24, 2017 (inception) through December 31, 2017 by $213. The Company determined that the modification did not have any impact on its consolidated financial statements.

Through December 31, 2017 and 2018, no cash dividends have been declared or paid.

Liquidation

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or Deemed Liquidation Event (as defined below), each holder of the then-outstanding Preferred Stock will be entitled to receive an amount equal to the greater of (i) the Original Issue Price plus any dividends declared but unpaid thereon, or (ii) the amount per share that would have been payable had all shares of Preferred Stock been converted into common stock immediately prior to such liquidation, dissolution, winding-up or Deemed Liquidation Event. If upon any such liquidation, dissolution, or winding-up or Deemed Liquidation Event, the assets available for distribution to stockholders are insufficient to pay the holders of shares of Preferred Stock the full amounts to which they are entitled, the holders of shares of Preferred Stock shall share ratably in any distribution of the assets available for distribution in proportion to the respective amounts which would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

After the payment of all preferential amounts to the holders of shares of Preferred Stock, the remaining assets of the Company available for distribution to its stockholders shall be distributed among the holders of shares of Preferred Stock and common stock, pro rata based on the number of shares held by each such holder.

Unless the holders of the Requisite Preferred elect otherwise, a Deemed Liquidation Event shall include a merger or consolidation (other than one in which stockholders of the Company own a majority by voting

power of the outstanding shares of the surviving or acquiring corporation) or a sale, lease, transfer, exclusive license or other disposition of all or substantially all of the assets of the Company.

Redemption

The Company's certificate of incorporation, as amended and restated, does not provide redemption rights to the holders of Preferred Stock.

6. Common stock

As of December 31, 2017 and 2018, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue 7,000,000 shares and 75,000,000 shares, respectively, of $0.0001 par value common stock. The voting, dividend and liquidation rights of the holders of the Company's common stock are subject to and qualified by the rights, powers and preferences of the holders of the Preferred Stock set forth above.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. The holders of common stock, voting exclusively and as a separate class, are entitled to elect one director of the Company. Common stockholders are entitled to receive dividends, as may be declared by the board of directors, if any, subject to the preferential dividend rights of Preferred Stock. Through December 31, 2017 and 2018, no cash dividends had been declared or paid.

As of December 31, 2017 and 2018, there were 696,000 shares and 734,694 shares of common stock issued and outstanding with 696,000 shares of common stock issued pursuant to restricted stock agreements with the founders (see Note 7). As of December 31, 2017 and 2018, the Company had reserved 5,000,000 shares and 68,479,233 shares, respectively, of common stock for the conversion of outstanding shares of Preferred Stock (see Note 5) and the number of shares remaining available for future issuance under the 2018 Stock Option and Grant Plan (see Note 7).

7. Stock-based compensation

2018 Stock option and grant plan

The Company's 2018 Stock Option and Grant Plan (the "2018 Plan") provides for the Company to grant incentive stock options or nonqualified stock options, restricted stock awards and other stock-based awards to employees, directors and consultants of the Company.

The total number of shares of common stock that may be issued under the 2018 Plan was 9,443,760 shares as of December 31, 2018, of which 3,748,823 shares remained available for future grants.

The 2018 Plan is administered by the board of directors or, at the discretion of the board of directors, by a committee of the board of directors. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, or its committee if so delegated, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the share of common stock on the date of grant and the term of stock option may not be greater than ten years. All incentive options granted to any person possessing more than 10% of the total combined voting power of all classes of shares may not have an exercise price of less than 110% of the fair market value of the common stock on the grant date. Stock options granted to employees, officers, members of the board of directors and consultants will typically vest over a four-year period. The Company's board of directors values the

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Company's common stock, taking into consideration its most recently available valuation of common stock performed by third parties as well as additional factors which may have changed since the date of the most recent contemporaneous valuation through the date of grant.

Shares that are expired, terminated, surrendered or canceled under the 2018 Plan without having been fully exercised will be available for future awards.

During the period January 24, 2017 (inception) through December 31, 2017, no shares were granted under the 2018 Plan. During the year ended December 31, 2018, the Company granted options to purchase 5,788,909 shares of common stock to employees, directors and consultants of the Company. The Company recorded stock-based compensation expense for options granted of $121 during the year ended December 31, 2018.

Stock option valuation

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

	Period January 24, 2017 (inception) through December 31, 2017	Year ended December 31, 2018
Weighted average risk-free interest rate	n/a	2.99%
Expected term (in years)	n/a	6.0
Expected volatility	n/a	70.88%
Expected dividend yield	n/a	0.00%
Weighted average fair value of common stock	n/a	$ 0.35

Stock options

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

	Number of options	Weighted-average exercise price	Weighted-average remaining contractual term (years)	Aggregate intrinsic value
Outstanding as of December 31, 2017	—	$ —	—	$ —
Granted	5,788,909	0.20	9.74	
Exercised	(38,694)	0.20		
Cancelled	(93,972)	0.20		
Outstanding as of December 31, 2018	5,656,243	$ 0.20	9.74	$ 10,577
Options exercisable as of December 31, 2018	303,788	$ 0.20	9.62	$ 568
Options unvested as of December 31, 2018	5,352,455	$ 0.20	9.75	$ 10,009

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

The weighted average grant-date fair value per share of stock options granted during the year ended December 31, 2018 was $0.26. The total fair value of options vested during the year ended December 31, 2018 was $42.

Restricted common stock

In March 2017, the Company issued an aggregate of 696,000 shares of restricted common stock under restricted stock agreements with the founders. Pursuant to the terms of the agreements, the restricted common stock is subject to a vesting schedule over a four-year period commencing in January 2017 and culminating in January 2020. During the vesting period, the Company has the right to repurchase up to all unvested shares at the amount paid if the relationship between the recipient and the Company ceases. Subject to the continued employment or other business relationship with the Company, all of the restricted common stock becomes fully vested within four years of the date of issuance.

In October 2017, 232,000 shares of restricted common stock were subject to repurchase by the Company when one of the founders terminated his relationship with the Company. The Company repurchased the shares in March 2018 for an immaterial amount and immediately reissued the shares to the remaining founders. In connection with the repurchase and reissuance of the shares, the Company amended the restricted stock agreements with the remaining founders such that the restricted common stock is now subject to a vesting schedule over a two-year period commencing in May 2018 and culminating in May 2020.

The following table summarizes restricted stock activity for the period January 24, 2017 (inception) through December 31, 2017 and the year ended December 31, 2018:

	Number of shares	Grant-date fair value
Unvested restricted common stock as of January 24, 2017 (inception)	—	—
Granted	696,000	$ 0.0001
Vested	—	—
Unvested restricted common stock as of December 31, 2017	696,000	$ 0.0001
Granted	—	—
Vested	(449,500)	$ 0.0001
Unvested restricted common stock as of December 31, 2018	246,500	$ 0.0001

During the period January 24, 2017 (inception) through December 31, 2017, no shares of restricted common stock had vested. The Company accounted for the acceleration of vesting under the amended restricted stock agreement as a modification of the original awards and recognized the remaining unvested shares prospectively over the revised vesting period. The total fair value of restricted stock vested during the year ended December 31, 2018 was insignificant.

Stock-based compensation

During the period January 24, 2017 (inception) through December 31, 2017, the Company did not grant any options and accordingly did not record any stock-based compensation expense for the period January 24, 2017 (inception) through December 31, 2017. The Company recorded total stock-based compensation for options granted during the year ended December 31, 2018 of $121, with $41 classified as research and development expense and $80 classified as general and administrative expense in the consolidated statements of operations and comprehensive loss.

As of December 31, 2018, total unrecognized compensation cost related to the unvested stock-based awards was $1,374, which is expected to be recognized over weighted average periods of 3.57 years.

8. Amgen license agreement

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

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

In addition, under the Amgen Agreement, Amgen is entitled to a 10% ownership interest of the outstanding shares of the Company's common stock, on a fully diluted and converted basis as of the Second Tranche Closing, provided that the percentage shall only be based on the First Tranche Closing and a maximum of $25,000 worth of shares of Series A Preferred Stock issued in the Second Tranche Closing. The Company was obligated to issue additional shares of Series A Preferred Stock, or such other class or series of stock issued, until the Company had raised aggregate cumulative proceeds of $25,000 from sales of equity securities. The Company assessed the Amgen anti-dilution right and determined that the right (i) meets the definition of a freestanding financial instrument that was not indexed to the Company's own stock and (ii) meets the definition of a derivative and did not qualify for equity classification. The initial fair value of the anti-dilution right liability of $1,639 was recorded as research and development expense in June 2018. The Company remeasured the liability associated with the anti-dilution right as of each reporting period since the date of issuance. Changes in the fair value of the anti-dilution right liability continued to be recognized until the Company satisfied the anti-dilution right obligation which occured in November 2018 with the completion of the Company's Second Tranche Closing. The Company recognized a loss of $5,765 within other expense in the consolidated statements of operations and comprehensive loss for the year

ended December 31, 2018, related to the change in fair value of the anti-dilution right liability prior to its extinguishment in November 2018.

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

Under the Amgen Agreement, the Company is obligated to make aggregate milestone payments to Amgen of up to $40,000 upon the achievement of specified clinical and regulatory milestones and aggregate milestone payments of up to $75,000 upon the achievement of specified commercial milestones for all products licensed under the agreement.

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

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

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

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

9. Income taxes

2017 U.S. tax reform

On December 22, 2017, H.R.1, known as the Tax Cuts and Jobs Act, was enacted. This new law did not have a significant impact on the Company's consolidated financial statements for the year ended December 31, 2017 because it maintains a valuation allowance on the all of its net operating losses and other deferred tax assets. However, the reduction of the U.S. federal corporate tax rate from 35% to 21% resulted in

increases to the amounts reflected in "Tax law change" in the Company's tax reconciliation table below for the year ended December 31, 2017.

As permitted by SEC Staff Accounting Bulletin 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act, the Company recorded provisional estimates during the year ended December 31, 2017, and have subsequently finalized its accounting analysis based on the guidance, interpretations, and data available as of December 31, 2018 and no further adjustments were made upon finalization of the accounting analysis.

Income taxes

During the period January 24, 2017 (inception) through December 31, 2017, and the year ended December 31, 2018, the Company recorded no income tax benefits for the net operating losses incurred or for the research and development tax credits generated in each period due to its uncertainty of realizing a benefit from those items. All of the Company's operating losses since inception have been generated in the United States.

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

	For the period January 24, 2017 (inception) through December 31, 2017	Year ended December 31, 2018
Current income tax provision:		
Federal	$ —	$ —
State	—	—
Total current income tax provision	—	—
Deferred income tax benefit:		
Federal	(1,045)	(4,198)
State	(317)	(1,239)
Total deferred income tax benefit	(1,362)	(5,438)
Change in deferred tax asset valuation allowance	1,362	(5,438)
Total provision for income taxes	$ —	$ —

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

	For the period January 24, 2017 (inception) through December 31, 2017	Year ended December 31, 2018
Federal statutory income tax rate	34.0%	21.0%
State income taxes, net of federal benefit	5.9	1.5
Research and development tax credits	1.9	0.1
Change in preferred stock tranche obligation	(0.0)	(16.0)
Remeasurement of deferred taxes due to the TCJA	(12.0)	(0.0)
Change in deferred tax asset valuation allowance	(29.8)	(6.6)
Effective income tax rate	(0.0)%	(0.0)%

Net deferred tax assets as of December 31, 2017 and 2018 consisted of the following:

	December 31,	
	2017	2018
Net operating loss carry forwards	$ 1,243	$ 2,899
Research and development tax credit carry forwards	119	231
License fees	—	3,669
Accruals, reserves and other	—	1
Total deferred tax assets	1,362	6,800
Valuation allowance	(1,362)	(6,800)
Net deferred tax assets	$ —	$ —

As of December 31, 2018, the Company had U.S. federal and state net operating loss carryforwards of $10,629 and $10,559, respectively, which may be available to offset future taxable income and begin to expire in 2037. The federal net operating loss carryforwards include $6,067, which may be carried forward indefinitely. As of December 31, 2018, the Company also had U.S. federal and state research and development tax credit carryforwards of $191 and $51, respectively, which may be available to offset future tax liabilities and begin to expire in 2032. During the year ended December 31, 2018, gross deferred tax assets, before valuation allowance, increased by approximately $5,438 due to the operating loss incurred by the Company during that period.

Utilization of the U.S. federal and state net operating loss carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, and corresponding provisions of state law, due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income or tax liabilities. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of

certain stockholders or public groups in the stock of a corporation by more than 50% over a three-year period. The Company has not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382, at any time since inception, utilization of the net operating loss carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before utilization. Further, until a study is completed by the Company and any limitation is known, no amounts are being presented as an uncertain tax position.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company's history of cumulative net losses incurred since inception and its lack of commercialization of any products or generation of any revenue from product sales since inception and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the net deferred tax assets as of December 31, 2017 and 2018. Management reevaluates the positive and negative evidence at each reporting period.

Changes in the valuation allowance for deferred tax assets during the year ended December 31, 2018 related primarily to the increase in net operating loss carryforwards and research and development tax credit carryforwards in 2018, and were as follows:

	December 31,	
	2017	2018
Valuation allowance as of January 24, 2017 (inception)	$ —	$ (1,362)
Increases recorded to income tax provision	593	—
Decreases recorded as a benefit to income tax provision	(1,955)	(5,438)
Valuation allowance as of December 31, 2017	$ (1,362)	$ (6,800)

As of December 31, 2017 and 2018, the Company had not recorded any amounts for unrecognized tax benefits. The Company's policy is to record interest and penalties related to income taxes as part of its income tax provision. As of December 31, 2017 and 2018, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts had been recognized in the Company's consolidated statements of operations and comprehensive loss. The Company files income tax returns in the U.S. and Massachusetts, as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending tax examinations. The Company is open to future tax examination under statute from 2017 to the present.

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10. Net loss per share and unaudited pro forma net loss per share

Net loss per share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows:

	For the period January 24, 2017 (inception) through December 31, 2017	Year ended December 31, 2018
Numerator:		
Net loss	$ (4,564)	$ (81,714)
Accruing dividends on redeemable convertible preferred stock	(213)	—
Accretion of redeemable convertible preferred stock to redemption value	—	(520)
Net loss attributable to common stockholders	$ (4,777)	$ (82,234)
Denominator:		
Weighted average common shares outstanding—basic and diluted		317,894
Net loss per share attributable to common stockholders—basic and diluted		$ (258.68)

As of December 31, 2017, there were no vested shares of common stock outstanding. Therefore, net loss per share attributable to common stockholders, basic and diluted, is not presented for the periods January 24, 2017 (inception) through December 31, 2017. The table above only reflects the net loss per share attributable to common stockholders, basic and diluted, for the year ended December 31, 2018.

The Company excluded 386,693 shares of restricted common stock, presented on a weighted average basis, from the calculations of basic net loss per share attributable to common stockholders for the year ended December 31, 2018, because those shares had not vested.

Prior to the execution of the 2018 Series A Agreement in June 2018, the holders of Series A Preferred Stock were entitled to cumulative dividends of $0.08 per share, or 8%. The cumulative accrual of dividends on Series A Preferred Stock are included in the calculation of net loss attributable to common stockholders for the period January 24, 2017 (inception) through December 31, 2017, however, were not presented for the year ended December 31, 2018 after the June 2018 Amendment to our Certificate of Incorporation in which the cumulative dividends clause was removed.

The Company's potentially dilutive securities, which include stock options, unvested restricted common stock and redeemable convertible preferred stock, have been excluded from the computation of diluted net loss per share attributable to common stockholders as the effect would be to reduce the net loss per share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from

the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	For the period January 24, 2017 (inception) through December 31, 2017	Year ended December 31, 2018
Options to purchase common stock	—	5,656,243
Unvested restricted common stock	696,000	246,500
Redeemable convertible preferred stock (as converted to common stock)	5,000,000	64,730,410
	5,696,000	70,633,153

Unaudited pro forma net loss per share

Unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2018 have been prepared to give effect to adjustments arising upon the closing of an IPO. Unaudited pro forma net loss attributable to common stockholders used in the calculation of unaudited pro forma basic and diluted net loss per share attributable to common stockholders does not include the effects of (i) the change in fair value of the preferred stock tranche obligation and (ii) the accretion of Preferred Stock to redemption value because the calculation gives effect to the conversion of all shares of Preferred Stock as if the proposed IPO had occurred on the later of January 1, 2018 or the issuance date of the Preferred Stock.

Unaudited pro forma basic and diluted weighted average common shares outstanding used in the calculations of unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2018 have been prepared to give effect, upon an IPO, to the automatic conversion of all outstanding shares of Preferred Stock into shares of common stock as if the proposed IPO had occurred on the later of January 1, 2018 or the issuance date of the Preferred Stock.

Unaudited pro forma basic and diluted net loss per share attributable to common stockholders was calculated as follows:

	Year ended December 31, 2018
Numerator:	
Net loss attributable to common stockholders	$ (82,234)
Accretion of redeemable convertible preferred stock to redemption value	520
Changes in fair value of preferred stock tranche obligation	62,150
Pro forma net loss attributable to common stockholders	$ (19,564)
Denominator:	
Weighted average common shares outstanding—basic and diluted	317,894
Pro forma adjustment to reflect automatic conversion of redeemable convertible preferred stock into common stock upon the closing of the proposed IPO	18,977,976
Pro forma weighted average common shares outstanding—basic and diluted	19,295,870
Pro forma net loss per share attributable to common stockholders—basic and diluted	$ (1.01)

11. Commitments and contingencies

Lease agreements

During the period January 24, 2017 (inception) through December 31, 2017 the Company did not enter into any lease agreements and incurred no rent expense.

The Company entered into a use and occupancy agreement for its new office space in Cambridge, Massachusetts on August 15, 2018, with Atlas Venture Life Science Advisors, LLC, a related party (See Note 12). The agreement commenced on August 15, 2018 and continues for an initial 9-month period after which the agreement becomes cancelable by either party upon 60 days written notice. Monthly lease payments include base rent for the office space of approximately $12 annually and non-rent shared tenant occupancy costs.

In October 2018, the Company entered into a lease agreement for office space in San Francisco, California. The lease expires in April 2019 with an option to automatically renew for successive 30 day periods. Monthly lease payments to be paid under the agreement total $5 which are subject to a 3% annual increase if the lease has not yet expired or been terminated.

The Company recognizes rent expense on a straight-line basis over the respective lease periods and has recorded rent expense of $12 for the year ended December 31, 2018. As of December 31, 2018, total future minimum commitments due under our leases are $26, all payable within one year.

Research and manufacturing commitments

During the year ended December 31, 2018, the Company entered into agreements with contract research organizations and contract manufacturing organizations to provide services in connection with its nonclinical studies and clinical trials and to manufacture clinical development materials, respectively. As of December 31, 2018, the Company had non-cancelable purchase commitments under these agreements totaling $553.

Indemnification agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and its executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not currently aware of any indemnification claims and has not accrued any liabilities related to such obligations in its consolidated financial statements as of December 31, 2017 or 2018.

Legal proceedings

The Company is not a party to any litigation and does not have contingency reserves established for any litigation liabilities. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses as incurred the costs related to such legal proceedings.

12. Related party transactions

Apple Tree Life Sciences, Inc.

During the period January 24, 2017 (inception) through December 31, 2017 and for the year ended December 31, 2018, the Company issued 5,000,000 shares and 8,000,000 shares, respectively, of Series A Preferred Stock to Apple Tree Partners IV, L.P. ("Apple Tree"). During the year ended December 31, 2018, the Company issued 880,568 shares of Series B preferred stock to Apple Tree. A partner of Apple Tree Life Sciences, Inc. ("ATLS") has served on the Company's board of directors since June 2018. The Company's founders, including the current Executive Vice President and Chief Operating Officer and Chief Scientific Officer, were formerly employees of ATLS until April 2017. From inception to September 2017, the Company received certain services from ATLS, including consulting, finance, human resources, legal, and other operational support, as well as research and development recruiting expenses. ATLS charged the Company a service fee consisting of allocated internal time incurred on behalf of the Company by ATLS employees, plus a pre-determined mark-up. Further, the Company paid or reimbursed ATLS at cost for any expenses incurred by third parties on its behalf.

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Expenses from services rendered by ATLS, inclusive of the mark-up, are as follows:

	For the period January 24, 2017 (inception) through December 31, 2017	Year ended December 31, 2018
Research and development expenses	$ 1,750	$ 1
General and administrative expenses	348	—
	$ 2,098	$ 1

As of December 31, 2017 and 2018, the Company did not owe any amounts to Apple Tree.

Atlas Venture Life Science Advisors, LLC

During 2018, the Company issued 10,666,667 shares of Series A Preferred Stock and 722,737 shares of Series B preferred stock to entities affiliated with Atlas Venture. ("Atlas") and a principal of Atlas was elected to the board of directors. During the year ended December 31, 2018, the Company incurred fees for certain research and development consulting services from Atlas totaling $23.

In August 2018, the Company entered into a use and occupancy agreement for its new office space with Atlas. The agreement commenced on August 15, 2018 and continues for an initial 9-month period after which the agreement becomes cancelable by either party upon 60 days written notice. Base rent for the office space is approximately $12 annually (See Note 11).

As of December 31, 2018, the Company owed $12 to Atlas, which was included in accounts payable in its consolidated balance sheets.

Versant Venture Capital VI, L.P.

During 2018, the Company issued 10,666,667 shares of Series A Preferred Stock and 722,737 shares of Series B preferred stock to entities affiliated with Versant Venture Capital VI, L.P. ("Versant") and a principal of Versant was elected to the board of directors. During the year ended December 31, 2018, the Company incurred fees for certain general and administrative services from Versant totaling $4. As of December 31, 2017 and 2018, the Company did not owe any amounts to Versant.

venBio Global Strategic Fund II, LP.

During 2018, the Company issued 10,666,667 shares of Series A Preferred Stock and 722,737 shares of Series B preferred stock to entities affiliated with venBio Global Strategic Fund II, LP. ("venBio") and a partner at venBio was elected to the board of directors. During the year ended December 31, 2018, the Company incurred fees for certain general and administrative services from venBio totaling $35. As of December 31, 2017, the Company did not owe any amounts to venBio. As of December 31, 2018, the Company owed $35 to venBio, which was included in accounts payable in its consolidated balance sheets.

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13. Benefit plans

The Company established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan covers all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Matching contributions to the plan may be made at the discretion of the Company's board of directors. The Company made no contributions to the plan during the period January 24, 2017 (inception) through December 31, 2017, and the year ended December 31, 2018, respectively.

14. Subsequent events

For its consolidated financial statements as of December 31, 2018 and for the year then ended, the Company evaluated subsequent events through March 19, 2019, the date on which those financial statements were issued.

Stock option grants

In January 2019, the Company granted options to employees for the purchase of 1,459,721 shares of common stock at an exercise price of $2.07 per share. The options have service-based vesting conditions and vest over a term of four years.

Amendment to lease agreement

In March 2019, the Company entered into its first amendment to the lease agreement in San Francisco, California (the "First Amendment") to extend the term of the lease and expand the square footage of the existing leased office space. The First Amendment lease expires in March 2021. Monthly lease payments to be paid under the amended agreement total $19 which are subject to a 3% annual increase beginning in October 2019 and continues for each successive year until the lease has expired or been terminated.

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

Akero Therapeutics, Inc.
Condensed consolidated balance sheets
(In thousands, except share and per share amounts)
(Unaudited)

	December 31, 2018	March 31, 2019	Pro Forma March 31, 2019
Assets			
Current assets:			
Cash and cash equivalents	$ 75,975	$ 69,796	$ 69,796
Prepaid expenses and other current assets	1,156	903	903
Total current assets	77,131	70,699	70,699
Deferred offering costs	—	1,327	1,327
Restricted cash	20	40	40
Total assets	$ 77,151	$ 72,066	$ 72,066
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)			
Current liabilities:			
Accounts payable	$ 1,373	$ 952	$ 952
Accrued expenses	969	1,452	1,452
Total current liabilities	2,342	2,404	2,404
Commitments and contingencies (Note 10)			
Redeemable convertible preferred stock (Series A and B), $0.0001 par value; 64,730,410 shares authorized, issued and outstanding as of December 31, 2018 and March 31, 2019; aggregate liquidation preference of $96,358 as of December 31, 2018 and March 31, 2019; no shares issued or outstanding, pro forma as of March 31, 2019	124,728	124,728	—
Stockholders' (deficit) equity:			
Common stock, $0.0001 par value, 75,000,000 shares authorized as of December 31, 2018 and March 31, 2019; 734,694 shares issued and outstanding as of December 31, 2018 and March 31, 2019, 65,465,104 shares issued and outstanding, pro forma as of March 31, 2019	—	—	7
Additional paid-in capital	36,646	36,861	161,582
Accumulated deficit	(86,565)	(91,927)	(91,927)
Total stockholders' (deficit) equity	(49,919)	(55,066)	69,662
Total liabilities, redeemable convertible preferred stock and stockholders' (deficit) equity	$ 77,151	$ 72,066	$ 72,066

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

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

Akero Therapeutics, Inc.
Condensed consolidated statements of operations and comprehensive loss
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2018	2019
Operating expenses:		
Research and development	$ 226	$ 4,063
General and administrative	195	1,449
Total operating expenses	421	5,512
Loss from operations	(421)	(5,512)
Other income:		
Other income, net	—	150
Total other income	—	150
Net loss attributable to common stockholders	$ (421)	$ (5,362)
Net loss per share attributable to common stockholders—basic and diluted	$ (3.39)	$ (10.38)
Weighted average common shares outstanding—basic and diluted	124,163	516,711
Pro forma net loss per share attributable to common stockholders—basic and diluted		$ (0.08)
Pro forma weighted average common shares outstanding—basic and diluted		65,247,121

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

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

Akero Therapeutics, Inc.
Condensed consolidated statements of redeemable convertible preferred stock and stockholders' deficit
(In thousands, except share amounts)
(Unaudited)

	Redeemable Convertible Preferred Stock		Common Stock		Treasury Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount			
Balances at December 31, 2017	5,000,000	$ 5,000	696,000	$—	—	$—	$ —	$ (4,564)	$ (4,564)
Repurchase of founders' common stock	—	—	(232,000)	—	232,000	—	—	—	—
Issuance of treasury stock as founders' common stock	—	—	232,000	—	(232,000)	—	—	—	—
Net loss	—	—	—	—	—	—	—	(421)	(421)
Balances at March 31, 2018	5,000,000	$ 5,000	696,000	$—	—	$—	$ —	$ (4,985)	$ (4,985)
Balances at December 31, 2018	64,730,410	$ 124,728	734,694	$—	—	$—	$36,646	$(86,565)	$(49,919)
Stock-based compensation expense	—	—	—	—	—	—	215	—	215
Net loss	—	—	—	—	—	—	—	(5,362)	(5,362)
Balances at March 31, 2019	64,730,410	$ 124,728	734,694	$—	—	$—	$ 36,861	$(91,927)	$(55,066)

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

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

Akero Therapeutics, Inc.
Condensed consolidated statements of cash flows
(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2018	2019
Cash flows used in operating activities:		
Net loss	$ (421)	$ (5,362)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	—	215
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(5)	197
Accounts payable	—	(564)
Accrued expenses	88	70
Net cash used in operating activities	(338)	(5,444)
Cash flows used in financing activities:		
Payment of initial public offering costs		(720)
Net cash used in financing activities	—	(720)
Net decrease in cash, cash equivalents and restricted cash	(338)	(6,164)
Cash and restricted cash at beginning of period	618	76,000
Cash, cash equivalents and restricted cash at end of period	$ 280	$ 69,836
Supplemental disclosure of non-cash investing and financing activities:		
Deferred offering costs included in accounts payable and accrued expenses	$ —	$ 556

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

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

Akero Therapeutics, Inc.
Notes to Unaudited Condensed Consolidated Financial Statements
(Amounts in thousands, except share and per share data)

1. Nature of the business and basis of presentation

Akero Therapeutics, Inc. ("Akero" or the "Company") is a clinical-stage biotechnology company focused on developing and commercializing transformative treatments for patients with serious metabolic diseases. Akero's initial focus is on nonalcoholic steatohepatitis ("NASH"), a disease without any approved therapies. NASH is a severe form of nonalcoholic fatty liver disease ("NAFLD"), characterized by inflammation and fibrosis in the liver that can progress to cirrhosis, failure, cancer of the liver, and death. We are developing AKR-001, an analog of fibroblast growth factor 21 ("FGF21"), for NASH and plan to initiate a Phase 2a clinical trial for AKR-001 in NASH patients with fibrosis in the middle of 2019.

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

In December 2018, the Company entered into a subscription agreement with Akero Securities Corporation ("Akero Securities") and acquired all of the outstanding shares of Akero Securities common stock for an immaterial amount, which resulted in Akero Securities becoming a wholly owned subsidiary of the Company. Akero Securities is incorporated under the laws of Massachusetts. The principal activities of this company are to engage exclusively in buying, selling, dealing in or holding securities on its own behalf.

The accompanying condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and include the accounts of the Company and its wholly owned subsidiary, Akero Securities, after elimination of all significant intercompany accounts and transactions. All adjustments necessary for the fair presentation of the Company's condensed consolidated financial statements for the periods have been presented. The Company's significant accounting policies are disclosed in the audited consolidated financial statements for the year ended December 31, 2018, included elsewhere in this prospectus. Since the date of those financial statements, there have been no changes to the Company's significant accounting policies.

Going concern

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

Since its inception, the Company has funded its operations primarily with proceeds from sales of redeemable convertible preferred stock. The Company has incurred recurring losses since its inception,

**Akero Therapeutics, Inc.
Notes to Unaudited Condensed Consolidated Financial Statements
(Amounts in thousands, except share and per share data)**

including a net loss of $5,362 for the three months ended March 31, 2019. In addition, as of March 31, 2019, the Company had an accumulated deficit of $91,927. The Company expects to continue to generate operating losses for the foreseeable future. As of April 30, 2019, the issuance date of these condensed consolidated financial statements, the Company expects that its existing cash and cash equivalents of $69,796 as of March 31, 2019, will be sufficient to fund its operating expenses and capital expenditure requirements for at least 12 months from the issuance date of these condensed consolidated financial statements. The future viability of the Company beyond that point is dependent on its ability to raise additional capital to finance its operations.

