Confidential Treatment Requested by Keros Therapeutics, Inc.
Pursuant to 17 C.F.R. § 200.83

As confidentially submitted to the Securities and Exchange Commission on November 3, 2020.
This draft registration statement has not been publicly filed with the Securities and Exchange Commission and all information herein remains strictly confidential.

Registration Statement No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

KEROS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**2834**	**81-1173868**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

99 Hayden Avenue, Suite 120, Building E
Lexington, Massachusetts 02421
Tel: (617) 314-6297
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Jasbir Seehra
Chief Executive Officer
Keros Therapeutics, Inc.
99 Hayden Avenue, Suite 120, Building E
Lexington, Massachusetts 02421
Tel: (617) 314-6297
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Marc A. Recht **Ryan S. Sansom** **Brandon Fenn** **Cooley LLP** **500 Boylston Street** **Boston, Massachusetts 02116** **(617) 937-2300**	**Esther Cho** **Head of Legal** **Keros Therapeutics, Inc.** **99 Hayden Avenue, Suite 120,** **Building E** **Lexington, Massachusetts 02421** **(617) 314-6297**	**Peter N. Handrinos** **Nathan Ajiashvili** **Latham & Watkins LLP** **200 Clarendon Street** **Boston, Massachusetts 02116** **(617) 948-6000**

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

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

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

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. ☐

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 number of the earlier effective registration statement for the same offering. ☐

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

Large Accelerated Filer	☐	Accelerated Filer	☐
Non-Accelerated Filer	☒	Smaller Reporting Company	☒
		Emerging Growth Company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided in Section 7(a)(2)(B) of the Securities Act. ☐

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, $0.0001 par value per share	$	$

(1) Includes additional shares that the underwriters have the option to purchase.
(2) Estimated pursuant to Rule 457(o) under the Securities Act of 1933, as amended, solely for purposes of calculating the registration fee.

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 the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

EXPLANATORY NOTE

Pursuant to the applicable provisions of the Fixing America's Surface Transportation Act, we are omitting our consolidated financial statements as of and for the six months ended June 30, 2020 and 2019. While this financial information is otherwise required by Regulation S-X, we reasonably believe that it will not be required to be included in the prospectus at the time of the contemplated offering. We intend to amend this registration statement to include all financial information required by Regulation S-X at the date of such amendment before distributing a preliminary prospectus to investors.

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

SUBJECT TO COMPLETION, DATED , 2020

PRELIMINARY PROSPECTUS

Shares

Common Stock

We are offering shares of common stock.

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

We are an "emerging growth company" under the federal securities laws and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and for future filings.

Investing in our common stock involves a high degree of risk. Before buying any shares, you should read carefully the discussion of the material risks of investing in our common stock under the heading "Risk Factors" starting on page 12 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of the securities that may be offered under this prospectus, nor have any of these organizations determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	PER SHARE	TOTAL
Public offering price	$	$
Underwriting discounts and commissions(1)	$	$
Proceeds, before expenses, to us	$	$

(1) We refer you to the section titled "Underwriting" for additional information regarding underwriting compensation.

Delivery of the shares of common stock is expected to be made on or about , 2020.

We have granted the underwriters an option for a period of 30 days to purchase up to an additional shares of our common stock. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be $, and the total proceeds to us, before expenses, will be $.

Joint Book-Running Managers

Jefferies **SVB Leerink** **Piper Sandler**

Co-Manager

H.C. Wainwright & Co.

The date of this prospectus is , 2020.

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We have not, and the underwriters have not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus, any amendment or supplement to this prospectus or any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares of common stock offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus, any amendment or supplement to this prospectus or any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: We have not, and the underwriters have not, 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. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside the United States.

PROSPECTUS SUMMARY

This summary highlights information contained in other parts of this prospectus. Because it is only a summary, it does not contain all of the information that you should consider before investing in our common stock and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information appearing elsewhere in this prospectus. You should read the entire prospectus carefully, especially "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements before deciding to buy shares of our common stock. Unless the context requires otherwise, references in this prospectus to "Keros," "the company," "we," "us" and "our" refer to Keros Therapeutics, Inc.

Overview

We are a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel treatments for patients suffering from hematological and musculoskeletal disorders with high unmet medical need. We are a leader in understanding the role of the Transforming Growth Factor-Beta, or TGF-ß, family of proteins, which are master regulators of red blood cell and platelet production as well as of the growth, repair and maintenance of muscle and bone. We have leveraged this understanding and developed a discovery approach to generate large and small molecules to address diseases of these tissues. Targeting TGF-ß signaling pathways has been clinically proven to elicit robust changes in blood cells, muscle and bone, which we believe provides a precedent and strong rationale for our strategy. Our lead protein therapeutic product candidate, KER-050, is being developed for the treatment of low blood cell counts, or cytopenias, including anemia and thrombocytopenia, in patients with myelodysplastic syndromes, or MDS, and in patients with myelofibrosis. We have initiated a Phase 2 clinical trial in patients with MDS and expect to report initial data from Part 1 of this trial in mid-2021. We also plan to initiate a Phase 2 clinical trial in patients with myelofibrosis in 2021. Our lead small molecule product candidate, KER-047, is being developed for the treatment of anemia resulting from iron imbalance, as well as for the treatment of fibrodysplasia ossificans progressiva, or FOP, a rare musculoskeletal disorder. We have completed our expanded Phase 1 clinical trial of KER-047 and expect to report topline data from this trial by the end of 2020. Our third product candidate, KER-012, is being developed for the treatment of disorders associated with bone loss, such as osteoporosis and osteogenesis imperfecta, and for the treatment of pulmonary arterial hypertension, or PAH. We plan to progress KER-012 into a Phase 1 clinical trial in the second half of 2021. We believe KER-047 and KER-012 offer substantial opportunities for us to continue to apply our understanding of TGF-ß signaling pathways and expand our development programs in related hematological and musculoskeletal disorders with high unmet medical need.

KER-050 is an engineered ligand trap comprised of a modified ligand-binding domain of the TGF-ß receptor known as activin receptor type IIA that is fused to the portion of the human antibody known as the Fc domain. KER-050 is designed to increase red blood cell and platelet production by inhibiting the signaling of a subset of the TGF-ß family of proteins to promote hematopoiesis. We believe KER-050 has the potential to provide benefit to patients suffering from red blood cell and platelet differentiation and maturation defects occurring across the spectrum from early through terminal stages of hematopoiesis, and consequently may be effective for many patients that have limited treatment options or are refractory to available therapies. We have completed a Phase 1 clinical trial evaluating the safety, tolerability and pharmacokinetics of KER-050 in healthy post-menopausal women. In this trial, we observed rapid and sustained increases in red blood cells, hemoglobin and reticulocytes, in addition to clinically meaningful increases in platelets after a single dose. Based on these findings and the results from preclinical studies, we believe KER-050 has a differentiated pharmacologic effect on red blood cells and platelets and has the potential to treat multiple cytopenias in diseases of ineffective hematopoiesis. In October 2020, we announced the dosing of the first two participants in our Phase 2 clinical trial evaluating KER-050 for the treatment of anemia and thrombocytopenia in very low-, low-, or intermediate-risk MDS. We expect to report initial data from Part 1 of this trial in mid-2021. Additionally, we plan to commence a Phase 2 clinical trial evaluating KER-050 for the treatment of patients with myelofibrosis-associated cytopenias in 2021.

KER-047 is designed to selectively and potently inhibit activin receptor-like kinase-2, or ALK2, a TGF-ß receptor. We believe that KER-047 has the potential to ameliorate excessive ALK2 signaling, which is directly implicated in anemias arising from iron imbalance and musculoskeletal disorders where the transformation of

soft tissue into bone, referred to as heterotopic ossification, leads to devastating immobility. We are developing KER-047 for the treatment of anemia resulting from iron imbalance as a direct consequence of elevated ALK2 signaling, including our initial target, iron-refractory iron deficiency anemia, or IRIDA. We are also developing KER-047 as a treatment for FOP, a rare genetic disease resulting from mutations in the ALK2 receptor that results in gain-of-function activity. In these patients, soft tissue, including muscles and tendons, develops normally, but remodels into bone after injury. In August 2020, we announced the completion of our planned single and multiple ascending dose cohorts in a Phase 1 clinical trial of KER-047 in healthy volunteers, as well as the expansion of this trial to evaluate additional cohorts of healthy volunteers. In the planned cohorts of this trial, we observed dose-dependent increases in serum iron and increased reticulocyte hemoglobin, which is a measure of hemoglobin content from newly-produced immature red blood cells, in the volunteers who received KER-047. We evaluated one additional cohort of healthy volunteers and terminated the trial after determining that the data from this cohort, in addition to the data from the planned cohorts of the trial, were sufficient to inform the design of the expected Phase 2 clinical trials of KER-047, and expect to report topline data by the end of 2020. As the data from this additional cohort was deemed sufficient to provide the necessary data, we currently do not plan to expand this trial into any additional cohorts of healthy volunteers. We also expect to commence two Phase 2 clinical trials, one in patients with iron deficiency anemia, or IDA, and one in patients with IRIDA, in 2021.

KER-012 is designed to bind to and inhibit the signaling of TGF-ß ligands, including activin A and activin B, which are key regulators of bone remodeling that act to suppress bone growth, to potentially increase bone mass. We believe that KER-012 has the potential to increase the signaling of bone morphogenic protein, or BMP, pathways through this inhibition of activin A and activin B signaling, and consequently treat diseases such as PAH that are associated with reduced BMP signaling due to inactivating mutations in the BMP receptors. We are developing KER-012 for the treatment of disorders associated with bone loss, such as osteoporosis and osteogenesis imperfecta, and for the treatment of PAH. In a rat model of PAH, rats receiving a rodent version of KER-012, or RKER-012, were protected from the thickening of the right ventricular wall. In addition, rats receiving a rodent version of KER-012 were protected from PAH-associated bone loss which we believe demonstrates proof-of-mechanism of KER-012 for the treatment of PAH and bone loss. We plan to advance KER-012 into a Phase 1 clinical trial in the second half of 2021.

Our Biological Focus

Our strategy focuses on the role of members of the TGF-ß family of proteins in the development of blood cells, muscle and bone. Aged and damaged cells are routinely replaced by new cells in normally functioning organs. These new cells are derived from stem cells that have the ability to differentiate into cells with specialized function when appropriate signals are provided to maintain the homeostatic state of the tissue. Members of the TGF-ß family of proteins, including activins and bone morphogenetic proteins, or BMPs, provide the necessary signals for this process of self-renewal and repair.

We seek to address the limitations of current therapeutic approaches to treating diseases whose manifestations are linked to dysfunction of TGF-ß signaling pathways by:

- Leveraging our comprehensive insights into the TGF-ß signaling pathways to discover therapeutics to treat hematological and musculoskeletal disorders.
- Expanding our library of proprietary molecules that are engineered to induce desired biological effects, such as increased blood cell production, inhibit heterotopic ossification and increased muscle and bone mass.
- Engineering proprietary molecules to selectively target specific proteins in the TGF-ß signaling pathways to provide therapeutic benefit while potentially minimizing safety risks.
- Developing product candidates for the treatment of diseases where targeting the TGF-ß signaling pathways has clinical validation or biological rationale to improve our probability of success in the clinic.
- Targeting the TGF-ß family of proteins, which are highly conserved throughout evolution, permitting the use of animal models to potentially predict with high confidence the therapeutic benefit in patients.

Our Pipeline

The following table sets forth our product candidates, their current development stages and anticipated upcoming milestones.

Program	Asset	Phase of Development				Status	Next Milestones*
		Preclinical	Phase 1	Phase 2	Phase 3		
Hematology	KER-050 (therapeutic protein)	Myelodysplastic syndromes (MDS)				Initiated Phase 2 clinical trial	**Initial data: mid-2021**
		Myelofibrosis (MF)				Completed Phase 1 clinical trial	Initiate Phase 2 clinical trial: 2021
Hematology / Musculoskeletal	KER-047 (small molecule)	Iron-deficiency anemia				Completed expanded Phase 1 clinical trial	Topline data: end of 2020
		Anemia from high hepcidin					
Musculoskeletal		Fibrodysplasia Ossificans Progressiva (FOP)					
Preclinical Pipeline	KER-012 (therapeutic protein)	Pulmonary Arterial Hypertension				Ongoing preclinical studies	Initiate Phase 1 clinical trial: H2 2021
		Bone Disorders					

* Anticipated clinical milestones are subject to the impact of COVID-19 on our business.

We are developing KER-050 for the treatment of cytopenias that occur due to ineffective hematopoiesis, including anemia and thrombocytopenia, in patients with MDS and in patients with myelofibrosis. KER-050 is designed to benefit patients suffering from defects in red blood cell and platelet differentiation and maturation across the spectrum from early through terminal stages of hematopoiesis. Consequently, KER-050 may be effective for many patients that have limited treatment options or are refractory to available therapies.

We are developing KER-047 for the treatment of anemia resulting from iron imbalance. We believe KER-047 is a potent and selective inhibitor of ALK2, a receptor whose excessive signaling is the underlying cause of the elevated hepcidin levels that lead to low iron bioavailability and anemia in a broad range of diseases. Further, we are developing KER-047 as a treatment for FOP, a rare genetic disease resulting from mutations in the ALK2 receptor that result in gain-of-function activity.

We are developing KER-012 for the treatment of disorders associated with bone loss, such as osteoporosis and osteogenesis imperfecta, and for the treatment of PAH. We believe KER-012 is a potent and selective inhibitor of certain TGF-ß ligands, including activin A and activin B, that are key regulators of bone remodeling that act to suppress bone growth. We believe that KER-012 has the potential to increase the signaling of BMP pathways through this inhibition of activin A and activin B signaling, and consequently treat diseases such as PAH that are associated with reduced BMP signaling due to inactivating mutations in the BMP receptors.

Market Overview

Our target markets include MDS-associated cytopenias, myelofibrosis-associated cytopenias, anemia resulting from iron imbalance, such as IDA and IRIDA, as well as FOP, osteoporosis, osteogenesis imperfecta and PAH.

MDS-Associated Cytopenias

In the United States, there are 60,000 to 170,000 patients with MDS and 15,000 to 20,000 new cases of MDS reported each year. Cytopenias in MDS are caused by defects occurring across the various stages of hematopoiesis, from the self-renewal of progenitor cells to differentiation in early through terminal stages. Anemia is the most frequent consequence of ineffective hematopoiesis in patients with MDS due to low red blood cell production, impacting 90% of MDS patients, approximately 40% of whom become transfusion dependent.

Another consequence is thrombocytopenia, a deficiency of platelets in the blood, which is impaired blood clotting that can cause bleeding. The prevalence of thrombocytopenia in patients with MDS has been reported at 40% to 65%. A deficiency of neutrophils in the blood, or neutropenia, also increases the risk of serious infections in patients with MDS and has been reported to affect approximately 20% of patients with MDS.

Myelofibrosis-Associated Cytopenias

Myelofibrosis is a relatively rare condition with an identified prevalence of 16,000 to 18,500 patients in the United States. Approximately 3,000 new patients are diagnosed with myelofibrosis each year, and the median age at diagnosis is approximately 60 years. Currently, there are limited therapeutic options to address the myelofibrosis-associated cytopenias. Within a year of diagnosis, 38% of patients with myelofibrosis are red blood cell transfusion dependent and eventually nearly all will develop transfusion dependence. Additionally, within a year of diagnosis, 26% of patients with myelofibrosis will develop thrombocytopenia and 51% will develop anemia. Approximately 45% of patients with myelofibrosis treated with JAK inhibitor ruxolitinib in a third-party Phase 3 clinical trial developed treatment-related grade 3 or 4 anemia.

IDA

It is estimated that approximately five million people in the United States have IDA and we estimate that a small fraction of the patients who are diagnosed with IDA, regardless of the underlying cause, are currently being treated with intravenous, or IV, iron. We estimate that the size of the total 2019 U.S., non-dialysis, IV iron replacement therapy market was approximately 1.5 million grams.

IRIDA

The prevalence of IRIDA worldwide is estimated to be less than one person in 1,000,000. IRIDA was first described in 1981 with the observation that patients with anemia were refractory to treatment with oral iron. However, the association of mutations in the TMPRSS6 gene with IRIDA was not identified until 2008, and genetic testing for IRIDA is not widely available. Furthermore, because affected individuals usually have normal growth and development, IRIDA can be difficult to diagnose. All of these factors contribute to an inability to accurately determine the prevalence of IRIDA.

FOP

The International Fibrodysplasia Ossificans Progressiva Association estimates that there are 3,500 people worldwide with FOP, with approximately 800 patients identified. There are 285 known cases in the United States.

Osteoporosis

It is estimated that more than 200 million people worldwide, including approximately 30% of all post-menopausal women in the United States and Europe, suffer from osteoporosis. It is also estimated that approximately 50% of women and 20% of men over the age of 50 will suffer at least one osteoporosis-related fracture in their remaining lifetime.

Osteogenesis Imperfecta

Osteogenesis imperfecta affects approximately one out of every 10,000 to 20,000 people worldwide, while an estimated 25,000 to 50,000 people in the United States are living with the condition.

Pulmonary Arterial Hypertension

We estimate that in the United States there are 750 to 2,000 new cases of PAH each year and 10,000 to 20,000 individuals living with the condition.

Our Strategy

Our mission is to deliver significant clinical benefit to patients suffering from hematological and musculoskeletal diseases by developing differentiated product candidates that are designed to alter TGF-ß signaling pathways. The key elements of our strategy include:

- Rapidly advance the clinical development of KER-050 for the treatment of patients with MDS- and myelofibrosis-associated cytopenias.

- Rapidly advance the clinical development of KER-047 for the treatment of anemias resulting from iron imbalance and musculoskeletal disorders where heterotopic ossification leads to devastating immobility.
- Advance KER-012 into and through clinical development for the treatment of disorders associated with bone loss, such as osteoporosis and osteogenesis imperfecta, and for the treatment of PAH.
- Pursue development and, if approved, commercialization of our product candidates in indications and regions where we believe we can maximize their value independently or through strategic collaborations.
- Leveraging our proprietary discovery approach and knowledge base to develop new therapeutics.

Our Team

We are led by a highly experienced management team and scientific advisory board who have more than 100 combined years of research and development on therapeutics in the TGF-ß family of proteins. Our team has collectively worked on marketed therapeutics such as Reblozyl, Tecfidera, Kalydeco and Waylivra, and led drug discovery and clinical development at companies including Acceleron Pharma Inc., Biogen Inc., Wyeth Pharmaceuticals Inc., Seres Therapeutics, Inc., Vertex Pharmaceuticals Incorporated and Akcea Therapeutics, Inc.

COVID-19 Business Update

With the global COVID-19 pandemic continuing throughout 2020, we have implemented business continuity plans designed to address and mitigate the impact of the COVID-19 pandemic on our employees, and our business operations, including our preclinical studies and clinical trials, supply chains and third-party providers. We are closely monitoring the COVID-19 situation as we evolve our business continuity plans and response strategy. On March 23, 2020, the governor of Massachusetts ordered the closure of all non-essential businesses effective March 24, 2020 through April 7, 2020, which was subsequently extended through May 18, 2020. On May 18, 2020, the governor of Massachusetts issued a new order implementing a phased re-opening of workplaces, effective May 18, 2020. As of October 5, 2020, the Commonwealth of Massachusetts officially entered step two of the third phase of re-opening for certain lower risk communities. Because of the nature of our operations, we are currently considered to be an essential business so, to date, our operations have only been partially affected by these orders. The outbreak and government measures taken in response have also had a significant impact, both direct and indirect, on third-party businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. In response to the spread of COVID-19, we have closed our principal executive office, with our administrative employees continuing their work outside of our office and limited the number of staff in any given research laboratory. We are currently preparing plans to reopen our office to allow employees to return to the office, which will be based on a phased approach that is principles-based and local in design, with a focus on continuity of preclinical studies and clinical trial activities, employee safety and optimal work environment. While we are experiencing limited financial impacts at this time, given the global economic slowdown, the overall disruption of global healthcare systems and the other risks and uncertainties associated with the pandemic, our business, financial condition, results of operations and growth prospects could be materially adversely affected.

Preclinical and Clinical Development

With respect to preclinical and clinical development, we have taken measures to implement remote and virtual approaches, including remote participant monitoring where possible, to maintain participant safety and trial continuity and to preserve study integrity. For several of our clinical development programs, we are experiencing, and expect to continue to experience, a disruption or delay in our ability to initiate trial sites and enroll and assess participants. As the COVID-19 pandemic continues, we have experienced and expect to continue to experience an impact on our ability to enroll participants in our clinical trials. We have experienced and expect to continue to experience an impact on the ability to supply study drug, report trial results or interact with clinicians, investigators, regulators, ethics committees or other important agencies due to limitations in regulatory authority employee resources or otherwise. In addition, we rely on contract research organizations, or CROs, or other third parties to assist us with clinical trials, and we cannot guarantee that they will continue to perform their contractual duties in a timely and satisfactory manner as a result of the COVID-19 pandemic. If the COVID-19 pandemic continues and persists for an extended period of time, we could experience significant

disruptions to our preclinical and clinical development timelines, which would adversely affect our business, financial condition, results of operations and growth prospects.