The Company is seeking to complete an initial public offering ("IPO") of its common stock. In the event the Company does not complete an IPO, the Company expects to seek additional funding through private equity financings, debt financings or other capital sources, including collaborations with other companies or other strategic transactions. The Company may not be able to obtain financing on acceptable terms, or at all. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders.

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

2. Summary of significant accounting policies

Unaudited Interim Financial Statements

The accompanying unaudited condensed consolidated financial statements have been prepared by the Company in accordance with accounting principles generally accepted in the United States, or GAAP, for interim financial reporting and as required by Regulation S-X, Rule 10-01. The unaudited condensed consolidated financial statements have been prepared on the same basis as the audited annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair statement of the Company's financial position as of March 31, 2019 and the results of its operations and its cash flows for the three months ended March 31, 2018 and 2019. The financial data and other information disclosed in these notes related to the three months ended March 31, 2018 and 2019 are unaudited. The results for the three months ended March 31, 2019 are not necessarily indicative of results to be expected for the year ending December 31, 2019, any other interim periods, or any future year or period.

Use of estimates

The preparation of the Company's condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, and the reported amounts of expenses during the reporting period. Significant estimates and assumptions reflected in these condensed consolidated financial statements include, but are not limited to, the accrual of research and development expenses, the valuations of common stock and the

Akero Therapeutics, Inc.
Notes to Unaudited Condensed Consolidated Financial Statements
(Amounts in thousands, except share and per share data)

valuation allowance for deferred tax assets. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates when there are changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates.

Unaudited pro forma information

The accompanying unaudited pro forma consolidated balance sheet as of March 31, 2019 has been prepared assuming the automatic conversion of all outstanding shares of redeemable convertible preferred stock into 64,730,410 shares of common stock upon an IPO, as if the proposed IPO had occurred on March 31, 2019.

In the accompanying condensed consolidated statements of operations, the unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the three months ended March 31, 2019 has been prepared assuming the automatic conversion of all outstanding shares of redeemable convertible preferred stock into shares of common stock upon an IPO, as if the proposed IPO had occurred on the later of January 1, 2018 or the issuance date of the redeemable convertible preferred stock.

Cash and Cash Equivalents

The Company classifies as cash and cash equivalents amounts on deposit in banks and cash invested temporarily in various instruments, primarily money market accounts, with original maturities of three months or less at the time of purchase. The carrying amounts reported in the condensed consolidated balance sheet represents the fair values of cash and cash equivalents.

Restricted cash

As of December 31, 2018 and March 31, 2019, the Company was required to maintain a separate cash balance of $20 to collateralize corporate credit cards with a bank, which was classified as restricted cash (non-current) on its condensed consolidated balance sheets.

As of December 31, 2018, the Company was required to maintain a separate cash balance of $5 for the benefit of the landlord in connection with one of the Company's office space lease, which was classified as other current assets on its consolidated balance sheets. As of March 31, 2019, in connection with the First Amendment to the lease , the Company was required to maintain a separate cash balance of $20 for the benefit of the landlord in connection with one of the Company's office space lease, which was classified as restricted cash (non-current) on its condensed consolidated balance sheets (see Note 10).

Emerging growth company

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

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Pursuant to 17 C.F.R. Section 200.83

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Recently adopted accounting pronouncements

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2014-09"), which supersedes existing revenue recognition guidance under GAAP. This standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The standard defines a five-step process to achieve this principle and will require companies to use more judgment and make more estimates than under the current guidance. The Company expects that these judgments and estimates will include identifying performance obligations in the customer contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts. In August 2015, the FASB issued ASU No. 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, which delayed the effective date of ASU 2014-09 such that the standard is effective for non-public entities for annual periods beginning after December 15, 2018 and for interim periods beginning after December 15, 2019. The FASB subsequently issued amendments to ASU 2014-09 that have the same effective date and transition date. The Company early adopted ASU 2014-09 as of January 1, 2018 and the adoption had no impact on the Company's financial position, results of operations or cash flows as the Company does not currently have any revenue-generating arrangements.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments (Topic 230)* ("ASU 2016-15"), to address diversity in practice in how certain cash receipts and cash payments are presented in the statement of cash flows. For non-public entities, ASU 2016-15 is effective for annual reporting periods beginning after December 15, 2018, including interim periods within those fiscal years. The adoption of ASU 2016-15 is required to be applied retrospectively. The Company early adopted ASU 2016-15 as of January 1, 2018, and its adoption had no impact on the Company's financial position, results of operations or cash flows.

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business* ("ASU 2017-01"), which clarifies the definition of a business and provides a screen to determine when an integrated set of assets and activities is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the asset is not a business. For non-public entities, ASU 2017-01 is effective for annual reporting periods beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. The Company early adopted ASU 2017-01 as of January 1, 2018, and its adoption had no impact on the Company's financial position, results of operations or cash flows.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting* ("ASU 2017-09"). The amendments in ASU 2017-09 clarifies that modification accounting is required only if the fair value, the vesting conditions or the classification of the awards (as equity or liability) changes as a result of the change in terms or conditions. For non-public entities, ASU 2017-09 is effective for annual reporting periods beginning after December 15, 2017, including interim periods within those fiscal years. The Company adopted ASU 2017-09 as of January 1, 2018. The adoption

of ASU 2017-09 did not have a material impact on the Company's financial position, results of operations or cash flows, but will impact the accounting for modifications of stock-based awards, if any, after the date of adoption.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"). These amendments expand the scope of *Topic 718, Compensation—Stock Compensation* (which currently only includes stock-based payments to employees) to include stock-based payments issued to nonemployees for goods or services. Consequently, the accounting for stock-based payments to nonemployees and employees will be substantially aligned. The ASU *supersedes Subtopic 505-50, Equity—Equity-Based Payments to Non-Employees*. This standard is effective for non-public companies for annual periods beginning after December 15, 2019, including interim periods within those fiscal years, with early adoption permitted as long as ASU 2014-09 has been adopted by the Company. The Company early adopted this guidance as of January 1, 2018.

Recently issued accounting pronouncements

In February 2016, the FASB issued ASU No. 2016-02*, Leases (Topic 842)* ("ASU 2016-02"), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less may be accounted for similar to existing guidance for operating leases today. For non-public entities, ASU 2016-02 is effective for annual reporting periods beginning after December 15, 2019, including interim periods within those fiscal years, and early adoption is permitted. The Company is in the process of completing its review of its existing lease agreements under ASC 842 and does not expect the adoption of ASU 2016-02 to have a material impact on its financial position, results of operations or cash flows.

In July 2017, the FASB issued ASU No. 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815) (Part I) Accounting for Certain Financial Instruments with Down Round Features (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception* ("ASU 2017-11"). Part I applies to entities that issue financial instruments such as warrants, convertible debt or convertible preferred stock that contain down-round features. Part II replaces the indefinite deferral for certain mandatorily redeemable noncontrolling interests and mandatorily redeemable financial instruments of non-public entities contained within Accounting Standards Codification ("ASC") Topic 480 with a scope exception and does not impact the accounting for these mandatorily redeemable instruments. For non-public entities, ASU 2017-11 is effective for annual reporting periods beginning after December 15, 2019, including interim periods within those fiscal years. The Company is currently evaluating the impact that the adoption of ASU 2017-11 will have on its consolidated financial statements.

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

3. Accrued expenses

Accrued expenses consisted of the following:

	December 31, 2018	March 31, 2019
Accrued employee compensation and benefits	$ 304	$ 146
Accrued external research and development expenses	430	614
Accrued legal and professional fees	106	650
Other accrued expenses	129	42
	$ 969	$ 1,452

4. Redeemable convertible preferred stock

As of December 31, 2018 and March 31, 2019, the Company's certificate of incorporation, as amended and restated (the "Amended and Restated Certificate of Incorporation"), authorized the Company to issue 64,730,410 shares of Preferred Stock, par value $0.0001 per share. The Preferred Stock is classified outside of stockholders' (deficit) equity because the shares contain redemption features that are not solely within the control of the Company.

As of each balance sheet date, the Preferred Stock consisted of the following:

	December 31, 2018				
	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A Preferred Stock	50,858,462	50,858,462	$ 79,457	$ 50,858	50,858,462
Series B Preferred Stock	13,871,948	13,871,948	45,271	$ 45,500	13,871,948
	64,730,410	64,730,410	$ 124,728	$ 96,358	64,730,410

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	March 31, 2019				
	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A Preferred Stock	50,858,462	50,858,462	$ 79,457	$ 50,858	50,858,462
Series B Preferred Stock	13,871,948	13,871,948	45,271	$ 45,500	13,871,948
	64,730,410	64,730,410	$ 124,728	$ 96,358	64,730,410

5. Common stock

As of December 31, 2018 and March 31, 2019, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue 75,000,000 shares of $0.0001 par value common stock. The voting, dividend and liquidation rights of the holders of the Company's common stock are subject to and qualified by the rights, powers and preferences of the holders of the Preferred Stock set forth in our annual consolidated financial statements and related notes included elsewhere in this prospectus.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. The holders of common stock, voting exclusively and as a separate class, are entitled to elect one director of the Company. Common stockholders are entitled to receive dividends, as may be declared by the board of directors, if any, subject to the preferential dividend rights of Preferred Stock. Through March 31, 2019, no cash dividends had been declared or paid.

As of December 31, 2018 and March 31, 2019, there were 734,694 shares of common stock issued and outstanding with 696,000 shares of common stock issued pursuant to restricted stock agreements with the founders (see Note 6). As of December 31, 2018 and March 31, 2019, the Company had reserved 67,019,512 shares of common stock for the conversion of outstanding shares of Preferred Stock (see Note 4) and the number of shares remaining available for future issuance under the 2018 Stock Option and Grant Plan (see Note 6).

6. Stock-based compensation

2018 Stock option and grant plan

The Company's 2018 Stock Option and Grant Plan (the "2018 Plan") provides for the Company to grant incentive stock options or nonqualified stock options, restricted stock awards and other stock-based awards to employees, directors and consultants of the Company.

The total number of shares of common stock that may be issued under the 2018 Plan was 9,443,760 shares as of March 31, 2019, of which 2,289,102 shares remained available for future grants.

The 2018 Plan is administered by the board of directors or, at the discretion of the board of directors, by a committee of the board of directors. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, or its committee if so delegated, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the share of common stock

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on the date of grant and the term of stock option may not be greater than ten years. All incentive options granted to any person possessing more than 10% of the total combined voting power of all classes of shares may not have an exercise price of less than 110% of the fair market value of the common stock on the grant date. Stock options granted to employees, officers, members of the board of directors and consultants will typically vest over a four-year period. The Company's board of directors values the Company's common stock, taking into consideration its most recently available valuation of common stock performed by third parties as well as additional factors which may have changed since the date of the most recent contemporaneous valuation through the date of grant.

Shares that are expired, terminated, surrendered or canceled under the 2018 Plan without having been fully exercised will be available for future awards.

During the three months ended March 31, 2018, no shares were granted under the 2018 Plan. During the three months ended March 31, 2019, the Company granted options to purchase 1,459,721 shares of common stock to employees, directors and consultants of the Company.

Stock option valuation

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

	Three Months Ended March 31,	
	2018	2019
Weighted average risk-free interest rate	n/a	2.57%
Expected term (in years)	n/a	6.00
Expected volatility	n/a	67.44%
Expected dividend yield	n/a	0.00%
Weighted average fair value of common stock	n/a	$ 2.07

Stock options

The following table summarizes the Company's stock option activity since December 31, 2018:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2018	5,656,243	$ 0.20	9.74	$ 10,577
Granted	1,459,721	2.07	9.80	
Outstanding as of March 31, 2019	7,115,964	$ 0.58	9.56	$ 12,072
Options exercisable as of March 31, 2019	428,700	$ 0.28	9.42	$ 857
Options unvested as of March 31, 2019	6,687,264	$ 0.60	9.57	$ 11,215

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

The weighted average grant-date fair value per share of stock options granted during the three months ended March 31, 2019 was $1.29. The total fair value of options vested during the three months ended March 31, 2019 was $46.

Restricted common stock

In March 2017, the Company issued an aggregate of 696,000 shares of restricted common stock under restricted stock agreements with the founders. Pursuant to the terms of the agreements, the restricted common stock is subject to a vesting schedule over a four-year period commencing in January 2017 and culminating in January 2020. During the vesting period, the Company has the right to repurchase up to all unvested shares at the amount paid if the relationship between the recipient and the Company ceases. Subject to the continued employment or other business relationship with the Company, all of the restricted common stock becomes fully vested within four years of the date of issuance.

In October 2017, 232,000 shares of restricted common stock were subject to repurchase by the Company when one of the founders terminated his relationship with the Company. The Company repurchased the shares in March 2018 for an immaterial amount and immediately reissued the shares to the remaining founders. In connection with the repurchase and reissuance of the shares, the Company amended the restricted stock agreements with the remaining founders such that the restricted common stock is now subject to a vesting schedule over a two-year period commencing in May 2018 and culminating in May 2020.

The following table summarizes restricted stock activity since December 31, 2018:

	Number of Shares	Grant-Date Fair Value
Unvested restricted common stock as of December 31, 2018	246,500	$ 0.0001
Granted	—	—
Vested	(43,500)	$ 0.0001
Unvested restricted common stock as of March 31, 2019 (unaudited)	203,000	$ 0.0001

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

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Stock-based compensation

The Company did not grant any options as of March 31, 2018 and accordingly did not record any stock-based compensation expense for the three months ended March 31, 2018. The Company recorded total stock-based compensation for options granted as of March 31, 2019 of $215, with $82 classified as research and development expense and $133 classified as general and administrative expense in the condensed consolidated statements of operations and comprehensive loss.

As of March 31, 2019, total unrecognized compensation cost related to the unvested stock-based awards was $3,035, which is expected to be recognized over a weighted average period of 3.39 years.

7. Amgen license agreement

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

During the three months ended March 31, 2019, the Company did not record any research and development expense in connection with the Amgen Agreement.

8. Income taxes

During the three months ended March 31, 2018 and 2019, the Company recorded a full valuation allowance on federal and state deferred tax assets since management does not forecast the Company to be in a profitable position in the near future.

9. Net loss per share and pro forma net loss per share

Net loss per share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows:

	Three Months Ended March 31,	
	2018	**2019**
Numerator:		
Net loss attributable to common stockholders—basic and diluted	$ (421)	$ (5,362)
Denominator:		
Weighted average common shares outstanding—basic and diluted	124,163	516,711
Net loss per share attributable to common stockholders—basic and diluted	$ (3.39)	$ (10.38)

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The Company excluded 571,837 shares and 217,983 shares of restricted common stock, presented on a weighted average basis, from the calculations of basic net loss per share attributable to common stockholders for the three months ended March 31, 2018 and 2019, respectively, because those shares had not vested.

The Company's potentially dilutive securities, which include stock options, unvested restricted common stock and redeemable convertible preferred stock, have been excluded from the computation of diluted net loss per share attributable to common stockholders as the effect would be to reduce the net loss per share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Three Months Ended March 31,	
	2018	**2019**
Options to purchase common stock	—	7,115,964
Unvested restricted common stock	560,667	203,000
Redeemable convertible preferred stock (as converted to common stock)	5,000,000	64,730,410
	5,560,667	72,049,374

Pro forma net loss per share

The pro forma basic and diluted weighted average common shares outstanding used in the calculations of unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the three months ended March 31, 2019 have been prepared to give effect, upon an IPO, to the automatic conversion of all outstanding shares of Preferred Stock into shares of common stock as if the proposed IPO had occurred on the later of January 1, 2018 or the issuance date of the Preferred Stock.

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Pro forma basic and diluted net loss per share attributable to common stockholders was calculated as follows:

	Three Months Ended March 31, 2019
Numerator:	
Net loss attributable to common stockholders	$ (5,362)
Pro forma net loss attributable to common stockholders	$ (5,362)
Denominator:	
Weighted average common shares outstanding—basic and diluted	516,711
Pro forma adjustment to reflect automatic conversion of redeemable convertible preferred stock into common stock upon the closing of the proposed IPO	64,730,410
Pro forma weighted average common shares outstanding—basic and diluted	65,247,121
Pro forma net loss per share attributable to common stockholders—basic and diluted	$ (0.08)

10. Commitments and contingencies

Lease agreements

The Company entered into a use and occupancy agreement for office space in Cambridge, Massachusetts on August 15, 2018, with Atlas Venture Life Science Advisors, LLC, a related party (See Note 11). The agreement commenced on August 15, 2018 and continues for an initial 9-month period after which the agreement becomes cancelable by either party upon 60 days written notice. Monthly lease payments include base rent for the office space of approximately $12 annually and non-rent shared tenant occupancy costs.

In October 2018, the Company entered into a lease agreement for office space in San Francisco, California. In March 2019, the Company amended this lease agreement (the "First Amendment") to extend the term of the lease and expand the square footage of the existing leased office space. The First Amendment lease expires in March 2021. Monthly lease payments to be paid under the amended agreement total $19 which are subject to a 3% annual increase beginning in October 2019 and continuing for each successive year until the lease has expired or been terminated. The Company provided a security deposit of approximately $20 during the three months ended March 31, 2019, which is included as a component of restricted cash on the Company's condensed consolidated balance sheet as of March 31, 2019.

The Company recognizes rent expense on a straight-line basis over the respective lease periods and has recorded rent expense of $49 for the three months ended March 31, 2019.

Research and manufacturing commitments

During the three months ended March 31, 2019, the Company entered into agreements with contract research organizations and contract manufacturing organizations to provide services in connection with its nonclinical studies and clinical trials and to manufacture clinical development materials, respectively. As of

March 31, 2019, the Company had non-cancelable purchase commitments under these agreements totaling $1,855.

Indemnification agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and its executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not currently aware of any indemnification claims and has not accrued any liabilities related to such obligations in its condensed consolidated financial statements as of March 31, 2019.

Legal proceedings

The Company is not a party to any litigation and does not have contingency reserves established for any litigation liabilities. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses as incurred the costs related to such legal proceedings.

11. Related party transactions

Apple Tree Life Sciences, Inc.

During the period January 24, 2017 (inception) through December 31, 2017 and for the year ended December 31, 2018, the Company issued 5,000,000 shares and 8,000,000 shares respectively, of Series A Preferred Stock to Apple Tree Partners IV, L.P. ("Apple Tree"). During the year ended December 31, 2018, the Company issued 880,568 shares of Series B preferred stock to Apple Tree. A partner of Apple Tree Life Sciences, Inc. ("ATLS") has served on the Company's board of directors since June 2018. The Company's founders, including the current Executive Vice President and Chief Operating Officer and Chief Scientific Officer, were formerly employees of ATLS until April 2017.

The Company did not incur any fees from ATLS during the three months ended March 31, 2018 and 2019. As of March 31, 2019, the Company did not owe any amounts to Apple Tree.

Atlas Venture Life Science Advisors, LLC

During 2018, the Company issued 10,666,667 shares of Series A Preferred Stock and 722,737 shares of Series B preferred stock to entities affiliated with Atlas Venture. ("Atlas") and a principal of Atlas was elected to the board of directors.

In August 2018, the Company entered into a use and occupancy agreement for its new office space with Atlas. The agreement commenced on August 15, 2018 and continues for an initial 9-month period after

which the agreement becomes cancelable by either party upon 60 days written notice. Base rent for the office space is approximately $12 annually (See Note 10).

As of March 31, 2019, in association with the use and occupancy agreement for its office space, the Company owed $5 to Atlas, which was included in accrued expenses in its condensed consolidated balance sheets.

Versant Venture Capital VI, L.P.

During 2018, the Company issued 10,666,667 shares of Series A Preferred Stock and 722,737 shares of Series B preferred stock to entities affiliated with Versant Venture Capital VI, L.P. ("Versant") and a principal of Versant was elected to the board of directors. During the three months ended March 31, 2018 and 2019, the Company did not incur any fees from Versant. As of March 31, 2019, the Company did not owe any amounts to Versant.

venBio Global Strategic Fund II, LP.

During 2018, the Company issued 10,666,667 shares of Series A Preferred Stock and 722,737 shares of Series B preferred stock to entities affiliated with venBio Global Strategic Fund II, LP. ("venBio") and a partner at venBio was elected to the board of directors. During the three months ended March 31, 2018 and 2019, the Company did not incur any fees from venBio. As of March 31, 2019, the Company did not owe any amounts to venBio.

12. Subsequent events

For its condensed consolidated financial statements as of March 31, 2019 and for the three months then ended, the Company evaluated subsequent events through April 30, 2019, the date on which those financial statements were issued.

Stock option grants

In April 2019, the Company granted options to employees and non-employees for the purchase of 1,958,258 shares of common stock at an exercise price of $2.28 per share. The options have service-based vesting conditions and vest over a term of four years.

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

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, FINRA filing fee and Nasdaq Global Market listing fee.

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

* To be completed 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.

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 January 24, 2017, we have issued the following securities that were not registered under the Securities Act:

(a) Issuances of capital stock

Set forth below is information regarding securities we have issued within the past three years that were not registered under the Securities Act.

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Pursuant to 17 C.F.R. Section 200.83

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 common stock 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 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.

(a) Grants and exercises of stock options

We have granted stock options to purchase an aggregate of 7,115,964 shares of our common stock, with an average exercise price of $0.58 per share, to employees, directors and consultants pursuant to the 2018 Plan. Since 2018, 38,694 shares of common stock have been issued upon the exercise of stock options pursuant to the 2018 Plan.

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.

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Item 16. Exhibits and financial statement schedules.

(a) Exhibits

Exhibit number	Description
1.1*	Form of Underwriting Agreement
3.1**	Third Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect.
3.2*	Form of Fourth Amended and Restated Certificate of Incorporation of Registrant, to be in effect prior to the completion of this offering.
3.3**	Amended and Restated Bylaws of the Registrant, as currently in effect.
3.4*	Form of Second Amended and Restated Bylaws of the Registrant, to be in effect prior to the completion of this offering.
4.1*	Specimen Common Stock Certificate.
4.2*	Second Amended and Restated Investors' Rights Agreement among the Registrant and certain of its stockholders, dated December 10, 2018.
5.1*	Opinion of Goodwin Procter LLP.
10.1#**	2018 Stock Option and Grant Plan, and form of award agreements thereunder.
10.2#*	2019 Stock Option and Grant Plan, and form of award agreements thereunder.
10.3#*	2019 Employee Stock Purchase Plan.
10.4#*	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.
10.5	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 March 12, 2019
10.6#*	Form of Employment Agreement
10.7†	Exclusive License Agreement, by and between the Registrant and Amgen Inc., dated June 7, 2018
21.1**	List of Subsidiaries of the Registrant.
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 (included on signature page).

* To be filed by amendment.

** Previously filed.

† Application has been made to the Securities and Exchange Commission for confidential treatment of certain provisions. Omitted material for which confidential treatment has been requested has been filed separately with the Securities and Exchange Commission.

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

(b) Financial Statements Schedules:

Schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

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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.

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Signatures

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of San Francisco, California, on the day of , 2019.

AKERO THERAPEUTICS, INC.

By: _____

Name: Andrew Cheng, M.D., Ph.D.
Title: *President, Chief Executive Officer and Director*

Power of attorney and signatures

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.	President, Chief Executive Officer and Director (Principal Executive Officer)	, 2019
_____ William White, J.D.	Executive Vice President, Chief Financial Officer, Head of Corporate Development (Principal Financial Officer and Principal Accounting Officer)	, 2019
_____ Kevin Bitterman, Ph.D.	Director	, 2019

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Name	Title	Date
_____ Seth L. Harrison, M.D.	Director	, 2019
_____ Jane P. Henderson	Director	, 2019
_____ Mark Iwicki	Director	, 2019
_____ Aaron Royston, M.D.	Director	, 2019
_____ Graham Walmsley, M.D., Ph.D.	Director	, 2019

Exhibit 10.5

SUBLEASE AGREEMENT

This Sublease Agreement ("***Sublease***") is dated as of October 23, 2018, for reference purposes only, by and between TRUCODE GENE REPAIR, INC., a Delaware corporation ("***Sublandlord***"), having an address of 170 Harbor Way, Third Floor, South San Francisco, California 94080, and AKERO THERAPEUTICS INC., a Delaware corporation ("***Subtenant***"), having an address of 400 Technology Square, 10th Floor, Cambridge, Massachusetts 02139. This Sublease shall be effective as of the date set forth in Section 2, below.

RECITALS

A. Sublandlord currently leases certain premises from Britannia Pointe Grand Limited Partnership, a Delaware limited partnership ("***Master Landlord***"), pursuant to the terms and conditions of that certain Lease dated April 10, 2018 (the "***Master Lease***"). Pursuant to the Master Lease, Sublandlord currently leases from Master Landlord those certain premises consisting of approximately 24,606 rentable square feet (as more particularly described in the Master Lease, the "***Master Premises***"), located on the third (3rd) floor of that certain building located at 170 Harbor Way, South San Francisco, California (the "***Building***"), within the project commonly known as Britannia Pointe Grand Business Park (the "***Property***"), as more particularly described in the Master Lease. All terms capitalized but undefined herein shall have the meanings ascribed to them in the Master Lease, a copy of which Master Lease has been made available to Subtenant.

C. Sublandlord desires to sublease that certain portion of the Master Premises, consisting of approximately 383 square feet contained in offices 316 and 317, and the cubicle across from office 317, as depicted on the attached Exhibit A (the "***Sublease Premises***") to Subtenant and Subtenant desires to sublease the Sublease Premises from Sublandlord pursuant to the terms and conditions of this Sublease.

AGREEMENT

NOW, THEREFORE, for good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, Sublandlord and Subtenant hereby agree as follows:

1. Sublease Premises.

1.1 Sublease Premises. Sublandlord hereby subleases to Subtenant the Sublease Premises, and Subtenant hereby subleases the Sublease Premises from Sublandlord, pursuant to the terms and conditions of this Sublease. Subtenant shall accept the Sublease Premises in the condition and state of repair on the Commencement Date (as defined in Section 3 below) in its "AS IS" and "WHERE IS" condition, and Sublandlord makes no representation or warranty regarding the Sublease Premises. Subtenant expressly acknowledges and agrees Sublandlord shall not have any obligation to perform any work to prepare the Sublease Premises for Subtenant's use and occupancy. By taking possession of the Sublease Premises, Subtenant is deemed to have accepted the Sublease Premises and agreed that the Sublease Premises are in good order and satisfactory condition, with no representation or warranty by Sublandlord as to the condition of the Sublease Premises or the suitability thereof for Subtenant's use. Pursuant to

California Civil Code Section 1938, Sublandlord is required to state as follows regarding the Sublease Premises:

> A Certified Access Specialist (CASp) can inspect the subject premises and determine whether the subject premises comply with all of the applicable construction-related accessibility standards under state law. Although state law does not require a CASp inspection of the subject premises, the commercial property owner or lessor may not prohibit the lessee or tenant from obtaining a CASp inspection of the subject premises for the occupancy or potential occupancy of the lessee or tenant, if requested by the lessee or tenant. The parties shall mutually agree on the arrangements for the time and manner of the CASp inspection, the payment of the fee for the CASp inspection, and the cost of making any repairs necessary to correct violations of construction-related accessibility standards within the premises.

1.2 Access; Bathrooms. In connection with Subtenant's use of the Sublease Premises, Subtenant shall have the non-exclusive right to use, subject to Sublandlord's reasonable rules and regulations, the Master Premises restrooms, and rights of ingress and egress through the hallways and accessways as are reasonably necessary for Subtenant's access to the Sublease Premises and the Master Premises restrooms. Subtenant acknowledges that there will be no separate demise of the Sublease Premises.

2. Effective Date; Master Landlord's Consent Required. This Sublease shall not become effective or binding upon either party until the date on which Master Landlord's written consent to this Sublease is fully-executed and delivered to Sublandlord and Subtenant (the "***Effective Date***"). Sublandlord hereby disclaims any representation or warranty, whether express or implied, to Subtenant that Sublandlord will obtain the consent of Master Landlord to this Sublease, but Sublandlord shall use good faith efforts to obtain the same in accordance with the provisions of the Master Lease and Subtenant shall cooperate with Sublandlord in its efforts to obtain the same. Sublandlord shall request such consent and Subtenant shall pay any fees or charges expressly provided for in the Master Lease with respect to the obtaining of such consent. Subtenant agrees promptly to provide any reasonable financial or other information requested by Master Landlord. Each party agrees promptly to execute and deliver a consent agreement in a form reasonably acceptable to Master Landlord and Subtenant. If Master Landlord's consent is not received within thirty (30) days of the full execution and delivery hereof, either party by notice to the other given prior to the receipt of Master Landlord's consent, may terminate this Sublease, in which case this Sublease shall be deemed void *ab initio* and Sublandlord shall promptly return to Subtenant all sums theretofore paid by Subtenant hereunder. Subtenant waives any claim against Master Landlord arising out of any failure or refusal by Master Landlord to grant consent. Simultaneously with the delivery to Sublandlord of an executed counterpart of this Sublease, and as a precondition to Sublandlord's obligation to deliver possession of the Sublease Premises to Subtenant, Subtenant shall deliver to Sublandlord (i) the Security Deposit (as defined in Section 6 of this Sublease) and (ii) the first installment of monthly Base Rent (as defined below).

3. Term; Renewal.

3.1 Initial Term. The initial term of this Sublease (the "***Initial Term***") shall commence on the date Master Landlord executes and delivers the Consent (the "***Commencement Date***") and shall expire on April 30, 2019 (as may be extended as set forth herein, the "***Expiration Date***"), subject to extension as set forth in Section 3.2.