Supply Chain

As for our third-party manufacturers, distributors and other partners, we are working closely with them to manage our supply chain activities and mitigate potential disruptions to our clinical supply as a result of the COVID-19 pandemic. We expect to have adequate supply for the development of our product candidates. However, if the COVID-19 pandemic persists for an extended period of time and begins to impact essential distribution systems such as FedEx and postal delivery, we could experience disruptions to our supply chain and operations, and associated delays in the manufacturing and supply of our product candidates, which would adversely impact our ability to carry out our clinical trials.

Financial Impact

The COVID-19 pandemic continues to rapidly evolve and has already resulted in a significant disruption of global financial markets. If the disruption persists and deepens, we could experience an inability to access additional capital, which could in the future negatively affect our operations. While we expect the COVID-19 pandemic to adversely affect our business operations, our clinical development and regulatory efforts, our corporate development objectives and the value of and market for our common stock will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, as a result of uncertainty regarding ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the United States, Australia and New Zealand and the effectiveness of actions taken globally to contain and treat the disease.

Risks Associated with Our Business

Our business is subject to a number of risks. These risks are discussed more fully in the section titled “Risk Factors” immediately following this prospectus summary. You should read these risks before you invest in our common stock. In particular, risks associated with our business include, but are not limited to, the following:

- We have a limited operating history, have incurred net losses in every year since our inception and anticipate that we will continue to incur net losses in the future.
- Even if we consummate this offering, we will need substantial additional funding in order to complete the development and commence commercialization of our product candidates. Failure to obtain this necessary capital when needed may force us to delay, reduce or eliminate certain of our product development or research operations.
- We are heavily dependent on the success of our product candidates, which are in early clinical development. If we are unable to advance our current or future product candidates through clinical trials, obtain marketing approval and ultimately commercialize any product candidates we develop, or experience significant delays in doing so, our business will be materially harmed.
- All of our product candidates are in preclinical or early clinical development. Clinical trials are difficult to design and implement, and they involve a lengthy and expensive process with uncertain outcomes. We may experience delays in completing, or ultimately be unable to complete, the development and commercialization of KER-050, KER-047, KER-012 or any future product candidates.
- If we are unable to successfully commercialize any product candidate for which we receive regulatory approval, or experience significant delays in doing so, our business will be materially harmed.
- We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.
- Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.
- We rely, and expect to continue to rely, on third parties, including independent clinical investigators, contracted laboratories and contract research organizations, to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.
- We rely on third parties to supply and manufacture our product candidates, and we expect to continue to rely on third parties to manufacture our products, if approved. The development of such product candidates and the commercialization of any products, if approved, could be stopped, delayed or

made less profitable if any such third party fails to provide us with sufficient quantities of product candidates or products or fails to do so at acceptable quality levels or prices or fails to maintain or achieve satisfactory regulatory compliance.
- Our future collaborations will be important to our business. If we are unable to enter into new collaborations, or if these collaborations are not successful, our business could be adversely affected.
- The COVID-19 coronavirus could adversely impact our business, including the timing or results of our preclinical studies and clinical trials.

Corporate Information

Keros Therapeutics, Inc. was originally incorporated under the laws of the State of Delaware under the name Keros Therapeutics, Inc. in December 2015. Our principal executive office is located at 99 Hayden Avenue, Suite 120, Building E, Lexington, Massachusetts 02421. Our telephone number is (617) 314-6297. Our website address is www.kerostx.com. Information contained in, or accessible through, our website does not constitute a part of, and is not incorporated into, this prospectus.

The Keros logo and the name Keros and other common law trademarks of Keros Therapeutics, Inc. appearing in this prospectus are the property of Keros Therapeutics, Inc. Solely for your convenience, trade names, trademarks and service marks contained in this prospectus may appear without the "®" or "™" symbols. Such references are not intended to indicate, in any way, that we will not assert, to the fullest extent possible under applicable law, our rights or the rights of the applicable licensor to those trade names, trademarks and service marks.

Implications of Being an Emerging Growth Company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, 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:

- being permitted to present in this prospectus only two years of audited financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- reduced disclosure about the compensation paid to our executive officers;
- not being required to submit to our stockholders advisory votes on executive compensation or golden parachute arrangements;
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act; and
- an exemption from new or revised financial accounting standards until they would apply to private companies and from compliance with any new requirements adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotation.

We may take advantage of these exemptions until December 31, 2025 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 (1) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (2) December 31, 2025; (3) the date on which we have issued more than $1.0 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 Securities and Exchange Commission, or the SEC. We may choose to take advantage of some but not all of these exemptions. We have taken advantage of certain 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 have elected to take advantage of the extended transition period to comply with new or revised accounting standards and to adopt certain of the reduced disclosure requirements available to emerging growth companies. As a result of the accounting standards election, we will not be subject to the same implementation timing for new or revised accounting standards as other public companies that are not emerging growth companies which may make comparison of our financials to those of other public companies more difficult. As a result of these elections, the information that we provide in this prospectus may be different than the information you may receive from other public companies in which you hold equity interests. In addition, it is

possible that some investors will find our common stock less attractive as a result of these elections, which may result in a less active trading market for our common stock and higher volatility in our stock price.

THE OFFERING

Common stock offered by us	shares.
Common stock to be outstanding immediately after this offering	shares (or shares if the underwriters exercise in full their option to purchase additional shares).
Option to purchase additional shares	We have granted the underwriters an option, exercisable for 30 days after the date of this prospectus, to purchase up to an additional shares from us.
Use of proceeds	We estimate that we will receive net proceeds of approximately $ million (or approximately $ million if the underwriters exercise in full their option to purchase additional shares), based on an assumed public offering price of $ per share, which is the last reported sale price of our common stock on the Nasdaq Global Market on , 2020, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, to advance the clinical development of KER-050, including the advancement of Phase 2 clinical trials in patients with MDS and in patients with myelofibrosis, to advance the clinical development of KER-047, including the initiation of separate Phase 2 clinical trials in patients with IDA and in patients with IRIDA, and to advance KER-012 into clinical development, including the initiation of a Phase 1 clinical trial. We intend to use the remainder of the net proceeds to fund other research and development activities, including activities related to our proprietary discovery approach, working capital and general corporate purposes. See “Use of Proceeds” for additional information.
Risk factors	You should carefully read “Risk Factors” on page 12 in this prospectus for a discussion of factors that you should consider before deciding to invest in our common stock.
Nasdaq Global Market symbol	“KROS”

The number of shares of our common stock to be outstanding after the closing of this offering is based on 20,185,730 shares of our common stock outstanding as of September 30, 2020 and excludes:

- 2,484,152 shares of our common stock issuable upon the exercise of options outstanding as of September 30, 2020, at a weighted-average exercise price of $10.95 per share;
- shares of our common stock issuable upon the exercise of options granted after September 30, 2020, at a weighted average exercise price of $ per share;
- 572,026 shares of our common stock reserved for future issuance pursuant to our 2020 Equity Incentive Plan, or 2020 Plan, as of September 30, 2020, as well as any shares reserved pursuant to provisions in our 2020 Plan that automatically increase the number of shares of common stock reserved for issuance under the 2020 Plan; and
- 182,341 shares of our common stock reserved for future issuance under our 2020 Employee Stock Purchase Plan, or ESPP, as of September 30, 2020, as well as any shares reserved pursuant to provisions in the ESPP that automatically increase the number of shares of common stock reserved for issuance under the ESPP.

Unless otherwise indicated, this prospectus reflects and assumes the following:

- no exercise of the outstanding options described above after September 30, 2020; and
- no exercise by the underwriters of their option to purchase additional shares of our common stock.

SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables set forth our summary consolidated financial data. We derived the summary consolidated statement of operations data for the years ended December 31, 2018 and 2019 from our audited consolidated financial statements included elsewhere in this prospectus. The summary consolidated statements of operations data for the nine months ended September 30, 2019 and 2020 and the summary consolidated balance sheet data as of September 30, 2020 have been derived from our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus. In our opinion, this unaudited interim condensed consolidated financial data has been prepared on a basis consistent with our audited consolidated financial statements and contains all adjustments, consisting only of normal and recurring adjustments, necessary for a fair presentation of such financial data. Our historical results are not necessarily indicative of the results that should be expected for any future period and our operating results for the nine-month period ended September 30, 2020 are not necessarily indicative of the results that may be expected for the fiscal year ended December 31, 2020 or any other interim periods or any future year or period.

When you read this summary consolidated financial data, it is important that you read it together with the historical consolidated financial statements and related notes to those statements, as well as the sections of this prospectus titled “Selected Consolidated Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

	YEAR ENDED DECEMBER 31,		NINE MONTHS ENDED SEPTEMBER 30,	
	2018	2019	2019	2020
			(unaudited)	
	(in thousands, except share and per share data)			
Consolidated Statement of Operations Data:				
Revenue:				
Research collaboration revenue	$ 10,000	$ 10,000	$	$
Total revenue	10,000	10,000		
Operating expenses:				
Research and development	(10,111)	(17,379)		
General and administrative	(1,580)	(3,184)		
Total operating expenses	(11,691)	(20,563)		
Loss from operations	(1,691)	(10,563)		
Other income, net:				
Interest income (expense), net	6	(8)		
Research and development incentive income	370	558		
Change in fair value of preferred stock tranche liability	(43)	(2,564)		
Other income, net	280	241		
Total other income (expense), net	613	(1,773)		
Loss before income taxes	(1,078)	(12,336)		
Income tax provision	(257)	—		
Net loss	$ (1,335)	$ (12,336)	$	$
Net loss attributable to common stockholders—basic and diluted	$ (2,346)	$ (14,136)	$	$
Net loss per share attributable to common stockholders—basic and diluted(1)	$ (1.08)	$ (6.08)	$	$
Weighted average common stock outstanding—basic and diluted(1)	2,174,514	2,326,857		

(1) See Note 12 to our consolidated financial statements appearing at the end of this prospectus for further details on the calculation of basic and diluted net loss per share attributable to common stockholders.

The following table presents our consolidated summary balance sheet data:

- on an actual basis as of September 30, 2020; and
- on an as adjusted basis to give effect to our sale of shares of our common stock in this offering at the assumed public offering price of $ per share, which is the last reported sale price of our common stock on the Nasdaq Global Market on , 2020, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

	AS OF SEPTEMBER 30, 2020	
	ACTUAL	AS ADJUSTED
	(unaudited) (in thousands)	
Consolidated Balance Sheet Data:		
Cash and cash equivalents	$	$
Working capital(1)		
Total assets		
Total liabilities		
Total stockholders' equity		

(1) Working capital is defined as current assets less current liabilities.

The as adjusted information discussed above is illustrative only and will depend on the actual initial public offering price and other terms of this offering determined at pricing. Each $1.00 increase or decrease in the assumed public offering price of $ per share, which is the last reported sale price of our common stock on the Nasdaq Global Market on , 2020, would increase or decrease each of cash and cash equivalents, working capital, total assets and total stockholders' equity by $ million, assuming that the number of shares of our common stock offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions. We may also increase or decrease the number of shares we are offering. Each increase or decrease of 1.0 million shares in the number of shares of our common stock offered by us would increase or decrease each of cash and cash equivalents, working capital, total assets and total stockholders' equity by $ million, assuming that the assumed public offering price remains the same, and after deducting estimated underwriting discounts and commissions.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this prospectus, including our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. In particular, risks associated with our business include, but are not limited to, the following:

- We have a limited operating history, have incurred net losses in every year since our inception and anticipate that we will continue to incur net losses in the future.
- We will need substantial additional funding in order to complete the development and commence commercialization of our product candidates. Failure to obtain this necessary capital when needed may force us to delay, reduce or eliminate certain of our product development or research operations.
- We are heavily dependent on the success of our product candidates, which are in early clinical development. If we are unable to advance our current or future product candidates through clinical trials, obtain marketing approval and ultimately commercialize any product candidates we develop, or experience significant delays in doing so, our business will be materially harmed.
- All of our product candidates are in preclinical or early clinical development stages. Clinical trials are difficult to design and implement, and they involve a lengthy and expensive process with uncertain outcomes. We may experience delays in completing, or ultimately be unable to complete, the development and commercialization of KER-050, KER-047, KER-012 or any future product candidates.
- If we are unable to successfully commercialize any product candidate for which we receive regulatory approval, or experience significant delays in doing so, our business will be materially harmed.
- We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.
- Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.
- We rely, and expect to continue to rely, on third parties, including independent clinical investigators, contracted laboratories and contract research organizations, to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.
- We rely on third parties to supply and manufacture our product candidates, and we expect to continue to rely on third parties to manufacture our products, if approved. The development of such product candidates and the commercialization of any products, if approved, could be stopped, delayed or made less profitable if any such third party fails to provide us with sufficient quantities of product candidates or products or fails to do so at acceptable quality levels or prices or fails to maintain or achieve satisfactory regulatory compliance.
- Our future collaborations will be important to our business. If we are unable to enter into new collaborations, or if these collaborations are not successful, our business could be adversely affected.
- The COVID-19 coronavirus could adversely impact our business, including the timing or results of our preclinical studies and clinical trials.

Risks Related to Our Financial Position and Need for Additional Capital

We have a limited operating history, have incurred net losses in every year since our inception and anticipate that we will continue to incur net losses in the future.

We are a clinical-stage biopharmaceutical company with a limited operating history. Since our inception in 2015, we have invested most of our resources in developing our product candidates, building our intellectual property portfolio, developing our supply chain, conducting business planning, raising capital and providing general and administrative support for these operations. Consequently, we have no meaningful operations

upon which to evaluate our business and predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing drug products. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures 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. We have not yet demonstrated the ability to progress any product candidate through late-stage clinical trials, we have no products approved for commercial sale and we have not generated any revenue from product sales to date. 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 losses in each period since our inception. For the years ended December 31, 2018 and 2019, we reported a net loss of $1.3 million and $12.3 million, respectively. For the three and nine months ended September 30, 2020, we reported a net loss of $ million and $ million, respectively. As of September 30, 2020, we had an accumulated deficit of $ 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 lead protein therapeutic product candidate, KER-050, our lead small molecule product candidate, KER-047, our third product candidate, KER-012, and any future product candidates we may develop.

We anticipate that our expenses will increase substantially if, and as, we:

- complete our Phase 2 clinical trial of KER-050 evaluating the treatment of cytopenias, including anemia and thrombocytopenia, in patients with myelodysplastic syndrome, or MDS;
- initiate a Phase 2 clinical trial of KER-050 evaluating the treatment of cytopenias, including anemia and thrombocytopenia, in patients with myelofibrosis in 2021;
- initiate a Phase 2 clinical trial of KER-047 in patients with iron deficiency anemia, or IDA, in 2021 and a Phase 2 clinical trial in patients with iron-refractory iron deficiency anemia, or IRIDA, in 2021;
- initiate a Phase 2 clinical trial of KER-047 in patients with fibrodysplasia ossificans progressive, or FOP;
- advance KER-012 into clinical development;
- continue the research and development of our other clinical- and preclinical-stage product candidates and discovery-stage programs;
- increase the amount of research and development activities to identify and develop product candidates using our proprietary discovery approach;
- make milestone, royalty or other payments under in-license or collaboration agreements;
- maintain, expand and protect our intellectual property portfolio;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with third parties;
- invest in or in-license other technologies; and
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, manufacturing challenges, safety issues or other regulatory challenges.

To become and remain profitable, we, our collaborators and any potential future collaborators must develop and eventually commercialize products with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials, obtaining marketing approval for product candidates, manufacturing, marketing and selling products for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is significant or large enough to achieve profitability. 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.

Even if we succeed in commercializing one or more of our product candidates, we will 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.

Even if we consummate this offering, we will need substantial additional funding in order to complete the development and commence commercialization of our product candidates. Failure to obtain this necessary capital when needed may force us to delay, reduce or eliminate certain of our product development or research operations.

To date, we have funded our operations primarily through private placements of our equity securities, upfront and expense reimbursement payments received from our collaborators and from our initial public offering, or IPO, in April 2020. We expect our expenses to increase in connection with our ongoing activities, particularly as we complete our Phase 2 clinical trial of KER-050 in patients with MDS, initiate our Phase 2 clinical trial of KER-050 in patients with myelofibrosis, initiate three Phase 2 clinical trials of KER-047, one in patients with IDA, one in patients with IRIDA and one in patients with FOP, advance KER-012 into clinical development and initiate later-stage clinical development, and continue to research, develop and initiate clinical trials of any other future product candidates. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our product development programs or any future commercialization efforts.

At September 30, 2020, we had $ million in cash and cash equivalents. We expect that our existing cash and cash equivalents, together with the proceeds from this offering, will enable us to fund our operating expenses and capital expenditure requirements until at least . We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our future capital requirements for KER-050, KER-047, KER-012 or our other preclinical programs will depend on many factors, including:

- the progress, timing and completion of preclinical studies and clinical trials for our current or any future product candidates, as well as the associated costs, including any unforeseen costs we may incur as a result of preclinical study or clinical trial delays due to the COVID-19 pandemic or other causes;
- the timing and amount of milestone and royalty payments we are required to make or are eligible to receive under our license agreement with The General Hospital Corporation;
- the number of potential new product candidates we identify and decide to develop;
- the need for additional or expanded preclinical studies and clinical trials beyond those that we plan to conduct with respect to our current and future product candidates;
- the costs involved in growing our organization to the size needed to allow for the research, development and potential commercialization of our current or any future product candidates;
- the costs involved in filing patent applications, maintaining and enforcing patents or defending against infringement or other claims raised by third parties;
- the maintenance of our existing license and collaboration agreements and the entry into new license and collaboration agreements;
- the time and costs involved in obtaining regulatory approval for our product candidates and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to any of our product candidates;
- the effect of competing technological and market developments;
- the cost of manufacturing KER-050, KER-047, KER-012 and future product candidates for clinical trials in preparation for marketing approval and in preparation for commercialization;
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own;
- the amount of revenues, if any, we may derive either directly or in the form of royalty payments from future sales of our product candidates, if approved; and

- market acceptance of any approved product candidates.

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 product or royalty 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.

Our ability to raise additional funds will depend on financial, economic and market conditions and other factors, over which we may have no or limited control. If we are unable to obtain additional funding, we could be forced to delay, reduce or eliminate some or all of our research and development programs and clinical development efforts, which would adversely affect our business prospects, or we may be unable to continue operations.

Raising additional capital may cause dilution to holders of our common stock in this offering, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our operations with our existing cash and cash equivalents, the net proceeds from this offering and revenue from our collaborations. In order to further advance development of our product candidates, discover additional product candidates and pursue our other business objectives, we will need to seek additional funds.

We cannot guarantee that future financing will be available in sufficient amounts or on commercially reasonable terms, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of holders of our common stock and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our common stock to decline. The sale of additional common stock or securities convertible or exchangeable into common stock would dilute all of our existing stockholders and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our common stock. The incurrence of indebtedness could result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt or declare dividends, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. 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 KER-050, KER-047, KER-012 or any future product candidate 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. Further, any additional fundraising efforts may divert our management from its day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates.

Risks Related to the Discovery, Development and Regulatory Approval of our Product Candidates

We are heavily dependent on the success of our product candidates, which are in early clinical development. If we are unable to advance our current or future product candidates through clinical trials, obtain marketing approval and ultimately commercialize any product candidates we develop, or experience significant delays in doing so, our business will be materially harmed.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. We are early in our product candidate development efforts, as both KER-050 and KER-047 are still in early-stage clinical trials and KER-012 is still in preclinical studies. Because KER-050 and KER-047 are our lead product candidates, if either KER-050 or KER-047 encounters safety or efficacy problems, development delays or regulatory issues or other problems, our development plans and business would be significantly harmed.

Our ability to generate product revenues, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of KER-050, KER-047, KER-012 and any future product candidates we develop, which may never occur. KER-050, KER-047, KER-012 and any future product candidates we develop will require additional preclinical and clinical development, management of clinical, preclinical and manufacturing activities, marketing approval in the United States and other jurisdictions for specific indications for use, demonstrating effectiveness to pricing and

reimbursement authorities, obtaining sufficient manufacturing supply for both clinical development and commercial production, building of a commercial organization and substantial investment and significant marketing efforts before we generate any revenues from product sales. The success of our current and future product candidates will depend on several factors, including the following:

- successful and timely completion of clinical trials and preclinical studies for which the U.S. Food and Drug Administration, or the FDA, or any comparable foreign regulatory authority agree with the design, endpoints or implementation;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- receiving regulatory approvals or authorizations for conducting our planned clinical trials or future clinical trials;
- initiation and successful patient enrollment in, and completion of, additional clinical trials on a timely basis;
- our ability to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate is safe and effective as a treatment for our targeted indications or, in the case of an applicable product candidates which is regulated as a biological product, that the applicable product is safe, pure, and potent for our targeted indications;
- our ability to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate's risk-benefit ratio for its proposed indication is acceptable;
- timely receipt of marketing approvals for our product candidates from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- establishing and scaling up, either alone or with third-party manufacturers, manufacturing capabilities of clinical supply for our clinical trials and commercial manufacturing, if any of our product candidates are approved;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates, both in the United States and internationally;
- successfully scaling a sales and marketing organization and launching commercial sales of our product candidates, if approved;
- acceptance of our product candidates' benefits and uses, if approved, by patients, the medical community and third-party payors;
- maintaining a continued acceptable safety profile of our product candidates following approval;
- effectively competing with companies developing and commercializing other therapies in the indications which our product candidates target;
- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors; and
- enforcing and defending intellectual property rights and claims.

If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize KER-050, KER-047, KER-012 or any future product candidates we develop, which would materially harm our business. If we do not receive marketing approvals for our current and future product candidates, we may not be able to continue our operations.

All of our product candidates are in preclinical or early clinical development stages. Clinical trials are difficult to design and implement, and they involve a lengthy and expensive process with uncertain outcomes. We may experience delays in completing, or ultimately be unable to complete, the development and commercialization of KER-050, KER-047, KER-012 or any future product candidates.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process and our future clinical trial results may not be successful. We cannot guarantee that any of our ongoing and planned clinical trials will be conducted as planned or completed on schedule, if at all. Moreover, even if these trials are initiated or conducted on a timely basis, issues may arise that could result in the suspension or termination of such clinical trials.

To date, we have not completed any clinical trials required for the approval of any of our product candidates. Although we have completed our Phase 1 clinical trial of KER-050 and our expanded Phase 1 clinical trial of KER-047, each in healthy volunteers, we may experience delays in our ongoing clinical trials or preclinical

studies and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time, have sufficient drug supply for our product candidates on a timely basis or be completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing, and our ongoing and future clinical trials may not be successful. We also may experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize KER-050, KER-047, KER-012 or any future product candidates, including:

- delays in or failure to obtain regulatory authorizations to commence a trial;
- delays in reaching a consensus with regulatory agencies as to the design or implementation of our clinical trials;
- delays in or failure to reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in or failure to obtain institutional review board, or IRB, or ethics committee approval at each site;
- delays in or failure to recruit a sufficient number of suitable patients to participate in a trial;
- failure to have patients complete a trial or return for post-treatment follow-up, including disruptions in our ability to treat patients or conduct post-treatment follow-up due to the COVID-19 pandemic;
- clinical sites deviating from trial protocol, missing data or dropping out of a trial;
- delays in adding new clinical trial sites;
- failure to manufacture sufficient quantities of our product candidates for use in clinical trials in a timely manner;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits, or safety or tolerability concerns that could cause us or our collaborators, as applicable, to suspend or terminate a trial if we or our collaborators find that the participants are being exposed to unacceptable health risks;
- failure to perform clinical trials in accordance with the FDA's or any other regulatory authority's good clinical practices, or GCP, requirements, or regulatory guidelines in other countries;
- changes in regulatory requirements, policies and guidelines;
- failure of our third-party research contractors to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- delays in establishing the appropriate dosage levels and frequency of dosing in clinical trials;
- the quality or stability of our product candidates falling below acceptable standards;
- delays due to the COVID-19 pandemic; and
- business interruptions resulting from geo-political actions, including war and terrorism, another outbreak of a contagious disease or natural disasters including earthquakes, typhoons, floods and fires.

In addition, disruptions caused by the COVID-19 pandemic have resulted in difficulties and delays in initiating, enrolling, conducting or completing our planned and ongoing preclinical studies and clinical trials, as applicable, and may increase the likelihood that we encounter additional difficulties and delays in the future. We could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs of the institutions in which such trials are being conducted, or the FDA or comparable foreign regulatory authorities, or recommended for suspension or termination by the Data Safety Monitoring Board for such trial. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product or treatment, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA or comparable foreign regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

Our product development costs will increase if we experience delays in clinical testing or marketing approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be

completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition and results of operations significantly.

Our clinical trials may fail to demonstrate substantial evidence of the safety and efficacy or safety, purity and potency of our product candidates or any future product candidates, which would prevent or delay or limit the scope of regulatory approval and commercialization.

To obtain the requisite regulatory approvals to market and sell any of our product candidates, including KER-050, KER-047, KER-012 and any other future product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our investigational drug products, such as KER-047, are safe and effective for use in each targeted indication, and in the case of our product candidates regulated as biological products, such as KER-050 and KER-012, that the product candidate is safe, pure and potent for use in its targeted indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical development process. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful, and a clinical trial can fail at any stage of testing. Further, the process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications, patient population and regulatory agency. Prior to obtaining approval to commercialize KER-050, KER-047, KER-012 and any future product candidates in the United States or abroad, we, our collaborators or our potential future collaborators must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses.

Clinical trials that we conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. If the results of our ongoing or future clinical trials are inconclusive with respect to the efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be delayed in obtaining marketing approval, if at all. Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications.

Even if the trials are successfully completed, clinical data are often susceptible to varying interpretations and analyses, and we cannot guarantee that the FDA or comparable foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. We cannot guarantee that the FDA or comparable foreign regulatory authorities will view our product candidates as having efficacy even if positive results are observed in clinical trials. Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction. To the extent that the results of the trials are not satisfactory to the FDA or comparable foreign regulatory authorities for support of a marketing application, approval of KER-050, KER-047, KER-012 and any future product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for a product candidate, the terms of such approval may limit the scope and use of the specific product candidate, which may also limit its commercial potential.

The results of preclinical studies and early-stage clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Initial success in our ongoing clinical trials may not be indicative of results obtained when these trials are completed or in later-stage trials.

The results of nonclinical and preclinical studies and clinical trials may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Furthermore, there can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development of any of our product candidates. There is a high failure rate for product candidates proceeding through clinical trials. Many companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway, or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA approval. Any such setbacks in our clinical development could have a material adverse effect on our business, financial condition and results of operations.

Additionally, some of the clinical trials we conduct may include open-label trials conducted at a limited number of clinical sites on a limited number of patients. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved product or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. Moreover, patients selected for early-stage clinical trials often include the most severe sufferers and their symptoms may have been bound to improve notwithstanding the new treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. Given that open-label Phase 2 clinical trials are planned for KER-050, the results from these clinical trials may not be predictive of future clinical trial results with these or other product candidates for which we include an open-label clinical trial when studied in a controlled environment with a placebo or active control.

Our product candidates may be associated with serious adverse, undesirable or unacceptable side effects or other properties or safety risks, which may delay or halt their clinical development, or prevent marketing approval. If such side effects are identified during the development of our product candidates or following approval we may suspend or abandon our development of such product candidates, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences following marketing approval.

Undesirable side effects that may be caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. While our lead product candidates, KER-050 and KER-047, have generally been well tolerated in our preclinical studies and clinical trials to date, the results from future preclinical studies and clinical trials, including of KER-012 and our other product candidates, may identify safety concerns or other undesirable properties of our product candidates.

The results of our ongoing and planned Phase 2 clinical trials of KER-050, our expanded Phase 1 clinical trial of KER-047, our planned Phase 2 clinical trials of KER-047, our planned Phase 1 clinical trial of KER-012 and future clinical trials of these and other product candidates may show that our product candidates cause undesirable or unacceptable side effects or even death. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and results of operations significantly.

Moreover, if our product candidates are associated with undesirable side effects in preclinical studies or clinical trials or have characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for the product candidate, if approved.

Additionally, adverse developments in clinical trials of pharmaceutical and biopharmaceutical products conducted by others may cause the FDA or other regulatory oversight bodies to suspend or terminate our clinical trials or to change the requirements for approval of any of our product candidates.

Additionally, if any of our product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product and require us to take our approved product off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- regulatory authorities may require a medication guide outlining the risks of such side effects for distribution to patients, or that we implement a risk evaluation and mitigation strategy, or REMS, plan to ensure that the benefits of the product outweigh its risks;
- we may be required to conduct additional clinical trials, which may lead to additional interactions with regulatory authorities;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us, our collaborators or our potential future partners from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our product candidates, if approved.

We may find it difficult to enroll patients in our clinical trials, which could delay or prevent us from proceeding with, or otherwise adversely affect, clinical trials of our product candidates.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timely completion of our clinical trials in accordance with their protocols depends, among other things, on our ability to recruit a sufficient number of eligible patients to participate and remain in the trial until its conclusion. Patients may be unwilling to participate in our clinical trials because of negative publicity from adverse events related to novel therapeutic approaches, competitive clinical trials for similar patient populations, the existence of current treatments or for other reasons, including the ongoing COVID-19 pandemic. Any delays related to patient enrollment or difficulties related to patient retention could result in increased costs, delays in advancing our product candidates, delays in testing the effectiveness of our product candidates or termination of the clinical trials altogether. We may not be able to identify, recruit and enroll a sufficient number of patients, or those with the required or desired characteristics, to complete our clinical trials in a timely manner. Patient enrollment and trial completion is affected by many factors, including the:

- size and nature of the patient population and process for identifying patients;
- proximity and availability of clinical trial sites for prospective patients;
- ability of patients to travel to clinical trial sites;
- eligibility and exclusion criteria for the trial;
- design of the clinical trial;
- safety profile, to date, of the product candidate under study;
- perceived risks and benefits of the product candidate under study;
- perceived risks and benefits of our approach;

- approval of competing product candidates currently under investigation for the treatment of similar diseases or conditions, or competing clinical trials for similar product candidates or targeting patient populations meeting our patient eligibility criteria;
- severity of the disease under investigation;
- degree of progression of the patient's disease at the time of enrollment and throughout the clinical trial;
- ability to obtain and maintain patient consent;
- risk that enrolled patients will drop out before completion of the trial;
- patient referral practices of physicians; and
- ability to adequately monitor patients during and after treatment.

Enrollment risks are heightened with respect to indications that are rare or orphan diseases, which may limit the pool of patients that may be enrolled in our planned clinical trials. For example, we are developing KER-047 for the treatment of FOP, which is a rare genetic disease, affecting an estimated 3,500 people worldwide. As a result, we may encounter difficulties enrolling subjects in our clinical trials evaluating KER-047 for the treatment of FOP due, in part, to the small size of this patient population. In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site.

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

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim, topline or preliminary data from our clinical trials. Preliminary and interim data from our clinical trials may change as more patient data become available. Preliminary or interim data from our clinical trials are not necessarily predictive of final results. Preliminary and interim data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues, more patient data become available and we issue our final clinical trial report. Interim, topline and preliminary 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, preliminary, topline and interim data should be viewed with caution until the final data are available. Material adverse changes in the final data compared to the interim data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product, if any, and our company in general. In addition, the information we choose to publicly disclose regarding a particular preclinical study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, if any, product candidate or our business. If the preliminary and interim data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, 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.

Before we can commence clinical trials for any product candidate, we must complete extensive preclinical studies that support any future Investigational New Drug, or IND, applications in the United States, or similar applications in other jurisdictions. We have not interacted with or submitted any IND to the FDA and all of our clinical trials have, to date, been conducted in Australia and New Zealand. Conducting preclinical testing is a lengthy, time-consuming and expensive process and delays associated with product candidates for which we are directly conducting preclinical testing and studies may cause us to incur additional operating expenses. While we are conducting a Phase 2 clinical trial for KER-050 in patients with MDS and plan to initially conduct a Phase 2 clinical trial for KER-050 in patients with myelofibrosis and two Phase 2 clinical trials for KER-047, one in patients with IDA and one in patients with IRIDA, outside of the United States, we cannot be certain of the timely completion or outcome of our preclinical testing and studies for our other product candidates and cannot predict if the FDA will accept our proposed clinical programs or if the outcome of our preclinical testing and foreign clinical trials will ultimately support the further development of our other product candidates. As a result, 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, and we cannot be sure that submission of INDs or similar applications will result in the FDA or comparable foreign regulatory authorities allowing clinical trials to begin.

Our research and development activities could be affected or delayed as a result of possible restrictions on animal testing.

Certain laws and regulations require us to test our product candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted, delayed or become more expensive.

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

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

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective as a treatment for our targeted indications, or, in the case of a product candidate regulated as a biological product, that the product candidate is safe, pure and potent for its proposed indication;
- the population studied may not be sufficiently broad or representative to assure safety or efficacy in the population for which we seek approval;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;

- the FDA or comparable foreign regulatory authorities may require additional preclinical studies or clinical trials beyond those that we currently anticipate;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a New Drug Application, or NDA, or a Biologics License Application, or BLA, as applicable, to the FDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or any comparable foreign regulatory authorities or the laws they enforce may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, financial condition and results of operations. The FDA and comparable foreign regulatory authorities have substantial discretion in the approval process, and determining when or whether regulatory approval will be obtained for any of our product candidates. Even if we believe the data collected from clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA or comparable foreign regulatory authorities. Separately, in response to the COVID-19 pandemic, the FDA has postponed most inspections of foreign and domestic manufacturing facilities and products, and as of October 2020, has only restarted domestic manufacturing facility inspection on a risk-based basis. Regulatory authorities outside the United States may continue to adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, if any, 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. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

The FDA and any comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.

We are presently conducting clinical development solely in Australia and New Zealand and may choose to conduct additional international clinical trials in the future. We have not interacted with or submitted any IND to the FDA. The acceptance of study data by the FDA or any comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practice, (ii) the trials are performed by clinical investigators of recognized competence and pursuant to compliance with current GCP requirements and (iii) the FDA is able to validate the data through an on-site inspection or other appropriate mean. Additionally, the FDA's clinical trial requirements, including the adequacy of the patient population studied and statistical powering, must be met. In addition, such foreign trials are subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any applicable foreign regulatory authority will accept data from trials conducted outside of its applicable jurisdiction. If the FDA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval for commercialization in the applicable jurisdiction.

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

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with current Good Manufacturing Practices, or cGMPs, and GCP requirements for any clinical trials that we conduct post-approval.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA or BLA, other marketing application, and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS program as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports and registration.

The FDA may impose consent decrees or 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 our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Products may be promoted only for the approved indications 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 and a company that is found to have improperly promoted off-label uses may be subject to significant liability including, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe, in their independent professional medical judgment, 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. 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. The federal government has levied large civil

and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling.

The holder of an NDA or BLA must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling, or manufacturing process. We could also be asked to conduct post-marketing clinical trials to verify the safety and efficacy of our products in general or in specific patient subsets. If original marketing approval was obtained via the accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial to confirm clinical benefit for our products. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

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

If approved, our investigational products regulated as biologics, including KER-050 and KER-012, may face competition from biosimilars approved through an abbreviated regulatory pathway.

We are developing KER-050 for the treatment of cytopenias, including anemia and thrombocytopenia, in patients with MDS and myelofibrosis, and KER-012 for the treatment of disorders associated with bone loss, such as osteoporosis and osteogenesis imperfecta, and for the treatment of PAH, both of which we anticipate will be regulated as a biological product. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, 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-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of the other company's product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our investigational medicines to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of litigation. Moreover, the extent to which a biosimilar, once licensed, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

If competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences.

We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of biopharmaceutical products. Currently, we have no products that have been approved for commercial sale; however, the current and future use of product candidates by us and our collaborators in clinical trials, and the potential sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients who use the product, healthcare providers, pharmaceutical companies, our collaborators or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for our product candidates or any prospects for commercialization of our product candidates. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products due to negative public perception;
- injury to our reputation;
- withdrawal of clinical trial participants or difficulties in recruiting new trial participants;
- initiation of investigations by regulators;
- costs to defend or settle the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenues from product sales; and
- the inability to commercialize any of our product candidates, if approved.

Although we believe we maintain adequate product liability insurance for our product candidates, it is possible that our liabilities could exceed our insurance coverage. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any of our product candidates. However, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired. Should any of the events described above occur, this could have a material adverse effect on our business, financial condition and results of operations.

Due to our limited resources and access to capital, we must, and have in the past decided to, prioritize development of certain product candidates over other potential product candidates. These decisions may prove to have been wrong and may adversely affect our ability to develop our own programs, our attractiveness as a commercial partner and may ultimately have an impact on our commercial success.

Because we have limited resources and access to capital to fund our operations, we must decide which product candidates to pursue and the amount of resources to allocate to each. Our decisions concerning the allocation of research, collaboration, management and financial resources toward particular proprietary molecules in our library, product candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources away from better opportunities. Similarly, our decisions to delay, terminate or collaborate with third parties in respect of certain product development programs may also prove not to be optimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the market potential of our product candidates or misread trends in the biopharmaceutical industry, in particular for our lead product candidates, KER-050, KER-047, as well as for KER-012, our business, financial condition and results of operations could be materially adversely affected.

We may seek orphan drug designation for product candidates we develop, and we may be unsuccessful or may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

As part of our business strategy, we may seek orphan drug designation for any product candidates we develop, and we may be unsuccessful. While we have not made a determination regarding whether we intend to seek orphan drug designation for any of our product candidates at this time, we may do so in the future. Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act in the United States, the FDA may designate a drug

as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards certain clinical trial costs, tax advantages and user-fee waivers.

Generally in the United States, if a drug with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug and indication for seven years, except in limited circumstances.

Even if we obtain orphan drug exclusivity for any of our product candidates, that exclusivity may not effectively protect the product candidate from competition because different therapies can be approved for the same condition and the same therapies can be approved for different conditions but used off-label. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. While we may seek orphan drug designation for applicable indications for our current and any future product candidates, we may never receive such designations. Even if we do receive such designations, there is no guarantee that we will benefit from those designations.

Risks Related to Commercialization of Our Product Candidates

If we are unable to successfully commercialize any product candidate for which we receive regulatory approval, or experience significant delays in doing so, our business will be materially harmed.

If we are successful in obtaining marketing approval from applicable regulatory authorities for KER-050, KER-047, KER-012 or any other product candidate, our ability to generate revenues from any such products will depend on our success in:

- launching commercial sales of such products, whether alone or in collaboration with others;
- receiving approved labels with claims that are necessary or desirable for successful marketing, and that do not contain safety or other limitations that would impede our ability to market such products;
- creating market demand for such products through marketing, sales and promotion activities;
- hiring, training, and deploying a sales force or contracting with third parties to commercialize such products in the United States;
- creating strategic collaborations with, or offering licenses to, third parties to promote and sell such products in foreign markets where we receive marketing approval;
- manufacturing such products in sufficient quantities and at acceptable quality and cost to meet commercial demand at launch and thereafter;
- establishing and maintaining agreements with wholesalers, distributors, and group purchasing organizations on commercially reasonable terms;
- maintaining patent and trade secret protection and regulatory exclusivity for such products;
- achieving market acceptance of such products by patients, the medical community, and third-party payors;
- achieving coverage and adequate reimbursement from third-party payors for such products;
- patients' willingness to pay out-of-pocket in the absence of such coverage and adequate reimbursement from third-party payors;
- effectively competing with other therapies; and
- maintaining a continued acceptable safety profile of such products following launch.

To the extent we are not able to do any of the foregoing, our business, financial condition, results of operations, stock price and prospects will be materially harmed.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly as they develop novel approaches to treating disease indications that our product candidates are also focused on treating. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel therapeutics or to in-license novel therapeutics that could make the product candidates that we develop obsolete. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products. We believe the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety, tolerability, reliability, convenience of use, price and reimbursement.

We compete in the segments of the biotechnology, pharmaceutical and other related industries that develop and market therapies for the treatment of hematological and musculoskeletal disorders. There are many other companies, including large biotechnology and pharmaceutical companies, that have commercialized and/or are developing therapies for the same therapeutic areas that our product candidates target. For example, FibroGen Inc. and Astellas Pharma Inc. are developing product candidates for the treatment of anemia, and Acceleron Pharma Inc., or Acceleron, Bristol-Myers Squibb Company and Disc Medicine are developing product candidates targeting diseases associated with MDS and myelofibrosis, including chronic anemia. Additionally, in April 2020, Acceleron received FDA approval of its product, Reblozyl, for the treatment of anemia failing an erythropoiesis stimulating agent and requiring two or more red blood cell units over eight weeks in adult patients with very low- to intermediate-risk MDS with ring sideroblasts or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis. In June 2020, Acceleron further announced that the European Commission approved Reblozyl for the treatment of transfusion-dependent anemia in adult patients with MDS or beta thalassemia and in September 2020, Acceleron announced that Health Canada approved Reblozyl for the treatment of adult patients with red blood cell transfusion-dependent anemia associated with beta thalassemia. Sierra Oncology, Inc. is developing momelotinib as a treatment for myelofibrosis. Additionally, Constellation Pharmaceutics, Inc. is also developing a product candidate as a treatment for myelofibrosis.

Other companies that are developing product candidates that are designed to target the TGF-ß signaling pathways include Scholar Rock Holding Corporation, Biogen Inc. and Regeneron Pharmaceuticals, Inc.