3.2 Automatic Renewal. Unless Subtenant or Sublandlord timely delivers a Notice of Termination to Sublandlord pursuant to Section 3.3, this Sublease shall automatically renew for successive thirty (30) day periods (each, a "***Renewal Term***"; and the Initial Term, as extended for any Renewal Term, referred to collectively as the "***Sublease Term***") and each such Renewal Term shall commence on the first day of the month immediately following the expiration of the Initial Term or the preceding Renewal Term, as the case may be, and expire on the last day of the same month. Upon the commencement of each Renewal Term, the words "***Expiration Date***" as used herein shall automatically be deemed to refer to the last day of such calendar month. For the avoidance of doubt, the Sublease Term shall not automatically extend beyond the day immediately preceding the "Lease Expiration Date" (as that term is defined in the Master Lease) ("***Outside Date***") and shall be deemed to expire on the Outside Date, in the absence of a subsequent agreement between Sublandlord and Subtenant (subject to Master Landlord's consent).

3.3 Notice of Termination. Subtenant or Sublandlord may elect that the Sublease Term will expire without automatic renewal pursuant to Section 3.2 provided such termination is effective (1) on or after the expiration of the Initial Term, and (2) on the last day of a calendar month provided that Subtenant or Sublandlord provide written notice of termination ("***Notice of Termination***") to the other party no later than sixty (60) days prior to the effective date of termination.

4. RESERVED.

5. Rent. Provided that Subtenant timely satisfies its rental and other obligations under this Sublease within the cure periods set forth herein, Sublandlord shall be responsible for the timely payment of Base Rent and Additional Rent under the Master Lease during the Sublease Term, and Subtenant shall pay to Sublandlord the following as sublease rent hereunder ("***Sublease Rent***"):

5.1 Sublease Base Rent. Beginning on the Commencement Date, and continuing during the Sublease Term, Subtenant shall pay to Sublandlord, as sublease rent ("***Base Rent***"), in lawful money of the United States of America, without any deduction, offset, prior notice or demand, in advance on the first date of each month of the Sublease Term from the Commencement Date through the expiration or earlier termination of this Sublease, the amount of $5,250.00 per month, which amount shall increase by three percent (3%) annually on the first day of the month in which the anniversary of the Commencement Date occurs, if this Sublease has not yet expired or terminated. Any Sublease Rent obligations for any partial month during the Sublease Term shall be prorated.

5.2 Additional Rent. Except for monthly payments of Direct Expenses pursuant to Section 5.3 below, Subtenant shall fully reimburse Sublandlord, within fifteen (15) days of receipt of invoices, for Subtenant's proportionate share of Additional Rent (as defined in the Master Lease), attributable to the Sublease Premises or Subtenant's use thereof during the Sublease Term. Subtenant's proportionate share of Sublandlord's Direct Expenses shall be 1.56% (referred to herein as "***Subtenant's Proportionate Share***"). Notwithstanding anything to the contrary in this Sublease, in the event any cost or expense is incurred under the Master Lease for either party's sole benefit (including the disproportionate use of utilities) or as a result of such party's request for certain services (such as after-hours HVAC charges), such party shall pay the entire cost thereof. Subtenant shall have no audit rights with respect to any Estimate Statement or Statement provided by Master Landlord to Sublandlord, and any such Estimate Statements or Statements shall be binding as between Sublandlord and Subtenant. The intent of the parties is that all payments of Direct Expenses and Additional Rent payable under the Master Lease relating to the Sublease Premises will be passed through to Subtenant during the Sublease Term. The terms of this Section 5.2 shall survive the expiration or earlier termination of the Sublease Term.

5.3 Services and Utilities. Subtenant shall be solely responsible, at its sole cost and expense, for payment for all services of any nature furnished with respect to the Sublease Premises in accordance with the Master Lease or this Sublease, including such services referenced in Section 6.1 of the Master Lease. Subtenant shall be responsible for and shall either reimburse Sublandlord for the cost of all utilities provided to the Sublease Premises or pay the provider directly, as directed from time to time by Sublandlord. If the Sublease Premises are not separately metered for a utility, Sublandlord shall reasonably and equitably allocate the cost of such utility among Sublandlord and Subtenant. Subtenant shall make payment for such expense for utilities within ten (10) days of receipt of any and all invoices and statements received from Master Landlord or Sublandlord with respect to the same. If Subtenant desires to use heat, ventilation or air conditioning during hours other than those for which Master Landlord is obligated to supply such utilities pursuant to the Master Lease, Sublandlord shall pass on Subtenant's request to Master Landlord. Subtenant shall reimburse Sublandlord for all Additional Rent payable by Sublandlord pursuant to the Master Lease equitably allocable to the Sublease Premises. The terms of this Section 5.3 shall survive the expiration or earlier termination of the Sublease Term.

6. Security Deposit. Subtenant shall deliver to Sublandlord a security deposit in the amount of $5,250.00 (the "***Security Deposit***") to secure the faithful observance and performance by Subtenant of the terms and conditions of this Sublease. If there is an Event of Default (as defined in Article 19 of the Master Lease) by Subtenant in the observance or performance of any of such terms and conditions beyond the date of any notice and cure period for such Event of Default, Sublandlord may use or apply all or any part of the Security Deposit for the payment of any Sublease Rent not paid when due or for the payment of any other amounts due Sublandlord by reason of such Event of Default, including any costs of Sublandlord's observing or performing such terms or conditions on Subtenant's behalf and any deficiencies in reletting or damages incurred by Sublandlord. If Sublandlord shall use or apply all or any part of the Security Deposit, Subtenant shall, within three (3) business days following notice from Sublandlord, deliver to Sublandlord additional funds so as to restore the Security Deposit to the to the amount before such application of funds by Sublandlord. The Security Deposit, or so much

thereof as shall not have been used or applied in accordance with this Section 6, shall be returned to Subtenant no later than thirty (30) days following the later of: (i) the expiration or sooner termination of this Sublease, and (ii) the surrender of the Sublease Premises to Sublandlord vacant and in accordance with this Sublease. Subtenant hereby waives the provisions of Section 1950.7 of the California Civil Code. If Sublandlord shall transfer the Security Deposit to an assignee of Sublandlord's interest under the Master Lease, the Sublandlord making such transfer and assignment shall be deemed released from all liability to Subtenant with respect to the Security Deposit or the return thereof, and Subtenant agrees to look solely to the transferee and assignee with respect thereto. Subtenant shall not assign (other than to an assignee of this Sublease) or encumber its interest in the Security Deposit and no such assignment or encumbrance shall be valid or binding upon Sublandlord.

7. Furniture, Fixtures, and Equipment. During the Sublease Term, Subtenant shall have the right, at no cost or expense to Subtenant, to use those items of Sublandlord's furniture, fixtures, and equipment that are located in the Sublease Premises (the "***FF&E***"). Sublandlord has not made, does not make, and will not make, any representations or warranties of any kind, express or implied, to Subtenant with respect to the FF&E including, without limitation, any representations or warranties as to the condition or functionality of the FF&E, or the suitability of the FF&E for Subtenant's purposes. Subtenant agrees to accept the FF&E for use and, if applicable, for purchase in its "*as is, where is, with all faults*" condition. From and after the Commencement Date, Subtenant shall be solely responsible, at Subtenant's sole cost and expense, for maintenance, repair, operation, replacement and, if applicable, removal and any repair and/or restoration of any damage to the Property caused by or resulting from such removal, from time to time, of the FF&E. The FF&E shall be surrendered with the Sublease Premises at the expiration or earlier termination of the Sublease Term.

8. Master Lease.

8.1 Sublease Subordinate to Master Lease; Subtenant's Covenants. This Sublease is in all respects subject and subordinate to all of the terms, provisions, covenants, stipulations, conditions and agreements of the Master Lease. Subtenant agrees as follows (to the extent certain provisions of the Master Lease are incorporated below, all references in such incorporated provision to the term "Tenant" shall be deemed to refer to Subtenant, all references to the term "Premises" shall be deemed to refer to the Sublease Premises, all references to the term "Lease" shall be deemed to refer to this Sublease, all references to the term "Lease Term" shall be deemed to refer to the Sublease Term, and all references to the term "Landlord" shall be deemed to refer to Sublandlord, each unless expressly stated, or the context would imply, otherwise):

(a) Summary of Basic Lease Information. Sections 2.1, 2.3, and 11 of the Summary of Basic Lease Information in the Master Lease are incorporated herein by reference.

(b) Permitted Use. Sections 5.1 and 5.2 of the Master Lease are incorporated herein by reference, except that the "Permitted Use" hereunder shall be: general office and administrative, consistent with the nature of a first class life sciences project in South San Francisco, California. Subtenant and Subtenant's Indemnified Parties (defined below) shall

not produce, use, store or generate any Hazardous Materials in our about the Master Premises or Sublease Premises, and Subtenant shall indemnify and hold harmless Master Landlord and Sublandlord for any breach of the obligations in this sentence, consistent with Sections 5.3.1.4.1 and 5.3.1.4.2 of the Master Lease.

(c) Services and Utilities. Sections 6.1, 6.3 and 6.4 of the Master Lease are incorporated herein by reference, except that references to "Landlord" therein shall mean the Master Landlord only (except that references to "Landlord" in Section 6.3 (except for the reference to Section 19.5 included therein) shall be deemed to refer also to Sublandlord under this Sublease). Any overstandard use by Subtenant shall be subject to Sublandlord's consent, and Subtenant shall pay all of Master Landlord's charges and fees for such request and use.

(d) Repairs and Maintenance. Sections 7.1, 7.3, and 7.4 of the Master Lease are incorporated herein by reference, except that references to "Landlord" therein shall be deemed to refer to Master Landlord only. With respect to maintenance, Subtenant shall perform all repair, maintenance and replacement obligations of Sublandlord (as described therein), as "Tenant" under the Master Lease, to the extent that such obligations relate to the Sublease Premises during the Sublease Term.

(e) Additions and Alterations. Article 8 of the Master Lease is incorporated herein by reference, except for the third and fourth grammatical sentences of Section 8.1. Subtenant shall not make any alterations, additions or improvements to the Sublease Premises without the prior written consent of (i) Master Landlord, which consent may be granted or withheld as set forth in Article 8 of the Master Lease, and (ii) Sublandlord, which consent may be withheld or conditioned in Sublandlord's sole and absolute discretion.

(f) Covenant Against Liens. Article 9 of the Master Lease is incorporated herein by reference.

(g) Indemnification and Insurance. Subtenant shall obtain the insurance coverages required by Section 10.3 of the Master Lease, as incorporated herein by reference. Each policy of insurance shall name Sublandlord as an additional insured. Sections 10.1, 10.4, 10.5 and 10.6 of the Master Lease are incorporated herein by reference, and the indemnification and exculpation in Section 10.1 shall run in favor of both Master Landlord and Sublandlord. The waiver of subrogation requirements in Section 10.5 of the Master Lease shall operate between Sublandlord and Subtenant, in the same manner as between Master Landlord and Sublandlord. Subtenant and Sublandlord each hereby waives any claims for consequential, special, or punitive damages against the other arising out of this Sublease or Subtenant's use of the Sublease Premises (except that this sentence shall not be construed to limit consequential damages recoverable from Subtenant in the event of (1) a holdover by Subtenant, or (2) a release of Hazardous Materials by Subtenant or any Subtenant Indemnified Parties (defined below)).

(h) Casualty Damage. In the event of a casualty as described in Article 11 of the Master Lease, Subtenant shall only be entitled to an abatement of Sublease Rent to the extent that Sublandlord is entitled to rental abatement under the Master Lease with respect to the Sublease Premises. Subtenant shall have the right to terminate this Sublease under the same circumstances that "Tenant" is entitled to terminate under Article 11 of the Master Lease, and

may exercise such right at the same times and in the same manner as "Tenant" may do so under such paragraph, but only in the event that the damage or casualty occurs in the Sublease Premises.

(i) Nonwaiver. Article 12 of the Master Lease is incorporated herein by reference.

(j) Condemnation. Article 13 of the Master Lease is incorporated herein by reference, but shall only apply to a condemnation of the Sublease Premises, and Subtenant shall have no rights with respect to a condemnation of any portion of the Master Premises not including the Sublease Premises, or any other premises or portion of the Property and references to "Landlord" therein shall mean Master Landlord.

(k) Assignment and Subletting. Article 14 of the Master Lease is incorporated herein by reference, provided that, Subtenant shall not assign or sublet the Sublease Premises without the prior written consent of (i) Master Landlord, which may be granted or withheld as set forth in Article 14 of the Master Lease, and (ii) Sublandlord, which consent may be withheld or conditioned in Sublandlord's sole and absolute discretion.

(l) Surrender. Article 15 of the Master Lease is incorporated herein by reference, and Subtenant shall be solely obligated to remove or restore the Sublease Premises as required by the Master Lease, as incorporated herein, and this Sublease. Subtenant shall have no obligation to remove any alterations or improvements made by or for Sublandlord.

(m) Holding Over. Article 16 of the Master Lease is incorporated herein by reference.

(n) Subordination; Estoppel Certificate. Articles 17 and 18 of the Master Lease are incorporated herein by reference, and Sublandlord may request an estoppel certificate or other documents from Subtenant pursuant to the requirements therein.

(o) Events of Default; Remedies. Article 19 of the Master Lease is incorporated herein by reference (except for Section 19.5 of the Master Lease, which is not incorporated herein).

(p) Covenant of Quiet Enjoyment. Article 20 of the Master Lease is incorporated herein by reference.

(q) Lines. Article 22 of the Master Lease is incorporated herein, except that Sublandlord's prior written consent shall be required before Subtenant may install any Lines, which consent may be withheld or conditioned in Sublandlord's reasonable discretion (provided that Sublandlord may require Subtenant to remove such Lines upon the expiration or earlier termination of the Sublease Term).

(r) Compliance with Laws. Article 24 of the Master Lease is incorporated herein by reference, except that references to "Landlord" therein shall mean the "Master Landlord" only.

(s) Late Charges. Article 25 of the Master Lease is incorporated herein by reference and shall apply to the Sublease Rent obligations hereunder.

(t) Right to Cure Default; Payments by Subtenant. Article 26 of the Master Lease is incorporated herein by reference, and references to "Landlord" therein shall mean both Master Landlord and Sublandlord.

(u) Entry by Landlord. Article 27 of the Master Lease is incorporated herein by reference, and references to "Landlord" therein shall mean both Master Landlord and Sublandlord.

(v) Parking. Article 28 of the Master Lease is incorporated herein by reference, provided that Subtenant will have rights to five (5) unreserved parking spaces, and Subtenant shall comply with Sublandlord's reasonable rules and regulations regarding use of parking.

(w) Miscellaneous. Except for Sections 29.18, 29.24, 29.26, 29.29 and 29.31, the entirety of Article 29 of the Master Lease is incorporated herein by reference.

(x) Consents. If any consent is required of Master Landlord for any action of "Tenant" under the Master Lease, then such consent shall be required from both Master Landlord and Sublandlord under this Sublease. Any consent or approval requested from Sublandlord in accordance with this Sublease shall be deemed reasonably withheld if Master Landlord withholds its consent or approval in accordance with the Master Lease.

Except as set forth above, the provisions of the Master Lease are not incorporated into this Sublease except as necessary to effectuate the terms and conditions of this Sublease. Neither party shall take any action or do or permit to be done anything which: (i) is or may be prohibited under the Master Lease; (ii) might result in a violation of or default under any of the terms, covenants, conditions or provisions of the Master Lease or any other instrument to which this Sublease is subordinate; or (iii) would result in any additional cost or other liability to Sublandlord or Subtenant respectively.

8.2 Sublandlord Not Responsible for Representations and Covenants of Master Landlord under Master Lease. Sublandlord shall not be deemed to have made any representation made by Master Landlord in any of the provisions of the Master Lease. Moreover, during the Sublease Term, Subtenant acknowledges and agrees that Sublandlord shall not be responsible for Master Landlord's covenants and obligations under the Master Lease. Without limiting the generality of the foregoing, Sublandlord shall not be obligated (i) to provide any of the services or utilities that Master Landlord has agreed in the Master Lease to provide, (ii) to make any of the repairs or restorations that Master Landlord has agreed in the Master Lease to make, (iii) to comply with any laws or requirements of public authorities with which Master Landlord has agreed in the Master Lease to comply, or (iv) to take any action with respect to the operation, administration or control of the Property or any of the Common Areas that the Master Landlord has agreed in the Master Lease to take, and Sublandlord shall have no liability to Subtenant on account of any failure of Master Landlord to do so, or on account of any failure by Master Landlord to observe or perform any of the terms, covenants or conditions of the Master

Lease required to be observed or performed by Master Landlord, provided that in the event that Subtenant determines in good faith that Master Landlord has not performed its obligations under the Master Lease, then upon receipt of written notice from Subtenant, Sublandlord shall be obligated to use commercially reasonable efforts to cause such breaches, defaults or failures of Master Landlord under the Master Lease to be resolved or otherwise settled; provided, further however: (A) Sublandlord shall not have any obligation to incur out-of-pocket expenses in connection with its covenants under this Section 8.2 and (B) Sublandlord shall not have any obligation to commence litigation or other dispute resolution proceedings to cause Master Landlord to comply with the Master Lease.

9. Indemnity by Subtenant. Subtenant shall indemnify Sublandlord, its officers, directors, shareholders, agents, representatives and employees (collectively "***Sublandlord Indemnified Parties***") against, and hold Sublandlord, and the Sublandlord Indemnified Parties harmless from, any and all demands, claims, causes of action, fines, penalties, damages, losses, liabilities, judgments, and expenses (including, without limitation, reasonable attorneys' fees and court costs) (collectively, "***Claims***") incurred in connection with, or arising from: (a) the use or occupancy of the Sublease Premises, Master Premises or the Property by Subtenant or any persons claiming under Subtenant; (b) any activity, work, or thing done, permitted or suffered by Subtenant in or about the Master Premises or Sublease Premises; (c) any acts, omissions, or negligence of Subtenant or any person claiming under Subtenant, or the contractors, agents, employees, invitees, or visitors of Subtenant or any such person; (d) any breach, violation, or nonperformance by Subtenant or any person claiming under Subtenant or the employees, agents, contractors, invitees, or visitors of Subtenant or any such person of any term, covenant, or provision of this Sublease or any law, ordinance, or governmental requirement of any kind; (e) any injury or damage to the person, or property of Sublandlord, or any Sublandlord Indemnified Parties, or any other person entering upon the Sublease Premises to the extent caused by Subtenant; and (f) Subtenant's failure to comply with the surrender provisions of this Sublease at the expiration or earlier termination of the Sublease Term, except to the extent any of the foregoing results from the gross negligence or willful misconduct of Sublandlord or its officers, directors, shareholders, agents, contractors, employees, invitees or visitors. If any action or proceeding is brought against Sublandlord, or any Sublandlord Indemnified Parties by reason of any such claim, Subtenant, upon notice from Sublandlord, shall defend the claim at Subtenant's expense with counsel reasonably satisfactory to Sublandlord.

10. Indemnity by Sublandlord. Sublandlord shall indemnify Subtenant, its officers, directors, shareholders, agents, representatives and employees (collectively "***Subtenant Indemnified Parties***") against, and hold Subtenant, and Subtenant's Indemnified Parties harmless from, any and all Claims incurred in connection with, or arising from: (a) any negligence or willful misconduct of Sublandlord or any Sublandlord Indemnified Party, or (b) any breach, violation, or nonperformance by Sublandlord of any term, covenant or provision of this Sublease, except to the extent resulting from the negligence or willful misconduct of Subtenant or its officers, directors, shareholders, agents, contractors, employees, invitees or visitors. If any action or proceeding is brought against Subtenant, its employees or agents by reason of any such claim, Sublandlord, upon notice from Subtenant, shall defend the claim at Sublandlord's expense with counsel reasonably satisfactory to Subtenant.

11. Master Landlord Notices. Sublandlord and Subtenant shall, promptly following receipt thereof, deliver to the other party a copy of any and all notices received from Master Landlord which would have any material effect upon the Sublease Premises or this Sublease.

12. Sublandlord's Right to Cure Subtenant Default. Upon an Event of Default (as defined in Article 19 of the Master Lease) by Subtenant under this Sublease (after lapse of any applicable notice and cure periods), Sublandlord may, without waiving or releasing any obligation of Subtenant hereunder and without waiving any rights or remedies at law or otherwise, make such payment or perform such act. All sums so paid or incurred by Sublandlord, together with interest thereon, from the date such sums were paid or incurred, at the annual rate equal to 10% per annum or the highest rate permitted by law, whichever is less, shall be payable to Sublandlord on demand as additional Sublease Rent.

13. Notices. Any notice, request, demand, consent, approval, or other communication required or permitted under this Sublease shall be in writing. All notices shall be addressed to the addresses set forth in the introductory paragraph, or such other address as the parties may notify each other from time to time, and shall be: (a) personally delivered; (b) sent by certified or registered mail, postage prepaid, return receipt requested; or (c) sent by a nationally recognized overnight courier service, with charges prepaid and a receipt provided therefor. All notices shall be deemed to have been given on the earlier of: (i) the date of actual receipt; or (ii) one (1) business day after being properly deposited with a nationally recognized overnight courier service.

14. Time Is of the Essence. Time is of the essence with respect to the performance of every provision of this Sublease in which time of performance is a factor.

15. Attorneys' Fees. If any action or proceeding is instituted by Sublandlord or Subtenant to construe, interpret or enforce the provisions of this Sublease, the prevailing party shall be entitled to the reimbursement of its reasonable attorneys' fees and costs incurred in connection with such proceeding by the non-prevailing party.

16. Brokers. Each party represents and warrants that it has not been represented by any broker in connection this Sublease, and each party hereby indemnifies, protects, defends (with legal counsel acceptable to the other party) and holds the other party free and harmless from and against any and all costs and liabilities, including, without limitation, reasonable attorneys' fees, for causes of action or proceedings that may be instituted by any broker, agent or finder, licensed or otherwise, claiming through, under or by reason of the conduct of such party in connection with this Sublease.

17. Counterparts. This Sublease may be executed in duplicate counterparts, each of which shall be deemed an original hereof. Electronically transmitted signatures shall be deemed originals.

18. Entire Agreement/Modification. This Sublease, including the Exhibits, contains all of the agreements of the parties hereto with respect to any matter covered or mentioned in this Sublease, and no prior agreements or understanding or letter or proposal pertaining to any such matters shall be effective for any purpose. This Sublease may only be modified by a writing

signed by Sublandlord and Subtenant. No provisions of this Sublease may be amended or added to, whether by conduct, oral or written communication, or otherwise, except by an agreement in writing signed by the parties hereto or their respective successors-in-interest.

19. Interpretation. The title and paragraph headings are not a part of this Sublease and shall have no effect upon the construction or interpretation of any part of this Sublease. Unless stated otherwise, references to paragraphs and subparagraphs are to those in this Sublease. This Sublease shall be strictly construed neither against Sublandlord nor Subtenant.

20. Authority. Subtenant hereby represents and warrants that Subtenant is a duly formed and existing entity qualified to do business in the State of California and that Subtenant has full right and authority to execute and deliver this Sublease and that each person executing this Sublease on behalf of Subtenant is authorized to do so. Sublandlord hereby represents and warrants that Sublandlord has full right and authority to execute and deliver this Sublease and that each person executing this Sublease on behalf of Sublandlord is authorized to do so.

21. Signage. Subtenant shall not be entitled to any signage.

22. OFAC Compliance. Subtenant and all beneficial owners of Subtenant are currently (a) in compliance with and shall at all times during the Sublease Term remain in compliance with the regulations of the Office of Foreign Assets Control ("***OFAC***") of the U.S. Department of Treasury and any statute, executive order, or regulation relating thereto (collectively, the "***OFAC Rules***"), (b) not listed on, and shall not during the Sublease Term be listed on, the Specially Designated Nationals and Blocked Persons List, Foreign Sanctions Evaders List, or the Sectoral Sanctions Identification List, which are all maintained by OFAC and/or on any other similar list maintained by OFAC or other governmental authority pursuant to any authorizing statute, executive order, or regulation, and (c) not a person or entity with whom a U.S. person is prohibited from conducting business under the OFAC Rules.

23. Sublandlord covenants not to (a) voluntarily surrender or terminate the Master Lease prior to the expiration of the Initial Term, or (b) enter into, without the consent of Subtenant, any amendment to the Master Lease which would adversely affect Subtenant's rights or increase Subtenant's monetary obligations under this Sublease. Notwithstanding anything contained in this Sublease to the contrary, Subtenant shall not be responsible for (i) any default of Sublandlord, its agents, employees or contractors under the Master Lease unless attributable to a default under this Sublease or the Master Lease by Subtenant, its agents, employees, contractors, invitees or anyone claiming by, through or under Subtenant, (ii) conditions at the Subleased Premises, for which the obligation to maintain and repair resides with Master Landlord under the Master Lease and/or which existed as of the Commencement Date, (iii) any violations of law resulting from such conditions described by (ii) above, (iv) the payment of any charges, fees and other costs imposed by Master Landlord on Sublandlord as a result of Sublandlord's default under the Master Lease (unless due to any default by Subtenant under this Sublease), and (v) making payment of any sums either to Master Landlord or Sublandlord in satisfaction of any charges accruing under the Master Lease (whether denominated as rent, rental, additional rent or otherwise) for any period prior or subsequent to the Term of this Sublease.

24. Sublandlord represents and warrants to Subtenant that (i) a true, correct and complete copy of the Master Lease (excluding redacted terms not relevant to Subtenant) has been delivered to Subtenant and the Master Lease has not been modified or amended, assigned or sublet in any manner as of the date hereof, (ii) the Master Lease is in full force and effect, (iii) to the best of Sublandlord's knowledge, Sublandlord is not in default under the Master Lease, and (iv) Sublandlord has not received any notice of default under the Master Lease.

[signature page follows]

IN WITNESS WHEREOF, Sublandlord and Subtenant have executed this Sublease as of the date first above written.

SUBLANDLORD:

Trucode Gene Repair, Inc.

By: /s/ Marshall Fordyce
Name: Marshall Fordyce
Title: CEO

SUBTENANT:

Akero Therapeutics, Inc.

By: /s/ Andrew Cheng
Name: Andrew Cheng
Title: President and CEO

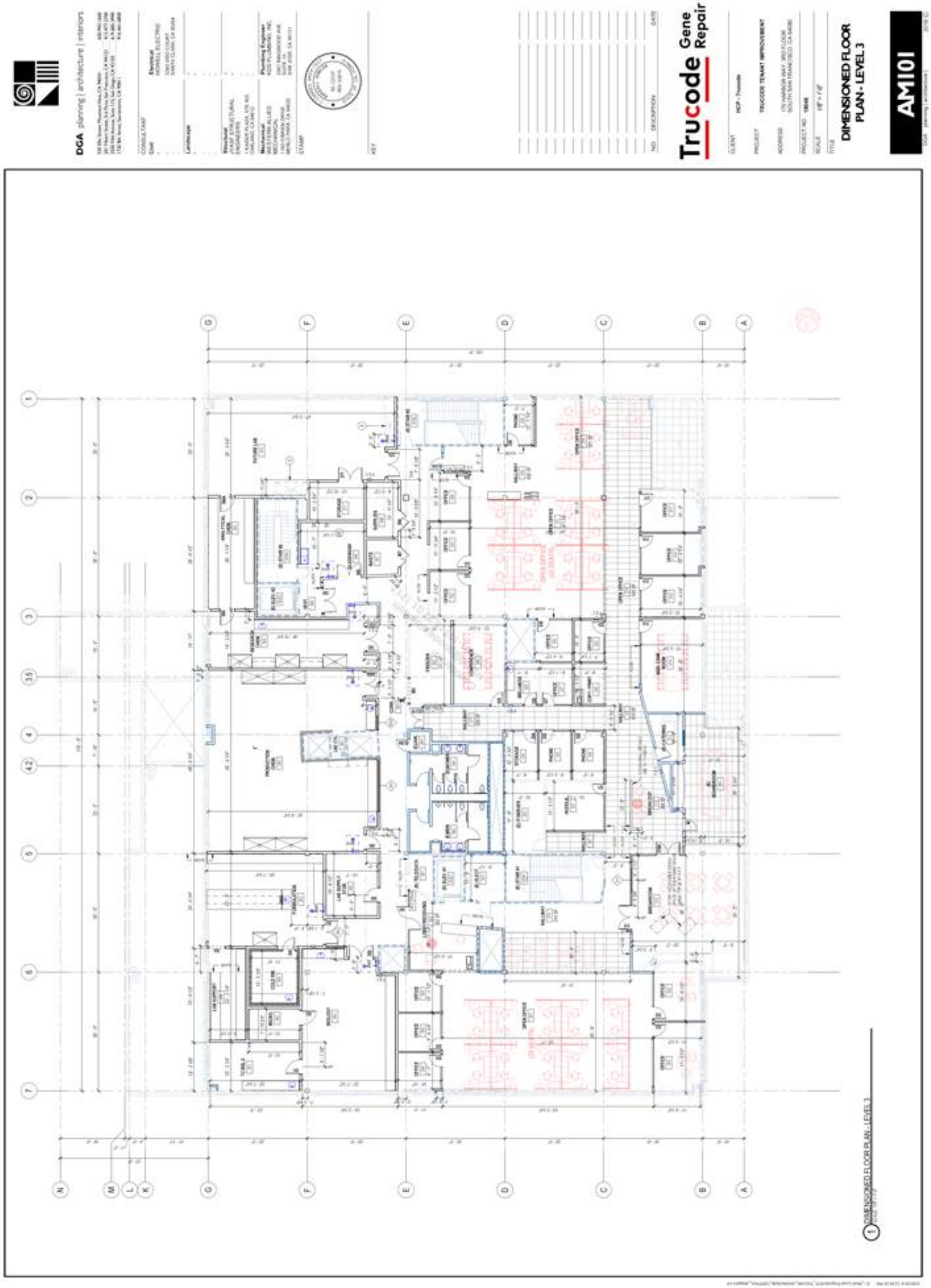
And By: /s/ Jonathan Young
Name: Jonathan Young
Title: EVP and COO

[Signature Page to Sublease]

EXHIBIT A

DEPICTION OF SUBLEASE PREMISES

[To Be Attached]



FIRST AMENDMENT TO CONSENT TO SUBLEASE AGREEMENT

THIS FIRST AMENDMENT TO CONSENT TO SUBLEASE AGREEMENT (this "**First Amendment**") is made as of March 12, 2019, by and among BRITANNIA POINTE GRAND LIMITED PARTNERSHIP, a Delaware limited partnership ("**Landlord**"), TRUCODE GENE REPAIR, INC., a Delaware corporation ("**Tenant**"), and AKERO THERAPEUTICS, INC., a Delaware corporation ("**Subtenant**").