There are currently no approved drugs for the treatment of FOP. However, Ipsen, through its subsidiary Clementia Pharmaceuticals Inc. and pursuant to a collaboration with Blueprint Medicines Corporation, as well as Regeneron Pharmaceuticals, Inc., BioCryst Pharmaceuticals, Inc. and Incyte Corporation are developing product candidates for the treatment of FOP that are intended to work, at least in part, through inhibition of aberrant ALK2 signaling.

We anticipate that we will continue to face intense and increasing competition as new treatments enter the market and advanced technologies become available. There can be no assurance that our competitors are not currently developing, or will not in the future develop, products that are equally or more effective or are more economically attractive than any of our current or future product candidates. Competing products may gain faster or greater market acceptance than our products, if any, and medical advances or rapid technological

development by competitors may result in our product candidates becoming non-competitive or obsolete before we are able to recover our research and development and commercialization expenses. If we or our product candidates do not compete effectively, it may have a material adverse effect on our business, financial condition and results of operations.

We do not have a sales or marketing infrastructure and have no experience in the sale or marketing of biopharmaceutical products. To achieve commercial success for any approved product, we must develop or acquire a sales and marketing organization, outsource these functions to third parties or enter into strategic collaborations.

We may decide to establish our own sales and marketing capabilities and promote our product candidates if and when regulatory approval has been obtained in the United States or in other jurisdictions. There are risks involved if we decide to establish our own sales and marketing capabilities or enter into arrangements with third parties to perform these services. Even if we establish sales and marketing capabilities, we may fail to launch our products effectively or to market our products effectively since we have no experience in the sales and marketing of biopharmaceutical products. In addition, recruiting and training a sales force is expensive and time consuming and could delay any product launch. In the event that any such launch is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or educate adequate numbers of physicians on the benefits of our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- unforeseen costs and expenses associated with creating an independent sales and marketing organization; and
- costs of marketing and promotion above those anticipated by us.

If we enter into arrangements with third parties to perform sales and marketing services, our product revenues or the profitability of these product revenues to us could be lower than if we were to market and sell any products that we develop ourselves. Such collaborative arrangements with partners may place the commercialization of our products outside of our control and would make us subject to a number of risks including that we may not be able to control the amount or timing of resources that our collaborative partner devotes to our products or that our collaborator's willingness or ability to complete its obligations, and our obligations under our arrangements may be adversely affected by business combinations or significant changes in our collaborator's business strategy. In addition, we may not be successful in entering into arrangements with third parties to sell and market our products or may be unable to do so on terms that are favorable to us. Acceptable third parties may fail to devote the necessary resources and attention to sell and market our products effectively.

If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we may not be successful in commercializing our products, if any, which in turn would have a material adverse effect on our business, financial condition and results of operations.

Even if a product candidate we develop receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success. The revenues that we generate from their sales may be limited, and we may never become profitable.

We have never commercialized a product candidate for any indication. Even if our product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third-party payors and others in the medical community. If any product candidates for which we obtain regulatory approval does not gain an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability. Market acceptance of our product candidates by the medical community, patients and third-party payors will depend on a number of factors, some of which are beyond our control. For example, physicians are often reluctant to switch their patients and patients may be

reluctant to switch from existing therapies even when new and potentially more effective or safer treatments enter the market.

Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. If any of our product candidates are approved but do not achieve an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability. The degree of market acceptance of any product for which we receive marketing approval will depend on a number of factors, including:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or comparable foreign regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA or comparable foreign regulatory authorities;
- the timing of market introduction of our product candidates in relation to other potentially competitive products;
- the cost of our product candidates in relation to alternative treatments;
- the amount of upfront costs or training required for physicians to administer our product candidates;
- the availability of coverage and adequate reimbursement from third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of comprehensive coverage and reimbursement by third-party payors and government authorities;
- the relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies;
- the effectiveness of our sales and marketing efforts and distribution support; and
- the presence or perceived risk of potential product liability claims.

Enacted and future healthcare legislation may increase the difficulty and cost for us to progress our clinical programs and obtain marketing approval of and commercialize our product candidates and may affect the prices we may set.

In the United States and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the ACA was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents (other than those designated as orphan drugs), which is apportioned among these entities according to their market share in certain government healthcare programs;
- 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;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- a licensure framework for follow on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of a Center for Medicare & Medicaid Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial, Congressional and executive branch challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance, delaying the implementation of certain ACA-mandated fees and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. On December 14, 2018, a U.S. District Court Judge in Texas ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act, or the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit ruled that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, although it is unclear when the Supreme Court will make a decision. It is also unclear how such litigation and other efforts to repeal and replace the ACA will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, led to aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through December 31, 2020, unless additional action is taken by Congress. 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. These new laws or any other similar laws introduced in the future may result in additional reductions in Medicare and other health care funding, which could negatively affect our customers and accordingly, our financial operations.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare and review the relationship between pricing and manufacturer patient programs. The Trump administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients and increase patient access to lower-cost generic and biosimilar drugs.

On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Additionally, on May 11, 2018, President Trump laid out his administration's "Blueprint" to lower drug prices and reduce out-of-pocket costs of prescription drugs that contained 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 Department of Health and Human Services, or HHS, has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. On July 24, 2020, the Trump administration announced four executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals, including a policy that would tie certain Medicare Part B drug prices to international drug prices, the details of which were released on September 13, 2020 and expanded the policy to cover certain Part D drugs; one that directs HHS to finalize the Canadian drug importation proposed rule previously issued by HHS and makes other changes allowing for

personal importation of drugs from Canada; one that directs HHS to finalize the rulemaking process on modifying the anti-kickback law safe harbors for discounts for plans, pharmacies, and pharmaceutical benefit managers; and one that reduces costs of insulin and epipens to patients of federally qualified health centers. The FDA also recently released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Although some of these and other 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. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Individual states in the United States have also 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. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates or put pressure on our product pricing.

In markets outside of the United States, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. It is possible that additional governmental action is taken in response to the COVID-19 pandemic. For example, the Trump administration issued an executive order on August 3, 2020 directing CMS to propose a regulation extending Medicare coverage for certain telemedicine services provided to certain Medicare beneficiaries beyond the duration of the COVID-19 public health emergency. CMS is required to propose the regulation within 60 days of the issuance of the executive order. Additionally, on August 6, 2020, the Trump administration issued another executive order that instructs the federal government to develop a list of “essential” medicines and then buy them and other medical supplies from U.S. manufacturers instead of from companies around the world, including China. The order is meant to reduce regulatory barriers to domestic pharmaceutical manufacturing and catalyze manufacturing technologies needed to keep drug prices low and the production of drug products in the United States. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Disruptions at the FDA, the SEC and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, otherwise prevent new products and services from being developed, approved or commercialized in a timely manner or at all, or otherwise prevent those agencies from performing normal business 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 the payment of user fees, statutory, regulatory and policy changes, and other events that may otherwise affect the FDA’s ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the Securities and Exchange Commission, or 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,

in recent years, including in 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. Separately, in response to the COVID-19 pandemic, the FDA has postponed most inspections of foreign and domestic manufacturing facilities and products, and as of October 2020, has only restarted domestic manufacturing facility inspection on a risk-based basis. Regulatory authorities outside the United States may continue to adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly 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, future government shutdowns or delays could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers may be subject to applicable healthcare regulatory laws, which could expose us to penalties. Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. 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;
- the U.S. federal civil and criminal false claims laws, including the civil False Claims Act, which can be enforced by private individuals on behalf of the government through civil whistleblower or qui tam actions, and civil monetary penalties laws prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal civil and criminal liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, 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;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations, which impose certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers and their business associates, independent contractors of a covered entity that perform certain services involving the use or disclosure of individually identifiable health information, as well as their covered subcontractors;
- the Federal Food, Drug, and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;

- the U.S. Public Health Service Act, which prohibits, among other things, the introduction into interstate commerce of a biological product unless a biologics license is in effect for that product;
- the U.S. Physician Payments Sunshine Act and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS information related to certain payments and other transfers of value made in the prior year to physicians, as defined under such law, and teaching hospitals, as well as ownership and investment interests held by such physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding their relationships with physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives during the previous year; and
- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and local laws and regulations that require drug manufacturers to file reports relating to drug pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws that require the registration of pharmaceutical sales representatives; and state laws governing 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.

In addition, our activities are also subject to certain federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Ensuring that our internal operations and future 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 do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

If the market opportunities for our product candidates are smaller than we believe they are, even assuming approval of a product candidate, our business may suffer.

Our projections of both the number of people who are affected by disease within our potential target indications, as well as the subset of these people who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, healthcare utilization databases and market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. Likewise, the potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our business, financial condition and results of operations.

Any product candidates we develop may become subject to unfavorable third-party coverage and reimbursement practices, as well as pricing regulations.

The availability and extent of coverage and adequate reimbursement by third-party payors, including government health administration authorities, private health coverage insurers, managed care organizations and other third-party payors is essential for most patients to be able to afford expensive treatments. Sales of any of our product candidates that receive marketing approval will depend substantially, both in the United States and internationally, on the extent to which the costs of our product candidates will be covered and reimbursed by third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, for example, principal decisions about reimbursement for new products are typically made by the CMS. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, one third-party payor's determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. As a result, the coverage determination process is often time-consuming and costly. This process will require us to provide scientific and clinical support for the use of our products to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

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. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of our products. Nonetheless, our product candidates may not be considered medically necessary or cost effective. 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.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. In many countries, particularly the countries of the European Union, medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives marketing approval. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

If we are unable to establish or sustain coverage and adequate reimbursement for any future product candidates from third-party payors, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved. Coverage policies and third-party payor 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.

Risks Related to Our Intellectual Property

Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

Our commercial success will depend in large part on obtaining and maintaining patent, trademark and trade secret protection of our proprietary technologies and our product candidates, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment, as well as successfully defending these patents against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents that cover these activities. If we are unable to secure and maintain patent protection for any product or technology we develop, or if the scope of the patent protection secured is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize any product candidates we may develop may be adversely affected.

The patenting process is expensive and time-consuming, and we may not be able to file, prosecute and maintain all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we may not pursue, obtain or maintain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors or licensees. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced.

Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates. Furthermore, for United States applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party or instituted by the United States Patent and Trademark Office, or USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications.

We cannot be certain that we are the first to invent the inventions covered by pending patent applications and, if we are not, we may be subject to priority disputes. We may be required to disclaim part or all of the term of certain patents or all of the term of certain patent applications. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim, and we may be subject to a third-party preissuance submission of prior art to the USPTO. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable or that even if found valid and enforceable, a competitor’s technology or product would be found by a court to infringe our patents. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities, and consider that we are free to operate in relation to our product candidates, but our competitors may achieve issued claims, including

in patents we consider to be unrelated, which block our efforts or may potentially result in our product candidates or our activities infringing such claims. The possibility exists that others will develop products which have the same effect as our products on an independent basis which do not infringe our patents or other intellectual property rights, or will design around the claims of patents that we have had issued that cover our products.

Recent or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. Under the enacted Leahy-Smith America Invents Act, or America Invents Act, enacted in 2013, the United States moved from a "first to invent" to a "first-to-file" system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a new post-grant review system. The effects of these changes are currently unclear as the USPTO only recently developed new regulations and procedures in connection with the America Invents Act and many of the substantive changes to patent law, including the "first-to-file" provisions, only became effective in March 2013. In addition, the courts have yet to address many of these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make or use compounds or cells that are similar to the biological compositions of our product candidates but that are not covered by the claims of our patents;
- the active biological ingredients in our current product candidates will eventually become commercially available in biosimilar drug products, and no patent protection may be available with regard to formulation or method of use;
- we or our licensors, as the case may be, may fail to meet our obligations to the U.S. government in regards to any in-licensed patents and patent applications funded by U.S. government grants, leading to the loss of patent rights;
- we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our pending patent applications will not result in issued patents;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our or their patents;
- it is possible that others may circumvent our owned or in-licensed patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our product candidates;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third parties;
- the inventors of our owned or in-licensed patents or patent applications may become involved with competitors, develop products or processes which design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;
- it is possible that our owned or in-licensed patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may

cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
- we have engaged in scientific collaborations in the past, and will continue to do so in the future. Such collaborators may develop adjacent or competing products to ours that are outside the scope of our patents;
- we may not develop additional proprietary technologies for which we can obtain patent protection;
- it is possible that product candidates or diagnostic tests we develop may be covered by third parties' patents or other exclusive rights; or
- the patents of others may have an adverse effect on our business.

We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.

We are dependent on patents, know-how and proprietary technology, both our own and licensed from others. Any termination of these licenses could result in the loss of significant rights and could harm our ability to commercialize our product candidates. See "Business—License and Collaboration Agreements" for additional information regarding our license agreements.

Disputes may also arise between us and our 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 candidates, and what activities satisfy those diligence obligations; and
- the inventorship or ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

In addition, intellectual property license agreements are complex, and certain provisions in such agreements 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 technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

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.

If we fail to comply with our obligations under our patent license with a third party, we could lose license rights that are important to our business.

We are a party to a license agreement pursuant to which we in-license key patent and patent applications for our product candidates. These existing licenses impose various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, our licensor may have the right to terminate the license, in which event we would not be able to develop or market the products covered by such licensed intellectual property. Termination of these agreements or reduction or elimination of our rights under these agreements, or restrictions on our ability to freely assign or sublicense our rights under such agreements when it is in the interest of our business to do so, may impede, delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements.

We may have limited control over the maintenance and prosecution of these in-licensed patents and patent applications, activities or any other intellectual property that may be related to our in-licensed intellectual

property. For example, we cannot be certain that such activities by our licensor have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights.

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

In addition to patent protection, we rely heavily upon know-how and to some extent trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third-parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

In addition, courts outside the United States are sometimes less willing to protect trade secrets. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology.

Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. We have also adopted policies and conduct training that provides guidance on our expectations, and our advice for best practices, in protecting our trade secrets.

Third-party claims of intellectual property infringement may prevent or delay our product discovery and development efforts.

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, inter partes review, post grant review, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and/or proprietary technologies infringe their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to our product candidates and programs. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent

rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

If a third-party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third party licenses its product rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products; and
- redesigning our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Third parties may assert that we are employing their proprietary technology without authorization. Generally, conducting clinical trials and other development activities in the United States is protected under the Safe Harbor exemption as set forth in 35 U.S.C. § 271. If and when KER-050, KER-047, KER-012 or another one of our product candidates is approved by the FDA, that certain third party may then seek to enforce its patent by filing a patent infringement lawsuit against us. While we do not believe that any claims of such patent that could otherwise materially adversely affect commercialization of our product candidates, if approved, are valid and enforceable, we may be incorrect in this belief, or we may not be able to prove it in a litigation. In this regard, patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof. There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. 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. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Even if such a license is available, it may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

Lastly, we may need to indemnify our customers and distributors against claims relating to the infringement of intellectual property rights of third parties related to our product candidates, including KER-050, KER-047 and KER-012. Third parties may assert infringement claims against our customers or distributors. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers or distributors, regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of our customers, suppliers or distributors, or may be required to obtain licenses for the product candidates or services they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products or services.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at universities or other biopharmaceutical or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, and although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

We may not be successful in obtaining or maintaining necessary rights to develop any future product candidates on acceptable terms.

Because our programs may involve additional product candidates that may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights.

Our product candidates may also require specific formulations to work effectively and efficiently and these rights may be held by others. We may develop products containing our compounds and pre-existing pharmaceutical compounds. We may be required by the FDA or comparable foreign regulatory authorities to provide a companion diagnostic test or tests with our product candidates. These diagnostic test or tests may be

covered by intellectual property rights held by others. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

Additionally, we sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. 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.

We may choose to challenge the patentability of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in an ex-parte re-exam, inter partes review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party's patent in patent opposition proceedings in the foreign patent offices. The costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our product candidates or proprietary technologies.

In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our owned and in-licensed issued patents or our pending applications, or that we or, if applicable, a licensor were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our owned and in-licensed patent applications or patents, which could require us to obtain rights to issued patents

covering such technologies. If another party has filed a U.S. patent application on inventions similar to those owned by or in-licensed to us, we or, in the case of in-licensed technology, the licensor may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. If we or one of our licensors is a party to an interference proceeding involving a U.S. patent application on inventions owned by or in-licensed to us, we may incur substantial costs, divert management's time and expend other resources, even if we are successful.

Interference proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all. Litigation or interference proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

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, there could 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 substantial adverse effect on the price of our common stock.

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 fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application process and following the issuance of a patent. While an inadvertent lapse, including due to the effect of the COVID-19 pandemic on us or our licensors' patent maintenance vendors, can in many 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. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

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

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering one of our 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. Such mechanisms include re-examination, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, 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. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates.

Moreover, the patents included in our patent portfolio may expire before, or soon after, our first product achieves marketing approval in the United States or foreign jurisdictions. For example, the patents related to novel ALK2 inhibitors in the patent family that we license from The General Hospital Corporation are expected to expire in April 2038, without taking into account any possible patent term adjustments or extensions. Upon the expiration of our current or future owned or licensed 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, results of operations, financial condition and prospects. We own pending patent applications covering our proprietary technologies or our product candidates that if issued as patents are expected to expire from 2037 through 2039, 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 in the U.S. and in ex-U.S. jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States or in ex-U.S. jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our 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 the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in the case *Amgen Inc. v. Sanofi*, the Federal Circuit held that a well-characterized antigen is insufficient to satisfy the written description requirement of certain claims directed to a genus of antibodies that are solely defined by function; and in the case of Assoc. for *Molecular Pathology v. Myriad Genetics, Inc*., the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. We cannot predict how these decisions or any future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Similarly, any adverse changes in the patent laws of other jurisdictions could have a material adverse effect on our business and financial condition.

Some of our in-licensed intellectual property that was discovered through government-funded programs may be subject to federal regulation such as "march-in" rights, certain reporting requirements and a preference for U.S. industry. Compliance with such regulations may limit our exclusive rights, subject us to expenditure of resources with respect to reporting requirements and limit our ability to contract with foreign manufacturers.

At least one of our in-licensed patent cases related to our KER-047 product candidate has been funded in part by the U.S. government and, therefore, is subject to certain federal regulations pursuant to the Bayh-Dole Act of 1980, or the Bayh-Dole Act, and it is possible that additional patent filings we may choose to in-license in the future may also be subject to similar regulations. In particular, the federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit to inventions produced with its financial assistance. The Bayh-Dole Act also provides federal agencies with "march-in rights." March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself. Intellectual property discovered under government-funded programs are also subject to certain reporting requirements, compliance with which may require us or our licensors to expend substantial resources. Such intellectual property is also subject to a preference for U.S. industry, which may limit our ability to contract with foreign product manufacturers for products covered by such intellectual property. Moreover, we sometimes collaborate with academic institutions to accelerate our preclinical research or development. While it is our policy to avoid engaging our university partners in projects in which there is a risk that federal funds may be commingled, we cannot be sure that any co-developed intellectual property will be free from government rights pursuant to the Bayh-Dole Act. Further, we may choose to license intellectual property in the future that may be subject to government rights pursuant to the Bayh-Dole Act. If, in the future, we co-own or license in technology which is critical to our business that is

developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

We have limited intellectual property rights outside the United States. Filing, prosecuting 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 can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as do federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. 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. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. Also, competitors may use our 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 have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims 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, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights generally. The initiation of proceedings by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

We may incur substantial costs as a result of litigation or other proceedings relating to patents, and we may be unable to protect our rights to our products and technology.

If we or our licensors choose to go to court to stop a third party from using the inventions claimed in our owned or in-licensed patents, that third party may ask the court to rule that the patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we or they, as the case may be, were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we or they, as the case may be, do not have the right to stop others from using the inventions.

There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the third party on the ground that such third party's activities do not infringe our owned or in-licensed patents. In addition, the U.S. Supreme Court has recently changed some legal principles that affect patent applications, granted patents and assessment of the eligibility or validity of these patents. As a consequence, issued patents may be found to contain invalid claims according to the newly revised eligibility and validity standards. Some of our owned or in-licensed patents may be subject to challenge and subsequent invalidation or significant narrowing of claim scope in proceedings before the USPTO, or during litigation, under the revised criteria which could also make it more difficult to obtain patents.

We, or our licensors, may not be able to detect infringement against our owned or in-licensed patents, as the case may be, which may be especially difficult for manufacturing processes or formulation patents. Even if we or our licensors detect infringement by a third party of our owned or in-licensed patents, we or our licensors, as the case may be, may choose not to pursue litigation against or settlement with the third party. If we, or our licensors, later sue such third party for patent infringement, the third party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defenses may make it impossible for us or our licensors to enforce our owned or in-licensed patents, as the case may be, against such third party.

If another party questions the patentability of any of our claims in our owned or in-licensed U.S. patents, the third-party can request that the USPTO review the patent claims such as in an *inter partes* review, *ex parte* re-exam or post-grant review proceedings. These proceedings are expensive and may result in a loss of scope of some claims or a loss of the entire patent. In addition to potential USPTO review proceedings, we may become a party to patent opposition proceedings in foreign patent offices, where either our owned or in-licensed foreign patents are challenged.