R E C I T A L S

A. Reference is hereby made to that certain Lease dated April 10, 2018, between Landlord and Tenant (the "**Lease**"), for certain premises located at 170 Harbor Way, South San Francisco, California 94080 (the "**Premises**").

B. On December 7, 2018, Landlord, Tenant and Subtenant entered into that certain Consent to Sublease Agreement (the "**Consent**"), whereby Landlord consented to the subletting by Subtenant of a portion of the Premises (the "**Sublet Premises**") as described in that certain Sublease dated October 23, 2018, between Tenant and Subtenant (the "**Sublease**").

C. Pursuant to Section 3 of the Consent and Article 14 of the Original Lease, Tenant and Subtenant have requested Landlord's consent to that certain First Amendment to Sublease Agreement dated February 27, 2019, between Tenant and Subtenant (the "**Sublease First Amendment**"), with respect to, *inter alia*, modification of the term of the Sublease and expansion of the Sublet Premises, as more particularly described in the Sublease First Amendment. A copy of the Sublease First Amendment is attached hereto as Exhibit A. Landlord is willing to consent to the Sublease First Amendment on the terms and conditions contained herein.

D. All defined terms not otherwise expressly defined herein shall have the respective meanings given in the Lease.

A G R E E M E N T

1. Landlord's Consent. Landlord hereby consents to the Sublease First Amendment; provided, however, notwithstanding anything contained in the Sublease First Amendment to the contrary, such consent is granted by Landlord only upon the terms and conditions set forth in this First Amendment. The Sublease First Amendment is subject and subordinate to the Lease. Landlord shall not be bound by any of the terms, covenants, conditions, provisions or agreements of the Sublease First Amendment. Subtenant acknowledges for the benefit of Landlord that Subtenant continues to accept the Sublet Premises in their presently existing, "as-is" condition and that Landlord has made no representation or warranty to Subtenant as to the compliance of the Sublet Premises with any law, statute, ordinance, rule or regulation. Tenant and Subtenant hereby represent and warrant to Landlord that the copy of the Sublease First Amendment attached hereto is a full, complete and accurate copy of the Sublease First Amendment, and that there are no other documents or instruments relating to the use of the Sublet Premises by Subtenant other than the Sublease and the Sublease First Amendment.

2. Reimbursement of Landlord. Tenant shall, within thirty (30) days after a written request to Tenant by Landlord, pay Landlord up to $2,000.00 to compensate Landlord for its reasonable review and processing fees, as well as any reasonable professional fees (including, without limitation, attorneys', accountants', architects', engineers' and consultants' fees) incurred by Landlord in connection with Landlord's review and consent of the Sublease First Amendment and its preparation and negotiation of this First Amendment.

3. Incorporation of Terms of Consent. The parties hereto acknowledge and agree that the terms set forth in Sections 3 and 4 (including Sections 4.1 through 4.10) of the Consent are incorporated herein and each time the word "Sublease" is used in such sections, the same shall mean both the Sublease and the Sublease First Amendment.

4. General Provisions.

4.1 Consideration for Sublease. Tenant and Subtenant represent and warrant that there are no additional payments of rent or any other consideration of any type payable by Subtenant to Tenant with regard to the Sublet Premises other than as disclosed in the Sublease and the Sublease First Amendment.

4.2 Brokerage Commission. Tenant and Subtenant covenant and agree that under no circumstances shall Landlord be liable for any brokerage commission or other charge or expense in connection with the Sublease and/or the Sublease First Amendment, and Tenant and Subtenant agree to protect, defend, indemnify and hold Landlord harmless from and against the same and from any cost or expense (including, but not limited to, attorneys' fees) incurred by Landlord in resisting any claim for any such brokerage commission or other charge or expense.

4.3 Recapture. This consent shall in no manner be construed as limiting Landlord's ability to exercise any rights to recapture any portion of the Premises, as set forth in the Lease, in the event of a proposed future sublease or assignment of such portion of the Premises.

4.4 Controlling Law. The terms and provisions of this First Amendment shall be construed in accordance with and governed by the laws of the State of California.

4.5 Binding Effect. This First Amendment shall be binding upon and inure to the benefit of the parties hereto, their heirs, successors and permitted assigns. As used herein, the singular number includes the plural and the masculine gender includes the feminine and neuter.

4.6 Captions. The paragraph captions utilized herein are in no way intended to interpret or limit the terms and conditions hereof; rather, they are intended for purposes of convenience only.

4.7 Partial Invalidity. If any term, provision or condition contained in this First Amendment shall, to any extent, be invalid or unenforceable, the remainder of this First Amendment, or the application of such term, provision or condition to persons or circumstances other than those with respect to which it is invalid or unenforceable, shall not be affected

thereby, and each and every other term, provision and condition of this First Amendment shall be valid and enforceable to the fullest extent permitted by law.

4.8 Attorneys' Fees. If any party hereto commences litigation against the other for the specific performance of this First Amendment, for damages for the breach hereof or otherwise for enforcement of any remedy hereunder, the parties hereto agree to and hereby do waive any right to a trial by jury and, in the event of any such commencement of litigation, the prevailing party shall be entitled to recover from the other party such costs and reasonable attorneys' fees as may have been incurred.

[signatures follow on next page]

IN WITNESS WHEREOF, the parties have executed this First Amendment as of the day and year first above written.

"Landlord"

BRITANNIA POINTE GRAND LIMITED PARTNERSHIP,
a Delaware limited partnership

By: /s/ Andrew Cressman

Name: Andrew Cressman

Its: VP

"Tenant"

TRUCODE GENE REPAIR, INC.,
a Delaware corporation

By: /s/ Marshall Fordyce

Name: Marshall Fordyce

Its: CEO

"Subtenant"

AKERO THERAPEUTICS, INC.,
a Delaware corporation

By: /s/ Andrew Cheng

Name: Andrew Cheng

Its: President and CEO

EXHIBIT A

THE SUBLEASE FIRST AMENDMENT

[Attached]

FIRST AMENDMENT TO SUBLEASE AGREEMENT

This FIRST AMENDMENT TO SUBLEASE AGREEMENT (this "***Amendment***") is made and entered into as of February 27, 2019, by and between TRUCODE GENE REPAIR, INC., a Delaware corporation ("***Sublandlord***"), and AKERO THERAPEUTICS, INC., a Delaware corporation ("***Subtenant***").

RECITALS

A. Sublandlord and Subtenant are parties to that certain Sublease Agreement dated October 23, 2018, (the "***Sublease***"), pursuant to which Subtenant subleases a portion of the Master Premises consisting of approximately 383 square feet of space (as more particularly described in Sublease, the "***Existing Sublease Premises***").

B. Sublandlord and Subtenant desire to amend the Sublease to lengthen the Sublease Term, to expand the Sublease Premises, and to make other modifications to the Sublease as set forth herein, subject to the consent of the Master Landlord as provided herein.

AGREEMENT

NOW, THEREFORE, for good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, Sublandlord and Subtenant hereby agree as follows:

1. **Capitalized Terms; Incorporation of Recitals**. All capitalized terms when used herein shall have the same meaning as is given such terms in the Sublease unless expressly superseded by the terms of this Amendment. The foregoing Recitals are incorporated by reference as if set forth fully herein.

2. **Master Landlord's Consent**. This Amendment shall not become effective or binding upon either party until the date on which Master Landlord's written consent to this Amendment is fully-executed and delivered to Sublandlord and Subtenant (the "***Expansion Commencement Date***"). If Master Landlord's consent is not received, the Sublease shall continue unaffected by this Amendment. Subtenant shall pay all costs or charges of Master Landlord in connection with its consent to this Amendment, and Subtenant shall reimburse Sublandlord for its costs incurred in preparation of this Amendment, including reasonable attorneys' fees.

3. **Sublease Premises**.

3.1. **Expansion of Sublease Premises** As of the Expansion Commencement Date, certain premises within the Master Premises shall be added to the Sublease Premises (such additional premises, the "***Expansion Sublease Premises***") and leased from Sublandlord to Subtenant on the terms and conditions set forth in the Sublease (as amended by this Amendment). Sublandlord and Subtenant agree that for the purpose of the Sublease, as amended by this Amendment, the Expansion Sublease Premises, together with the Existing Sublease Premises, shall be conclusively deemed to contain 3,691 rentable square feet. From and after the Expansion Commencement Date, the term "***Sublease Premises***" shall be deemed to refer to the Expansion Sublease Premises, together with the

Existing Sublease Premises, which Sublease Premises is as depicted on **Exhibit A** attached hereto and incorporated herein.

3.2. **Master Premises Common Areas**. The first sentence of Section 1.2 of the Sublease is hereby deleted and replaced with the following: "In connection with Subtenant's use of the Sublease Premises, Subtenant shall have the non-exclusive right to use, subject to Sublandlord's reasonable rules and regulations, the Master Premises restrooms and kitchen area/breakroom ("***Master Premises Common Areas***"), and rights of ingress and egress through the hallways and accessways as are reasonably necessary for Subtenant's access to the Sublease Premises and the Master Premises Common Areas.

4. **Modification of Sublease Term; Sublandlord Termination Right**. The "***Expiration Date***" of the Sublease is hereby amended to be the date that is the last day of the month in which the second (2nd) anniversary of the Expansion Commencement Date occurs. Sections 3.2 and 3.3 of the Sublease are hereby intentionally deleted, and the parties acknowledge that Subtenant shall have no right or option to extend the Sublease Term or continue its occupancy month to month after the Expiration Date. The "***Sublease Term***" shall be deemed to refer to the term of the Sublease, as extended by this Amendment. Notwithstanding anything to the contrary in the Sublease or this Amendment, Sublandlord may terminate this Sublease upon at least ninety (90) days prior written notice to Subtenant ("***Termination Notice***"). The Termination Notice shall specify the date of termination (the "***Termination Date***"), which shall be the last day of a calendar month and at least ninety (90) days after the date the Termination Notice is delivered to Subtenant. After delivery of a Termination Notice, the Termination Date shall be deemed to be the Expiration Date for purposes of determining the Sublease Term.

5. **Rent**.

5.1. **Base Rent**. Commencing on the Expansion Commencement Date, and continuing throughout the Sublease Term, Subtenant shall pay Base Rent for the Sublease Premises in the amount of $18,900.87 per month, which amount shall increase by 3.5% on October 1, 2019, and each successive October 1 during the Sublease Term.

5.2. **Additional Rent**. From and after the Expansion Commencement Date, "***Subtenant's Proportionate Share***" shall be fifteen percent (15%).

5.3. **Services and Utilities**. For the avoidance of doubt, Subtenant shall be responsible to reimburse Sublandlord for Subtenant's proportionate share of costs relating to any utilities, supplies or services supplied directly by Sublandlord (as opposed to supplied by Master Landlord and charged to Sublandlord as an operating expense or otherwise) for the benefit of the Sublease Premises, which include, without limitation, janitorial, coffee, wi-fi, etc. Such payments shall be due within ten (10) days of Subtenant's receipt of an invoice, and the obligations of this Section 5.3 shall survive expiration or earlier termination of the Sublease Term.

6. **Security Deposit**. The Security Deposit is hereby increased from $5,250.00 to $20,247.08, and concurrently with Subtenant's execution of this Amendment, Subtenant shall deposit with Sublandlord an amount equal to $14,997.08 representing the increase in the Security

Deposit ("*Security Deposit Increase*"). If Master Landlord's consent to this Amendment is not obtained and this Amendment is thereafter cancelled and/or deemed void, Sublandlord shall return the Security Deposit Increase to Subtenant within thirty (30) days of Subtenant's written request.

7. **Signage**. Subject to the consent of Master Landlord, Subtenant shall have rights to building-standard lobby signage relating to the Sublease Premises.

8. **Miscellaneous**.

8.1. **Brokers**. Sublandlord and Subtenant hereby warrant to each other that they have had no dealings with any real estate broker or agent in connection with the negotiation of this Amendment, and that they know of no real estate broker or agent who is entitled to a commission in connection with this Amendment. Each party agrees to indemnify and defend the other party against and hold the other party harmless from any and all claims, demands, losses, liabilities, lawsuits, judgments, and costs and expenses (including, without limitation, reasonable attorneys' fees) with respect to any leasing commission or equivalent compensation alleged to be owing on account of the indemnifying party's dealings with any real estate broker or agent. The terms of this Section shall survive the expiration or earlier termination of the Sublease.

8.2. **Counterparts; Electronic Signatures**. This Amendment may be executed in any number of counterparts, each of which shall be deemed an original, but all of which when taken together shall constitute one and the same instrument. The signature page of any counterpart may be detached therefrom without impairing the legal effect of the signature(s) thereon provided such signature page is attached to any other counterpart identical thereto except having additional signature pages executed by other parties to this Amendment attached thereto. A facsimile, email, or portable document format (PDF) signature on this Amendment shall be equivalent to, and have the same force and effect as, an original signature.

8.3. **Authorized Signatories**. Each of Sublandlord and Subtenant represents hereby that the individual(s) executing this Amendment on behalf of such party has the authority to execute and deliver the same on behalf of the party hereto for which such signatory is acting.

8.4. **No Further Modification; Ratification**. Except as set forth in this Amendment, all of the terms and provisions of the Sublease shall apply and shall remain unmodified and in full force and effect. In the event of any conflict between the provisions of this Amendment and the provisions of the Sublease the provisions of this Amendment shall prevail. Whether or not specifically amended by this Amendment, all of the terms and provisions of the Sublease are hereby amended to the extent necessary to give effect to the purpose and intent of this Amendment.

8.5. **OFAC**. Subtenant represents and warrants to Sublandlord that Subtenant is currently in compliance with and shall at all times, remain in compliance with the regulations of the Office of Foreign Asset Control ("**OFAC**") of the Department of the Treasury (including those named on OFAC's Specially Designated and Blocked Persons List) and any statute, executive order (including the September 24, 2001, Executive Order Blocking Property and Prohibiting Transactions with Persons Who Commit, Threaten to Commit, or Support Terrorism), or other governmental action relating thereto.

[signatures contained on following page]

IN WITNESS WHEREOF, this Amendment has been executed as of the day and year first above written.

SUBLANDLORD:

TRUCODE GENE REPAIR, INC.,
a Delaware corporation

By: /s/ Marshall Fordyce

Name: Marshall Fordyce

Its: CEO

SUBTENANT:

AKERO THERAPEUTICS, INC.,
a Delaware corporation

By: /s/ Andrew Cheng

Name: Andrew Cheng

Its: President and CEO

And By: /s/ Jonathan Young

Name: Jonathan Young

Its: EVP and COO

EXHIBIT A

DEPICTION OF SUBLEASE PREMISES

(see attached)

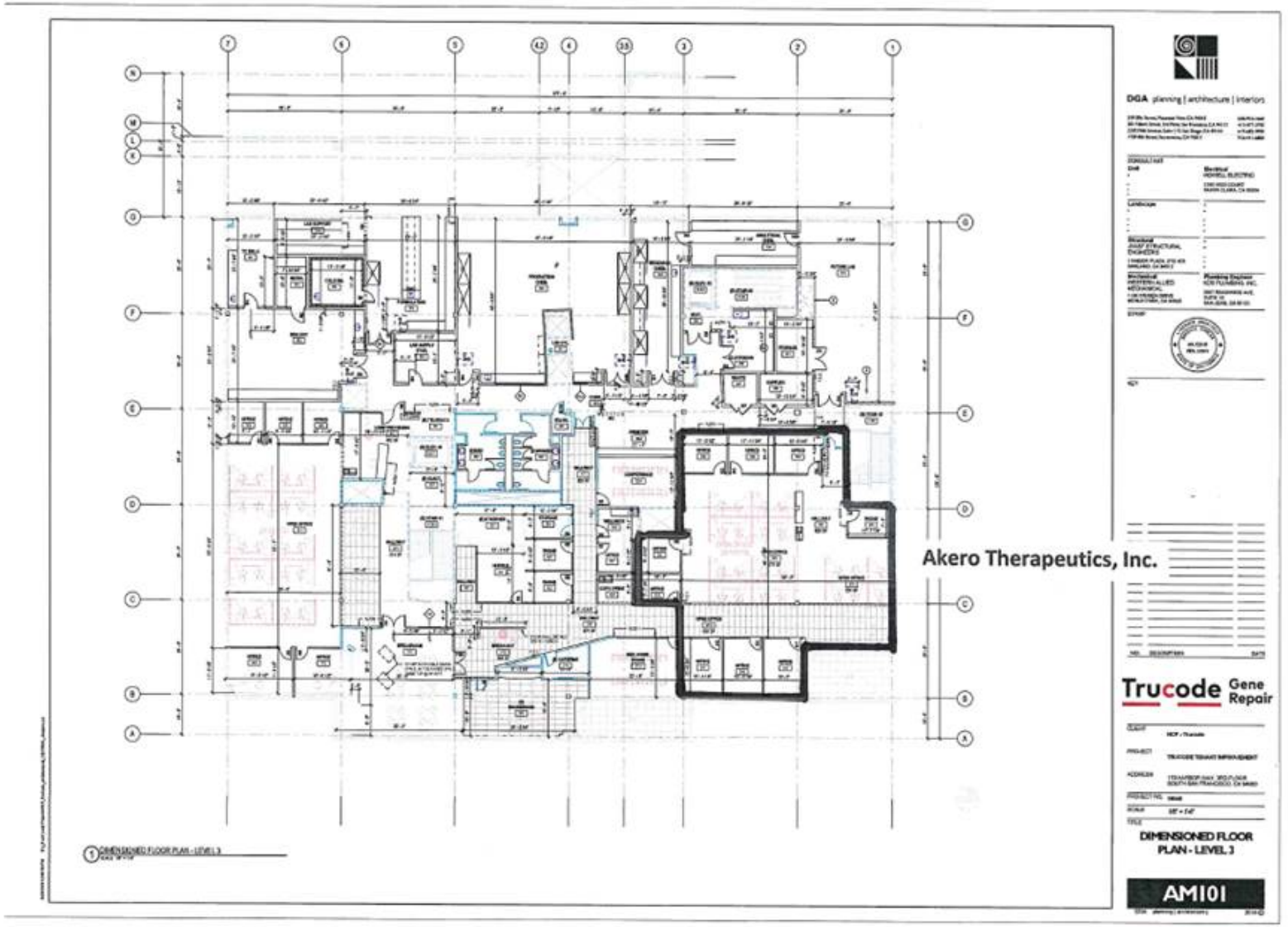

DGA planning | architecture | interiors
Akero Therapeutics, Inc.
Trucode Gene Repair
DIMENSIONED FLOOR PLAN - LEVEL 3
AM101

Exhibit 10.7

CONFIDENTIAL

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 406 PROMULGATED UNDER THE SECURITIES ACT OF 1933, AS AMENDED.

EXCLUSIVE LICENSE AGREEMENT

by and between

AMGEN INC.

and

AKERO THERAPEUTICS, INC.

Dated as of June 7, 2018

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 406 PROMULGATED UNDER THE SECURITIES ACT OF 1933, AS AMENDED.

TABLE OF CONTENTS

Exhibit List

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 406 PROMULGATED UNDER THE SECURITIES ACT OF 1933, AS AMENDED.

EXCLUSIVE LICENSE AGREEMENT

This EXCLUSIVE LICENSE AGREEMENT (this "**Agreement**") is entered into as of June 7, 2018 (the "**Effective Date**") by and between AMGEN INC., a Delaware corporation having an address at One Amgen Center Drive, Thousand Oaks, California 91320 ("**AMGEN**"), and AKERO THERAPEUTICS, INC., a Delaware corporation having an address at 271 Waverly Oaks, Suite 104, Waltham, Massachusetts 02452 ("**AKERO**"). AKERO and AMGEN are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**".

RECITALS

WHEREAS, AMGEN possesses certain rights to patents and other intellectual property related to the Product (as hereinafter defined);

WHEREAS, AKERO desires to license from AMGEN such intellectual property rights, and to commercially develop, manufacture, use and distribute the Product based upon the same throughout the world, and AMGEN desires to grant such a license to AKERO in accordance with the terms and conditions of this Agreement; and

WHEREAS, concurrently with the execution and delivery of this Agreement, the Parties are entering into (i) a stock purchase agreement with the other investors named therein providing for the issuance to AMGEN of Series A Preferred Stock of AKERO and (ii) related financing documents.

NOW, THEREFORE, in consideration of the premises and the mutual promises and covenants contained in this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:

ARTICLE 1. DEFINITIONS

All references to particular Exhibits, Articles or Sections shall mean the Exhibits to, and Articles and Sections of, this Agreement, unless otherwise specified. For the purposes of this Agreement and the Exhibits hereto, the following words and phrases shall have the following meanings:

Section 1.1 "**Abandoned Patent Right**" has the meaning set forth in Section 4.2 (AMGEN Step-In Right).

Section 1.2 "**Additional Shares**" has the meaning set forth in Section 3.1.1(b).

Section 1.3 "**Affiliate**" means, with respect to any Person, any other Person that, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such Person, for as long as such control exists. For purposes of the definition of "Affiliate", "control" means the direct or indirect ownership of more than fifty percent (50%) of the voting or economic interest of a Person, or the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of a Person. For clarity, once a Person ceases to be an Affiliate of a Party, then, without any further action, such Person shall cease to have any rights, including license and sublicense rights, under this

Agreement by reason of being an Affiliate of such Party.

Section 1.4 "**Agreement**" has the meaning set forth in the Preamble.

Section 1.5 "**AKERO**" has the meaning set forth in the Preamble.

Section 1.6 "**AKERO Cell Lines**" has the meaning set forth in Section 2.3.3(a).

Section 1.7 "**AKERO Indemnified Parties**" has the meaning set forth in Section 7.1 (By AMGEN).

Section 1.8 "**AKERO Manufacturing IP**" has the meaning set forth in Section 4.8.1.

Section 1.9 "**AMGEN**" has the meaning set forth in the Preamble.

Section 1.10 "**AMGEN Cell Line**" means the proprietary cell line that AMGEN has developed for the generation of the Product. For avoidance of doubt, the AMGEN Cell Line is a Licensed Material hereunder.

Section 1.11 "**AMGEN Indemnified Parties**" has the meaning set forth in Section 7.1.2 (By AKERO).

Section 1.12 "**AMGEN Ownership Percentage**" has the meaning set forth in Section 3.1.1(b).

Section 1.13 "**Anti-Corruption Laws**" means Laws, regulations, or orders prohibiting the provision of a financial or other advantage for a corrupt purpose or otherwise in connection with the improper performance of a relevant function, including without limitation, the U.S. Foreign Corrupt Practices Act (FCPA) and similar laws governing corruption and bribery, whether public, commercial or both, to the extent applicable.

Section 1.14 "**Audited Party**" has the meaning set forth in Section 3.5 (Records and Audits).

Section 1.15 "**Biosimilar Version**" means (a) in respect of a Product sold in the United States, a biological product approved under the Public Health Service Act section 351(k) that is highly similar to such Product, notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between such biological product and the Product in terms of the safety, purity and potency; (b) in respect of a Product sold in the European Union, a biological product approved under Article 10(4) of Directive 2001/83/EC and Section 4, Part II, Annex I to such Directive based on the demonstration of the similar nature of such biological product and the Product; and (c) in respect of a Product sold outside the United States and the European Union, a biological product approved under a similar pathway to (a) or (b) if such pathway exists and, if such pathway does not exist, a marketing approval granted by a regulatory authority to such Third Party with reference to such Product.

Section 1.16 "**CEO Delegate**" means the Chief Executive Officer of each Party or their respective delegate.

Section 1.17 "**cGMP**" means all applicable standards relating to current good manufacturing practices for fine chemicals, intermediates, bulk products and/or finished pharmaceutical drugs, including (a) all applicable requirements detailed in the FDA's current Good Manufacturing Practices regulations, 21 C.F.R. Parts 210 and 211, (b) all applicable requirements detailed in the

EMA's "EU guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use," and (c) all applicable Laws promulgated by any Governmental Authority having jurisdiction over the manufacture of the applicable compound or pharmaceutical drug product, as applicable.

Section 1.18 "**Clinical Trial**" means a Phase 1 Clinical Trial, Phase 2 Clinical Trial or Phase 3 Clinical Trial or any equivalent thereof.

Section 1.19 "**CMO**" means a Third Party commercial manufacturing organization or similar organization providing biopharmaceutical services.

Section 1.20 "**Commercially Reasonable Efforts**" means those efforts and resources commensurate with those efforts commonly used in the pharmaceutical industry by a company of comparable size in connection with the development or commercialization of pharmaceutical products that are of similar status, including, with respect to commercial potential, the proprietary position of the product, the regulatory status and approval process, the probable profitability of the applicable product and other relevant factors such as technical, legal, scientific or medical factors. In determining the level of efforts constituting "**Commercially Reasonable Efforts**," the following shall not be taken into account: (a) any other pharmaceutical product AKERO is then researching, developing or commercializing, alone or with one or more collaborators or (b) any payment required to be made to AMGEN hereunder.

Section 1.21 "**Confidential Information**" has the meaning set forth in Section 8.1.1 (Confidential Information).

Section 1.22 "**Control**" or "**Controlled**" means, with respect to any Know-How, material, Patent Right, or other intellectual property right, the possession (whether by ownership or license) by a Party or its Affiliate of the ability to grant to the other Party a license, sublicense or access as provided herein to such Know-How, material, Patent Right, or other intellectual property right, without violating the terms of any agreement or other arrangement with any Third Party, or being obligated to pay any royalties or other consideration therefor, in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such license, sublicense or access; ***provided, however***, that if (a) AMGEN would Control any Know-How, material, Patent Right, or other intellectual property right *but for* an obligation to pay royalties or other consideration in connection with a transfer or grant to AKERO of such Know-How, material, Patent Right, or other intellectual property right and (b) AKERO agrees in writing to reimburse AMGEN for all such royalties or other consideration, then such Know-How, material, Patent Right, or other intellectual property right shall be deemed Controlled by AMGEN.

Section 1.23 "**Covered**" by (a) Licensed Know-How means that such Licensed Know-How was used in the Exploitation of the Product, and (b) a Patent Right means that a Valid Claim (absent a license thereunder or ownership thereof) would be Infringed by the Exploitation of the Product; if a Valid Claim is a pending claim, then such pending claim shall be treated as if it were issued as then pending for the purposes of determining Infringement at the time coverage is assessed. Cognates of the word "**Cover**" shall have correlative meanings.

Section 1.24 "**Defending Party**" has the meaning set forth in Section 4.4 (Defense of Third

Party Claims).

Section 1.25 "Designated Investment Document Terms" means:

(a) Sections 1.1 (Sale and Issuance of Preferred Stock), 1.2 (Closing; Delivery), 1.3 (Call Option), 2.1 (Organization, Good Standing, Corporate Power and Qualification), 2.2 (Capitalization), 2.4 (Authorization) and 2.5 (Valid Issuance of Shares) of the Purchase Agreement]

(b) Section FOURTH, B.3.3. (Series A Preferred Stock Protective Provisions) of the Amended and Restated Certificate of Incorporation of Akero Therapeutics, Inc., dated as of the date hereof (the "**Restated Charter**");

(c) Article 2 (Agreement Among the Company, the Investors and the Stockholders) of the Right of First Refusal and Co-Sale Agreement, dated as of the date hereof, by and among AKERO, the Investors (as such term is defined therein) and the Key Holders (as such term is defined therein) (the "**Right of First Refusal and Co-Sale Agreement**");

(d) Articles 2 (Registration Rights), 3 (Information and Observer Rights) and 4 (Rights to Future Stock Issuances) and Section 6.6 (Amendment and Waivers) of the Investors' Rights Agreement, dated as of the date hereof, by and among AKERO and the Investors (as such term is defined therein) (the "**Investors' Rights Agreement**");

(e) Articles 1 (Voting Provisions Regarding Board of Directors) and 5 ("Bad Actor" Matters) and Section 7.8(f) of the Voting Agreement, dated as of the date hereof, by and among AKERO, the Key Holders (as such term is defined therein) and the Investors (as such term is defined therein) (the "**Voting Agreement**"); and

(f) The terms of the letter agreement, dated as of the date hereof, by and between AKERO and AMGEN (the "**Side Letter**").

Section 1.26 "**Disclosing Party**" has the meaning set forth in Section 8.1.1 (Confidential Information).

Section 1.27 "**Effective Date**" has the meaning set forth in the Preamble.

Section 1.28 "**EMA**" means the European Medicines Agency or any successor entity thereto.

Section 1.29 "**Enforcing Party**" has the meaning set forth in Section 4.3.3 (Cooperation with Respect to Enforcement).

Section 1.30 "**Exploit**" means to research, develop, make, have made, use, offer for sale, sell, import, export or otherwise exploit, or transfer possession of or title in, a product. Cognates of the word "**Exploit**" shall have correlative meanings.

Section 1.31 "**FDA**" means the United States Food and Drug Administration or any successor entity thereto.

Section 1.32 "**First Commercial Sale**" means, with respect to the Product in any country, the

first sale for end use or consumption of the Product in such country after Marketing Approval has been granted in such country.

Section 1.33 "**FTE Rate**" means [***] per hour.

Section 1.34 "**GAAP**" means United States generally accepted accounting principles applied on a consistent basis. Unless otherwise defined or stated herein, financial terms shall be calculated under GAAP.

Section 1.35 "**Governmental Authority**" means any court, agency, department, authority or other instrumentality of any national, state, county, city or other political subdivision.

Section 1.36 "**Government Official**" means (i) any official or employee of any Governmental Authority, or any department, agency, or instrumentality thereof (including without limitation commercial entities owned or controlled, directly or indirectly, by a Governmental Authority), (ii) any political party or official thereof, or any candidate for political office, in the Territory, (iii) any official or employee of any public international organization, or (iv) any family members of any of the foregoing.

Section 1.37 "**Infringe**" or "**Infringement**" means any infringement as determined by Law, including, without limitation, direct infringement, contributory infringement or any inducement to infringe.

Section 1.38 "**Initial Product**" means AMGEN's proprietary product known as AMG 876 having an amino acid sequence as set forth on **Exhibit D**.

Section 1.39 "**Initiation**" means, with respect to a human clinical trial, the first dosing in the first patient in such clinical trial.

Section 1.40 "**Investment Documents**" means the Purchase Agreement, the Restated Charter, the Right of First Refusal and Co-Sale Agreement, the Investors' Rights Agreement, the Voting Agreement and the Side Letter.

Section 1.41 "**Investors' Rights Agreement**" has the meaning set forth in the definition of "Designated Investment Document Terms".

Section 1.42 "**Issuing Party**" has the meaning set forth in Section 8.2.2 (Review).

Section 1.43 "**Know-How**" means non-public techniques, technology, trade secrets, inventions (whether patentable or not), methods, know-how, data and results (including pharmacological, toxicological and clinical data and results), analytical and quality control data and results, regulatory documents, and other information, compositions of matter, cells, cell lines, assays, animal models and other physical, biological, or chemical material.

Section 1.44 "**Law**" means, individually and collectively, any and all laws, ordinances, rules, directives, administrative circulars and regulations of any kind whatsoever of any Governmental Authority within the applicable jurisdiction, including, but not limited to, Anti-Corruption Laws.

Section 1.45 "**Licensed Field**" means any and all uses.

Section 1.46 "**Licensed Know-How**" means all Know-How that (a) is Controlled by AMGEN

or its Affiliates and (b) is or was actually used by AMGEN or its respective Affiliates in research and development of the Product prior to the Effective Date, including the Know-How set forth on **Exhibit A**.

Section 1.47 "**Licensed Materials**" means those materials set forth on Table 1 of **Exhibit A**, including the AMGEN Cell Line, reagents and other biological materials, all to the extent (a) Controlled by AMGEN or its Affiliates, (b) in compliance with applicable Laws and (c) in accordance with the relevant informed consents, if applicable.

Section 1.48 "**Licensed Patents**" means the Patent Rights Controlled by AMGEN or its Affiliates as of the Effective Date and set forth on **Exhibit B**.

Section 1.49 "**Licensed Technology**" means the Licensed Patents and the Licensed Know-How.

Section 1.50 "**Losses**" has the meaning set forth in Section 7.1 (By AMGEN).

Section 1.51 "**Major Market Territory**" means the [***].

Section 1.52 "**Marketing Approval**" means all approvals, licenses, registrations or authorizations of the Regulatory Authority in a country or region, necessary for the manufacture, use, storage, import, marketing, distribution and sale of the Product in such country or region.

Section 1.53 "**Milestone Events**" shall have the meaning set forth in Section 3.1.2 (Milestone Payments).

Section 1.54 "**Milestone Payments**" shall have the meaning set forth in Section 3.1.2 (Milestone Payments).

Section 1.55 [***] means, with respect to the Product, the gross sales price of the Product sold by AKERO, its Affiliates or Sublicensee(s) (the "**Selling Party**") to Third Parties, less (without duplication):

[***]

[***]

[***]

[***]

[***]

[***]

[***]

Net Sales will be determined from books and records maintained in accordance with

GAAP, consistently applied throughout the organization and across all products of the entity whose sales of the Product are giving rise to Net Sales.

Net Sales shall also include, with respect to the Product sold or otherwise disposed of for any consideration other than an exclusively monetary consideration on bona fide arms'-length terms, an amount equal to the average sales price for the Product having the same dosage form and strength during the applicable reporting period in the country where such sale or other disposal occurred when the Product is sold alone and not with other products, or if the Product is not sold alone in such country during the applicable reporting period, then an amount equal to the average sales price during the applicable reporting period generally achieved for the Product having the same dosage form and strength. For the avoidance of doubt, disposition of Product for, or use of Product in, clinical trials or other scientific testing, as free samples, or under compassionate use, patient assistance, or test marketing programs or other similar programs or studies, in each case where no consideration is received for such Product, shall not result in any Net Sales.

Where the Product is sold in combination with other pharmaceutical products, diagnostic products, or active ingredients (collectively, "**Combination Components**") the Net Sales applicable to such transaction shall be calculated by multiplying the total Net Sales of such combined product by the fraction A/(A+B), where A is the actual price of the Product in the same dosage amount or quantities in the applicable country during the applicable quarter if sold separately, and B is the sum of the actual prices of all Combination Components with which the Product is combined, in the same dosage amount or quantities in the applicable country during the applicable quarter if sold separately. If A or B cannot be determined because values for the Product or Combination Components with which the Product is combined are not available separately in a particular country, then AMGEN and AKERO shall discuss an appropriate allocation for the fair market value of the Product and Combination Components with which the Product is combined to mutually determine Net Sales for the relevant transactions based on an equitable method of determining the same that takes into account variations in potency, the relative contribution of each therapeutically active ingredient or other component, and relative value to the end user of each therapeutically active ingredient or other component.

Sales of the Product between or among AKERO and its Affiliates or Sublicensees shall be excluded from the computation of Net Sales and no payments shall be payable on such sales except where such Affiliates or Sublicensees are end users.

Section 1.56 "**Option**" has the meaning set forth in Section 4.8.1.

Section 1.57 "**Option Date**" has the meaning set forth in Section 4.8.1.

Section 1.58 "**Option Notice**" has the meaning set forth in Section 4.8.1.

Section 1.59 "**Party**" has the meaning set forth in the Preamble.

Section 1.60 "**Patent Rights**" means the rights and interests in and to all U.S. and foreign (a) patents, including, without limitation, certificates of invention, registrations, reissues, extensions, substitutions, confirmations, renewals, re-registrations, re-examinations, revalidations, patents of additions or like filing thereof; and (b) patent applications, including, without limitation,

provisional, converted provisional, non-provisional, continued prosecution application, continuation, divisional or continuation-in-part thereof, any patents issuing therefrom, and any substitution, extension, registration, confirmation, reissue, re-examination, renewal or like filing thereof.

Section 1.61 "**Permitted CMO**" means (a) a Third Party commercial manufacturing organization identified on **Exhibit C** (and all such Third Party's Affiliates), as such schedule may be updated by mutual written agreement by the Parties from time to time or (b) any other party deemed to be a Permitted CMO pursuant to the terms of Section 2.4.2.

Section 1.62 "**Permitted CMO Agreement**" has the meaning set forth in Section 2.3.3(a).

Section 1.63 "**Permitted CMO Request**" has the meaning set forth in Section 2.3.3(d).

Section 1.64 "**Person**" means any corporation, limited or general partnership, limited liability company, joint venture, trust, unincorporated association, governmental body, authority, bureau or agency, any other entity or body, or an individual.

Section 1.65 "**Phase 1 Clinical Trial**" means any initial stage human clinical trial in which the Product is introduced into humans and is conducted mainly, but not limited to, to evaluate the safety, metabolism and pharmacokinetic properties, clinical pharmacology, and if possible, to gain early evidence on effectiveness of the Product that would satisfy the requirements of 21 C.F.R. § 312.21(a) or its non-U.S. equivalents.

Section 1.66 "**Phase 2 Clinical Trial**" means any human clinical trial of the Product conducted mainly to test the effectiveness and to determine the common short-term side effects and risks associated with the Product for purposes of identifying the appropriate dose for a Phase 3 Clinical Trial for a particular indication or indications that would satisfy the requirements of 21 CFR § 312.21(b) or its non-U.S. equivalents. A "**Phase 2/3 Clinical Trial**" shall be deemed to be a Phase 2 Clinical Trial with respect to the portion of that clinical trial that is regarded as its Phase 2 component, in accordance with the applicable protocol.

Section 1.67 "**Phase 3 Clinical Trial**" means any human clinical trial of the Product designed to: (a) gather additional information about the effectiveness and safety of the Product that is needed to evaluate the overall benefit-risk relationship of the Product for its intended use; (b) provide the clinical basis of commercial labeling; and (c) support regulatory approval of the Product, that would satisfy the requirements of 21 CFR § 312.21(c) or its non-U.S. equivalents. A "**Phase 2/3 Clinical Trial**" shall be deemed to be a Phase 3 Clinical Trial with respect to the portion of that clinical trial that is regarded as its Phase 3 component, in accordance with the applicable protocol.

Section 1.68 "Pivotal Trial" means a clinical trial of a Product in human patients, which trial is designed (a) to establish that the Product is safe and efficacious for its intended use; (b) to define warnings, precautions and adverse reactions that are associated with the Product in the dosage range to be prescribed; (c) to be, either by itself or together with one or more other clinical trials having a comparable design and size, the final human clinical trial in support of Regulatory Approval of the Product and (d) consistent with 21 CFR § 312.21(c) (as hereafter modified or amended) and any of its foreign equivalents. For the avoidance of doubt, it is the

intent of the Parties that a pivotal trial shall be a phase III trial, ***provided,*** that any phase II clinical trial that is subsequently used as a pivotal trial shall be deemed a pivotal trial only upon, and at such time as, an application for Regulatory Approval is accepted by the FDA or a foreign equivalent regulatory authority using such phase II clinical trial as the basis for such Regulatory Approval.

Section 1.69 "**Product**" means any therapeutic product for use in the Licensed Field that incorporates or practices the Licensed Technology, in any form or formulation, including for clarity, all line extensions of any such product and the Initial Product.

Section 1.70 "**Product Lots**" has the meaning set forth in Section 5.4 (Product Supply).

Section 1.71 "**Proper Conduct Practices**" means, in relation to any Person, such Person and each of its Representatives, not, directly or indirectly, (a) making, offering, authorizing, providing or paying anything of value in any form, whether in money, property, services or otherwise to any Governmental Authority, Government Official, or other Person charged with similar public or quasi-public duties, or to any customer, supplier, or any other Person, or to any employee thereof, or failing to disclose fully any such payments in violation of the laws of any relevant jurisdiction to (i) obtain favorable treatment in obtaining or retaining business for it or any of its Affiliates, (ii) pay for favorable treatment for business secured, (iii) obtain special concessions or for special concessions already obtained, for or in respect of it or any of its Affiliates, in each case which would have been in violation of any Law, (iv) influence an act or decision of the recipient (including a decision not to act) in connection with the Person's or its Affiliate's business, (v) induce the recipient to use his or her influence to affect any government act or decision in connection with the Person's or its Affiliate's business or (vi) induce the recipient to violate his or her duty of loyalty to his or her organization, or as a reward for having done so; (b) engaging in any transactions, establishing or maintaining any fund or assets in which it or any of its Affiliates shall have proprietary rights that have not been recorded in the books and records of it or any of its Affiliates; (c) making any unlawful payment to any agent, employee, officer or director of any Person with which it or any of its Affiliates does business for the purpose of influencing such agent, employee, officer or director to do business with it or any of its Affiliates; (d) violating any provision of applicable Anti-Corruption Laws; (e) making any payment in the nature of bribery, fraud, or any other unlawful payment under the Law of any jurisdiction where it or any of its Affiliates conducts business or is registered; or (f) if such Person or any of its Representatives is a Government Official, improperly using his or her position as a Government Official to influence the award of business or regulatory approvals to or for the benefit of such Person, its Representatives or any of their business operations, or failing to recuse himself or herself from any participation as a Government Official in decisions relating to such Person, its Representatives or any of their business operations.

Section 1.72 "**Purchase Agreement**" has the meaning set forth in Section 3.1.1(b).

Section 1.73 "**Receiving Party**" has the meaning set forth in Section 8.1.1 (Confidential Information).

Section 1.74 "**Regulatory Approval**" means final approval of an Application by the FDA, or final approval of a comparable document filed with an equivalent health regulatory authority in

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any other country or in the European Union (using the centralized process, decentralized process or mutual recognition or member state national authorization) — but not necessarily also any required pricing and/or reimbursement approvals. "**Application**" means a new drug application pursuant to and/or as defined in the United States Federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder, or similar application filed with an equivalent regulatory body in another country or multinational region.

Section 1.75 "**Regulatory Authority**" means any Governmental Authority or other authority responsible for granting Marketing Approvals for the Product, including the FDA, EMA and any corresponding national or regional regulatory authorities.

Section 1.76 "**Regulatory Exclusivity**" means, with respect to the Product, any exclusive marketing rights or data exclusivity rights conferred by the applicable Regulatory Authority with respect to the Product (that would satisfy the requirements of 21 CFR § 314.108 or its non-U.S. equivalents) other than a Patent Right.

Section 1.77 "**Regulatory Filing**" means any all (a) submissions, non-administrative correspondence, notifications, registrations, licenses, authorizations, applications and other filings with any Governmental Authority with respect to the research, clinical investigation, development, manufacture, distribution, pricing, reimbursement, marketing or sale of the Product and (b) Marketing Approvals for the Product.

Section 1.78 "**Release**" has the meaning set forth in Section 8.2.2 (Review).

Section 1.79 "**Representatives**" means, as to any Person, such Person's Affiliates and its and their successors, controlling Persons, directors, officers and employees.

Section 1.80 "**Restated Charter**" has the meaning set forth in the definition of "Designated Investment Document Terms".

Section 1.81 "**Reviewing Party**" has the meaning set forth in Section 8.2.2 (Review).

Section 1.82 "**Right of First Refusal and Co-Sale Agreement**" has the meaning set forth in the definition of "Designated Investment Document Terms".

Section 1.83 "**Royalty Term**" has the meaning set forth in Section 3.1.4 (Royalty Rate; Royalty Term).

Section 1.84 "**Safety Database**" has the meaning set forth in Section 5.5.

Section 1.85 "**Selling Party**" has the meaning set forth in the definition of "Net Sales."

Section 1.86 "**Series A Preferred Stock**" has the meaning set forth in Section 3.1.1(b).

Section 1.87 "**Side Letter**" has the meaning set forth in the definition of "Designated Investment Document Terms".

Section 1.88 "**Sublicensee(s)**" means any Person other than an Affiliate of AKERO to which AKERO has granted a sublicense under this Agreement.

Section 1.89 "**Sublicense Notice**" has the meaning set forth in Section 2.2.

Section 1.90 "**Term**" has the meaning set forth in Section 9.1 (Term).

Section 1.91 "**Territory**" means the entire world.

Section 1.92 "**Third Party**" means a Person other than (a) AMGEN or any of its Affiliates and (b) AKERO or any of its Affiliates.

Section 1.93 "**Valid Claim**" means a claim of any issued and unexpired patent or patent application within the Licensed Patents that has not been (i) revoked or held invalid or unenforceable by a final decision of a court or governmental agency of competent jurisdiction (and which decision can no longer be appealed or was not appealed within the time allowed) or (ii) held to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise; ***provided, however,*** that if a claim of a pending patent application within the Licensed Patents shall not have issued within seven (7) years after the earliest filing date from which such claim takes priority, such claim shall not constitute a Valid Claim for the purposes of this Agreement unless and until a Patent Right issues with such claim (from and after which time the same would be deemed a Valid Claim).

Section 1.94 "**VAT**" has the meaning set forth in Section 3.6.3 (VAT).

Section 1.95 "**Voting Agreement**" has the meaning set forth in the definition of "Designated Investment Document Terms".

ARTICLE 2. LICENSE GRANT

Section 2.1 Grant.

2.1.1 Exclusive License. Subject to the terms and conditions of this Agreement, AMGEN hereby grants to AKERO (a) an exclusive (even as to AMGEN and its Affiliates), royalty bearing, sublicensable (but only in accordance with Section 2.2 (Sublicenses)), license under the Licensed Patents, in each case, solely to Exploit Products in the Licensed Field in the Territory during the Term, and (b) a non-exclusive, royalty bearing, sublicensable (but only in accordance with Section 2.2 (Sublicenses)), license under the Licensed Know-How, in each case, solely to Exploit the Product in the Licensed Field in the Territory during the Term.

2.1.2 Non-Exclusive License. AMGEN hereby grants to AKERO a nonexclusive, royalty-free, sub-licensable (through multiple tiers) license to Patent [***], solely for the manufacture of the Initial Product during the Term.

Section 2.2 Sublicenses. AKERO and its Affiliates shall be entitled, without the prior consent of AMGEN, to grant one or more sublicenses, in full or in part, by a written agreement to Third Parties (with the right to sublicense through multiple tiers), ***provided, however,*** that as a

condition precedent to and requirement of any such sublicense: (a) any such permitted sublicense shall be consistent with and subject to the terms and conditions of this Agreement; (b) AKERO will continue to be responsible for full performance of AKERO's obligations under the Agreement and will be responsible for all actions of such Sublicensee as if such Sublicensee were AKERO hereunder; and (c) any such Sublicensee shall agree in writing to be bound by the substantially similar obligations of AKERO hereunder that are relevant to the rights sublicensed to AKERO to Sublicensee under such sublicense agreement, including with respect to Article 8 (Confidentiality), and Sections 7.1 (Indemnity), 9.2.2 (Termination for IP Challenge) and 9.5 (Effects of Termination). Further, within thirty (30) days of sublicensing any rights to [***], AKERO shall provide written notice to AMGEN (a "**Sublicense Notice**"). The Sublicense Notice shall include the name of the Third Party and a summary of the sublicense terms.

Section 2.3 Transfer of Licensed Know-How and Licensed Materials.

2.3.1 AMGEN shall transfer to AKERO (or, in the case of AMGEN's transfer of the AMGEN Cell Line, to the Permitted CMO) the Licensed Know-How and Licensed Materials listed on **Exhibit A**, in accordance with a schedule to be mutually agreed by the Parties, ***provided***, that AMGEN shall use commercially reasonable efforts (except during AMGEN's summer corporate shutdown period) to provide certain quantities of not-for-human-use drug product, cGMP drug substance and proprietary AMGEN reagents (identified on **Exhibit A** as 30-day deliverables) within thirty (30) days following the Effective Date (and AMGEN shall use commercially reasonable efforts to provide such other Licensed Materials as may be reasonably required by AKERO to undertake AKERO's planned 120-day toxicology studies in rat and monkey), and ***provided***, that such overall transfer must be completed within six (6) months after the Effective Date), ***provided, further, however***, that such six (6)-month transfer timeline may be reasonably extended for items that, despite diligent efforts by AMGEN, are not practicable to transfer within such six (6)-month period, in which case AMGEN shall continue to use diligent efforts to transfer such items as promptly as practicable after such period but in any event within twelve (12) months after the Effective Date. The Licensed Know-How will be transferred in a customary electronic format to the extent available and otherwise in the original paper format, and AMGEN will provide limited consulting support, in accordance with this Section 2.3. AMGEN transfers the Licensed Materials to AKERO "as is" and makes no other representations to AKERO in connection therewith. The Parties acknowledge that there are extensive documents, materials and information related to the Product, and that it is the intent of the Parties that the transfer of documents, materials and information hereunder be limited. Accordingly, AMGEN shall not have any obligation to transfer to AKERO any Licensed Know-How or Licensed Materials other than those set forth on **Exhibit A**, except that, during the first twelve (12) months following the Effective Date, AKERO may notify AMGEN of any missing Licensed Know-How and AMGEN agrees to use reasonable efforts to locate such missing Licensed Know-How and deliver it to AKERO promptly, in the format specified above. AKERO shall assist AMGEN in meeting its obligations under any relevant informed consents relating to any information or blood or tissue samples transferred to AKERO, including with respect to the destruction or ceasing the use thereof. AMGEN shall notify AKERO promptly following the completion of its transfer of the Licensed Know-How and Licensed Materials as set forth herein. Following such notification, AKERO shall promptly either (x) confirm to AMGEN that such

transfer is complete or (y) notify AMGEN, with reasonable specificity, of any Licensed Know-How and/or Licensed Materials that remain to be transferred, and, in the case of clause (y) above, promptly following AKERO's notification, the Parties shall in good faith discuss and attempt to resolve such dispute.

2.3.2 AMGEN shall provide, at its expense, consulting support (not to exceed [***] in the aggregate) in connection with such transfer and the Exploitation of the Product in the Territory during the six (6)-month period (or up to a twelve (12)-month period if extended in accordance with this Section 2.5) after the Effective Date. If AKERO requires additional consulting support in excess of [***] in the aggregate or beyond such period after the Effective Date in connection with such transfer or the Exploitation of the Product in the Territory, then AKERO may request such additional support in writing. AMGEN shall notify AKERO within ten (10) days after receipt of such request whether it, in its sole discretion, is willing to provide such additional consulting support, which support shall be at AKERO's expense, at the FTE Rate for the relevant AMGEN employees.

2.3.3 With respect to AMGEN's transfer of the AMGEN Cell Line, the Parties agree that the following procedures shall apply:

(a) Prior to such transfer, AKERO shall designate, and enter into a binding agreement with, one of the Permitted CMOs, which agreement shall provide for, among other things, (i) confidentiality and non-use provisions at least as protective as those set forth hereunder under Section 8.1 (Confidential Information) and (ii) such additional provisions as are required to comply with the manufacturing and other limitations set forth in this Section 2.3.3 (such agreement, the "Permitted CMO Agreement"). Upon AMGEN's reasonable request, AKERO shall provide to AMGEN a copy of any such Permitted CMO Agreement (including any material amendment thereto) executed by AKERO; provided that the financial terms (and any other terms AKERO is required to keep confidential) of any such agreement may be redacted to the extent not pertinent to AMGEN's confirmation of the restrictive provisions set forth in this Section 2.3.3. For avoidance of doubt, if AKERO (itself, or through a Third Party, Affiliate, or Sublicensee) uses any Licensed Materials and/or Licensed Know-How (excluding any AMGEN Cell Line, but including any Product sequence set forth on the Exhibit D) to create its own cell lines ("AKERO Cell Lines"), such AKERO Cell Lines shall not be the AMGEN Cell Line, and the Permitted CMO restrictions set forth herein shall not apply to AKERO's exploitation of AKERO Cell Lines.

(b) Following AKERO's and such Permitted CMO's entry into the Permitted CMO Agreement, AMGEN shall, at the direction and expense (for both internal costs at the FTE Rate and out of pocket costs) of AKERO, transfer the AMGEN Cell Line to the Permitted CMO to generate the Product.

(c) AKERO agrees that it shall not, and it shall use its commercially reasonable efforts to cause the Permitted CMO not to: (i) reverse engineer or otherwise deconstruct the AMGEN Cell Line or the initial AMGEN cell culture media provided therewith, or to determine or to seek to determine information (including, but not limited to, the gene or amino acid sequence) or characteristics regarding the AMGEN Cell Line or such media, other than as expressly required to manufacture the Product; (ii) clone, express, or otherwise produce any

products or materials (including, without limitation, any progeny or derivatives thereof) from the AMGEN Cell Line, other than as expressly permitted under this Agreement; (iii) notwithstanding anything to the contrary in Section 8.3.1 (Right to Publish), publish or otherwise publicly disclose the AMGEN Cell Line; or (iv) permit any non-controlled security access to the AMGEN Cell Line or otherwise transfer or provide any of the AMGEN Cell Line to a Third Party or any of its Affiliates, other than as expressly required to manufacture the Product (provided such access or transfer is in accordance with this Agreement).

(d) Upon a termination or expiration of the Permitted CMO Agreement (including as a result of the appointment, with prior written notice to AMGEN, by AKERO of a replacement Permitted CMO), the Permitted CMO shall promptly return any remaining AMGEN Cell Lines and related Licensed Know-How and Licensed Materials to AMGEN. If, at any time, AKERO desires to add a new Third Party commercial manufacturer to **Exhibit C**, it shall notify AMGEN in writing (a "**Permitted CMO Request**"), and AMGEN shall have the right, for sixty (60) days after receipt of such Permitted CMO Request, to inspect, at a reasonable time and on a reasonable basis (at AMGEN's cost), such manufacturer's facilities to confirm its ability to fully comply with the restrictive provisions set forth in this Section 2.3.3. AMGEN may reject a Permitted CMO Request if it reasonably determines that the proposed manufacturer is unable to comply with the restrictive provisions set forth in this Section 2.3.3, and AMGEN will promptly notify AKERO thereof (and its reasons therefor).

(e) AKERO acknowledges that any materials transferred by AMGEN to AKERO under this Agreement are experimental in nature and may have unknown characteristics and therefore agrees to use prudence and reasonable care in the use, handling, storage, transportation and disposition and containment of any such materials. Accordingly, no such materials, other than the Product Lots, shall be used in any human application, including any clinical trial.

Section 2.4 Limited Grant. AKERO acknowledges that the rights and licenses granted under this Article 2 (License Grant) and elsewhere in this Agreement are limited to the scope expressly granted. Accordingly, except for the rights expressly granted under this Agreement, notwithstanding anything in this Agreement to the contrary, nothing in this Agreement shall be construed as granting by implication, estoppel or otherwise, any right, title or interest in, to or under any AMGEN patents other than the Licensed Patents regardless of whether such other patents are dominant or subordinate to any Licensed Patent.

Section 2.5 Reserved Rights. All rights that are not specifically granted herein are reserved to AMGEN. The Parties agree, without diminishing the rights granted to AKERO under Section 2.1 (Grant), AMGEN shall retain all rights that it Controls to the Licensed Know-How to Exploit any product other than the Product, *provided* that in no event shall AMGEN retain or have any right during the Term to practice any claim that is issued in a Licensed Patent which claim references a Product or the Initial Product, whether such claim issues before or after the Effective Date.

Section 2.6 Limited Exploitation of Rights. Without limiting the provisions of Section 2.4 (Limited Grant) or Section 2.5 (Reserved Rights), AKERO agrees (on behalf of itself and its Affiliates), and shall cause each of its Sublicensees to agree as a condition to the grant of a sublicense pursuant to Section 2.2 (Sublicenses), not to Exploit any Licensed Know-How or Licensed Patents in connection with any products or services other than the Product.

ARTICLE 3. FEES, ROYALTIES AND PAYMENTS

Section 3.1 Upfront Payment, Milestone Payments and Royalties.

3.1.1 Upfront Payment. In consideration of the rights granted herein to AKERO, AKERO shall make the following upfront payment to AMGEN, in the form of a monetary payment and the issuance of certain equity in AKERO.

(a) Within ten (10) days following the Effective Date, AKERO shall pay to AMGEN the amount of $5,000,000.

(b) On the Effective Date, AKERO shall issue and deliver to AMGEN 2,653,333 shares of Series A Preferred Stock (the "**Series A Preferred Shares**") of AKERO pursuant to the terms of the Purchase Agreement, dated as of the date hereof, by and among AKERO and certain investors party thereto (the "**Purchase Agreement**"), such shares evidencing an ownership interest of ten percent (10%) of the outstanding and issued common stock of AKERO calculated on a fully diluted and converted basis (the "**AMGEN Ownership Percentage**") as of the Effective Date of this Agreement. Thereafter, [***].

3.1.2 Milestone Payments. AKERO shall pay to AMGEN certain milestone payments ("**Milestone Payments**") following the first occurrence of certain milestone events, as set forth in Section 3.1.3 (Milestone Event/Payment Table) (the "**Milestone Events**"). AKERO shall pay to AMGEN the applicable Milestone Payment within [***] after (i) [***], and (ii) [***]. For clarity, (a) each Milestone Payment is payable only once, (b) no Milestone Payment shall be payable for subsequent or repeated achievements of such Milestone Event with respect to one or more of the same or different Products, and (c) no more than $[***] shall be payable to AMGEN under this Section 3.1.2. Each of the Milestone Payments shall be non-refundable and non-creditable.

3.1.3 Milestone Event/Payment Table. The Milestone Events and Milestone Payments to be made pursuant to Section 3.1.2 (Milestone Payments) shall be as follows:

Milestone Event	Milestone Payment
[***]	$ [***]
[***]	$ [***]
[***]	$ [***]
[***]	$ [***]
[***]	$ [***]

Milestone Event	Milestone Payment
[***]	$ [***]

*[***].

3.1.4 Royalty Rate; Royalty Term. AKERO shall pay to AMGEN a royalty on annual Net Sales of Products sold by a Selling Party during the applicable Royalty Term as follows:

Net Sales	Royalty Rate
Net Sales up to and including $[***]	[***]%
Net Sales exceeding $[***]	[***]%
Net Sales exceeding $[***]	[***]%

Royalties will be payable on a quarterly basis; any such payments shall be made within [***] after the end of the calendar quarter during which the applicable Net Sales occurred. AKERO's obligation to pay royalties with respect to a Product in a particular country shall commence upon the First Commercial Sale of such Product in such country and shall expire on a country-by-country basis on the later of (a) the date on which the Exploitation of such Product is no longer Covered by a Valid Claim of a Licensed Patent in such country, (b) the loss of Regulatory Exclusivity for such Product in such country, or (c) the tenth (10^{th}) anniversary of the First Commercial Sale of such Product in such country (the "**Royalty Term**").

3.1.5 Royalty Reductions. On a country-by-country basis, in the event that the Exploitation of a Product is not Covered by a Valid Claim of a Licensed Patent in such country, then the royalty rate set forth in Section 3.1.4 (Royalty Rate; Royalty Term) with respect to Net Sales for such Product in such country shall be reduced by [***], effective as of the date such Product is no longer Covered by a Valid Claim of a Licensed Patent in such country.

3.1.6 Biosimilar Competition. On a country-by-country and Product-by-Product basis, following the marketing approval and launch of a Biosimilar Version, the then-applicable royalty rates for the calculation of the royalty payments on Net Sales of the Product corresponding to the Biosimilar Version for the applicable country for any calendar quarter or portion thereof shall, thereafter, be reduced by [***] and, if the Net Sales of such Product in such country have declined by more than [***] as compared with the average Net Sales in the [***] immediately prior to the entry of the Biosimilar Version in such country for more than [***], the then-applicable royalty rates for the calculation of the royalty payments on Net Sales of such Product shall, thereafter, be reduced by an additional [***]; provided, that, after the removal of such Biosimilar Version from such country, the royalty shall revert to being paid in full for the remainder of the Royalty Term.