In the future, we may be involved in similar proceedings challenging the patent rights of others, and the outcome of such proceedings is highly uncertain. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. The costs of these opposition or similar proceedings could be substantial, and may result in a loss of scope of some claims or a loss of the entire patent. An unfavorable result at the USPTO or other patent office may result in the loss of our right to exclude others from practicing one or more of our inventions in the relevant country or jurisdiction, which could have a material adverse effect on our business.

Patent terms may be inadequate to protect our competitive position on our 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 such as patent term adjustments and/or extensions, may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including biosimilars. 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 such candidates are commercialized. 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.

If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984 Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed. Further, for our licensed patents, we may not have the right to control prosecution, including filing with the USPTO, of a petition for patent term extension under the Hatch-Waxman Act. Thus, if one of our licensed patents is eligible for patent

term extension under the Hatch-Waxman Act, we may not be able to control whether a petition to obtain a patent term extension is filed, or obtained, from the USPTO.

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

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trade names or trademarks that incorporate variations of our unregistered trade names or trademarks. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

Risks Related to Our Reliance on Third Parties

We rely, and expect to continue to rely, on third parties, including independent clinical investigators, contracted laboratories and CROs, to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators, contracted laboratories and third-party CROs, to conduct our preclinical studies and clinical trials in accordance with applicable regulatory requirements and to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with good laboratory practices, or GLPs, as applicable, and GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible, reproducible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Regulatory authorities enforce these GLPs and GCPs through periodic inspections of laboratories conducting GLP studies, trial sponsors, principal investigators and trial sites. If we, our investigators or any of our CROs or contracted laboratories fail to comply with applicable GLPs and GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional preclinical studies or clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our preclinical studies or clinical trials comply with applicable GLP or GCP regulations. In addition, our clinical trials must be conducted with product, including biologic product, produced in compliance with applicable cGMP regulations. Our failure to comply with these regulations may require us to repeat preclinical studies or clinical trials, which would delay the regulatory approval process.

Further, these laboratories, investigators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. If independent laboratories, investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of any product candidates that we develop. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated.

The COVID-19 pandemic and government measures taken in response have also had a significant impact on our CROs, and we expect that they will face further disruption which may affect our ability to initiate and complete our preclinical studies and clinical trials.

There is a limited number of third-party service providers that specialize or have the expertise required to achieve our business objectives. If any of our relationships with these third-party laboratories, CROs or clinical investigators terminate, we may not be able to enter into arrangements with alternative laboratories, CROs or investigators or to do so in a timely manner or on commercially reasonable terms. If laboratories, CROs or clinical investigators 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 preclinical or clinical protocols, regulatory requirements or for other reasons, our preclinical or 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 and our ability to generate revenues could be delayed.

Switching or adding additional laboratories or CROs (or investigators) involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new laboratory or CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our contracted laboratories and 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 results of operations.

In addition, clinical investigators may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the preclinical study or clinical trial, the integrity of the data generated at the applicable preclinical study or clinical trial site may be questioned and the utility of the preclinical study or clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA. Any such delay or rejection could prevent us from commercializing our clinical-stage product candidate or any future product candidates.

We rely on third parties to supply and manufacture our product candidates, and we expect to continue to rely on third parties to manufacture our products, if approved. The development of such product candidates and the commercialization of any products, if approved, could be stopped, delayed or made less profitable if any such third party fails to provide us with sufficient quantities of product candidates or products or fails to do so at acceptable quality levels or prices or fails to maintain or achieve satisfactory regulatory compliance.

We do not currently have the infrastructure or capability internally to manufacture our product candidates for use in the conduct of our preclinical studies and clinical trials or for commercial supply, if our products are approved. We rely on, and expect to continue to rely on, contract manufacturing organizations, or CMOs. Any replacement of our CMOs could require significant effort and expertise because there may be a limited number of qualified CMOs. This could be particularly problematic where we rely on a single-source supplier, as is currently the case for the manufacture of each of KER-050 and KER-047.

Reliance on third-party providers may expose us to more risk than if we were to manufacture our product candidates ourselves. We are dependent on our CMOs for the production of our product candidates in accordance with relevant regulations, such as cGMP, which includes, among other things, quality control, quality assurance and the maintenance of records and documentation. Moreover, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting product development activities that could harm our competitive position.

If we were to experience an unexpected loss of supply of or if any supplier were unable to meet our demand for any of our product candidates, we could experience delays in our research or planned clinical trials or commercialization. For example, the extent to which the COVID-19 pandemic impacts our ability to procure sufficient supplies for the development of our product candidates will depend on the severity and duration of the

spread of the virus, and the actions undertaken to contain COVID-19 or treat its effects. We could be unable to find alternative suppliers of acceptable quality, in the appropriate volumes and at an acceptable cost. Moreover, our suppliers are often subject to strict manufacturing requirements and rigorous testing requirements, which could limit or delay production. Any changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around manufacturing and testing requirements generally or with respect to our technology in particular, could also limit or delay production. The long transition periods necessary to switch manufacturers and suppliers, if necessary, could significantly delay our clinical studies and the commercialization of our products, if approved, which could materially adversely affect our business, financial condition and results of operation.

In complying with the applicable manufacturing regulations of the FDA and comparable foreign regulatory authorities, we and our third-party suppliers must spend significant time, money and effort in the areas of design and development, testing, production, record-keeping and quality control to assure that the products meet applicable specifications and other regulatory requirements. The facilities used by our contract manufacturers to manufacture our product candidates are subject to review by the FDA pursuant to inspections that will be conducted after we submit our NDA or BLA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMP requirements for manufacture of drug and biologic products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, we will not be able to secure or maintain regulatory approval for our product candidates manufactured at these manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory agency does not approve these facilities for the manufacture of our product candidates or if any agency withdraws its approval in the future, we and they may need to find alternative manufacturing facilities, which would negatively impact the ability to develop, obtain regulatory approval for or market our product candidates, if approved. The failure of our manufacturers to comply with regulatory requirements could also result in an enforcement action against us, including the seizure of products and shutting down of production. If any of our third-party suppliers fails to comply with cGMP or other applicable manufacturing regulations, our ability to develop and commercialize the products could suffer significant interruptions. We face risks inherent in relying on a single CMO, as any disruption, such as a fire, natural hazards or vandalism at the CMO could significantly interrupt our manufacturing capability. All of our CMOs currently do not have alternative production plans in place or disaster-recovery facilities available. In case of a disruption, we will have to establish alternative manufacturing sources. This would require substantial capital on our part, which we may not be able to obtain on commercially acceptable terms or at all. Additionally, we would likely experience months of manufacturing delays as the CMO builds or locates replacement facilities and seeks and obtains necessary regulatory approvals. If this occurs, we will be unable to satisfy manufacturing needs on a timely basis, if at all.

Our future collaborations will be important to our business. If we are unable to enter into new collaborations, or if these collaborations are not successful, our business could be adversely affected.

A part of our strategy is to strategically evaluate and, as deemed appropriate, enter into additional strategic collaborations in the future when strategically attractive, including potentially with major biotechnology or pharmaceutical companies. We have limited capabilities for product development and do not yet have any capability for commercialization. Accordingly, we may enter into collaborations with other companies to provide us with important technologies and funding for our programs and technology. If we fail to enter into or maintain collaborations on reasonable terms or at all, our ability to develop our existing or future research programs and product candidates could be delayed, the commercial potential of our product could change and our costs of development and commercialization could increase. Furthermore, we may find that our programs require the use of intellectual property rights held by third parties, and the growth of our business may depend in part on our ability to acquire or in-license these intellectual property rights.

Any future collaborations we enter into may pose a number of risks, including, but not limited to, the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization

programs or license arrangements based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as a strategic transaction that may divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products and product candidates if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- collaborators with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- if a collaborator of ours is involved in a business combination, the collaborator might de-emphasize or terminate the development or commercialization of any product candidate licensed to it by us; and
- collaborations may be terminated by the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

If our collaborations do not result in the successful discovery, development and commercialization of product candidates or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under such collaboration. All of the risks relating to product development, regulatory approval and commercialization described in this prospectus also apply to the activities of our therapeutic collaborators.

Additionally, if one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be adversely affected.

We face significant competition in seeking appropriate collaborative partners. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon an 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. These factors may include the design or results of preclinical studies or clinical trials, the likelihood of regulatory approval, 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, the existence of any uncertainty with respect to our ownership of technology (which can exist if there is a challenge to such ownership regardless of the merits of the challenge) and industry and market conditions generally. The collaborator 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.

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, 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 product candidates or bring them to market and generate product revenue.

If we engage in future acquisitions or strategic collaborations, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

From time to time, we may evaluate various acquisition opportunities and strategic collaborations, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic collaboration may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and marketing approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions or pursue collaborations in the future, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities, and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

Risks Related to Our Employee Matters, Managing Our Growth and Other Risks Relating to Our Operations

The COVID-19 coronavirus could adversely impact our business, including the timing or results of our preclinical studies and clinical trials.

Since December 2019, a novel strain of coronavirus, COVID-19, has spread to multiple countries, including the United States, Australia and New Zealand, where we have planned or ongoing preclinical studies and clinical trials. On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a global pandemic. On March 23, 2020, the governor of Massachusetts ordered the closure of all non-essential businesses effective March 24, 2020, through April 7, 2020, which was subsequently extended through May 18, 2020. On May 18, 2020, the governor of Massachusetts issued a new order implementing a phased re-opening of workplaces, effective May 18, 2020. As of October 5, 2020, the Commonwealth of Massachusetts officially entered step two of the third phase of re-opening for certain lower risk communities. Because of the nature of our operations, we are currently considered to be an essential business so, to date, our operations have only been partially affected by these orders. The outbreak and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. In response to the spread of COVID-19, we have closed our principal executive office with our administrative employees continuing their work outside of our office and limited the number of staff in any given research and development laboratory. If COVID-19 continues to spread in the

United States, Australia and New Zealand, we may experience disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruption in global shipping that may affect the transport of clinical trial materials;
- changes in local regulations as part of a response to COVID-19 which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- interruptions in preclinical studies due to restricted or limited operations at our research and development laboratory facility;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- refusal of the FDA to accept data from clinical trials in these affected geographies; and
- interruption or delays to our sourced discovery and clinical activities.

The COVID-19 pandemic continues to rapidly evolve. The extent to which the outbreak impacts our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States, Australia, New Zealand and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States, Australia, New Zealand and other countries to contain and treat the disease. In addition, while the potential impact and duration of the COVID-19 pandemic on the global economy and our business in particular may be difficult to assess or predict, the pandemic has resulted in, and may continue to result in, significant disruption of global financial markets, reducing our ability to access capital, which could negatively affect our liquidity in the future. Moreover, to the extent the COVID-19 pandemic adversely affects our business, financial condition and results of operations, it may also have the effect of heightening many of the other risks described in this “Risk Factors” section.

We are highly dependent on our key personnel, including our Chief Executive Officer, Chief Scientific Officer and Chief Medical Officer. If we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract, motivate and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management and particularly on the services of our scientific personnel including Jasbir Seehra, Ph.D., our Chief Executive Officer, Jennifer Lachey, Ph.D., our Chief Scientific Officer, and Claudia Ordonez, M.D., our Chief Medical Officer. We believe that their drug discovery and development experience and overall biopharmaceutical company management experience would be difficult to replace. Any of our executive officers could leave our employment at any time, as all of our employees are “at-will” employees. The loss of the services of our key personnel and any of our other executive officers, key employees, and scientific and medical advisors, and our inability to find suitable replacements, could result in delays in our research and development objectives and harm our business.

Recruiting and retaining qualified employees, consultants and advisors for our business, including scientific and technical personnel, also will be critical to our success. Competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies and academic institutions for skilled individuals. In addition, failure to succeed in preclinical studies, clinical trials or applications for marketing approval may make it more challenging to recruit and retain qualified personnel. The inability to recruit, or the loss of services of certain executives, key employees, consultants or advisors, may impede the progress of our research, development and commercialization objectives and have a material adverse effect on our business, financial condition, results of operations and prospects.

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

As of September 30, 2020, we had 32 full-time employees, including 22 employees engaged in research and development and ten employees engaged in management or general and administrative activities. As our clinical development and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect we will need additional managerial, operational, sales, marketing, financial, legal and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our development efforts effectively, including the clinical and FDA review process for KER-050, KER-047, KER-012 and any future product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize KER-050, KER-047, KER-012 and any other product candidates we develop will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. The services include substantially all aspects of clinical trial management and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of KER-050, KER-047, KER-012 and our other product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring qualified new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize KER-050, KER-047, KER-012 and our other product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our internal computer systems, or those used by our contract research organizations, or other contractors or consultants, may fail or suffer security breaches, which could adversely affect our business.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business, particularly during the COVID-19 pandemic. Despite the implementation of security measures, our internal computer systems and those of our future CROs and other contractors and consultants are vulnerable to damage or unauthorized access or use resulting from computer viruses, malware, cyber-attacks or cyber-intrusions over the Internet, denial or degradation of service attacks, ransomware, hacking, phishing and other social engineering attacks, attachments to emails, actions of persons inside our organization or persons with access to the systems upon which we depend. The techniques used to sabotage or to obtain unauthorized access to information systems, and networks in which data is stored or through which data is transmitted

change frequently, and we may be unable to implement adequate preventative measures. While we have not 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, our business operations, and the privacy or confidentiality of the information that we maintain. For example, the loss of preclinical or clinical data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, as a result of the COVID-19 pandemic, we may face increased cybersecurity risks due to our reliance on internet technology and the number of our employees that are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities.

The costs to respond to a security breach and/or to mitigate any security vulnerabilities that may be identified could be significant, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service, negative publicity, and other harm to our business and our competitive position. Any security breach affecting us, our CROs, contractors, consultants or other partners or our industry, whether real or perceived, could harm our reputation, erode confidence in the effectiveness of our security measures and lead to regulatory scrutiny. Likewise, we may rely on third parties for the manufacture of our 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 face governmental reporting obligations, incur liability and the further development and commercialization of our product candidates could be delayed.

We may have contractual and legal obligations to notify relevant stakeholders of security breaches. Most jurisdictions have enacted laws requiring companies to notify individuals, regulatory authorities, and others of security breaches involving certain types of data. In addition, our agreements with collaborators may require us to notify them in the event of a security breach. Such mandatory disclosures are costly, could lead to negative publicity, may cause our collaborators to lose confidence in the effectiveness of our security measures and require us to expend significant capital and other resources to respond to and/or alleviate problems caused by the actual or perceived security breach.

We may not have adequate insurance coverage for security incidents or breaches or information system failures. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage and coverage for errors and omissions will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

Failure to comply with existing and future data protection laws and regulations could lead to government enforcement actions, including civil or criminal fines or penalties, private litigation, other liabilities and adverse publicity and could negatively affect our operating results and business. Compliance or the failure to comply with such laws and regulations could increase the costs of our products, could limit their use or adoption, and could otherwise negatively affect our operating results and business.

We, our service providers and any potential collaborators may be subject to or affected by federal, state, local and foreign data protection laws and regulations, such as laws and regulations that address privacy and data security. In the United States, numerous federal and state laws and regulations, including federal and state health information privacy laws, state data breach notification laws, and federal and state consumer protection laws, including Section 5 of the Federal Trade Commission Act, that govern the collection, use, disclosure and protection of health information and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties, including research institutions from which we obtain clinical trial data, that are subject to privacy and security requirements under HIPAA, as amended by HITECH. Depending on the facts and circumstances, we could be subject to civil, criminal and administrative penalties and fines if we violate HIPAA.

In addition, certain state and foreign laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than U.S. federal law and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. For instance, the California Consumer Privacy Act of 2018, or CCPA, which became effective on January 1, 2020, gives

California residents expanded rights to access and require deletion of their personal information, opt out of the sale of personal information, and receive detailed information about how their personal information is used. The CCPA authorizes private lawsuits to recover statutory damages for certain data breaches. Although the CCPA exempts some data regulated by HIPAA and certain data regarding clinical trials, the CCPA, to the extent applicable to our business and operations, may increase our compliance costs and potential liability with respect to other personal information we maintain about California residents. Other privacy legislation has been proposed at the federal and state levels, which, if enacted, could adversely affect our business.

Our operations may also be subject to increased scrutiny or attention from foreign data protection authorities. Our clinical trial programs and research collaborations outside the United States may implicate foreign data protection laws, including in Europe, Australia, and New Zealand. Many countries have established, or are in the process of establishing, privacy and data security legal frameworks with which we, our collaborators, service providers, including our CROs, and contractors must comply. For example, European data protection laws, including, without limitation, the European Union's General Data Protection Regulation, or GDPR, which went into effect in May 2018 and introduces strict requirements for processing the personal information of individuals in Europe, including clinical trial data, may apply to the company to the extent it processes the personal data of data subjects within the European Economic Area, or the EEA, and the United Kingdom. The processing of sensitive personal data, such as health information, may impose heightened compliance burdens under the GDPR and is a topic of active interest among foreign regulators. The GDPR increases our obligations with respect to clinical trials conducted in the EU by expanding the definition of personal data to include coded data and requiring changes to informed consent practices and more detailed notices for clinical trial participants and investigators. In addition, the GDPR increases the scrutiny of transfers of personal data from clinical trial sites located in the EEA to the United States and other jurisdictions that the European Commission does not recognize as having "adequate" data protection laws; in July 2020, the Court of Justice of the European Union limited how organizations could lawfully transfer personal data from the EEA to the United States by invalidating the EU-US Privacy Shield and imposing further restrictions on use of the standard contractual clauses, which could increase our costs and our ability to efficiently process personal data from the EEA. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater, litigation, regulatory investigations, enforcement actions that require us to change the way we use personal data, and/or prohibitions on the use of personal data. Relatedly, following the United Kingdom's withdrawal from the EEA and the EU, and the expiry of the transition period, companies will have to comply with the GDPR and the GDPR as incorporated into United Kingdom national law, the latter regime having the ability to separately fine up to the greater of £17.5 million or 4% of global turnover. The relationship between the United Kingdom and the EU in relation to certain aspects of data protection law remains unclear, for example around how data can lawfully be transferred between each jurisdiction, which exposes us to further compliance risk.

We may publish privacy policies and other documentation regarding our collection, processing, use and disclosure of personal information and/or other confidential information. Although we endeavor to comply with our published policies and other documentation, we may at times fail to do so or may be perceived to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our employees or vendors fail to comply with our published policies and documentation. Such failures can subject us to potential foreign, local, state and federal action if they are found to be deceptive, unfair, or misrepresentative of our actual practices. Moreover, subjects about whom we or our collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information.

Compliance with U.S. and foreign data protection laws and regulations could require us to take on more onerous obligations in our contracts, increase our costs of legal compliance, restrict our ability to collect, use and disclose data, or in some cases, impact our or our partners' or suppliers' ability to operate in certain jurisdictions. Failure to comply with these laws and regulations could result in government investigations and/or 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.

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

We are exposed to the risk that our employees, independent contractors, vendors, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and comparable foreign regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the United States and abroad; or laws that require the reporting of financial information or data accurately. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, 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, financial condition and results of operations.

We conduct certain research and development operations through our Australian wholly-owned subsidiary. If we lose our ability to operate in Australia, or if our subsidiary is unable to receive the research and development incentive payment allowed by Australian regulations, our business and results of operations could suffer.

In October 2018, we formed a wholly-owned Australian subsidiary, Keros Therapeutics Australia Pty Ltd, to conduct various preclinical studies and clinical trials for our product candidates in Australia. Due to the geographical distance and lack of employees currently in Australia, as well as our lack of experience operating in Australia, we may not be able to efficiently or successfully monitor our clinical activities in Australia, including conducting preclinical studies and clinical trials. Furthermore, we have no assurance that the results of any clinical trials that we conduct for our product candidate in Australia will be accepted by the FDA or comparable foreign regulatory authorities for development and commercialization approvals.

In addition, current Australian tax regulations provide for a refundable research and development incentive payment equal to 43.5% of qualified expenditures. We received incentive payments of approximately $0.8 million during the nine-month period ending September 30, 2020 for research expenditures made during 2018 and 2019. If our subsidiary loses its ability to operate in Australia, or if we are ineligible or unable to receive the research and development incentive payment, or the Australian government significantly reduces or eliminates the incentive program, our business and results of operation may be adversely affected.

A variety of risks are associated with operating our business internationally which could materially adversely affect our business.

We conduct certain research and development operations in Australia and New Zealand and may conduct certain future clinical trials outside of the United States. Additionally, while we have not taken any steps to enter

into any non-U.S. markets, we may do so in the future. Accordingly, we are subject to risks related to operating in foreign countries, including:

- different standards of care in various countries that could complicate the evaluation of our product candidates;
- different United States and foreign drug import and export rules;
- reduced protection for intellectual property rights in certain countries;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad;
- compliance with the FCPA and other anti-corruption and anti-bribery laws;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- different payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- potential liability resulting from development work conducted by foreign partners;
- business interruptions resulting from natural disasters, outbreaks of contagious diseases, such as COVID-19, or geopolitical actions, including war and terrorism, or systems failure including cybersecurity breaches; and
- compliance with evolving and expansive foreign data privacy laws, such as the GDPR.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations. We can face serious consequences for violations.