3.1.7 Third-Party Intellectual Property. In the event that a Third Party Controls intellectual property relating to a Product that is reasonably necessary for the

Exploitation of a Product, then AKERO shall have the right (but not the obligation) to obtain such license to such Third Party intellectual property; ***provided, however,*** that AKERO has received written advice from its counsel that it would be advisable to obtain a license to such Third Party intellectual property in connection with the Exploitation of the Product. In such an event, [***] of the royalties that AKERO actually pays to such Third Party for the Exploitation of the Product in a country during a calendar quarter may be credited against royalties otherwise payable by AKERO to AMGEN under Section 3.1 (Royalty Rate; Royalty Term) for Net Sales of the Product in such country in such calendar quarter.

3.1.8 Maximum Reduction. The maximum aggregate reduction with respect to the royalty rate for a Product in any calendar quarter during the applicable Royalty Term in any country pursuant to Sections 3.1.5 (Royalty Reduction), 3.1.6 (Biosimilar Competition) and 3.1.7 (Third-Party Intellectual Property) shall be [***].

3.1.9 Mutual Convenience of the Parties. The royalty and other payment obligations set forth hereunder have been agreed to by the Parties for the purpose of reflecting and advancing their mutual convenience, including the ease of calculating and paying royalties and other amounts to AMGEN. AKERO hereby stipulates to the fairness and reasonableness of such royalty and other payment obligations and covenants not to allege or assert, nor to allow any of its Affiliates or Sublicensees, as applicable, to allege or assert, nor further to cause or support any other Third Parties to allege or assert, that any such royalty or other payment obligations are unenforceable or illegal in any way.

Section 3.2 Method of Payment. Unless otherwise agreed by the Parties, all payments due from AKERO to AMGEN under this Agreement shall be paid in U.S. Dollars by wire transfer or electronic funds transfer of immediately available funds to the following account (or such other account as AMGEN may direct from time to time by written notice to AKERO):

Beneficiary Name: Amgen Inc.
Beneficiary Account #: [***]
ABA#: [***]
Swift Code: [***]

After the First Commercial Sale of the first Product and until expiration of the last Royalty Term, AKERO shall prepare and deliver to AMGEN royalty reports of the sale of the Product by the Selling Parties for each calendar quarter within forty-five (45) days of the end of each such calendar quarter specifying in the aggregate and country-by-country basis: (a) total gross amounts for the Product sold or otherwise disposed of by a Selling Party; (b) amounts deducted by category in accordance with the definition of "Net Sales" in Article 1 (Definitions) from gross amounts to calculate Net Sales; (c) Net Sales; and (d) royalties payable.

Section 3.3 Currency Conversion. In the case of sales outside the United States, payments received by AKERO will be expressed in the U.S. Dollar equivalent calculated on a quarterly basis in the currency of the country of sale and converted to their U.S. Dollar equivalent using the average rate of exchange over the applicable calendar quarter to which the sales relate, in accordance with GAAP and the then current standard methods of AKERO or the applicable

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 406 PROMULGATED UNDER THE SECURITIES ACT OF 1933, AS AMENDED.

Sublicensee, to the extent reasonable and consistently applied; ***provided, however,*** that if, at such time, AKERO or such Sublicensee does not use a rate for converting into U.S. Dollar equivalents that is maintained in accordance with GAAP, then AKERO or such Sublicensee shall use a rate of exchange which corresponds to the rate of exchange for such currency reported in *The Wall Street Journal*, Internet U.S. Edition at www.wsj.com, as of the last day of the applicable reporting period (or, if unavailable on such date, the first date thereafter on which such rate is available). AKERO will inform AMGEN as to the specific exchange rate translation methodology used for a particular country or countries and cause any Sublicensees to comply with the terms of this Section 3.3.

Section 3.4 Late Payments. In the event that any payment due hereunder is not made when due, the payment shall accrue interest beginning on the day following the due date thereof, calculated at the annual rate of the sum of (a) [***] plus (b) the prime interest rate quoted by *The Wall Street Journal*, Internet U.S. Edition at www.wsj.com on the date said payment is due, the interest being compounded on the last day of each calendar quarter; ***provided, however,*** that in no event shall said annual interest rate exceed the maximum rate permitted by Law. Each such payment when made shall be accompanied by all interest so accrued. Said interest and the payment and acceptance thereof shall not negate or waive the right of any Party to seek any other remedy, legal or equitable, to which it may be entitled because of the delinquency of any payment including, but not limited to, termination of this Agreement as set forth in Article 9 (Term and Termination).

Section 3.5 Records and Audits. AKERO will keep complete and accurate records of the underlying revenue and expense data relating to the calculations of Net Sales generated in the then current calendar year and payments required under this Agreement, and during the preceding three (3) calendar years. AMGEN will have the right, once annually at its own expense, to have a nationally recognized, independent, certified public accounting firm, selected by it and subject to AKERO's prior written consent (which shall not be unreasonably withheld, conditioned or delayed), review any such records of AKERO and its Affiliates and Sublicensees (the "**Audited Party**") in the location(s) where such records are maintained by the Audited Party upon reasonable written notice (which shall be no less than thirty (30) days' prior written notice) and during regular business hours and under obligations of strict confidence, for the sole purpose of verifying the basis and accuracy of payments made under Article 3 (Fees, Royalties and Payments) within the thirty-six (36) month period preceding the date of the request for review. No calendar year will be subject to audit under this Section 3.5 more than once. AKERO will receive a copy of each such report concurrently with receipt by AMGEN. Should such inspection lead to the discovery of a discrepancy to AMGEN's detriment, AKERO will, within forty-five (45) days after receipt of such report from the accounting firm, pay any undisputed amount of the discrepancy together with interest at the rate set forth in Section 3.4 (Late Payments). AMGEN will pay the full cost of the review unless the underpayment of amounts due to AMGEN is [***] for

the entire period being examined, in which case AKERO will pay the cost charged by such accounting firm for such review. Should the audit lead to the discovery of a discrepancy to AKERO's detriment, AKERO may credit the amount of the discrepancy, without interest, against future payments payable to AMGEN under this Agreement, and if there are no such payments payable, then AMGEN shall pay to AKERO the amount of the discrepancy, without

interest, within [***] days of AMGEN's receipt of the report.

Section 3.6 Taxes.

3.6.1 Sales Tax. AKERO is responsible for the payment of any state or local, sales or use, or similar fees or taxes arising as a result of the transfer of Licensed Materials by AMGEN to AKERO pursuant to Section 2.3 (Transfer of Licensed Know-How and Licensed Materials) and Product Lots pursuant to Section 5.4, and AKERO will remit such fees or taxes to AMGEN, as the collection agent, upon invoice.

3.6.2 Withholding. In the event that any Law requires AKERO to withhold taxes with respect to any payment to be made by AKERO pursuant to this Agreement, AKERO will notify AMGEN of such withholding requirement prior to making the payment to AMGEN and provide such assistance to AMGEN, including the provision of such standard documentation as may be required by a tax authority, as may be reasonably necessary in AMGEN's efforts to claim an exemption from or reduction of such taxes. AKERO will, in accordance with such Law withhold taxes from the amount due, remit such taxes to the appropriate tax authority, and furnish AMGEN with proof of payment of such taxes within thirty (30) days following the payment. If taxes are paid to a tax authority, AKERO shall provide reasonable assistance to AMGEN to obtain a refund of taxes withheld, or obtain a credit with respect to taxes paid.

3.6.3 VAT. All payments due to AMGEN from AKERO pursuant to this Agreement shall be paid exclusive of any value-added tax ("**VAT**") (which, if applicable, shall be payable by AKERO upon receipt of a valid VAT invoice). If AMGEN determines that it is required to report any such tax, AKERO shall promptly provide AMGEN with applicable receipts and other documentation necessary or appropriate for such report. For clarity, this Section 3.6.3 is not intended to limit AKERO's right to deduct value-added taxes in determining Net Sales.

ARTICLE 4. PATENT PROSECUTION, MAINTENANCE AND INFRINGEMENT

Section 4.1 Prosecution and Maintenance. AKERO shall have the first right to file, prosecute and maintain all Patent Rights specified under Licensed Patents, at AKERO's sole expense using outside counsel reasonably acceptable to AMGEN. AKERO will use Commercially Reasonable Efforts to prepare, file, prosecute, defend and maintain all Patent Rights specified under Licensed Patents; ***provided, however,*** that AKERO does not represent or warrant that any patent will issue or be granted based on patent applications contained in the Licensed Patents. AMGEN shall reasonably cooperate with AKERO's requests for data, affidavits, and other information and assistance to support prosecution and maintenance of the Patent Rights in the Licensed Patents; ***provided, however,*** that AKERO shall reimburse AMGEN for its reasonable expenses with respect to such cooperation (including AMGEN's or its Affiliate's employee's time at the FTE Rate), within forty-five (45) days of receiving a written invoice therefor. AKERO shall keep AMGEN reasonably informed, in person or by telephone or email, regarding the status of such prosecution and maintenance activities, and AKERO shall promptly upon receipt forward to AMGEN copies of any significant office actions, communications, and correspondence relating

to the Licensed Patents. AMGEN shall have the right to comment on and to discuss prosecution and maintenance activities with AKERO, and AKERO shall consider the same in good faith and shall provide AMGEN with copies of all proposed filings and correspondence to give AMGEN the opportunity to review and comment.

Section 4.2 AMGEN Step-In Right. Notwithstanding the foregoing, if AKERO declines to file, prosecute or maintain any Patent Rights, elects to allow any Patent Rights to lapse in any country, or elects to abandon any Patent Rights (in each case to the extent contained in the Licensed Patents) before all appeals within the respective patent office have been exhausted (each, an "**Abandoned Patent Right**"), then:

(a) AKERO shall provide AMGEN with reasonable notice of such decision so as to permit AMGEN to decide whether to file, prosecute or maintain such Abandoned Patent Rights and to take any necessary action (which notice shall, in any event, be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Abandoned Patent Right with the U.S. Patent & Trademark Office or any foreign patent office).

(b) AMGEN, at AMGEN's expense, may assume control of the filing, prosecution and/or maintenance of such Abandoned Patent Rights.

(c) AMGEN shall have the right to transfer the responsibility for such filing, prosecution and maintenance of such Abandoned Patent Rights to patent counsel (outside or internal) selected by AMGEN.

(d) AKERO shall assist and cooperate with AMGEN's reasonable requests to support prosecution and maintenance of such Abandoned Patent Rights; ***provided, however,*** that AMGEN shall reimburse AKERO for its reasonable expenses with respect to such cooperation (including AKERO's employee's time at the FTE Rate).

(e) In the event a patent issues with respect to any such Abandoned Patent Rights, AMGEN shall provide reasonable notice to AKERO thereof and such Abandoned Patent Right shall be excluded from the license granted by AMGEN to AKERO under Section 2.1 (Grant), unless AKERO (i) reimburses AMGEN for its internal and external costs and expenses related to the prosecution and maintenance of such Abandoned Patent Right within sixty (60) days of notice of issuance of any such patent and (ii) assumes, in writing, the responsibility for the continued prosecution and maintenance of such Patent Rights in accordance with the provisions of Section 4.1 (Prosecution and Maintenance).

Section 4.3 Enforcement.

4.3.1 AKERO Enforcement. Each Party will notify the other promptly in writing when any Infringement of a Licensed Patent by a Third Party is uncovered or reasonably suspected. AKERO shall have the first right to enforce any patent within the Licensed Patents

against any Infringement or alleged Infringement thereof, and shall at all times keep AMGEN informed as to the status thereof. AKERO may, at its own expense, institute suit against any such infringer or alleged infringer and control and defend and settle such suit in a manner consistent with the terms and provisions hereof and recover any damages, awards or settlements resulting therefrom, subject to Section 4.5 (Recovery). AMGEN shall reasonably cooperate in any such litigation (including joining or being named a necessary party thereto) at AKERO's expense. AKERO shall not enter into any settlement of any claim described in this Section 4.3.1 that admits to the invalidity or unenforceability of the Licensed Patents, incurs any financial liability on the part of AMGEN or requires an admission of liability, wrongdoing or fault on the part of AMGEN, without AMGEN's prior written consent, in each case, such consent not to be unreasonably withheld.

4.3.2 AMGEN Enforcement. If AKERO elects not to enforce any patent within the Licensed Patents, then it shall so notify AMGEN in writing within thirty (30) days of receiving notice that an Infringement exists (or such shorter period as may be necessary to prevent exhaustion of a statute of limitations (or laches) applicable to such Infringement), and AMGEN may, in its sole judgment, and at its own expense, take steps to enforce any such patent and control, settle, and defend such suit in a manner consistent with the terms and provisions hereof, and recover any damages, awards or settlements resulting therefrom, subject to Section 4.5 (Recovery). AKERO shall reasonably cooperate in any such litigation (including joining or being named a necessary party thereto) at AMGEN's expense. AMGEN shall not enter into any settlement of any claim described in this Section 4.3.2 that admits to the invalidity or unenforceability of the Licensed Patents, incurs any financial liability on the part of AKERO or requires an admission of liability, wrongdoing or fault on the part of AKERO without AKERO's prior written consent, such consent not to be unreasonably withheld.

4.3.3 Cooperation with Respect to Enforcement. Irrespective of which Party controls an action pursuant to this Section 4.3 , the Parties will collaborate in the choice of counsel with respect to such enforcement action and the enforcing Party will consider in good faith the comments of the other Party with respect to strategic decisions and their implementation with respect to such action. In furtherance of the foregoing, the Party initiating or defending any such enforcement action (the "**Enforcing Party**") shall keep the other Party reasonably informed of the progress of any such enforcement action, and such other Party shall have the individual right to participate with counsel of its own choice at its own expense.

Section 4.4 Defense of Third Party Claims. If either (a) any Product Exploited by or under authority of AKERO becomes the subject of a Third Party's claim or assertion of Infringement of a patent relating to the Exploitation of such Product in the Licensed Field in the Territory, or (b) a declaratory judgment action is brought naming either Party as a defendant and alleging invalidity or unenforceability of any of the Licensed Patents, the Party first having notice of the claim or assertion shall promptly notify the other Party, and the Parties shall promptly confer to consider the claim or assertion and the appropriate course of action. Subject to Article 7 (Indemnification), unless the Parties otherwise agree in writing, each Party shall have the right to defend itself against a suit that names it as a defendant (the "**Defending Party**"). If AMGEN is named in such legal action but not AKERO, then AKERO shall have the right to join, at its own

expense, any such legal action and to be represented in such action by its own counsel. Neither Party shall enter into any settlement of any claim described in this Section 4.4 that admits to the invalidity, narrowing of scope or unenforceability of the Licensed Patents or this Agreement, incurs any financial liability on the part of the other Party, requires an admission of liability, wrongdoing or fault on the part of the other Party, without such other Party's prior written consent, in each case, such consent not to be unreasonably withheld, conditioned or delayed. In any event, the other Party shall reasonably assist the Defending Party and cooperate in any such litigation at the Defending Party's request and the Defending Party shall reimburse the other Party's reasonable out-of-pocket costs associated therewith.

Section 4.5 Recovery. Except as otherwise provided, the costs and expenses of the Party bringing suit under Section 4.3 (Enforcement) shall be borne by such Party, and any damages, settlements or other monetary awards recovered shall be shared as follows: (a) the amount of such recovery actually received by the Party controlling such action shall first be applied to the out-of-pocket costs of each Party in connection with such action; and then (b) the remainder of the recovery shall be shared as follows:

(a) If AKERO is the Enforcing Party, [***] and

(b) If AMGEN is the Enforcing Party, [***].

Section 4.6 Patent Term Extensions and Filings for Regulatory Exclusivity Periods.

(a) AKERO will advise AMGEN when it is considering any patent term extension or supplementary protection certificates or their equivalent for the Licensed Patents.

(b) Parties will use good faith efforts to mutually agree on (i) which Licensed Patents to list on any patent listings required for any Regulatory Exclusivity for Products or (ii) any patent term extension or supplementary protection certificates or their equivalent for the Licensed Patents; ***provided,*** that [***].

Section 4.7 Patent Marking. AKERO will mark, and will cause all other Selling Parties to mark, the Product with all Licensed Patents in accordance with applicable Law, which marking obligation will continue for as long as (and only for as long as) required under applicable Law.

Section 4.8 Right of First Refusal with Respect to AKERO Manufacturing IP.

4.8.1 If AKERO develops Patent Rights or Know-How that incorporates, uses or is derived from Patent [***] (the "**AKERO Manufacturing IP**"), AKERO shall notify (the "**Option Notice**") AMGEN within [***] (such date, the "**Option Date**") and hereby grants to AMGEN, the exclusive option (the "**Option**") to negotiate and enter into an exclusive license to AKERO Manufacturing IP subject to AKERO's retained right and license to use such AKERO Manufacturing IP to Exploit the Product in the Licensed Field in the Territory during the Term. The Option Notice shall include [***]. AMGEN must exercise the Option by providing to AKERO, within the [***] month period immediately following the Option Date, written notice of AMGEN's desire to negotiate and execute an exclusive license agreement, whereupon the

Parties shall negotiate in good faith an exclusive license agreement on commercially reasonable terms. Any exclusive license granted pursuant to this Agreement between AKERO and AMGEN will be an exclusive, sub-licensable (through multiple tiers), transferable, worldwide license to make, use, sell, offer for sale, import and otherwise exploit any products and/or processes under AKERO's rights in such AKERO Manufacturing IP but subject to AKERO's retained right and license to use such AKERO Manufacturing IP to Exploit the Product in the Licensed Field in the Territory during the Term. Any license negotiated under this Section 4.8.1 will be on customary terms consistent with pharmaceutical industry licenses between for-profit entities for commercial development, and shall include, but not be limited to, the following provisions: fees and royalties customary for similar technologies and the stage of development, patent prosecution, infringement, indemnity and termination. If AMGEN timely exercises its Option, the terms of the exclusive license will be negotiated in good faith within [***] of the date such Option is exercised, or within such longer period of time as the Parties may mutually agree in writing. Prior to the expiration of the applicable option period, AKERO will not grant any Person any rights in or to the applicable Manufacturing IP.

4.8.2 In the event such a mutually acceptable exclusive license agreement is not executed within such [***] period, following the date AMGEN exercises the option hereunder, AKERO shall have no further obligation to AMGEN with respect thereto. Further, if the Parties fail to reach agreement on an exclusive license terms during the option period, [***].

ARTICLE 5. OBLIGATIONS OF THE PARTIES

Section 5.1 Responsibility. Following the Effective Date and at all times during the Term (except as expressly stated otherwise herein), AKERO shall be responsible for, and shall bear all costs associated with, the worldwide research, development and commercialization of the Product, including regulatory, manufacturing, distribution, marketing and sales activities. Subject to the express written terms of this Agreement, all decisions concerning the development, marketing and sales of Product including the clinical and regulatory strategy, design, sale, price and promotion of Product covered under this Agreement shall be within the sole discretion of AKERO.

Section 5.2 Diligence. AKERO shall (directly and/or through one or more Affiliates and/or Sublicensees) use Commercially Reasonable Efforts to develop and commercialize the Product. The foregoing shall include use of Commercially Reasonable Efforts with respect to each of the Major Market Territories. AKERO shall notify AMGEN immediately upon obtaining Marketing Approval for the Product in each country.

Section 5.3 Reports. On an annual basis, AKERO shall submit to AMGEN a report providing a status of AKERO's and its Affiliates' and Sublicensees' activities related to the Exploitation of the Product during the preceding [***] month period, and future activities related to the Exploitation of the Product it then-currently expects to initiate during the following [***] month period.

Section 5.4 Product Supply. The Parties shall reasonably cooperate and assist each other in transferring ownership of Product drug product and/or Product drug substance (such material,

collectively, the "**Product Lots**") set forth in **Exhibit A** attached hereto as promptly as reasonably practicable following the Effective Date; ***provided, however***, that neither Party shall be required to pay money to any Third Party, commence any litigation with, or offer or grant any accommodation (financial or otherwise) to any Third Party. Such Product Lots shall be delivered EXW (Ex Works) (Incoterms 2010) AMGEN, Thousand Oaks, California. Any expense for shipment shall be borne by AKERO (including any import or export duties or taxes). Subject to the terms of this Section 5.4 and Section 6.2 (Additional AMGEN Warranties), AMGEN transfers the Product Lots to AKERO "as is", and makes no other representation to AKERO in connection therewith. The Parties have entered into a Quality Agreement substantially in the form attached hereto as **Exhibit F**, dated as of the date hereof, governing the quality of the Product Lots to be supplied pursuant to this Section 5.4. For the avoidance of doubt, Product Lots consisting of drug product as set forth in **Exhibit A** supplied pursuant to this Section 5.4 shall be labeled for their intended clinical use as set forth in **Exhibit A** and the labeling of any Product drug product manufactured after the Effective Date shall be the responsibility of AKERO. Except for the Licensed Materials and such Product Lots to be transferred to AKERO, AKERO shall be responsible for, and shall bear the cost of, obtaining (whether by manufacturing or causing to be manufactured) research, clinical and commercial supplies of the Product. From and after the Effective Date, AKERO shall be responsible for all costs and expenses in connection with the storage of, and any stability studies performed on, the Product Lots.

Section 5.5 Safety Database. Within forty-five (45) days following the Effective Date, AMGEN and AKERO shall initiate the transfer to AKERO of the global safety database for the Product (the "**Safety Database**"). AMGEN and AKERO shall jointly work to complete the transfer of such Safety Database within ninety (90) days of the Effective Date. Prior to the completion of the transfer of the Safety Database, AKERO and AMGEN shall reasonably cooperate and use diligent efforts to ensure compliance with safety reporting requirements related to the Product and AMGEN shall provide safety information to AKERO as AKERO might reasonably request or otherwise as necessary to satisfy AKERO' regulatory or other legal obligations. Following the completion of the transfer of the Safety Database, AKERO shall assume ownership and control of the global Safety Database.

ARTICLE 6.REPRESENTATIONS

Section 6.1 Mutual Warranties. Each of AMGEN and AKERO represent and warrant that:

(a) it is duly organized and validly existing under the Law of the jurisdiction of its incorporation, and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;

(b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the individual executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate action;

(c) it shall comply with all Applicable Law (including Applicable Law relating

to data protection and privacy), Proper Conduct Practices, Anti-Corruption Laws in connection with the performance of its rights, duties and obligations under this Agreement; and

(d) this Agreement is legally binding upon it and enforceable in accordance with its terms. The execution, delivery and performance of this Agreement by it does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material applicable Law.

Section 6.2 Additional AKERO Warranties. AKERO represents and warrants that:

(a) it has not been debarred, excluded or the subject of debarment or exclusion proceedings by any Governmental Authority; and

(b) it has established and maintains reasonable internal policies and controls, including codes of conduct and ethics and reasonable reporting requirements, intended to ensure compliance with Anti-Corruption Laws and other Applicable Law, to the extent applicable to such Party under the laws of the jurisdiction of its incorporation, including healthcare compliance, privacy laws and data protection laws.

Section 6.3 Additional AMGEN Warranties. AMGEN represents and warrants that, as of the Effective Date (except with respect to clause (f) below):

(a) AMGEN Controls the Patent Rights listed on **Exhibit B** and such Licensed Patents are subject to the licenses granted to AKERO pursuant to this Agreement;

(b) AMGEN has the rights necessary to grant the licenses to AKERO to Licensed Know-How set forth on **Exhibit A** that AMGEN grants pursuant to this Agreement;

(c) To AMGEN's knowledge, the Licensed Patents constitute [***] as of the Effective Date [***];

(d) The Patent Rights listed on **Exhibit B** are not subject to any liens or encumbrances and AMGEN has not granted to any Third Party any rights or licenses under such Patent Rights or Licensed Know-How that would conflict with the licenses granted to AKERO hereunder. None of the Licensed Patents is in-licensed by AMGEN. No patent application or registration within the Licensed Patents is the subject of any pending interference, opposition, cancellation or patent protest pursuant to 37 C.F.R. §1.291 unless otherwise noted on **Exhibit B**;

(e) With the exception of Patent [***], AMGEN has no knowledge of any claim or litigation that has been brought or threatened in writing by any Third Party alleging that the Licensed Patents are invalid or unenforceable or that the manufacture, sale, offer for sale, or importation of the Product in the

Licensed Field infringes or misappropriates or would infringe or misappropriate any right of any Third Party; and

(f) All Product Lots provided to AKERO by AMGEN pursuant Section 5.4, as of the date each such Product Lot is provided to AKERO, shall conform to the applicable specifications and, to the extent identified as cGMP materials in **Exhibit A**, shall have been manufactured, packaged, stored and labeled (as applicable) in accordance with cGMP.

Section 6.4 Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS ARTICLE 6 (REPRESENTATIONS), NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, QUALITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT, OR VALIDITY OF PATENT CLAIMS. NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS A REPRESENTATION MADE OR WARRANTY GIVEN BY EITHER PARTY THAT EITHER PARTY WILL BE SUCCESSFUL IN OBTAINING ANY PATENT RIGHTS, OR THAT ANY PATENTS WILL ISSUE BASED ON A PENDING APPLICATION. WITHOUT LIMITING THE RESPECTIVE RIGHTS AND OBLIGATIONS OF THE PARTIES EXPRESSLY SET FORTH HEREIN, EACH PARTY SPECIFICALLY DISCLAIMS ANY GUARANTEE THAT THE PRODUCTS WILL BE SUCCESSFUL, IN WHOLE OR IN PART.

Section 6.5 AKERO Covenants. AKERO covenants to AMGEN that:

(a) it will use its best efforts to comply with (i) all U.S. Laws and the Laws of the country in which such clinical studies are conducted, and (ii) the known or published standards of the FDA and the Regulatory Authority in such country, in each case (clauses (i) and (ii)) in the conduct of all preclinical and clinical studies for the Product and the manufacturing of the Product, and it will use best efforts to cause its contractors to so comply. Neither AKERO, nor any officer, employee or agent of AKERO, will knowingly make an untrue statement of a material fact to any Regulatory Authority with respect to the Product (whether in any submission to such Regulatory Authority or otherwise), and neither will knowingly fail to disclose a material fact required to be disclosed to any Regulatory Authority with respect to the Product;

(b) it will not knowingly employ any personnel or knowingly use a contractor or consultant that has been debarred by the FDA (or subject to a similar sanction of a Regulatory Authority), or that is subject of an FDA debarment investigation or proceeding (or similar proceeding of a Regulatory Authority);

(c) it will not knowingly use in connection with the research, development, manufacture or commercialization to take place pursuant to this Agreement any employee, consultant or investigator that has been

debarred, excluded or the subject of debarment or exclusion proceedings by any Governmental Authority;

(d) it shall promptly provide the other Party with written notice upon receiving a formal notification that it is the target of a formal or informal request for information, subpoena, investigation, litigation, penalty, or claim from any Governmental Authority, or any third party, for violation or potential violation of any applicable Anti-Corruption Law or Proper Conduct Practices;

(e) prior to beginning any development or commercialization of any Product under this Agreement, each of its employees, agents, independent contractors or Affiliates involved in the development or commercialization of any Product shall be required to undergo compliance training with respect to Proper Conduct Practices and Anti-Corruption Laws;

(f) it shall use only legitimate and ethical business practices in connection with activities conducted in connection with this Agreement whether directly, through the use of Representatives or otherwise, and shall not take any action that would subject any other Party to penalties under any Applicable Law;

(g) it shall cause its Affiliates and its and their officers, directors, employees and agents to comply with this Agreement, including the covenants in this Section 6.5;

(h) it shall use its best efforts to comply with all applicable (i) U.S. Laws prohibiting the re-export, directly or indirectly, of certain controlled U.S.-origin items without a license to parties located in certain countries or appearing on certain U.S. Government lists of restricted parties; (ii) U.S. Laws prohibiting participation in non-U.S. boycotts that the United States does not support; (iii) U.S. Laws prohibiting the sale of products to parties from any country subject to U.S. economic sanctions or who are identified on related U.S. Government lists of restricted parties; and (iv) data privacy laws of the applicable jurisdiction, including the national and sub-national laws based on the European Union Data Protection Directive 95/46/EC, and all data breach notification and information securities laws and regulations specific thereto; and

(i) as of the Effective Date to and through the expiration or termination of this Agreement, (i) it, and, to the best of its knowledge, its owners, directors, officers, employees, or any agent, representative, subcontractor or other third party acting for or on such its behalf, shall not, directly or indirectly, offer, pay, promise to pay, or authorize such offer, promise or payment, of anything of value, to any Person for the purposes of obtaining or retaining business through any improper advantage in connection with this Agreement, or that would otherwise violate any applicable Laws, rules and

regulations concerning or relating to public or commercial bribery or corruption, and (ii) that its books, accounts, records and invoices related to this Agreement or related to any work conducted for or on behalf of the other Party are and will be complete and accurate. AMGEN may request from time to time that AKERO complete a compliance certification regarding the foregoing.

ARTICLE 7. INDEMNIFICATION

Section 7.1 Indemnity.

7.1.1 By AMGEN. AMGEN agrees to defend AKERO and its (and its Affiliates') directors, officers, employees and agents (the "**AKERO Indemnified Parties**") at AMGEN's cost and expense, and will indemnify and hold AKERO and the other AKERO Indemnified Parties harmless from and against any claims, losses, costs, damages, fees or expenses (including legal fees and expenses) (collectively, "**Losses**") to the extent resulting from any Third Party claim (including product liability claims) arising out of or otherwise relating to (a) the negligence or willful misconduct of AMGEN or its Affiliates in connection with its activities under this Agreement, (b) the breach of this Agreement or the representations and warranties made hereunder by AMGEN, (c) the death or injury of a person to the extent directly caused by the failure of any Product Lot delivered to AKERO hereunder to be manufactured in compliance with cGMP (to the extent identified as cGMP materials in **Exhibit A**) but excluding any event that could have been avoided or mitigated by the exercise of reasonable or customary care by any AKERO Indemnified Party, its sublicensees or collaborators, the applicable health care professionals or the users of the Product or that results from the storage, processing, handling, transport or maintenance of the Product after delivery or (d) the exercise by AMGEN of rights retained by or conveyed to AMGEN under Sections 2.5 or 9.5.1 after termination of this Agreement; except, in the case of each of (a), (b), (c) and (d) of this Section 7.1.1, to the extent such Losses result from clause (a), (b) or (c) of Section 7.1.2 (By AKERO). In the event of any such claim against the AKERO Indemnified Parties by a Third Party, the foregoing indemnity obligations shall be conditioned upon (x) AKERO promptly notifying AMGEN in writing of the claim (***provided, however,*** that any failure or delay to notify shall not excuse any obligations of AMGEN except to the extent AMGEN is actually prejudiced thereby) and (y) AKERO granting AMGEN sole management and control, at AMGEN's sole expense, of the defense of the claim and its settlement (***provided, however,*** that AMGEN shall not settle any such claim without the prior written consent of AKERO (not to be unreasonably withheld, conditioned or delayed) if such settlement does not include a complete release from liability or if such settlement would involve AKERO undertaking an obligation (including the payment of money by a AKERO Indemnified Party), would bind or impair a AKERO Indemnified Party, or includes any admission of wrongdoing or that any intellectual property or proprietary right of AKERO or this Agreement is invalid, narrowed in scope or unenforceable), and (z) the AKERO Indemnified Parties cooperating with AMGEN (at AMGEN's expense). If, based on the reasonable advice of counsel to the AKERO Indemnified Parties, the AKERO Indemnified Parties have separate defenses from AMGEN or there is a conflict of interest between the AKERO Indemnified Parties

and AMGEN, then the AKERO Indemnified Parties shall be permitted, at their own expense, to retain counsel of its choosing to represent them in such action or proceeding. Any obligation of AMGEN under this Section 7.1.1 with respect to the failure of any Product or Product Lot delivered to AKERO hereunder to be manufactured in compliance with cGMP shall be subject to clause (c) of this Section 7.1.1 and shall not be covered by or subject to clause (a) or (b) of this Section 7.1.1.

7.1.2 By AKERO. AKERO agrees to defend AMGEN and its (and its Affiliates') directors, officers, employees and agents (the "**AMGEN Indemnified Parties**") at AKERO's cost and expense, and will indemnify and hold AMGEN and the other AMGEN Indemnified Parties harmless from and against any Losses to the extent resulting from any Third Party claim (including product liability claims) arising out of or otherwise relating to (a) the negligence or willful misconduct of AKERO, its Affiliates, or their respective Sublicensees in connection with its activities under this Agreement, (b) the breach of this Agreement or the representations, warranties and covenants made hereunder by AKERO, or (c) the Exploitation of the Product by or on behalf of AKERO, its Affiliates, or their respective Sublicensees (including from product liability and intellectual property infringement claims); except, in each case, to the extent such Losses result from clause (a), (b), (c) or (d) of Section 7.1 (By AMGEN). In the event of any such claim against the AMGEN Indemnified Parties by a Third Party, the foregoing indemnity obligations shall be conditioned upon (x) AMGEN promptly notifying AKERO in writing of the claim (***provided, however,*** that any failure or delay to notify shall not excuse any obligation of AKERO except to the extent AKERO is actually prejudiced thereby) and (y) AMGEN granting AKERO sole management and control, at AKERO's sole expense, the defense of the claim and its settlement (***provided, however,*** that AKERO shall not settle any such claim without the prior written consent of AMGEN if such settlement does not include a complete release from liability or if such settlement would involve undertaking an obligation (including the payment of money by an AMGEN Indemnified Party), would bind or impair an AMGEN Indemnified Party, or includes any admission of wrongdoing or that any intellectual property or proprietary right of AMGEN or this Agreement is invalid, narrowed in scope or unenforceable), and (z) the AMGEN Indemnified Parties cooperating with AKERO (at AKERO's expense). If, based on the reasonable advice of counsel to the AMGEN Indemnified Parties, the AMGEN Indemnified Parties have separate defenses from AKERO or there is a conflict of interest between the AMGEN Indemnified Parties and AKERO, then the AMGEN Indemnified Parties shall be permitted, at their own expense, to retain counsel of its choosing to represent them in such action or proceeding.

Section 7.2 LIMITATION OF DAMAGES. IN NO EVENT SHALL EITHER PARTY BE LIABLE HEREUNDER TO THE OTHER PARTY FOR ANY PUNITIVE, INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING LOST REVENUE, LOST PROFITS, OR LOST SAVINGS) HOWEVER CAUSED AND UNDER ANY THEORY, EVEN IF IT HAS NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. THE LIMITATIONS SET FORTH IN THIS SECTION 7.2 SHALL NOT APPLY WITH RESPECT TO (A) ANY BREACH OF ARTICLE 8 (CONFIDENTIALITY) OR (B) THE INTENTIONAL MISCONDUCT OR GROSS NEGLIGENCE OF A PARTY. NOTHING IN THIS SECTION 7.2 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION

RIGHTS OR OBLIGATIONS OF A PARTY UNDER THIS ARTICLE 7 (INDEMNIFICATION) WITH RESPECT TO ANY DAMAGES PAID BY THE OTHER PARTY TO A THIRD PARTY IN CONNECTION WITH A THIRD-PARTY CLAIM.

Section 7.3 Insurance. At least [***] days prior to the Initiation of any clinical trial by or on behalf of AKERO or its Affiliates, AKERO shall at its own expense procure and maintain during the Term (and for [***] years thereafter) clinical trial liability insurance coverage adequate to cover its obligations hereunder and which is/are consistent with normal business practices of prudent pharmaceutical companies. Additionally, at least [***] days prior to First Commercial Sale, AKERO shall at its own expense procure and maintain during the Term (and for [***] years thereafter) product liability insurance coverage adequate to cover its obligations hereunder and which is consistent with normal business practices of prudent pharmaceutical companies. Each insurance policy required by and procured by AKERO under this Section 7.3 shall name AMGEN as an additional insured. Such insurance shall not be construed to create a limit of AKERO's liability with respect to its indemnification obligations under this Article 7 (Indemnification). AKERO shall provide AMGEN with a certificate of insurance or other evidence of such insurance, upon request. AKERO shall provide AMGEN with written notice at least thirty (30) days prior to the cancellation, non-renewal or a material change in such insurance which materially adversely affects the rights of AMGEN hereunder, and ten (10) days prior written notice of cancellation for non-payment of premiums. AKERO's insurance hereunder shall be primary with respect to the obligations for which AKERO is liable hereunder.

ARTICLE 8. CONFIDENTIALITY

Section 8.1 Confidential Information.

8.1.1 Confidential Information. Each Party ("**Disclosing Party**") may disclose to the other Party ("**Receiving Party**"), and Receiving Party may acquire during the course and conduct of activities under this Agreement, certain proprietary or confidential information of Disclosing Party in connection with this Agreement. The term "**Confidential Information**" will mean all information of any kind, whether in written, oral, graphical, machine-readable or other form, whether or not marked as confidential or proprietary, which are transferred, disclosed or made available by Disclosing Party or at the request of Receiving Party, including any of the foregoing of Third Parties.

8.1.2 Restrictions. During the Term and for [***] years thereafter, Receiving Party will keep all Disclosing Party's Confidential Information in confidence with the same degree of care with which Receiving Party holds its own confidential information (but in no event less than a commercially reasonable degree of care). Receiving Party will not use Disclosing Party's Confidential Information except in connection with the performance of its obligations and exercise of its rights under this Agreement. Receiving Party has the right to disclose Disclosing Party's Confidential Information without Disclosing Party's prior written consent, to the extent and only to the extent reasonably necessary, to Receiving Party's Affiliates and their employees, subcontractors, consultants or agents who have a need to know such Confidential Information in order to perform its obligations and exercise its rights under this

Agreement and who are required to comply with the restrictions on use and disclosure in this Section 8.1.2. Receiving Party will use diligent efforts to cause those entities and persons to comply with the restrictions on use and disclosure in this Section 8.1.2. Receiving Party assumes responsibility for those entities and persons maintaining Disclosing Party's Confidential Information in confidence and using same only for the purposes described herein.

8.1.3 **Exceptions.** Receiving Party's obligation of nondisclosure and the limitations upon the right to use the Disclosing Party's Confidential Information will not apply to the extent that Receiving Party can demonstrate that the Disclosing Party's Confidential Information: (a) was known to Receiving Party or any of its Affiliates prior to the time of disclosure; (b) is or becomes public knowledge through no fault or omission of Receiving Party or any of its Affiliates; (c) is obtained by Receiving Party or any of its Affiliates from a Third Party under no obligation of confidentiality to Disclosing Party; or (d) has been independently developed by employees, subcontractors, consultants or agents of Receiving Party or any of its Affiliates without the use of Disclosing Party's Confidential Information, as evidenced by contemporaneous written records.

8.1.4 **Permitted Disclosures.** Receiving Party may disclose Disclosing Party's Confidential Information to the extent (and only to the extent) such disclosure is reasonably necessary in the following instances:

(a) in order to comply with applicable law (including any securities law or regulation or the rules of a securities exchange) or with a legal or administrative proceeding;

(b) in connection with prosecuting or defending litigation, Marketing Approvals and other Regulatory Filings and communications, and filing, prosecuting and enforcing Patents in connection with Receiving Party's rights and obligations pursuant to this Agreement; and

(c) in connection with exercising its rights hereunder, to its Affiliates; potential and future collaborators (including Sublicensees where AKERO is the Receiving Party); potential and permitted acquirers or assignees; and potential investment bankers, investors and lenders;

provided, however, that (1) with respect to Sections 8.1.4(a) or 8.1.4(b) (other than Marketing Approvals and other Regulatory Filings and communications), where reasonably possible, Receiving Party will notify Disclosing Party of Receiving Party's intent to make any disclosure pursuant thereto sufficiently prior to making such disclosure so as to allow Disclosing Party adequate time to take whatever action it may deem appropriate to protect the confidentiality of the information to be disclosed, and (2) with respect to Section 8.1.4(c), each of those named people and entities are required to comply with the restrictions on use and disclosure in Section 8.1.2 (Restrictions) (other than investment bankers, investors and lenders, which must be bound prior to disclosure by

commercially reasonable obligations of confidentiality).

Section 8.2 Terms of this Agreement; Publicity.

8.2.1 Restrictions. The Parties agree that the terms of this Agreement will be treated as Confidential Information of both Parties, and thus may be disclosed only as permitted by Section 8.1.4 (Permitted Disclosures). Except as required by Law, each Party agrees not to issue any press release or public statement disclosing information relating to this Agreement or the transactions contemplated hereby or the terms hereof without the prior written consent of the other Party not to be unreasonably withheld (or as such consent may need to be obtained in accordance with Section 8.2.2 (Review) or Section 8.3.1 (Right to Publish)).

8.2.2 Review. In the event either Party (the "**Issuing Party**") desires to issue a press release or other public statement disclosing information relating to this Agreement or the transactions contemplated hereby or the terms hereof, the Issuing Party will provide the other Party (the "**Reviewing Party**") with a copy of the proposed press release or public statement (the "**Release**"). The Issuing Party will specify with each such Release, taking into account the urgency of the matter being disclosed, a reasonable period of time within which the Receiving Party may provide any comments on such Release (but in no event less than five (5) business days). If the Receiving Party provides any comments, the Parties will consult on such Release and work in good faith to prepare a mutually acceptable Release. Either Party may subsequently publicly disclose any information previously contained in any Release, provided that the other Party provided its written consent hereto as stated in Section 8.2.1 (Restrictions). For the avoidance of doubt (and notwithstanding anything contained in this Agreement to the contrary), AKERO, in its sole discretion, may make disclosures relating to the development or commercialization of the Product, including the results of research and any clinical trial conducted by AKERO or any health or safety matter related to the Product.

Section 8.3 Publications.

8.3.1 Right to Publish. Subject to the provisions of Sections 8.1 (Confidential Information), 8.2 (Terms of this Agreement; Publicity), 8.3.2 (Review) and 8.3.3 (Amgen Publications), AKERO shall have the right to publish with respect to Products in publications, and to make scientific presentations on Products. Neither Party shall publish the sequence of the Product or information concerning the manufacture of the Product without the prior written consent of the other Party.

8.3.2 Review. Except as required by Law or court order, for any proposed publication or presentation regarding the Product, AKERO: (a) shall transmit a copy of the proposed publication for review and comment to AMGEN at least [***] days prior to the submission of such publication to a Third Party; (b) shall postpone such publication for up to an additional [***] days upon request of AMGEN (or its applicable licensee) to allow the consideration of appropriate patent applications or other protection to be filed; (c) upon request of AMGEN (or its applicable licensee) shall remove all Confidential Information of AMGEN (or its applicable licensee) (excluding, for clarity, anything permitted to be disclosed by AKERO pursuant to the last sentence of Section 8.2.2 (Review)); and (d) shall consider all reasonable

comments made by AMGEN (or its applicable licensee). Authorship by AKERO of any publication arising from the Agreement will be undertaken in accordance with the International Committee of Medical Journal Editors (ICMJE) guidelines for authorship. Consistent with those guidelines, authorship will be based upon substantial contribution to the design, analysis, interpretation of data, drafting and/or critically revising any publication(s) derived from the Agreement, and authors must engage in the drafting of the publication or revise it critically for important intellectual content. AKERO agrees to maintain evidence of its compliance with the ICMJE guidelines for authorship, and that it will provide such evidence to AMGEN upon request.

Section 8.4 Relationship to the Confidentiality Agreement. This Agreement supersedes that certain Confidential Disclosure Agreement between the Parties dated March 9, 2017, as amended by Amendment Number 1 to Confidential Disclosure Agreement Number [***] dated March 14, 2017; ***provided, however,*** that all "Confidential Information" disclosed or received by the Parties thereunder will be deemed "Confidential Information" hereunder and will be subject to the terms and conditions of this Agreement.

Section 8.5 Attorney-Client Privilege. Neither Party is waiving, nor will be deemed to have waived or diminished, any of its attorney work product protections, attorney-client privileges or similar protections and privileges recognized under the applicable Law of any jurisdiction as a result of disclosing information pursuant to this Agreement, or any of its Confidential Information (including Confidential Information related to pending or threatened litigation) to the receiving Party, regardless of whether the disclosing Party has asserted, or is or may be entitled to assert, such privileges and protections. The Parties may become joint defendants in proceedings to which the information covered by such protections and privileges relates and may determine that they share a common legal interest in disclosure between them that is subject to such privileges and protections, and in such event, may enter into a joint defense agreement setting forth, among other things, the foregoing principles but are not obligated to do so.

ARTICLE 9. TERM AND TERMINATION

Section 9.1 Term. The term of this Agreement (the "**Term**") shall commence on the Effective Date, and unless terminated earlier as provided in this Article 9 (Term and Termination), shall continue in full force and effect until expiration of the last-to-expire Royalty Term for the Product in the Territory. Upon expiration of this Agreement, the licenses granted to AKERO by AMGEN under this Agreement to Exploit the Product shall be fully paid-up, irrevocable and non-exclusive.

Section 9.2 Termination by AMGEN.

9.2.1 Breach.

(a) AMGEN shall have the right to terminate this Agreement in full in the event AKERO shall have materially breached or defaulted in the performance of any of its obligations hereunder or the Designated Investment Document Terms and such breach or default shall have continued for [***] days after written notice thereof is provided to AKERO by AMGEN, such notice describing the alleged material breach in sufficient detail to put AKERO on notice. The

foregoing [***] day cure period shall be shortened to [***] days for breaches that consist of a failure to pay amounts as and when due hereunder. Any termination of this Agreement under this Section 9.2.1 shall become effective at the end of the applicable cure period, unless AKERO has cured such breach or default prior to the expiration of such cure period, or, if such breach or default is not susceptible to cure within such cure period, such termination shall be effective upon such written notice of such breach or default from AMGEN.

(b) If AKERO disputes in good faith the existence or materiality of a breach specified in a notice provided by AMGEN to AKERO pursuant to Section 9.2.1(a), and AKERO provides notice to AMGEN of such dispute within the applicable cure period, AKERO may require the CEO Delegates to meet and confer in good faith to resolve such breach condition and AMGEN shall not have the right to terminate this Agreement until [***] days following such notice. The CEO Delegates of the Parties shall, as soon as reasonably practicable, after AKERO's notice of such dispute, meet and confer in good faith regarding such dispute at such time and place as mutually agreed upon by the Parties. It is understood and acknowledged that during the pendency of such a dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder.

9.2.2 **Termination for IP Challenge.** AMGEN will have the right to terminate this Agreement in full upon written notice to AKERO in the event AMGEN discovers or receives notice that AKERO or any of its Affiliates or Sublicensees directly challenged in a legal or administrative proceeding the patentability, enforceability or validity of any Licensed Patents; provided, however, that AMGEN will not have the right to terminate this Agreement under this Section 9.2.1(a) if (a) for any such challenge by any Sublicensee, AKERO terminates such Sublicense within sixty (60) days of AMGEN's notice to AKERO under this Section 9.2.1(a) or (b) such challenge is dismissed within [***] days of AMGEN's notice to AKERO under this Section 9.2.1(a) and not thereafter continued.

Section 9.3 Termination by AKERO.

9.3.1 **Breach.**

(a) AKERO shall have the right to terminate this Agreement in full in the event AMGEN shall have materially breached or defaulted in the performance of any of its obligations hereunder and such breach or default shall have continued for [***] days after written notice thereof is provided to AMGEN by AKERO, such notice describing the alleged material breach in sufficient detail to put AMGEN on notice. The foregoing [***] day cure period shall be shortened to [***] days for breaches that consist of a failure to pay amounts as and when due hereunder. Any termination of this Agreement under this Section 9.3.1 shall become effective at the end of the applicable cure period, unless AMGEN has cured such breach or default prior to the expiration of such cure period, or, if such breach or default is not susceptible to cure within such cure period, such termination shall be effective upon such written notice of such breach or default from AKERO.

(b) If AMGEN disputes in good faith the existence or materiality of a breach specified in a notice provided by AKERO to AMGEN pursuant to Section 9.3.1(a), and AMGEN provides notice to AKERO of such dispute within the applicable cure period, AMGEN may require the CEO Delegates to meet and confer in good faith to resolve such breach condition and AKERO shall not have the right to terminate this Agreement until [***] days following such notice. The CEO Delegates of the Parties shall, as soon as reasonably practicable after AMGEN's notice of such dispute, meet and confer in good faith regarding such dispute at such time and place as mutually agreed upon by such Parties. It is understood and acknowledged that during the pendency of such a dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder.

9.3.2 Discretionary Termination. AKERO will have the right to terminate this Agreement in full [***] days after delivery of written notice to AMGEN thereof if AKERO concludes due to scientific, technical, regulatory or commercial reasons, including (a) safety or efficacy concerns, including adverse events of the Product, (b) concerns relating to the present or future marketability or profitability of the Product, (c) reasons related to patent coverage or (d) existing and anticipated competition, renders the Exploitation of the Product no longer commercially practicable for AKERO. Following any such notice of termination, AKERO shall have no further obligation pursuant to Section 5.2 (Diligence) to further Exploit any Product, however, AKERO shall use its reasonable efforts to facilitate a smooth, orderly and prompt transition of any of the Product Controlled by AKERO prior to the effective date of termination of this Agreement from AKERO to AMGEN.

Section 9.4 Termination Upon Bankruptcy. Either Party may terminate this Agreement if, at any time, the other Party shall (a) file in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of that Party or of its assets, (b) propose a written agreement of composition or extension of its debts, (c) be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition has not been dismissed within sixty (60) days after the filing thereof, (d) propose or be a party to any dissolution or liquidation, (e) make an assignment for the benefit of its creditors or (f) admit in writing its inability generally to meet its obligations as they fall due in the general course.

Section 9.5 Effects of Termination. Upon termination by either Party under Section 9.2 (Termination by AMGEN), Section 9.3 (Termination by AKERO) or Section 9.4 (Termination Upon Bankruptcy):

(a) AKERO will responsibly wind-down, in accordance with accepted pharmaceutical industry norms and ethical practices and all legal and regulatory requirements, any on-going clinical studies for which it has responsibility hereunder in which patient dosing has commenced or, if reasonably practicable and not adverse to patient safety and requested by AMGEN, AKERO shall complete such trials and AMGEN shall reimburse AKERO its reasonable, out-of-pocket costs and internal labor costs at the FTE Rate associated therewith. For the purpose of clarity, except as

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provided for above, AKERO may wind-down any ongoing clinical trials prior to the date of termination in accordance with accepted pharmaceutical industry norms and ethical practices and AKERO will be responsible for any costs associated with such wind-down.

(b) A termination of this Agreement will automatically terminate any sublicense granted by AKERO pursuant to Section 2.1 (Sublicenses) unless AMGEN has explicitly approved survival of such sublicense in writing, in which case all rights under such sublicense shall be deemed to survive termination as long as Sublicensee complies with its obligations thereunder, and provided that in no event will AMGEN be obligated to fulfill any of AKERO's obligations under such sublicense.

(c) All rights and licenses granted by AMGEN to AKERO in Article 2 (License Grant) will terminate, and AKERO and its Affiliates, and (subject to Section 9.5(b)) Sublicensees will cease all use of Licensed Know-How and Licensed Patents and all Exploitation of any Product, except to the extent required hereunder.

(d) Upon AMGEN's request, all Marketing Approvals and other Regulatory Filings and communications owned (in whole or in part) or otherwise controlled by AKERO and its Affiliates, and (subject to Section 9.5(b)) Sublicensees, and all other documents relating to or necessary to further Exploit the Product, as such items exist as of the effective date of such termination (including all documents related to completed and ongoing clinical studies) will be assigned to AMGEN to the extent practicable (or, if not so assigned, AKERO shall make the benefit of the foregoing reasonably available to AMGEN), and AKERO will provide to AMGEN one (1) copy of the foregoing and all documents contained in or referenced in any such items, together with the raw and summarized data for any clinical studies (and where reasonably available, electronic copies thereof). All expenses in relation to such assignment will be borne by AMGEN. In the event of any failure to obtain assignment, AKERO hereby consents and grants to AMGEN the right to access and reference (without any further action required on the part of AKERO, whose authorization to file this consent with any Regulatory Authority is hereby granted) any such item.

(e) AKEROS, on behalf of itself and its Affiliates, agrees to grant to AMGEN and its Affiliates, at AMGEN's request, a perpetual and irrevocable non-exclusive, royalty-free, sub-licensable (through multiple tiers) license to AKEROS Patent Rights solely to Exploit the Product (solely as such AKEROS Patent Rights and Product exist on the effective date of termination) in the Licensed Field in the Territory (but, for clarity, not including any other products other than the Product as it exists on the effective date of termination). For purposes of this Section 9.5(e),

"**AKEROS Patent Rights**" means a [***]. Notwithstanding the foregoing, other than in conjunction with a termination by AKEROS pursuant to Section 9.3.2 (Discretionary Termination), the Parties agree that in conjunction with any license granted under this Section 9.5(e), they will [***] enter into a customary license agreement pursuant to which AMGEN would pay AKEROS a royalty of (i) [***] of net sales or (ii) in the event that AKEROS has obtained Marketing Approval for the Product, [***] of net sales. AKEROS agrees (and shall cause its Affiliates to so agree) to reasonably cooperate with AMGEN and its designee(s) to facilitate a smooth, orderly and prompt transition of the Exploitation of the Product in the Territory to AMGEN and/or its designee(s) in accordance with a transition plan to be reasonably agreed to by the Parties.

AKERO shall duly execute and deliver, or cause to be duly executed and delivered, such instruments and shall do and cause to be done such activities and things, including the filings of such assignments, agreements, documents and instruments, as may be reasonably necessary under, or as AMGEN may reasonably request in connection with, AMGEN's rights under this Section 9.5 .

Section 9.6 Survival. In addition to the termination consequences set forth in Section 9.5 (Effects of Termination), the following provisions will survive termination or expiration of this Agreement: Articles 1 (Definitions), 3 (Fees, Royalties and Payments) (with respect to sales made before such expiration or termination and with respect to Milestone Events achieved prior to the expiration or date of notice of termination), 7 (Indemnification), 8 (Confidentiality) and 10 (Miscellaneous) and Sections 2.4 (Limited Grant), 4.3 (Enforcement) through 4.5 (Recovery) (inclusive) (with respect to any action initiated prior to such expiration or termination), 6.3 (Disclaimer) and 9.5 (Effects of Termination), and this Section 9.6. Termination or expiration of this Agreement are neither Party's exclusive remedy and will not relieve the Parties of any liability or obligation which accrued hereunder prior to the effective date of such termination or expiration nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement nor prejudice either Party's right to obtain performance of any obligation. All other rights and obligations will terminate upon expiration of this Agreement.

ARTICLE 10. MISCELLANEOUS

Section 10.1 Entire Agreement; Amendment. This Agreement and all Exhibits attached to this Agreement and the Investment Documents constitute the entire agreement between the Parties as to the subject matter hereof. All prior and contemporaneous negotiations, representations, warranties, agreements, statements, promises and understandings with respect to the subject matter of this Agreement are hereby superseded and merged into, extinguished by and completely expressed by this Agreement. None of the Parties shall be bound by or charged with any written or oral agreements, representations, warranties, statements, promises or

understandings not specifically set forth in this Agreement. No amendment, supplement or other modification to any provision of this Agreement shall be binding unless in writing and signed by all Parties.

Section 10.2 Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to any section of this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(35A) of the U.S. Bankruptcy Code to the extent permitted thereunder. The Parties shall retain and may fully exercise all of their respective rights and elections under the U.S. Bankruptcy Code. Upon the bankruptcy of any Party, the non-bankrupt Party shall further be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property, and such, if not already in its possession, shall be promptly delivered to the non-bankrupt Party, unless the bankrupt Party elects to continue, and continues, to perform all of its obligations under this Agreement.

Section 10.3 Independent Contractors. The relationship between AKERO and AMGEN created by this Agreement is solely that of independent contractors. This Agreement does not create any agency, distributorship, employee-employer, partnership, joint venture or similar business relationship between the Parties. Neither Party is a legal representative of the other Party, and neither Party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever. Each Party shall use its own discretion and shall have complete and authoritative control over its employees and the details of performing its obligations under this Agreement.

Section 10.4 Governing Law; Jurisdiction. This Agreement and its effect are subject to and shall be construed and enforced in accordance with the law of the State of New York, without regard to its conflicts of laws, except as to any issue which depends upon the validity, scope or enforceability of any Licensed Patent, which issue shall be determined in accordance with the laws of the country in which such patent was issued. Each of the Parties hereby irrevocably and unconditionally consents to submit to the exclusive jurisdiction of the courts of the State of New York for any matter arising out of or relating to this Agreement and the transactions contemplated hereby, and agrees not to commence any litigation relating thereto except in such courts. Each of the Parties hereby irrevocably and unconditionally waives any objection to the laying of venue of any matter arising out of this Agreement or the transactions contemplated hereby in the courts of the State of New York and hereby further irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such matter brought in any such court has been brought in an inconvenient forum. The Parties agree that a final judgment in any such matter shall be conclusive and may be enforced in other jurisdictions by suits on the judgment or in any other manner provided by law. Any proceeding brought by either Party under this Agreement shall be exclusively conducted in the English language.

Section 10.5 Notice. All notices or communication required or permitted to be given by either Party hereunder shall be deemed sufficiently given if mailed by registered mail or certified mail, return receipt requested, or sent by overnight courier, such as Federal Express, to the other Party at its respective address set forth below or to such other address as one Party shall give notice of to the other from time to time hereunder. Mailed notices shall be deemed to be received on the

third (3rd) business day following the date of mailing. Notices sent by overnight courier shall be deemed received the following business day.

If to AKERO:	Akero Therapeutics, Inc. 230 Park Avenue, Suite 2800 New York, New York 10169 Attn: Jonathan M. Young, President and CEO
With copies to:	***via email***: Akero Therapeutics, Inc. Attn: [***]
And:	Goodwin Procter LLP 100 Northern Avenue Boston, MA 02210 Attn: Christopher Denn
If to AMGEN:	Amgen Inc. One Amgen Center Drive Thousand Oaks, CA 91320 Attn: Corporate Secretary

Section 10.6 Compliance with Law; Severability. Nothing in this Agreement shall be construed to require the commission of any act contrary to Law. If any one or more provisions of this Agreement is held to be invalid, illegal or unenforceable, the affected provisions of this Agreement shall be curtailed and limited only to the extent necessary to bring it within the applicable legal requirements and the validity, legality and enforceability of the remaining provisions of this Agreement shall not in any way be affected or impaired thereby.

Section 10.7 Non-Use of Names. AMGEN shall not use the name, trademark, logo, or physical likeness of AKERO or any of its officers, directors or employees, or any adaptation of any of them, in any advertising, promotional or sales literature, without AKERO's prior written consent. AMGEN shall require its Affiliates to comply with the foregoing. AKERO shall not use the name, trademark, logo, or physical likeness of AMGEN or any of its officers, directors or employees, or any adaptation of any of them, in any advertising, promotional or sales literature, without AMGEN's prior written consent. AKERO shall require its Affiliates and Sublicensees to comply with the foregoing in connection with each such Sublicensee's sublicense.

Section 10.8 Successors and Assigns. Neither this Agreement nor any of the rights or obligations created herein may be assigned by either Party, in whole or in part, without the prior written consent of the other Party, not to be unreasonably withheld or delayed except that either Party shall be free to assign this Agreement (a) to an Affiliate of such Party (for so long as such Affiliate remains an Affiliate) provided that such Party shall remain liable and responsible to the other Party for the performance and observance of all such duties and obligations by such Affiliate, or (b) in connection with any merger, consolidation or sale of such Party or sale of all

or substantially all of the assets of the Party that relate to this Agreement, without the prior consent of the non-assigning Party. This Agreement shall bind and inure to the benefit of the successors and permitted assigns of the Parties hereto. Any assignment of this Agreement in contravention of this Section 10.8 shall be null and void.