We are presently conducting clinical development solely in Australia and New Zealand and may choose to conduct additional international clinical trials in the future. The U.S. Foreign Corrupt Practices Act, or FCPA, prohibits companies and their employees and third-party intermediaries from paying, offering, promising or authorizing others to pay or offer 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 certain accounting provisions requiring the company 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. The FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are owned and operated by the government, and doctors and other hospital employees are considered foreign officials. We can be held liable for the corrupt or other illegal activities of our employees, representatives, contractors, business partners and agents, even if we do not explicitly authorize or have actual knowledge of such activities. Noncompliance with the FCPA and anti-corruption laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and/or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage and other collateral consequences. If any subpoenas or investigations are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed.

In addition, our products may be subject to export controls, trade sanctions laws and regulations. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could

be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or products targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to, existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell our products would likely adversely affect our business.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our research and development activities involve the use of biological and hazardous materials and produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological waste or hazardous waste insurance coverage, workers compensation or property and casualty and general liability insurance policies that include coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

The December 2017 tax reform law could adversely affect our business and financial condition.

On December 22, 2017, the Tax Act was enacted and significantly revised the Internal Revenue Code of 1986, as amended, or the Code. The Tax Act, among other things, contained significant changes to U.S. federal corporate income taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted taxable income (except for certain small businesses), limitation of the deduction for net operating losses, or NOLs, to 80% of current year taxable income and elimination of NOL carry backs (in each case applicable to NOLs arising in taxable years beginning after December 31, 2017), one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many other business deductions and credits, including the reduction of the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally known as "orphan drugs." On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security, or CARES, Act was signed into law. The CARES Act changes certain provisions of the Tax Act. Under the CARES Act, NOLs arising in taxable years beginning after December 31, 2017 and before January 1, 2021 may be carried back to each of the five taxable years preceding the tax year of such loss, but NOLs arising in taxable years beginning after December 31, 2020 may not be carried back. In addition, the CARES Act eliminates the limitation on the deduction of NOLs to 80% of current year taxable income for taxable years beginning before January 1, 2021, and increases the amount of interest expense that may be deducted to 50% of adjusted taxable income for taxable years beginning in 2019 or 2020. Notwithstanding the

reduction in the corporate income tax rate, the overall impact of the Tax Act, as modified by the CARES Act, is uncertain and our business, financial conditions, results of operations and growth prospects could be materially and adversely affected. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, as modified by the CARES Act. The impact of the Tax Act, as modified by the CARES Act, on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

Our ability to use our net operating loss carryforwards and certain tax credit carryforwards may be subject to limitation.

As of December 31, 2019, we had $11.5 million of U.S. federal, $11.1 million of state and $4.3 million of foreign NOL carryforwards. Under the Tax Act, as modified by the CARES Act, federal NOLs incurred in taxable years beginning after December 31, 2017 can be carried forward indefinitely, but the deductibility of federal NOLs in taxable years beginning after December 31, 2020, is limited. The CARES Act also provides for the ability for companies to carry back net operating losses for up to 5 years. We evaluated the provisions of the CARES Act and, as a result, recorded an income tax receivable of approximately $0.2 million related to the carry back of our 2019 net operating loss to claim a refund for prior federal tax liabilities and, as a result, our net operating loss carryforwards will be reduced.

Our NOL carryforwards are subject to review and possible adjustment by the U.S. and state tax authorities. In addition, under Sections 382 and 383 of the Code and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation’s ability to use its pre-change NOL carryforwards and R&D credits to offset its post-change income may be limited. This could limit the amount of NOLs or R&D credit carryforwards that we can utilize annually to offset future taxable income or tax liabilities. Subsequent ownership changes and changes to the U.S. tax rules in respect of the utilization of NOLs and R&D credits carried forward may further affect the limitation in future years. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Additionally, we have not undertaken a study on our determination of our U.S. R&D credits. Consequently, our U.S. R&D credits may change, and in any event are subject to review and adjustment by the tax authorities.

Risks Related to Our Common Stock and this Offering

An active, liquid and orderly trading market may not develop for our common stock and as a result it may be difficult for you to sell your shares of our common stock.

Prior to our IPO in April 2020, there was no public market for shares of our common stock. Although our common stock is currently listed on the Nasdaq Global Market, we cannot assure you that an active trading market for our shares will develop or be sustained. In the absence of an active trading market for our common stock, investors may not be able to sell their shares of common stock without depressing the market price for the common stock, or may not be able to sell the shares at all. An inactive trading market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to enter into collaborations or acquire other companies or technologies using our shares as consideration.

Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expense related to the ongoing development of our product candidates and preclinical development programs;
- results of preclinical studies and future clinical trials, or the addition or termination of future clinical trials or funding support by us, or current or future collaborators or licensing partners;
- our execution of any collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under existing or future arrangements or the termination or modification of any such existing or future arrangements;

- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- additions and departures of key personnel;
- strategic decisions by us, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if any of our product candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such product candidates;
- regulatory developments affecting our product candidates; and
- general economic conditions, as well as economic conditions specifically affecting the biopharmaceutical industry, including those related to the ongoing COVID-19 pandemic.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

The market price of our common stock has been and is likely to continue to be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock in this offering.

The market price of our common stock has been and is likely to continue to be highly volatile and may fluctuate substantially as a result of a variety of factors, some of which are related in complex ways. As a result of this volatility, you may not be able to sell your common stock at or above the public offering price. The market price for our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including the factors listed below and other factors described in this “Risk Factors” section:

- results of preclinical studies and clinical trials of KER-050, KER-047, KER-012 and any other product candidate we may develop or those of our competitors;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- commencement or termination of collaboration, licensing or similar arrangements for our development programs;
- announcements by our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- failure or discontinuation of any of our development programs;
- results of clinical trials of product candidates of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to the development of KER-050, KER-047, KER-012 and any other product candidate we may develop;
- variations in our financial results or those of companies that are perceived to be similar to us;
- announcements or expectations of additional financing efforts by us;
- sales of our common stock by us, our insiders or other stockholders;
- expiration of market stand-off or lock-up agreements;
- recommendations and changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, political, and market conditions and overall fluctuations in the financial markets in the United States and abroad; and
- investors’ general perception of us and our business.

The stock market in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme price and volume fluctuations that have been often unrelated or disproportionate to the operating performance of the issuer. In addition, the trading prices for common stock of other pharmaceutical, biopharmaceutical and biotechnology companies have been highly volatile as a result of

the COVID-19 pandemic. The COVID-19 outbreak continues to rapidly evolve. The extent to which the outbreak may impact our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence.

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

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against public companies following declines in the market prices of their securities. This risk is especially relevant for biopharmaceutical companies, which have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and our resources, which could harm our business, operating results, financial condition and cash flows.

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

You will suffer immediate and substantial dilution with respect to the common stock you purchase in this offering. Based on the assumed public offering price of $ per share, which is the last reported sale price of our common stock on the Nasdaq Global Market on , 2020, and assuming that the underwriters do not exercise their option to acquire additional common stock in this offering, purchasers of common stock in this offering will experience immediate dilution of $ per share, representing the difference between our pro forma as adjusted net tangible book value per share after giving effect to this offering and the assumed public offering price. In the past, we have issued options to purchase common stock at prices significantly below the assumed public offering price. To the extent these outstanding securities are ultimately exercised, investors purchasing common stock in this offering will sustain further dilution. See "Dilution" for a more detailed description of the dilution to new investors in the offering.

We have broad discretion in how we use the proceeds of this offering and may not use these proceeds effectively, which could affect our results of operations and cause our stock price to decline.

We will have considerable discretion in the application of the net proceeds of this offering. We intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, to advance the clinical development of KER-050, including the advancement of Phase 2 clinical trials in patients with MDS and in patients with myelofibrosis, to advance the clinical development of KER-047, including the initiation of separate Phase 2 clinical trials in patients with IDA and in patients with IRIDA, to advance KER-012 into clinical development, including the initiation of a Phase 1 clinical trial, and the remainder to fund other research and development activities, including activities related to our proprietary discovery approach, working capital and general corporate purposes. See "Use of Proceeds." As a result, investors will be relying upon management's judgment with only limited information about our specific intentions for the use of the balance of the net proceeds of this offering. We may use the net proceeds for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

Additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner, we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Pursuant to our 2020 Equity Incentive Plan, or 2020 Plan, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. The number of shares of our

common stock reserved for issuance under our 2020 Plan will automatically increase on January 1 of each year, for a period of ten years, from January 1, 2021 continuing through January 1, 2030, by 4.0% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares as may be determined by our board of directors. If our board of directors elects to increase the number of shares available for future grant by the maximum amount each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

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

You should not rely on an investment in our common stock to provide dividend income. 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, which may never occur, as the only way to realize any return on their investment.

Our executive officers, directors, and stockholders and their affiliates who beneficially own more than 5% of our common stock will continue to exercise significant influence over our company after this offering, which will limit your ability to influence corporate matters and could delay or prevent a change in corporate control.

As of September 30, 2020, our executive officers, directors and stockholders and their affiliates who beneficially own more than 5% of our common stock beneficially held a significant percentage of our outstanding common stock. As a result, these stockholders, if they act together, will be able to exercise significant influence over our management and affairs and the outcome of matters submitted to our stockholders for approval, including the election of directors and any sale, merger, consolidation, or sale of all or substantially all of our assets. These stockholders acquired their shares of common stock at prices per share that were substantially less than the per share price of the shares of common stock being sold in this offering, these stockholders may have interests with respect to their common stock that are different from those of investors in this offering, and the concentration of voting power among these stockholders may have an adverse effect on the price of our common stock. In addition, this concentration of ownership might adversely affect the market price of our common stock by:

- delaying, deferring or preventing a change of control of our company;
- impeding a merger, consolidation, takeover or other business combination involving our company; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our company.

See “Principal Stockholders” in this prospectus for more information regarding the ownership of our outstanding common stock by our executive officers, directors, principal stockholders and their respective affiliates.

Conflicts of interest may arise because some members of our board of directors are representatives of our principal stockholders.

Certain of our principal stockholders or their affiliates are venture capital funds or other investment vehicles that could invest in entities that directly or indirectly compete with us. As a result of these relationships, conflicts may arise between the interests of the principal stockholders or their affiliates and the interests of other stockholders, and members of our board of directors that are representatives of such principal stockholders may not be disinterested in such conflicts. Neither the principal stockholders nor the representatives of the principal stockholders on our board of directors, by the terms of our amended and restated certificate of incorporation, are required to offer us any transaction opportunity of which they become aware and could take any such opportunity for themselves or offer it their other affiliates, unless such opportunity is expressly offered to them solely in their capacity as members of our board of directors.

A significant portion of our total outstanding shares are eligible to be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

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 September 30, 2020. This includes the shares that we are selling in this offering, which may be resold in the public market immediately without restriction, unless purchased by our affiliates or existing stockholders. Of the remaining shares, shares are currently restricted as a result of securities laws or lock-up agreements, but will become eligible to be sold after the offering as described in the "Underwriting" section of this prospectus.

In connection with this offering, we, our directors, officers and certain stockholders have agreed that for a period of 90 days following the date of this prospectus, subject to certain exceptions, we or they will not offer for sale, sell, contract to sell, grant any option for the sale of, transfer or otherwise dispose of any shares of our common stock, options or warrants to acquire shares of our common stock or any security or instrument related to our common stock, or enter into any swap, hedge or other arrangement that transfers any of the economic consequences of ownership of our common stock without the prior written consent of Jefferies LLC, SVB Leerink LLC and Piper Sandler & Co. on behalf of the underwriters. See the section titled "Underwriting" for a more complete description of the lock-up agreements with the underwriters.

Sales of a substantial number of such shares upon expiration of the lock-up agreements, the perception that such sales may occur, or early release of these agreements, could cause our market price to fall or make it more difficult for you to sell your common stock at a time and price that you deem appropriate.

In addition, we have filed a registration statement on Form S-8 registering the issuance of 3,290,172 shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under this registration statement on Form S-8 are available for sale in the public market subject to vesting arrangements and exercise of options, the lock-up agreements described above and the restrictions of Rule 144 under the Securities Act in the case of our affiliates. In addition, certain holders of shares of our common stock have rights, subject to some 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. If we were to register the resale of these shares, they could be freely sold in the public market. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

If securities or industry analysts publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will rely, in part, on the research and reports that industry or financial analysts publish about us or our business. We do not have any control over these analysts. If one or more of the analysts covering our business downgrade their evaluations of our stock or publish inaccurate or unfavorable research about our business, the price of our stock would likely decline. If one or more of these analysts cease to cover our stock or fail to publish reports on us regularly, we could lose visibility in the market for our stock, which, in turn, could cause our stock price and trading volume to decline.

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

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Stock Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. 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 to substantially increase our legal and financial compliance costs and to make some activities more time consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. We are evaluating these rules and regulations, and cannot predict or estimate the amount or timing of additional costs we may incur or the timing of such costs. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. The increased costs may require us to reduce costs in other areas of our business or increase the prices of our

services. Moreover, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

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

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including (i) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (ii) reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements and (iii) exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not approved previously. In addition, as an emerging growth company, we are only required to provide two years of audited financial statements and two years of selected financial data in this prospectus. Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards. Until the date that we are no longer an "emerging growth company" or affirmatively and irrevocably opt out of the exemption provided by Section 7(a)(2)(B) of the Securities Act, upon issuance of a new or revised accounting standard that applies to our financial statements and that has a different effective date for public and private companies, we will disclose the date on which adoption is required for non-emerging growth companies and the date on which we will adopt the recently issued accounting standard.

We could be an emerging growth company until December 31, 2025, although circumstances could cause us to lose that status earlier, including if we are deemed to be a "large accelerated filer," which occurs when the market value of our common stock that is held by non-affiliates equals or exceeds $700.0 million as of the prior June 30, or if we have total annual gross revenue of $1.07 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31, or if we issue more than $1.0 billion in non-convertible debt during any three-year period before that time, in which case we would no longer be an emerging growth company immediately. Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in this prospectus and in our periodic reports and proxy statements.

We cannot predict if investors will find our common stock less attractive because we may rely on the exemptions and reduced disclosure obligations applicable to emerging growth companies and smaller reporting companies. 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 share price may be more volatile.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Pursuant to Section 404 of the Sarbanes-Oxley Act, our management will be required to report upon the effectiveness of our internal control over financial reporting beginning with the annual report for our fiscal year ending December 31, 2021. When we lose our status as an "emerging growth company" and a "smaller reporting company," our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Securities Exchange Act of 1934, as amended, or the Exchange Act, we will need to

implement additional financial and management controls, reporting systems and procedures and hire additional accounting and finance staff.

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

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

We are 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. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make a required related party transaction disclosure. 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.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- prohibit our stockholders from calling a special meeting of our stockholders;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a stockholder rights plan, or so-called “poison pill,” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 66 2/3% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns 15% or more of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired 15% or more of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

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

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) will be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders;
- any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws;
- any action or proceeding to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws; and
- any action asserting a claim against us or any of our directors, officers or other employees governed by the internal affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction.

In addition, our amended and restated certificate of incorporation provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, unless we consent in writing to the selection of an alternative forum.

These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage these types of lawsuits. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. For example, the Court of Chancery of the State of Delaware recently determined that a provision stating that U.S. federal district courts are the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act is not enforceable. However, on March 18, 2020, this decision was ultimately overturned by the Delaware Supreme Court. If a court were to find the exclusive-forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve substantial risks and uncertainties. These forward-looking statements are contained principally in the sections of this prospectus titled “Prospectus Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business,” but are also contained elsewhere in this prospectus. In some cases, you can identify forward-looking statements by the words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “objective,” “ongoing,” “plan,” “predict,” “project,” “potential,” “should,” “will,” or “would,” or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our 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 expectations of the future, about which we cannot be certain.

These forward-looking statements include statements about:

- the timing of announcement of data for our Phase 2 clinical trial for our lead protein therapeutic product candidate, KER-050, in patients with MDS;
- the timing of initiation of our Phase 2 clinical trial for KER-050 in patients with myelofibrosis-associated cytopenias;
- the timing of announcement of data of our expanded Phase 1 clinical trial for our lead small molecule product candidate, KER-047, and the timing of initiation for future clinical trials for KER-047, including the timing of initiation of our three Phase 2 clinical trials of KER-047;
- the timing of initiation of our Phase 1 clinical trial for our third product candidate, KER-012;
- risks associated with the COVID-19 pandemic, which may adversely impact our business, preclinical studies and clinical trials;
- our ability to receive the required regulatory approvals and clearances to successfully market and sell our products in the United States and certain other countries;
- our ability to successfully advance our pipeline of additional product candidates;
- our ability to develop sales and marketing capabilities;
- the rate and degree of market acceptance of any products we are able to commercialize;
- our ability to develop sales and marketing capabilities;
- the effects of increased competition as well as innovations by new and existing competitors in our market;
- our ability to obtain funding for our operations;
- our ability to establish and maintain collaborations;
- our ability to effectively manage our anticipated growth;
- our ability to maintain, protect and enhance our intellectual property rights and proprietary technologies;
- our ability to operate our business without infringing the intellectual property rights and proprietary technology of third parties;
- costs associated with defending intellectual property infringement, product liability and other claims;
- regulatory developments in the United States, Australia, New Zealand and other foreign countries;
- our ability to attract and retain qualified employees;
- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act;
- statements regarding future revenue, hiring plans, expenses, capital expenditures, capital requirements and stock performance;
- our expected use of proceeds of this offering; and
- the future trading prices of our common stock and the impact of securities analysts’ reports on these prices.

We caution you that the foregoing list may not contain all of the forward-looking statements made in this prospectus.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions described under the section titled “Risk Factors” and elsewhere in this prospectus. We also operate in a very competitive and rapidly changing environment. New risks emerge from time to time and it is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances described in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements contained in this prospectus.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance, events, circumstances or achievements reflected in the forward-looking statements will ever be achieved or occur. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus to conform these statements to actual results or to changes in our expectations.

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 you are cautioned not to unduly rely upon these statements.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

INDUSTRY AND MARKET DATA

This prospectus includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties as well as our own estimates of potential market opportunities. 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 believe that these third-party sources and estimates are reliable, but have not independently verified them. Our estimates of the potential market opportunities for our product candidates include several key assumptions based on our industry knowledge, industry publications, third-party research and other surveys, which may be based on a small sample size and may fail to accurately reflect market opportunities. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions.

In addition, projections, assumptions and estimates of our future performance and the future performance of the industry in which we operate is necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section of this prospectus titled “Risk Factors” and elsewhere in this prospectus. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

USE OF PROCEEDS

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

Each $1.00 increase or decrease in the assumed public offering price of $ per share would increase or decrease the net proceeds to us from this offering by approximately $ 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 underwriting discounts and commissions payable by us. We may also increase or decrease the number of shares we are offering. Each 1,000,000 share increase or decrease in the number of shares offered by us would increase or decrease the net proceeds to us from this offering by approximately $ million, assuming that the assumed public offering price of $ per share remains the same, and after deducting underwriting discounts and commissions payable by us.

We intend to use the net proceeds of this offering, together with our existing cash and cash equivalents, to advance the clinical development of KER-050, including the advancement of Phase 2 clinical trials in patients with MDS and in patients with myelofibrosis, to advance the clinical development of KER-047, including the initiation of separate Phase 2 clinical trials in patients with IDA and in patients with IRIDA, and to advance KER-012 into clinical development, including the initiation of a Phase 1 clinical trial. We intend to use the remainder to fund other research and development activities, including activities related to our proprietary discovery approach, working capital and general corporate purposes.

We may also use a portion of the remaining net proceeds to in-license, acquire or invest in complementary businesses, technologies, products or assets. However, we have no current commitments or obligations to do so.

This expected use of the net proceeds from this offering represents our intentions based upon our current plans and prevailing business conditions, which could change in the future as such plans and conditions evolve. Predicting the cost necessary to develop product candidates can be difficult, and the amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development, the status of and results from preclinical studies and clinical trials, any collaborations that we may enter into with third parties and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Based on our current plans, we believe that our existing cash and cash equivalents, together with the net proceeds from this offering, will enable us to fund our operating expenses and capital expenditure requirements into . The expected net proceeds from this offering will not be sufficient for us to fund any of our product candidates through regulatory approval, and we will need to raise substantial additional capital to complete the development and commercialization of our product candidates. For additional information regarding our potential capital requirements, see “Risk Factors.”

DIVIDEND POLICY

We have never declared or paid any dividends on our capital stock. We currently intend to retain all available funds and any future earnings for the operation and expansion of our business and, therefore, we do not anticipate declaring or paying cash dividends in the foreseeable future. The payment of dividends will be at the discretion of our board of directors and will depend on our results of operations, capital requirements, financial condition, prospects, contractual arrangements, any limitations on payment of dividends present in any future debt agreements and other factors that our board of directors may deem relevant.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and our capitalization as of September 30, 2020:

- on an actual basis; and
- on an as adjusted basis to give effect to the issuance and sale of shares of common stock in this offering at the assumed public offering price of $ per share, which is the last reported sale price of our common stock on the Nasdaq Global Market on , 2020, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The as adjusted information below is illustrative only and our capitalization following the completion of this offering is subject to adjustment based on the actual public offering price of our common stock and other terms of this offering determined at pricing. You should read this table together with the sections of this prospectus titled “Selected Consolidated Financial Data,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and the related notes appearing elsewhere in this prospectus.

	AS OF SEPTEMBER 30, 2020	
	ACTUAL	AS ADJUSTED(1)
	(in thousands, except share and per share data)	
Cash and cash equivalents	$	$
Stockholders’ equity:		
Common stock, $0.0001 par value per share; 200,000,000 shares authorized, 20,185,730 shares issued and outstanding, actual; and 200,000,000 shares authorized, shares issued and outstanding, as adjusted		
Preferred stock, $0.0001 par value per share; 10,000,000 shares authorized, no shares issued or outstanding, actual and as adjusted		
Additional paid-in capital		
Accumulated deficit		
Total stockholders’ equity		
Total capitalization	$	$

(1) Each $1.00 increase or decrease in the assumed public offering price of $ per share, which is the last reported sale price of our common stock on the Nasdaq Global Market on , 2020, would increase or decrease the as adjusted cash and cash equivalents, additional paid-in capital, total stockholders’ equity and total capitalization by approximately $ 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 underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. Each 1,000,000 share increase or decrease in the number of shares offered by us would increase or decrease as adjusted cash and cash equivalents, additional paid-in capital, total stockholders’ equity and total capitalization by approximately $ million, assuming that the assumed public offering price of $ per share remains the same, and after deducting underwriting discounts and commissions payable by us.

The number of shares of our common stock shown as issued and outstanding in the table above is based on 20,185,730 shares of our common stock outstanding as of September 30, 2020 and excludes:

- 2,484,152 shares of our common stock issuable upon the exercise of options outstanding as of September 30, 2020, at a weighted-average exercise price of $10.95 per share;
- shares of our common stock issuable upon the exercise of options granted after September 30, 2020, at a weighted average exercise price of $ per share;
- 572,026 shares of our common stock reserved for future issuance pursuant to our 2020 Equity Incentive Plan, or 2020 Plan, as of September 30, 2020, as well as any shares reserved pursuant to provisions in our 2020 Plan that automatically increase the number of shares of common stock reserved for issuance under the 2020 Plan; and

- 182,341 shares of our common stock reserved for future issuance under our 2020 Employee Stock Purchase Plan, or ESPP, as of September 30, 2020, as well as any shares reserved pursuant to provisions in the ESPP that automatically increase the number of shares of common stock reserved for issuance under the ESPP.

DILUTION

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

Our historical net tangible book value as of September 30, 2020 was $ million, or $ per share of common stock. Our historical net tangible book value is the amount of our total tangible assets less our liabilities and preferred stock, which is not included within stockholders' deficit. Historical net tangible book value per share is our historical net tangible book value divided by the number of shares of common stock outstanding as of September 30, 2020.

After giving effect to the sale of shares of common stock in this offering at the assumed public offering price of $ per share, which is the last reported sale price of our common stock on the Nasdaq Global Market on , 2020, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of September 30, 2020 was $ million, or $ per share of common stock. This amount represents an immediate increase in as adjusted net tangible book value of $ per share to our existing stockholders and an immediate dilution of $ per share to new investors participating in this offering. We determine dilution per share to new investors by subtracting as adjusted net tangible book value per share after this offering from the assumed public offering price per share paid by new investors.

The following table illustrates this dilution on a per share basis to new investors:

Assumed public offering price per share		$
Historical net tangible book value per share as of September 30, 2020	$	
Increase in net tangible book value per share attributed to new investors purchasing shares from us in this offering		
As adjusted net tangible book value per share after giving effect to this offering		
Dilution per share to new investors participating in this offering		$

The dilution information discussed above is illustrative only and will change based on the actual public offering price and other terms of this offering determined at pricing. Each $1.00 increase or decrease in the assumed public offering price of $ per share, which is the last reported sale price of our common stock on the Nasdaq Global Market on , 2020, would increase or decrease the as adjusted net tangible book value per share after this offering by approximately $, and dilution in as adjusted net tangible book value per share to new investors participating 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 the underwriting discounts and commissions and the estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. Each 1,000,000 share increase in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase the as adjusted net tangible book value per share after this offering by $ and decrease the dilution to investors participating in this offering by $ per share, assuming that the assumed public offering price of $ per share remains the same, and after deducting the underwriting discounts and commissions and the estimated offering expenses payable by us. Each 1,000,000 share decrease in the number of shares offered by us, as set forth on the cover page of this prospectus, would decrease the as adjusted net tangible book value per share after this offering by approximately $ and increase the dilution to investors participating in this offering by approximately $ per share, assuming that the assumed public offering price remains the same, and after deducting the underwriting discounts and commissions and the estimated offering expenses payable by us.

If the underwriters exercise in full their option to purchase an additional shares of our common stock in this offering, the as adjusted net tangible book value would increase to $ per share, representing an immediate increase to existing stockholders of $ per share and the dilution per share to new investors participating in this offering would be $ per share, based on the assumed public offering price of

$ per share, which is the last reported sale price of our common stock on the Nasdaq Global Market on , 2020, after deducting underwriting discounts and commissions payable by us.

The table and calculations above are based on 20,185,730 shares of our common stock outstanding as of September 30, 2020 and excludes:

- 2,484,152 shares of our common stock issuable upon the exercise of options outstanding as of September 30, 2020, at a weighted-average exercise price of $10.95 per share;
- shares of our common stock issuable upon the exercise of options granted after September 30, 2020, at a weighted average exercise price of $ per share;
- 572,026 shares of our common stock reserved for future issuance pursuant to our 2020 Equity Incentive Plan, or 2020 Plan, as of September 30, 2020, as well as any shares reserved pursuant to provisions in our 2020 Plan that automatically increase the number of shares of common stock reserved for issuance under the 2020 Plan; and
- 182,341 shares of our common stock reserved for future issuance under our 2020 Employee Stock Purchase Plan, or ESPP, as of September 30, 2020, as well as any shares reserved pursuant to provisions in the ESPP that automatically increase the number of shares of common stock reserved for issuance under the ESPP.

To the extent that any outstanding options are exercised, or new shares are issued under our equity incentive plans at per share prices below the price to the public in this offering, there will be further dilution to investors participating in this offering. 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.

SELECTED CONSOLIDATED FINANCIAL DATA

The following tables set forth our selected consolidated financial data for the periods ended on and as of the dates indicated. We derived the selected consolidated statements of operations data for the years ended December 31, 2018 and 2019 and the selected consolidated balance sheet data as of December 31, 2018 and 2019 from our audited consolidated financial statements included elsewhere in this prospectus. The selected consolidated statements of operations data for the nine months ended September 30, 2019 and 2020 and the selected consolidated balance sheet data as of September 30, 2020 have been derived from our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus. In our opinion, this unaudited interim condensed consolidated financial data has been prepared on a basis consistent with our audited consolidated financial statements and contains all adjustments, consisting only of normal and recurring adjustments, necessary for a fair presentation of such financial data. Our historical results are not necessarily indicative of the results that should be expected for any future period and our operating results for the nine-month period ended September 30, 2020 are not necessarily indicative of the results that may be expected for the fiscal year ended December 31, 2020 or any other interim periods or any future year or period.

The selected consolidated financial data below should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and related notes included elsewhere in this prospectus. The selected consolidated financial data in this section are not intended to replace the consolidated financial statements and are qualified in their entirety by our consolidated financial statements and related notes included elsewhere in this prospectus.

	YEAR ENDED DECEMBER 31,		NINE MONTHS ENDED SEPTEMBER 30,	
	2018	2019	2019	2020
			(unaudited)	
	(in thousands, except share and per share data)			
Consolidated Statement of Operations Data:				
Revenue:				
Research collaboration revenue	$ 10,000	$ 10,000	$	$
Total revenue	10,000	10,000		
Operating expenses:				
Research and development	(10,111)	(17,379)		
General and administrative	(1,580)	(3,184)		
Total operating expenses	(11,691)	(20,563)		
Loss from operations	(1,691)	(10,563)		
Other income, net:				
Interest income (expense), net	6	(8)		
Research and development incentive income	370	558		
Change in fair value of preferred stock tranche liability	(43)	(2,564)		
Other income, net	280	241		
Total other income (expense), net	613	(1,773)		
Loss before income taxes	(1,078)	(12,336)		
Income tax provision	(257)	—		
Net loss	$ (1,335)	$ (12,336)	$	$
Net loss attributable to common stockholders—basic and diluted	$ (2,346)	$ (14,136)	$	$
Net loss per share attributable to common stockholders—basic and diluted(1)	$ (1.08)	$ (6.08)	$	$
Weighted average common stock outstanding—basic and diluted(1)	2,174,514	2,326,857		

(1) See Note 12 to our consolidated financial statements appearing at the end of this prospectus for further details on the calculation of basic and diluted net loss per share attributable to common stockholders.

	AS OF DECEMBER 31,		AS OF SEPTEMBER 30, 2020
	2018	2019	(unaudited)
		(in thousands)	
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$ 23,259	$ 7,020	
Working capital(1)	14,062	4,441	
Total assets	27,412	10,955	
Total liabilities	14,654	10,460	
Convertible preferred stock(2)	19,941	19,941	
Total stockholders' (deficit) equity	(7,183)	(19,446)	

(1) Working capital is defined as current assets less current liabilities.
(2) All outstanding shares of our convertible preferred stock automatically converted into 10,725,129 shares of our common stock in connection with the completion of our initial public offering.

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 "Selected Consolidated Financial Data" and our consolidated financial statements and the related notes included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this prospectus, our actual results could differ materially from the results described in or implied by these forward-looking statements. You should carefully read the "Risk Factors" section of this prospectus to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section entitled "Special Note Regarding Forward-Looking Statements".

Overview

We are a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel treatments for patients suffering from hematological and musculoskeletal disorders with high unmet medical need. We are a leader in understanding the role of the Transforming Growth Factor-Beta, or TGF-ß, family of proteins, which are master regulators of red blood cell and platelet production as well as of the growth, repair and maintenance of muscle and bone. We have leveraged this understanding and developed a discovery approach to generate large and small molecules to address diseases of these tissues. Targeting TGF-ß signaling pathways has been clinically proven to elicit robust changes in blood cells, muscle and bone, which we believe provides a precedent and strong rationale for our strategy. Our lead protein therapeutic product candidate, KER-050, is being developed for the treatment of low blood cell counts, or cytopenias, including anemia and thrombocytopenia, in patients with myelodysplastic syndromes, or MDS, and in patients with myelofibrosis. We have initiated a Phase 2 clinical trial in patients with MDS and expect to report initial data from Part 1 of this trial in mid-2021. We also plan to initiate a Phase 2 clinical trial in patients with myelofibrosis in 2021. Our lead small molecule product candidate, KER-047, is being developed for the treatment of anemia resulting from iron imbalance, as well as for the treatment of fibrodysplasia ossificans progressiva, or FOP, a rare musculoskeletal disorder. We have completed our expanded Phase 1 clinical trial of KER-047 and expect to report topline data from this trial by the end of 2020. Our third product candidate, KER-012, is being developed for the treatment of disorders associated with bone loss, such as osteoporosis and osteogenesis imperfecta, and for the treatment of pulmonary arterial hypertension, or PAH. We plan to progress KER-012 into a Phase 1 clinical trial in the second half of 2021. We believe KER-047 and KER-12 offer substantial opportunities for us to continue to apply our understanding of TGF-ß signaling pathways and expand our development programs in related hematological and musculoskeletal disorders with high unmet medical need.

Since our inception in 2015, we have devoted the majority of our efforts into business planning, research and development of our product candidates, including by conducting clinical trials and preclinical studies, raising capital and recruiting management and technical staff to support these operations. To date, we have not generated any revenue from product sales as none of our product candidates have been approved for commercialization. We have historically financed our operations primarily through the sale of convertible preferred stock and cash received from licensing agreements.

On April 13, 2020, we completed an initial public offering, or IPO, of our common stock, in which we issued and sold 6,900,000 shares of common stock, which includes 900,000 shares issued and sold pursuant to the full exercise of the underwriters' option to purchase additional shares, at a public offering price of $16.00 per share. The aggregate net proceeds to us from the IPO were approximately $100.1 million after deducting underwriting discounts and commissions and offering expenses. The shares began trading on the Nasdaq Global Market on April 8, 2020. Upon completion of the IPO, all of our outstanding shares of convertible preferred stock converted into 10,725,129 shares of our common stock.

On March 31, 2020, we effected a one-for-2.1703 reverse stock split of our issued and outstanding shares of common stock and convertible preferred stock, as well as a proportional adjustment to the existing conversion ratios for our convertible preferred stock. All issued and outstanding common stock and convertible preferred

stock and related share and per share amounts contained in this prospectus have been retroactively adjusted to reflect the reverse stock split for all periods presented.

We have incurred recurring operating losses since inception in 2015. Our ability to generate product revenue sufficient to achieve profitability will depend on the successful development and commercialization of one or more of our product candidates. Our net loss was $ million and $ million for the three and nine months ended September 30, 2020, respectively. As of September 30, 2020, we had an accumulated deficit of $ million. We expect to continue to generate operating losses and negative operating cash flows for the foreseeable future in connection with our ongoing activities.

We will not generate any revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for one or more of our product candidates. If we obtain regulatory approval for any of our product candidates, we expect to incur significant expenses related to developing our internal commercialization capability to support product sales, marketing and distribution.

As a result, we will need substantial additional funding to support our operating activities as we advance our product candidates through clinical development, seek regulatory approval and prepare for and, if any of our product candidates are approved, proceed to commercialization. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operating activities through a combination of equity offerings, debt financings, and license and development agreements in connection with any future collaborations. Adequate funding may not be available to us on acceptable terms, or at all.

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

As of September 30, 2020, we had cash and cash equivalents of $ million. We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our operating expenses and capital expenditure requirements into . See "— Liquidity and Capital Resources."

COVID-19 Business Update

With the global COVID-19 pandemic continuing throughout the first half of 2020, we have implemented business continuity plans designed to address and mitigate the impact of the COVID-19 pandemic on our employees, and our business operations, including our preclinical studies and clinical trials, supply chains and third-party providers. We are closely monitoring the COVID-19 situation as we evolve our business continuity plans and response strategy. On March 23, 2020, the governor of Massachusetts ordered the closure of all non-essential businesses effective March 24, 2020 through April 7, 2020, which was subsequently extended through May 18, 2020. On May 18, 2020, the governor of Massachusetts issued a new order implementing a phased re-opening of workplaces, effective May 18, 2020. As of October 5, 2020, the Commonwealth of Massachusetts officially entered step two of the third phase of re-opening for certain lower risk communities. Because of the nature of our operations, we are currently considered to be an essential business so, to date, our operations have only been partially affected by these orders. The outbreak and government measures taken in response have also had a significant impact, both direct and indirect, on third-party businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. In response to the spread of COVID-19, we have closed our principal executive office, with our administrative employees continuing their work outside of our office and limited the number of staff in any given research laboratory. We are currently preparing plans to reopen our office to allow employees to return to the office, which will be based on a phased approach that is principles-based and local in design, with a focus on continuity of preclinical studies and clinical trial activities, employee safety and optimal work environment. While we are experiencing limited financial impacts at this time, given the global economic slowdown, the overall disruption of global healthcare systems and the other risks and uncertainties associated with the pandemic, our business, financial condition, results of operations and growth prospects could be materially adversely affected.

Preclinical and Clinical Development

With respect to preclinical and clinical development, we have taken measures to implement remote and virtual approaches, including remote participant monitoring where possible, to maintain participant safety and trial continuity and to preserve study integrity. For several of our clinical development programs, we are experiencing, and expect to continue to experience, a disruption or delay in our ability to initiate trial sites and enroll and assess participants. As the COVID-19 pandemic continues, we have experienced and expect to continue to experience an impact on our ability to enroll participants in our clinical trials. We have experienced and expect to continue to experience an impact on the ability to supply study drug, report trial results or interact with clinicians, investigators, regulators, ethics committees or other important agencies due to limitations in regulatory authority employee resources or otherwise. In addition, we rely on contract research organizations, or CROs, or other third parties to assist us with clinical trials, and we cannot guarantee that they will continue to perform their contractual duties in a timely and satisfactory manner as a result of the COVID-19 pandemic. If the COVID-19 pandemic continues and persists for an extended period of time, we could experience significant disruptions to our preclinical and clinical development timelines, which would adversely affect our business, financial condition, results of operations and growth prospects.

Supply Chain

As for our third-party manufacturers, distributors and other partners, we are working closely with them to manage our supply chain activities and mitigate potential disruptions to our clinical supply as a result of the COVID-19 pandemic. We expect to have adequate supply for the development of our product candidates. However, if the COVID-19 pandemic persists for an extended period of time and begins to impact essential distribution systems such as FedEx and postal delivery, we could experience disruptions to our supply chain and operations, and associated delays in the manufacturing and supply of our product candidates, which would adversely impact our ability to carry out our clinical trials.

Financial Impact

The COVID-19 pandemic continues to rapidly evolve and has already resulted in a significant disruption of global financial markets. If the disruption persists and deepens, we could experience an inability to access additional capital, which could in the future negatively affect our operations. While we expect the COVID-19 pandemic to adversely affect our business operations, our clinical development and regulatory efforts, our corporate development objectives and the value of and market for our common stock will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, as a result of uncertainty regarding ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the United States and Australia and the effectiveness of actions taken globally to contain and treat the disease.

Licensing Agreements

2016 Exclusive Patent License Agreement with The General Hospital Corporation

In April 2016, we entered into an exclusive patent license agreement with The General Hospital Corporation, or MGH, and such agreement was subsequently amended in May 2017 and February 2018. Under the license agreement with MGH, or the MGH Agreement, we obtained an exclusive, worldwide license, with the right to sublicense, under certain patents and technical information of MGH, to make, have made, use, have used, sell, have sold, lease, have leased, import, have imported or otherwise transfer licensed products and processes for use in the treatment, diagnosis, palliation and prevention of diseases and disorders in humans and animals. We are required to use commercially reasonable efforts to develop and commercialize licensed products and processes, and must achieve certain required diligence milestones.

Under the terms of the MGH Agreement, we made an initial license payment of $0.1 million in 2016 and reimbursed MGH approximately $0.3 million of prior patent prosecution expenses related to the licensed patents in 2017. We also issued MGH an aggregate of 358,674 shares of our common stock. Additionally, we are required to pay a nominal annual maintenance fee prior to the first commercial sale of our first product or process, a mid-five digit annual maintenance fee after the first commercial sale of our first product or process that is creditable against royalties, certain clinical and regulatory milestone payments for the first three products or indications to achieve such milestones, which milestone payments are $8.6 million in the aggregate, and certain commercial milestone payments for the first three products or indications to achieve such milestones, which milestone payments are $18.0 million in the aggregate. We are also obligated to pay tiered royalties on

net sales of licensed products ranging in the low-single digits to mid-single digits. The royalty rates are subject to up to a maximum 50% reduction for lack of a valid claim, in the event that it is necessary for us to obtain a license to any third-party intellectual property related to the licensed products, and generic competition. The obligation to pay royalties under the MGH Agreement expires on a licensed product-by-licensed product and country-by-country basis upon the later of expiry of the last valid claim of the licensed patents that cover such licensed product in such country and ten years from the first commercial sale of such product in such country. We are also obligated to pay a percentage of non-royalty-related payments received by us from sublicensees ranging in the sub-teen double digits and a change of control fee equal to a low-single digit percentage of the payments received as part of any completed transaction up to a low-seven digit amount.

Termination of 2017 Research Collaboration and Exclusive License Agreement with Novo Nordisk A/S

In December 2017, we entered into a research collaboration and exclusive license agreement with Novo Nordisk A/S, or Novo Nordisk. Under the agreement with Novo Nordisk, or the Novo Nordisk Agreement, we are collaborating with Novo Nordisk on research and development of fusion molecules consisting of a ligand binder present as part of a larger molecule, or ligand traps. Pursuant to the Novo Nordisk Agreement, Novo Nordisk had the right to select a prespecified number of ligand traps for further development and commercialization by Novo Nordisk. Following execution, Novo Nordisk selected one existing ligand trap to further develop and commercialize and prior to the completion of the two-year research program, selected a second ligand trap arising from the collaboration. Under the terms of the Novo Nordisk Agreement, we received $20.0 million in 2018, $16.0 million of which represented the initial license fee and $4.0 million of which related to research funding ($2.0 million for each year of the two-year research program).