Section 10.9 Waivers. A Party's consent to or waiver, express or implied, of any other Party's breach of its obligations hereunder shall not be deemed to be or construed as a consent to or waiver of any other breach of the same or any other obligations of such breaching Party. A Party's failure to complain of any act, or failure to act, by the other Party, to declare the other Party in default, to insist upon the strict performance of any obligation or condition of this Agreement or to exercise any right or remedy consequent upon a breach thereof, no matter how long such failure continues, shall not constitute a waiver by such Party of its rights hereunder, of any such breach, or of any other obligation or condition. A Party's consent in any one instance shall not limit or waive the necessity to obtain such Party's consent in any future instance and in any event no consent or waiver shall be effective for any purpose hereunder unless such consent or waiver is in writing and signed by the Party granting such consent or waiver.

Section 10.10 No Third Party Beneficiaries. Except as expressly provided with respect to AMGEN Indemnified Parties and AKERO Indemnified Parties in Article 9 (Indemnification) and AMGEN's licensees, nothing in this Agreement shall be construed as giving any Person, other than the Parties hereto and their successors and permitted assigns, any right, remedy or claim under or in respect of this Agreement or any provision hereof.

Section 10.11 Headings; Exhibits. Article and Section headings used herein are for convenient reference only, and are not a part of this Agreement. All Exhibits are incorporated herein by this reference.

Section 10.12 Interpretation. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense (and/or). The term "including" (or cognates thereof) as used herein shall mean including (or the cognate thereof), without limiting the generality of any description preceding such term. The term "will" as used herein means "shall." All references to a "business day" or "business days" in this Agreement means any day other than a day which is a Saturday, a Sunday or any day banks are authorized or required to be closed in the United States. The language in all parts of this Agreement shall be deemed to be the language mutually chosen by the Parties. The Parties and their counsel have cooperated in the drafting and preparation of this Agreement, and this Agreement therefore shall not be construed against any Party by virtue of its role as the drafter thereof.

Section 10.13 Equitable Relief. Each Party acknowledges that a breach by it of the provisions of this Agreement may not reasonably or adequately be compensated in damages in an action at law and that such a breach may cause the other Party irreparable injury and damage. By reason thereof, each Party agrees that the other Party is entitled to seek, in addition to any other remedies it may have under this Agreement or otherwise, preliminary and permanent injunctive and other equitable relief to prevent or curtail any breach of this Agreement by the other Party and is otherwise entitled to specific performance of the terms hereof; ***provided, however***, that no specification in this Agreement of a specific legal or equitable remedy will be construed as a

waiver or prohibition against the pursuing of other legal or equitable remedies in the event of such a breach.

Section 10.14 Force Majeure. Neither Party shall be held liable or responsible to the other Party, nor be deemed to have defaulted under or breached this Agreement, for failure or delay in fulfilling or performing any term of this Agreement to the extent, and for so long as, such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, including fire, floods, embargoes, power shortage or failure, acts of war (whether war be declared or not), insurrections, riots, terrorism, civil commotions, strikes, lockouts or other labor disturbances, acts of God, or any acts, omissions, or delays in acting by any governmental authority or the other Party; ***provided, however,*** that the affected Party promptly notifies the other Party in writing (and continues to provide monthly status updates to the other Party for the duration of the effect); and ***provided further, however,*** that the affected Party shall use its commercially reasonable efforts to avoid or remove such causes of non-performance and to mitigate the effect of such occurrence, and shall continue performance with reasonable dispatch whenever such causes are removed.

Section 10.15 Further Assurances. Each Party shall execute, acknowledge, and deliver such further instructions, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

Section 10.16 Counterparts. This Agreement may be executed in counterparts by a single Party, each of which when taken together shall constitute one and the same agreement, and may be executed through the use of facsimiles or .pdf or other electronically transmitted documents.

[*Signature page follows*]

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IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first set forth above.

AKERO THERAPEUTICS, INC.	AMGEN INC.
By: /s/ Jonathan Young	By: /s/ Sean E. Harper
Name: Jonathan Young	Name: Sean E. Harper
Title: President	Title: EVP, Research & Development

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EXHIBIT A
LICENSED KNOW-HOW

Amgen to use commercially reasonable efforts to provide documents and/or Know-How within [***] following the Effective Date, as indicated below.

Note: References to certain Amgen proprietary information and personal information redacted from documents.

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EXHIBIT B

LICENSED PATENTS

Country	Current Status	Filing Date	Filing Number	Grant Date	Grant Number	Amgen Reference No.
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EXHIBIT D

PRODUCT SEQUENCE

[***]

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EXHIBIT E

QUALITY AGREEMENT

(*attached.*)

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EXHIBIT E

QUALITY AGREEMENT

Between

AKERO THERAPEUTICS, INC. ("AKERO")

and

Amgen Inc. ("Amgen" and together, the "Parties")

The Parties have entered into that certain Exclusive License Agreement, dated as of June 7, 2018, with respect to the grant by AMGEN to AKERO of a license to, among other things, commercially develop, manufacture, use and distribute a molecule known as AMG 876. This Quality Agreement is intended by the Parties to set forth a plan for the quality assurance groups of AMGEN and AKERO in connection with the license of AMG 876. By signing below, the respective quality assurance representatives acknowledge and agree to the provisions of this Quality Agreement.

	Agreed and accepted for		**Agreed and accepted for**
	AKERO Therapeutics, Inc.		**Amgen Inc.**
By:	/s/ Jonathan Young	By:	/s/ Paul Mowad
Name:	Jonathan Young	Name:	Paul Mowad
Title:	President	Title:	Director, Quality
Date:	June 7,2018	Date:	June 7, 2018

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This QUALITY AGREEMENT (this "Quality Agreement") effective as of June 7, 2018 ("Effective Date") is entered into by and between AKERO Therapeutics, Inc., a Delaware corporation having an address at 271 Waverly Oaks, Suite 104, Waltham, Massachusetts 02452 ("AKERO") and Amgen Inc., a Delaware corporation, located at One Amgen Center Drive, Thousand Oaks, California 91320-1799 ("AMGEN"). AKERO and AMGEN may each be singularly referred to as a "Party" or, collectively, as the "Parties".

1. BACKGROUND INFORMATION

1.1 AMGEN and AKERO have entered into that certain Exclusive License Agreement, dated as of June 7, 2018, as may be amended or restated from time to time (the "License Agreement"), with respect to, among other things, the grant by AMGEN to AKERO of a license to, among other things, commercially develop, manufacture, use and distribute the Product (as defined below), which contains or comprises the compound known as AMG 876.

1.2 This Quality Agreement defines the quality obligations and responsibilities of the Parties and their respective affiliates or approved contractors with respect to the license to AKERO in accordance with the License Agreement and the quality aspects of the Product.

2. SCOPE

2.1 The provisions of this Quality Agreement are incorporated as part of the provisions of the License Agreement, and this Quality Agreement is entered into in accordance with Section 5.4.1. of the License Agreement. The terms of the License Agreement shall remain in full force and effect. In the event of any conflict between the License Agreement and this Quality Agreement, the License Agreement shall control.

2.2 This Quality Agreement may be amended only by mutual written agreement of the Parties.

2.3 Attachments are part of this Quality Agreement. If an Attachment conflicts with the body of this Quality Agreement, the body of this Quality Agreement shall control. Attachments to this Quality Agreement are intended to provide additional definition to the applicable topic and, as such, should be updated to reflect the current information and business process, as applicable. Amendment of the Attachments does not require re-approval of this Quality Agreement unless this Quality Agreement itself is affected. Attachments and all amendments of Attachments shall be approved by mutual written agreement of the Parties.

2.4 All activities under this Quality Agreement shall be performed in compliance with applicable cGMP regulations.

2.5 This Quality Agreement shall expire upon termination, cancellation, or expiration, as the case may be, of the License Agreement, or the earlier mutual written agreement of the Parties.

2.6 Approval of this Quality Agreement supersedes any and all prior quality agreements between AKERO and Amgen as it relates to the Product.

3. DEFINITIONS

3.1 All capitalized terms not otherwise defined in this Quality Agreement shall have the meaning ascribed to them in the License Agreement.

3.2 As used in this Quality Agreement, the following terms shall have the meanings set forth in this Article. Any terms defined elsewhere in this Quality Agreement shall be given equal weight and importance as though set forth in this Article.

Term	Definition
Batch Record	A single unexecuted or executed record or a compilation of all executed records, forms, and supporting documents related to the manufacture of a specific batch of product.
Certificate of Analysis (CoA)	An approved record for a given batch containing the analytical test results required by the Specifications for the product or material.
Certificate of Compliance (CoC)	Certificate including a statement of compliance with all applicable laws and regulations, including, without limitation, cGMP for a specific product batch and may contain the usage decision.
cGMP	All applicable standards relating to current good manufacturing practices for fine chemicals, intermediates, bulk products and/or finished pharmaceutical drugs, including (a) all applicable requirements detailed in the FDA's current Good Manufacturing Practices regulations, 21 C.F.R. Parts 210 and 211, (b) all applicable requirements detailed in the European Medicine Agency's (EMA)"EU guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use," and (c) all applicable Laws promulgated by any Governmental Authority having jurisdiction over the manufacture of the applicable compound or pharmaceutical drug product, as applicable.
Complaint (Product complaint) Potency, Purity, Strength	Any written, electronic or verbal communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of a drug, its labeling or packaging, or device after release for distribution.
Deviation/ Nonconformance	The term "Deviation/Nonconformance" shall mean a departure from an approved instruction or established standard or operating procedure incurred during the manufacture, packaging, testing, or storage of the Product prior to delivery to AKERO, which were determined by AMGEN procedures to potentially impact the quality, potency, purity, identity, strength, efficacy, or safety of the Product. The terms Deviation or Nonconformance can be used interchangeably.
Drug Product (DP)	The term used when referring to both intermediate and final drug products, that contain an active ingredient, labeled and packaged. The dosage form in the final immediate packaging intended for investigational use.
Drug Substance (DS)	Any substance or mixture of substances intended to be used in a manufacture of a drug (medicinal) product and that, when used in

Term	Definition
	the production of a drug, becomes an active ingredient of the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body. DS is typically manufactured by either chemical/enzymatic reactions (Chemical Entity) or cell culture/fermentation processes (Biological Entity) and purification step(s).
Manufacturer's Release	Release of Product to AKERO by AMGEN, according to AMGEN's procedures and cGMP regulations.
Master Batch Record	The original approved record that serves as the template for the Batch Record for each Product Lot.
Material Change	A change which materially modifies the regulatory filing for the Product or is determined by AMGEN to have significant potential to materially affect the safety, quality, identity, potency, strength, or purity of the Product. Per AMGEN's change classification, this would represent a level 2 or level 3 change.
Product	Shall mean the cGMP pharmaceutical Drug Substance AMG 876 manufactured by AMGEN and supplied to AKERO under the License Agreement. For the sake of clarity, Product shall not include Drug Product.
Qualified Person	The term "Qualified Person" shall mean personnel who meet the definition of a Qualified Person in Directive 2001/83/cc and who, for Product manufactured within or for the European Community, ensures that each batch has been produced and tested/checked in accordance with the Applicable Directives and the Product marketing authorization, and must certify in a register or equivalent document, as operations are carried out and before any release, that each production batch satisfies the provisions of European Union regulation.
Recall	A "recall" or "market withdrawal" (each as defined per Section 7.3 of Title 21 (Food and Drugs) of the Code of Federal Regulations, or, with respect to a jurisdiction other than the United States, the equivalent regulations of the applicable Regulatory Authority in such jurisdiction) of Product or any lots thereof.
Reference Sample	Sample collected from the manufacture of Product for the purpose of being analyzed, should the need arise, to support significant investigations.
Regulatory Approval	Final approval of an Application by the FDA, or final approval of a comparable document filed with an equivalent health regulatory authority in any other country or in the European Union (using the centralized process, decentralized process or mutual recognition or member state national authorization) — but not necessarily also any required pricing and/or reimbursement approvals.

Term	Definition
Regulatory Authority	Any Governmental Authority or other authority responsible for granting Marketing Approvals for the Product, including the FDA, EMA and any corresponding national or regional regulatory authorities.
Reprocessing	Introducing an intermediate or active pharmaceutical ingredient, including one that does not conform to cGMP or Product standards or Specifications, back into the process and repeating a step (e.g., filtration) that is part of the established manufacturing process.
Reserve Samples	Term that encompasses both reference and retention samples.
Retention Samples	A sample taken during the manufacturing process for identification quality and compliance purposes. The sample is packaged and stored under controlled conditions for a defined time period following completion of the process (including fill and finish).
Rework	Subjecting an intermediate that does not conform to one or more processing steps that are different from the established manufacturing process to obtain acceptable quality intermediate or Product.
Specifications	The set of analytical methods, requirements, and acceptance criteria as used to judge the identity, purity and potency of all source materials, raw materials, and finished filled Product, which comprises the material.
Territory	Globally.

4. ROLES AND RESPONSIBILITIES

Without limiting any other provision of this Quality Agreement, the Parties agree that this Quality Agreement is intended to carry out the following guiding principles:

4.1 The responsibilities of the Parties with respect to the Product in compliance with license requirements, Regulatory Approvals, cGMPs, applicable Scope of work, and Specifications, are as set forth in the provisions that follow. This Quality Agreement is intended to further articulate the quality-related obligations of the Parties under the License Agreement.

4.2 The Parties acknowledge that each Party shall have the right to perform responsibilities hereunder through its Affiliates (as defined in the License Agreement) and/or contractors, provided that each Party shall remain responsible and liable for such performance as if such responsibilities were performed (or not performed) by such Party; provided, however, that the Quality Agreement may not be transferred or assigned to a third party by either Party without the other Party's written consent.

4.3 The Parties shall comply with all relevant laws, including without limitation applicable legislation.

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5. COMMUNICATION

5.1 AMGEN and AKERO agree to provide verbal communication to one another as necessary or appropriate to meet the need for timely communication. Both Parties also agree to follow up and confirm promptly in writing those verbal communications which could materially affect performance under this Agreement or could materially affect the safety, identity, strength, potency, or quality of Product, to ensure clarity of issue(s).

5.2 All official communications and documentation between AMGEN and AKERO will be conducted in English.

5.3 Routine verbal and written communications required hereunder shall be delivered to the individuals designated on the notification list set forth in **Attachment A** attached to this Quality Agreement.

5.4 Each Party will notify the other within one (1) business day of receipt of any communication with any local Regulatory Authority regarding Product, and forward any written communication within three (3) business days in the original language and English translation, if necessary.

5.5 Each Party must notify the other in writing of any (potential) theft, counterfeits and illegal diversion of Product manufactured by AMGEN within twenty-four (24) hours upon awareness of such events. Investigation results will be provided upon completion.

6. BATCH DISPOSITION (PRODUCT RELEASE)

6.1 AMGEN Quality Responsibility

6.1.1 AMGEN shall be responsible for the Manufacturer's Release of the Product to AKERO. All the Product provided to AKERO by AMGEN pursuant to the License Agreement shall be manufactured, bulk packaged, tested, stored, and released in accordance with all applicable laws, cGMPs and the Specifications set forth in the License Agreement.

6.1.2 AMGEN shall provide to AKERO the disposition package for each batch from Product supplied to AKERO, upon shipment (each, a "**Disposition Package**"). The documents to be included in each Disposition Package are provided in **Attachment B.**

6.2 AKERO Quality Responsibility

6.2.1 AKERO shall be solely responsible for the further processing (fill/finish), packaging, labeling, and final release of the Product for distribution and/or use (including investigational use) within the Territory after reviewing the Disposition Package provided by AMGEN.

6.2.2 A Qualified Person authorized by AKERO will be responsible for certification of Product for distribution/ use in clinical trials in the European Union, according to the requirements set out in the European Union cGMPs.

6.2.3 AKERO shall be deemed to have conclusively and fully accepted the Product unless AKERO notifies AMGEN in writing of any claim to the effect that the Product received did not meet the Specifications or cGMP within thirty (30) calendar days after transfer of the Product to AKERO.

7. QUALITY CONTROL

7.1 AMGEN will conduct release testing of Product according to AMGEN Quality Specifications and its methods, policies and procedures

7.2 Unless it is required by a Regulatory Authority in order to determine if the Product meets Specifications or if the Product is comparable to AKERO's product, and with AMGEN's written consent, which consent shall not be unreasonably withheld, conditioned or delayed, AKERO shall accept the Product without performing additional testing.

7.3 If additional testing is required, AKERO shall be responsible for sampling upon receipt and conducting testing, as required. Such testing will be conducted by AKERO (or if AMGEN expressly consents in writing, by appropriately qualified laboratories, which consent shall not be unreasonably withheld, conditioned or delayed) by appropriately qualified personnel according to testing procedures mutually agreed by Parties

7.4 Stability Testing of Product

7.4.1 AMGEN will conduct routine stability testing of the Product according to AMGEN's stability program, for products manufactured by AMGEN.

7.4.1.1 Cell bank stability monitoring responsibilities will become responsibility of AKERO upon physical transfer of the cell bank.

7.4.1.2 Stability Testing of Product and intermediates will become the responsibility of PIPPEN upon physical transfer of the stability samples.

7.4.2 AKERO will not conduct any stability testing on the Product manufactured by Amgen, unless authorized to do so by AMGEN or required by a Regulatory Authority.

8. REFERENCE AND RETENTION SAMPLES

8.1 AMGEN shall retain Reference Samples for each manufactured batch of Product released to AKERO per AMGEN established procedures and cGMP requirements.

8.2 AKERO shall be responsible for retaining Reference Samples for Product distributed in the Territory, per regulatory requirements in the applicable jurisdiction.

8.3 AMGEN shall be responsible for retaining Retention Samples per AMGEN requirements for products packaged by AMGEN.

8.4 For products packaged by AKERO, AKERO is responsible for retaining additional retention samples as required by applicable Regulatory Authorities.

8.5 The retention period to follow will be according to regulatory requirements in Territory.

9. CONTROLLED DOCUMENTS

9.1 AMGEN shall make readily available to AKERO, upon request, only documents related to lots of the Product supplied to AKERO which shall include release documentation, summaries of change controls, complaint investigations, deviation/ nonconformances summaries, and stability summary data, as agreed between the Parties.

9.2 AMGEN shall retain controlled documents related to manufacturing and analytical data per AMGEN's established procedures and cGMP requirements.

10. LABELING

10.1 AMGEN shall label Drug Substance primary containers per AMGEN's established procedure.

10.2 AKERO shall be responsible for generating and approving Product labels and packaging for investigational use. AKERO' Quality and Regulatory Affairs are responsible for reviewing and approving the labels for compliance with Territory regulatory requirements.

10.3 AKERO shall be responsible for all Product labeling and packaging manufacturing operations in accordance with cGMPs.

11. SHIPPING, RECEIVING, STORAGE AND DESTRUCTION

11.1 Shipping of Product by AMGEN

11.1.1 AMGEN shall be responsible to pack the Product for shipment in a qualified shipper in accordance with AMGEN procedures and Specifications.

11.1.2 Unless otherwise agreed by the Parties, Product shall be shipped in accordance with the License Agreement.

11.2 Receiving and Storage of Product by AKERO

11.2.1 AKERO shall obtain all government approvals and submit all appropriate documents, forms and reports as required by Governmental Authorities (as defined in the License Agreement) for the import and export of the Product. AKERO shall be responsible for any applicable import clearance.

11.2.2 Upon receipt of shipment, AKERO or its designees shall be responsible for reviewing shipping temperature recording data, inspecting security seals and labels for evidence of tampering, and performing reconciliation of unlabeled Product against shipper upon receipt of shipment per AKERO' procedures. AKERO shall notify AMGEN Quality within five (5) business days after becoming aware of any discrepancies.

11.2.3 AKERO shall be responsible for adequate storage of the Product upon receipt according to the storage requirements specified in the Specifications.

11.2.4 Any nonconformances that occur during Product shipment from AMGEN to AKERO, including temperature excursions, shall be investigated per Section 12 of this Quality Agreement, if applicable.

11.3 Shipping of Product by AKERO

11.3.1 AKERO shall be responsible for performing the necessary shipper qualification required to ensure appropriate storage and transport of Product.

11.3.2 AKERO shall ensure that adequate controls are in place to ensure the temperature is monitored throughout transportation of Product.

11.3.3 AKERO shall be responsible for evaluating temperature excursions that may occur during the transportation and/or storage of Product for AKERO-sponsored clinical studies to ensure Product was maintained within acceptable storage conditions as listed in Specifications.

11.4 Destruction and Reconciliation

11.4.1 AKERO shall be responsible for the destruction of any rejected, unused and partially used Product in accordance with applicable Laws and cGMP.

11.5 Product returns

11.5.1 Returned products from end-users including patients, hospitals, pharmacies, clinics, healthcare practitioners should not be restocked.

12. INVESTIGATIONS OF NONCONFORMANCES, DISCREPANCIES

12.1 Pre-release non-conformances

12.1.1 AMGEN shall provide to AKERO a list of (pre-release) nonconformances determined to have potential impact on the safety, identity, strength, potency, and quality of the lot in the Disposition package.

12.2 Post-release nonconformances

12.2.1 Each party shall notify the other party within reasonable amount of time of any nonconformance determined to have potential impact on the safety, identity, strength, potency, and quality of the lot or portion of the lot which has been released (post-release) to the market in the Territory to enable AKERO and/or AMGEN to comply with applicable regulatory reporting requirements.

12.2.2 AMGEN will provide support, as necessary and reasonable, to enable AKERO to comply with applicable reporting requirements to Regulatory Authorities.

12.2.3 AKERO shall notify AMGEN immediately of any possible shipping nonconformances, such as temperature excursions, upon reviewing shipping records.

12.3 AMGEN and AKERO shall each notify the other Party within three (3) business days if they become aware that Product is alleged or proven to be the subject of a recall, field alert or biological product deviation.

13. DISPUTE RESOLUTION

13.1.1 AMGEN shall be responsible for performing investigations to resolve disputes relating to non-compliance or nonconformance of Product with the Specifications or cGMPs, and solely shall determine the outcome.

13.2 AMGEN shall communicate to PIPPENAKERO the outcome of such investigation upon completion.

14. PRODUCT COMPLAINTS

14.1 AKERO shall notify AMGEN within one (1) business day after first awareness of any product complaints which may include, but are not limited to, communication that alleges deficiencies relating to identity, quality, durability, reliability, safety, effectiveness or performance of a drug, condition of labeling, or packaging, after it is released by AKERO in the Territory.

14.1.1 Complaints shall be reported by writing to the following e-mail address: [***]

14.2 AMGEN shall investigate complaints submitted by AKERO according to AMGEN's applicable policies and procedures.

14.3 AMGEN shall provide updates and/ or closure report within forty five (45) calendar days upon receipt of the customer complaint.

15. ADVERSE EVENTS

15.1 Intentionally omitted.

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16. AUDITS AND INSPECTIONS

16.1 Audits by AKERO

16.1.1 Upon the request of AKERO and approval by AMGEN, not to be unreasonably withheld, AMGEN shall permit AKERO to conduct a one (1)-time paper-based audit to confirm compliance with this Quality Agreement, Specifications, cGMPs; or in the event of the need for a "*For Cause*" audit, in the case of a quality or regulatory event, which events may include recall of the supplied Product in the Territory or clinical stock recovery, or repeated product complaints or Deviations, not to exceed two (2) audits per twenty four (24)-month period.

16.1.2 All audits require prior written request by AKERO and shall be conducted during normal AMGEN business hours.

16.1.3 AKERO shall provide AMGEN written notification of a paper-based audit not less than forty-five (45) calendar days in advance. The written notification must clearly state the scope of the audit and regulatory standards in the Territory, specified in this Quality Agreement, to be used to conduct the audit.

16.1.4 The scope, agenda, and timeline must be approved by Quality Assurance at AMGEN prior to conducting any audit, such approval not to be unreasonably withheld.

16.1.5 All audits of AMGEN are limited to the facilities where the Product is manufactured, or Quality Systems and documentation directly related to the Product, and where Batch Records related to Product provided to AKERO are stored.

16.1.6 "*For Cause*" audits of AMGEN facilities will be conducted in the presence of AMGEN representatives. Audits shall be conducted by not more than two (2) AKERO representatives at each AMGEN facility, and, unless otherwise agreed upon by AMGEN, for not more

than three (3) business days at each site.

16.1.7 At AKERO' or AMGEN's request, an exit meeting shall be held with AKERO and its representatives and AMGEN and its representatives to discuss audit findings, if any.

16.1.8 AKERO shall provide AMGEN with a copy of the audit report within thirty (30) calendar days upon completion of the audit. AMGEN shall provide AKERO with a written response, identifying corrective actions and timelines, for review and comment within thirty (30) calendar days of receipt of such audit report. AKERO comments shall be given reasonable consideration prior to implementation of any corrective action plan.

16.1.9 The audit of a third party contract manufacturer (CMO) of AMGEN will be subject to the terms and limitations of AMGEN's contractual rights and obligations with such contract manufacturer, which shall be disclosed to PIPPEN upon request in the form of a letter including the name of the auditor that performed the audit, that such audit was performed and completed, and that the CMO was in compliance with cGMPs.

16.1.10 All information contained in the audit report shall be deemed confidential information of AMGEN under the License Agreement.

16.1.11 AMGEN shall be solely responsible for all agreements with AMGEN managed third party contractors and for conducting all audits of non-AMGEN facilities relating to

manufacturing, testing and/or storage sites of Product per AMGEN procedures.

16.2 Audits by AMGEN

16.2.1 AMGEN shall, consistent with its policies and procedures, schedule and perform internal audits and audits of its subcontractors for Product with respect to facilities, processes and procedures. AMGEN shall promptly notify AKERO, in writing, of any critical observations directly related to the Product promptly and in any event no later than three (3) business days after AMGEN receives notice thereof.

16.3 Regulatory Authority Inspections

16.3.1 AKERO shall use commercially reasonable efforts to waive or avoid the need for any inspection by Governmental Authorities (as defined in the License Agreement) of AMGEN's manufacturing facilities and/or documentation with respect to product and/or placebo.

16.3.2 Each Party shall notify the other within twenty-four (24) hours upon notification by any Regulatory Authority of any intended inspection of AMGEN's facilities or records relating to the manufacturing, testing, and storage of the supplied Product.

16.3.3 AMGEN will be solely responsible for hosting and managing regulatory inspections at its facilities.

16.3.3.1 Not more than one (1) AKERO representative may be present at such inspections upon approval by AMGEN, given that such approval may not be unreasonably withheld.

16.3.4 Each Party shall inform the other Party of any critical and major regulatory inspection observations by other Government Authorities that are related to the Product and/or Territory.

16.3.5 Responses to regulatory inspections

16.3.5.1 For inspections occurring at AMGEN sites, AMGEN shall be the first to receive the inspection report, unless restricted by regulatory requirements.

16.3.5.2 The Party who received the inspection report shall provide the report to the other Party within twenty-four (24) hours of receipt, and shall be responsible for translation, if required.

16.3.5.3 The Party whose facility was audited shall be responsible for authoring and providing responses to the Regulatory Authority.

16.3.5.4 The non-authoring party shall have a right to review and comment on proposed responses. The final response shall be provided to each party.

17. REPROCESSING/ REWORK

17.1 AMGEN will not conduct any reprocessing or reworking of materials of Product without prior written approval by AKERO.

18. RECALLS AND CORRECTIONS OF PRODUCT

18.1 If any problems are discovered and identified as potentially requiring a Product recall, stock recovery, or correction in any country, the discovering Party shall notify the other immediately, and in any event, within twenty-four (24) hours of identification of such problem. Such notice shall be provided prior to executing a recall, stock recoveries, or correction in any country.

18.2 AMGEN (either itself or via participation through a committee) shall have the right to initiate a recall, stock recovery, or correction. PIPPEN shall not conduct such recall, stock recovery, or correction without the prior written consent of AMGEN.

18.3 Each Party will provide the other Party with reasonable assistance in connection with any such events as may reasonably be requested by such other Party.

18.4 Each Party shall meet all applicable regulatory requirements related to Product recalls, stock recoveries, and correction.

18.5 Each Party shall be responsible for Product distributed within the Territory for its own clinical studies.

19. SUBCONTRACTING

19.1 Intentionally omitted.

20. RESPONSIBLE PERSONS: CONTACT INFORMATION

20.1 The individuals listed in **Attachment A** shall be the key points of contact between AMGEN and AKERO relating to the rights and obligations of the Parties in this Quality Agreement.

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LIST OF ATTACHMENTS:

Attachment A: Responsible Persons and Contact Information

Attachment B: AMGEN Disposition Package

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ATTACHMENT A

Responsible Persons and Contact Information

AKERO

Name	Email Address	Contact Number	Responsibility
[***]	[***]	[***]	[***]

AMGEN

Name	Email Address	Contact Number	Responsibility
[***]	[***]	[***]	[***]

Exhibit A version date: June 7, 2018

Agreed and accepted for:

AKERO THERAPEUTICS, INC.

By: /s/ Jonathan Young

Name: Jonathan Young

Title: President

Date: June 7,2018

Agreed and accepted for:

AMGEN INC.

By: /s/ Paul Mowad

Name: Paul Mowad

Title: Director, Quality

Date: June 7, 2018

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ATTACHMENT B

AMGEN Disposition Package

The following documents are to comprise the AMGEN Disposition Package to support the release of the Product to AKERO:

Stage of Manufacture	Disposition Package Documents
Drug Substance Manufacture	CoA CoC Nonconformance's lot summary report

Attachment B version date: June 7, 2018

Agreed and accepted for:

AKERO THERAPEUTICS, INC.

By: /s/ Jonathan Young

Name: Jonathan Young

Title: President

Date: June 7,2018

Agreed and accepted for:

AMGEN INC.

By: /s/ Paul Mowad

Name: Paul Mowad

Title: Director, Quality

Date: June 7, 2018

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CHANGE SUMMARY

Change	Justification
Initial Quality Agreement	Required pursuant to License Agreement