On October 26, 2020, Novo Nordisk gave written notice of termination of the Novo Nordisk Agreement, effective six months following the delivery of notice, on April 26, 2021. Upon termination, all worldwide rights to all ligand traps selected under the Novo Nordisk Agreement, along with all rights to develop our molecules in the fields of diabetes, obesity, nonalcoholic steatohepatitis and cachexia, will revert to us. Under the terms of the Novo Nordisk Agreement, Novo Nordisk is obligated to continue to reimburse the Company for certain research and development costs through April 26, 2021. Upon effectiveness of the termination, such reimbursements will cease.

Components of Our Results of Operations

Revenue

To date, we have not generated any revenue, and do not expect to generate any revenue in the foreseeable future, from product sales. We have generated revenue solely from the Novo Nordisk Agreement. We may in the future generate revenue from other strategic collaborations.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts and the preclinical and clinical development of our current and potential future product candidates, and include:

- salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions;
- expenses incurred under agreements with third parties, including CROs that conduct research, preclinical and clinical activities on our behalf, as well as contract manufacturing organizations, or CMOs, that manufacture drug product for use in our preclinical studies and clinical trials;
- license fees incurred in connection with license agreements;
- research and development supplies and services expenses;
- facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs;
- cost of outside consultants, including their fees and related travel expenses, engaged in research and development functions;
- expenses related to regulatory affairs; and

- fees related to our scientific advisory board.

We expense research and development costs as incurred. Costs for external development activities are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our consolidated financial statements as prepaid or accrued research and development expenses. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses and expensed as the related goods are delivered or the services are performed.

Research and development activities are central to our business model. We expect that our research and development expenses will continue to increase for the foreseeable future as we continue ongoing and initiate new clinical trials for our product candidates and continue to discover and develop additional product candidates. If any of our product candidates enter into later stages of clinical development, they will 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. There are numerous factors associated with the successful commercialization of any product candidates we may develop in the future, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development program and plans.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive, finance, corporate and business development and administrative functions. General and administrative expenses also include professional fees for legal, patent, accounting, information technology, auditing, tax and consulting services, and travel expenses and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expect that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research and development and potential commercialization of our product candidates. We also expect to incur increased expenses associated with being a public company, including costs of accounting, audit, legal, regulatory and tax compliance services, director and officer insurance costs, and investor and public relations costs.

Other Income, Net

Interest Income (Expense), Net

Interest income (expense), net primarily consists of interest earned on money market accounts and interest expense related to leasehold improvement debt amortization. Our interest income (expense) has not been significant to date.

Research and Development Incentive Income

Research and development incentive income includes payments under the Research and Development Incentive Program, or the R&D Incentive from the Australian government. The R&D Incentive is one of the key elements of the Australian government's support for Australia's innovation system and was developed to assist businesses recover some of the costs of undertaking research and development. The R&D Incentive provides tax offsets to eligible companies that engage in research and development activities and has two core components:

- 43.5% refundable tax offset for certain eligible research and development entities with an aggregated turnover of less than $20.0 million per annum; and
- 38.5% non-refundable tax offset for all other eligible research and development entities. Unused offset amounts may be able to be carried forward for use in future income years.

We have assessed our research and development activities and expenditures to determine which activities and expenditures are likely to be eligible under the R&D Incentive. We recognize the amount we expect to be reimbursed for qualified expenses as income at each period end. We estimate the refundable tax offset

available to us based on available information at the time. This estimate is also reviewed by our external tax advisors on an annual basis.

Other Income, Net

Other income, net primarily consists of unrealized gains on foreign currency and dividend income earned on money market fund accounts.

Change in Fair Value of Preferred Stock Tranche Obligation

The change in fair value of our preferred stock tranche obligation fluctuates based on remeasurement at each reporting period. Our preferred stock tranche obligation stems from our obligation to issue additional shares to investors upon the closing of additional tranches of preferred stock. Upon the waiver of the Series B-2 preferred stock milestone by our board of directors in March 2020, this liability was fully settled. Until settlement, fluctuations in the fair value of our preferred stock tranche obligation were based on the remeasurement at each reporting period.

Results of Operations

Comparison for the years ended December 31, 2018 and 2019

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

	YEAR ENDED DECEMBER 31,	
	2018	2019
Revenue		
Research collaboration revenue	$ 10,000	$ 10,000
Total revenue	10,000	10,000
Operating expenses:		
Research and development	(10,111)	(17,379)
General and administrative	(1,580)	(3,184)
Total operating expenses	(11,691)	(20,563)
Loss from operations	(1,691)	(10,563)
Other income, net:		
Interest income (expense), net	6	(8)
Research and development incentive income	370	558
Change in fair value of preferred stock tranche obligation	(43)	(2,564)
Other income, net	280	241
Total other income (expense), net	613	(1,773)
Loss before income taxes	(1,078)	(12,336)
Income tax provision	(257)	—
Net loss	$ (1,335)	$ (12,336)

Revenue

Our revenue for the years ended December 31, 2018 and 2019 is entirely related to the upfront payment of $16.0 million and annual collaboration fees of $2.0 million per year received as part of the Novo Nordisk Agreement, whereby we granted Novo Nordisk an exclusive license to develop and commercialize the licensed products listed under that agreement and Novo Nordisk granted us a non-exclusive license to its applicable intellectual property so that we could perform the activities we are responsible for, as stated in the Novo Nordisk Agreement. We recognized $10.0 million of the revenue over the two-year term of the Novo Nordisk Agreement in each of 2018 and 2019, in accordance with our pattern of performance of the research and development activities required under the Novo Nordisk Agreement.

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2018 and 2019 (in thousands):

	YEAR ENDED DECEMBER 31,		INCREASE/ (DECREASE)
	2018	2019	
Personnel expenses (including share-based compensation)	$ 1,660	$ 3,637	$ 1,977
Preclinical and development expenses	6,646	11,266	4,620
Facilities and supplies	1,434	1,409	(25)
Professional fees	180	780	600
Other expenses	191	287	96
	$ 10,111	$ 17,379	$ 7,268

Research and development expenses were $17.4 million for the year ended December 31, 2019, compared to $10.1 million for the year ended December 31, 2018. The increase of $7.3 million was primarily due to a $4.6 million increase in the costs related to our Phase 1 clinical trial of KER-050, as well as an increase of $2.0 million in personnel costs from the increased headcount required to support our Phase 1 clinical trial progress in 2019.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the years ended December 31, 2018 and 2019 (in thousands):

	YEAR ENDED DECEMBER 31,		INCREASE
	2018	2019	
Personnel expenses (including stock-based compensation)	$ 947	$ 1,458	$ 511
Facilities and supplies	300	469	169
Legal and professional fees	212	1,090	878
Other expenses	121	167	46
	$ 1,580	$ 3,184	$ 1,604

General and administrative expenses were $3.2 million for the year ended December 31, 2019, compared to $1.6 million for the year ended December 31, 2018. The increase of $1.6 million was primarily due to a $0.9 million increase in professional fees, as well as a $0.5 million increase in personnel expenses stemming from an increase in headcount to support our growth as we move towards becoming a public company.

Research and Development Incentive Income

Income related to the R&D Incentive was $0.6 million for the year ended December 31, 2019, compared to $0.4 million for the year ended December 31, 2018. The increase of $0.2 million was primarily due to an increase in research and development spending in Australia.

Other Income (Expense), Net

Other income (expense), net was ($1.8) million for the year ended December 31, 2019, compared to $0.6 million for the year ended December 31, 2018. The decrease of $2.4 million is related to the increase in the fair value of the preferred stock tranche obligation from $2.4 million as of December 31, 2018 to $5.0 million as of December 31, 2019, which was driven by the increase in the value of our preferred stock.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. Our net losses were $ million and $ million for the nine months ended September 30, 2020 and 2019, respectively. As of September 30, 2020 and December 31, 2019, we had an accumulated deficit of $ million and $19.7 million, respectively. To date, we have devoted the majority of our efforts into business planning, research and development of our

product candidates, including by conducting clinical trials and preclinical studies, raising capital and recruiting management and technical staff to support these operations. Our primary uses of cash are to fund operating expenses, primarily research and development expenditures. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our product candidates. Furthermore, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company.

We do not have any products approved for sale. We do not expect to generate any revenue from product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which we expect will take a number of years. Since our inception, we have funded our operations primarily through equity financings and through the Novo Nordisk Agreement. In April 2020, we completed our IPO whereby we sold an aggregate of 6,900,000 shares of our common stock for aggregate net proceeds of approximately $100.1 million after deducting underwriting discounts and commissions and offering expenses.

As of September 30, 2020, we had cash and cash equivalents of $ million. We believe that the expected net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to enable us to fund our operating expenses through at least the next months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Due to the numerous risks and uncertainties associated with the development of our product candidates and programs, and because the extent to which we may enter into collaborations with third parties for development of our product candidates is unknown, we are unable to estimate the timing and amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates. Our future funding requirements, both near and long-term, will depend on many factors, including:

- the progress, timing and completion of preclinical studies and clinical trials for our current or any future product candidates, as well as the associated costs, including any unforeseen costs we may incur as a result of preclinical study or clinical trial delays due to the COVID-19 pandemic or other causes;
- the timing and amount of milestone and royalty payments we are required to make or are eligible to receive under our license agreement with The General Hospital Corporation;
- the number of potential new product candidates we identify and decide to develop;
- the need for additional or expanded preclinical studies and clinical trials beyond those that we plan to conduct with respect to our current and future product candidates;
- the costs involved in growing our organization to the size needed to allow for the research, development and potential commercialization of our current or any future product candidates;
- the costs involved in filing patent applications, maintaining and enforcing patents or defending against infringement or other claims raised by third parties;
- the maintenance of our existing license and collaboration agreements and the entry into new license and collaboration agreements;
- the time and costs involved in obtaining regulatory approval for our product candidates and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to any of our product candidates;
- the effect of competing technological and market developments;
- the costs of operating as a public company;
- the cost of manufacturing KER-050, KER-047, KER-012 and future product candidates for clinical trials in preparation for marketing approval and in preparation for commercialization;
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own;
- the amount of revenues, if any, we may derive either directly or in the form of royalty payments from future sales of our product candidates, if approved; and
- market acceptance of any approved product candidates.

In addition, the COVID-19 pandemic continues to rapidly evolve and has already resulted in a significant disruption of global financial markets. If the disruption persists and deepens, we could experience an inability to

access additional capital when and if needed. If we are unable to obtain funding, we could be forced to delay, reduce or eliminate some or all of our research and development programs and clinical development efforts, which would adversely affect our business prospects, or we may be unable to continue operations. 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 product or royalty 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. Adequate additional funding may not be available to us on acceptable terms, or at all. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies.

Cash Flows

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

	YEAR ENDED DECEMBER 31,		NINE MONTHS ENDED SEPTEMBER 30,	
	2018	2019	2019	2020
			(Unaudited)	
Net cash provided by (used in) operating activities	$ (7,042)	$ (15,998)	$	$
Net cash used in investing activities	(217)	(271)		
Net cash provided by financing activities	11,463	14		
Net increase (decrease) in cash and cash equivalents, and restricted cash	$ 18,288	$ (16,255)	$	$

Operating Activities

During the year ended December 31, 2018, operating activities provided $7.0 million of cash, primarily from a cash receipt of $20.0 million from Novo Nordisk related to the Novo Nordisk Agreement that was previously included in prepaid expenses and other current assets. Of the $20.0 million received, $16.0 million was the upfront payment for the Novo Nordisk Agreement and $4.0 million was related to the collaboration payments due from Novo Nordisk for both 2017 and 2018, as all cash was received in 2018. This cash inflow was partially offset by a $10.0 million decrease in deferred revenue related to the portion of the Novo Nordisk Agreement upfront payment that was recognized as revenue in 2018. The inflow was also offset by other changes in our operating assets and liabilities including a $0.4 million increase in the R&D Incentive receivable relating to refunds for qualified research and development spending during the year as well as a $0.2 million non-cash expense for our non-cash lease expense related to our right-of-use asset and a $0.2 million decrease in our corresponding operating lease liability.

During the year ended December 31, 2019, cash used in operating activities was $16.0 million, primarily stemming from a $10.0 million decrease in deferred revenue for the portion of the Novo Nordisk payment recognized as revenue in 2019, as well as a $0.6 million increase in our R&D Incentive receivable. The $16.0 million cash outflow was partially offset by a $2.5 million increase in accounts payable and accrued expenses, a $2.6 million increase in our preferred stock tranche obligation, and a $1.9 million decrease in prepaid and other current assets.

Investing Activities

During the years ended December 31, 2018 and 2019, we used $0.2 million and $0.3 million of cash, respectively, for investing activities related to purchases of property and equipment.

Financing Activities

During the year ended December 31, 2018, net cash provided by financing activities was $11.5 million, primarily from the net proceeds received from the issuance of Series B-1 preferred stock in November 2018.

Net cash provided by financing activities of less than $0.1 million during the year ended December 31, 2019 stemmed from exercises of options to purchase common stock.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations at December 31, 2019 and the effects of such obligations are expected to have on our liquidity and cash flow in future periods (in thousands):

	PAYMENTS DUE BY PERIOD				
	TOTAL	LESS THAN 1 YEAR	1 TO 3 YEARS	4 TO 5 YEARS	MORE THAN 5 YEARS
Operating lease commitments	$ 1,448	$ 468	$ 980	$ —	$ —
Loan for leasehold improvements	195	65	130	—	—
Total	$ 1,643	$ 533	$ 1,110	$ —	$ —

We have entered into an operating lease for rental space in Lexington, Massachusetts. The table above includes future minimum lease payments under the non-cancelable lease arrangement. A portion of the contractual obligations and commitments is related to the loan we received from the landlord of $0.2 million for leasehold improvements. This will be repaid in full by December 2022 when the lease expires, but principal payments became due in monthly installments beginning 18 months after the commencement of the lease, which was March 2017.

We may incur contingent payments upon our achievement of clinical, regulatory and commercial milestones, as applicable, or royalty payments that we are required to make under the MGH Agreement pursuant to which we have in-licensed certain intellectual property. Due to the uncertainty of the achievement and timing of the events requiring payment under these agreements, the amounts to be paid by us are not fixed or determinable at this time and are excluded from the table above. Under the terms of the MGH Agreement, we are obligated to pay MGH designated amounts when any licensed product achieves certain developmental milestones. Following the commencement of commercial sales of the licensed products, we will pay designated amounts when certain milestone events occur. The development milestones and commercial milestones range from $50,000 to $10.0 million depending upon the significance of the particular milestone. We are also required to pay MGH royalties on all sales of licensed products, with such royalties ranging from the low-single digits to mid-single digits of sales, as well as royalties ranging in the low-double digits of sublicense income depending on the stage of development of the relevant product or process when the sublicense is granted. In conjunction with the execution of the MGH Agreement, we issued MGH five percent of our outstanding fully diluted capital on April 15, 2016, or 358,674 shares of common stock, for proceeds of less than $0.1 million.

Critical Accounting Policies and Significant Judgments and Estimates

This management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses and the disclosure of contingent assets and liabilities in our 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 greater 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.

Revenue Recognition

To date, our revenues have consisted solely of payments received related to the Novo Nordisk Agreement. We apply the revenue recognition guidance in accordance with Financial Accounting Standards Board Accounting

Standards Codification Subtopic 606, Revenue from Contracts with Customers, or ASC 606, which was adopted January 1, 2018 using the full retrospective method. Under ASC 606, we recognize revenue when our customers obtain control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services.

To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of ASC 606, we perform the following five steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) we satisfy each performance obligation. We only apply the five-step model to contracts when it is probable that we will collect consideration we are entitled to in exchange for the goods or services we transfer to our customer. All variable consideration, including milestones and royalties, is constrained until the cumulative revenue related to the consideration is no longer probable of reversal.

The consideration allocated to each performance obligation is recognized as revenue when control is transferred for the related goods or services. For performance obligations which consist of licenses and other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition. We currently measure progress according to the expenditure of research and development efforts, based on costs incurred, as this is the best indicator of performance.

We receive payments from our customers based on billing schedules established in each contract. Upfront payments and fees are recorded as deferred revenue upon receipt or when due until we satisfy our obligations under these arrangements. Amounts are recorded as accounts receivable when our right to consideration is unconditional.

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. 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. 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.

Preferred Stock Tranche Obligation

The initial fair value of the preferred stock tranche obligation recognized in connection with our issuances of convertible preferred stock in April 2016, August 2016, and November 2018 was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The initial fair value of the obligation was estimated based on results of a third-party valuation performed in connection with the initial issuances. This obligation is remeasured prior to the issuance of subsequent tranches, and at each subsequent reporting period. See Note 8 to our annual consolidated financial statements included elsewhere in this prospectus for additional information regarding our issuances of preferred stock.

The tranche obligation was determined using the binomial pricing model, which takes into account the probability of both achievement and failure to achieve the tranche milestones and issue the subsequent shares. The binomial pricing model calculates the tranche obligation as the difference between the expected value of the Series B-1/B-2 Preferred Stock at the time the tranche milestone is met and the contractual purchase price

for the tranche shares, and then discounts this value back to the initial issuance date. In determining the fair values of the tranche obligations, estimates and assumptions impacting fair value include the estimated future values of our Series B-1/B-2 Preferred Stock, discount rates, estimated time to liquidity, and probability of each tranche closing. We determined the per share future value of the Series B-1/B-2Preferred Stock by back-solving to the initial proceeds of the financings. We remeasured each tranche obligation at each reporting period and prior to settlement. The purchase price of the preferred stock at initial issuance, and all subsequent issuances was higher than the fair value of our common stock.

Stock-Based Compensation

We account for all stock-based compensation awards granted to employees and non-employees as stock-based compensation expense at fair value. Our stock-based payments include stock options and grants of common stock, including common stock subject to vesting. The measurement date for awards is the date of grant, and stock-based compensation costs are recognized as expense over the requisite service period, which is generally the vesting period, on a straight-line basis. Stock-based compensation expense is classified in the accompanying statements of operations based on the function to which the related services are provided. We recognize stock-based compensation expense for the portion of awards that have vested. Forfeitures are recorded as they occur. The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model.

Determination of the Fair Value of Common Stock

Prior to our initial public offering, the estimated fair value of our common stock was determined by management and approved by our board of directors, utilizing our enterprise value determined by a third-party valuation expert, and in accordance with the guidance outlined in the American Institute of Certified Public Accountants Technical Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation.

Our management considered various objective and subjective factors to determine the fair value of our common stock as of each grant date, including:

- the prices at which we sold shares of preferred stock and the superior rights and preferences of the preferred stock relative to our common stock at the time of each grant;
- the progress of our research and development programs, including the status and results of preclinical studies for our product candidates;
- our stage of development and commercialization and our business strategy;
- external market conditions affecting the biopharmaceutical industry and trends within the biopharmaceutical industry;
- our financial position, including cash on hand, and our historical and forecasted performance and operating results;
- the lack of an active public market for our common stock and our preferred stock;
- the likelihood of achieving a liquidity event, such as an initial public offering, or IPO, or sale of our company in light of prevailing market conditions; and
- the analysis of IPOs and the market performance of similar companies in the biopharmaceutical industry.

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

Options Granted

The following table sets forth, by grant date, the number of shares subject to options granted from January 1, 2018 through September 30, 2020, the exercise price per common share of the options, the fair value per common share on each grant date, and the estimated per share fair value of the options:

GRANT DATE	NUMBER OF COMMON SHARES SUBJECT TO OPTIONS GRANTED	EXERCISE PRICE PER COMMON SHARE(1)	FAIR VALUE PER COMMON SHARE AT GRANT DATE(1)	ESTIMATED PER-SHARE FAIR VALUE OF OPTIONS(2)
March 26, 2018	591,008	$ 0.30	$ 0.30	$ 0.19
June 21, 2018	42,389	$ 0.30	$ 0.30	$ 0.19
September 17, 2018	50,682	$ 0.30	$ 0.30	$ 0.19
October 28, 2018	23,038	$ 0.30	$ 0.30	$ 0.19
June 12, 2019	85,241	$ 0.48	$ 0.48	$ 0.32
June 19, 2019	169,113	$ 0.48	$ 0.48	$ 0.32
July 22, 2019	59,897	$ 0.48	$ 0.48	$ 0.32
September 19, 2019	156,658	$ 0.48	$ 0.48	$ 0.32
April 7, 2020	1,147,436	$ 16.00	$ 16.00	$ 12.51
May 4, 2020	41,468	$ 29.02	$ 29.02	$ 22.63
May 29, 2020	201,700	$ 28.74	$ 28.74	$ 22.37
September 3, 2020	28,900	$ 50.77	$ 50.77	$ 40.57

(1) The exercise price per common share of options represents the fair value of our common stock on the date of grant. For all grants issued prior to the closing of our IPO on April 13, 2020, the fair value of common stock was determined by our board of directors, after taking into account our most recently available contemporaneous valuation of our common stock as well as additional factors that may have changed since the date of such contemporaneous valuation through the date of grant. For all grants issued subsequent to the closing of our IPO on April 13, 2020, the fair value of common stock is the last reported sale price of our common stock as reported on the Nasdaq Global Market on the date of grant.

(2) The estimated fair value of options reflects the weighted average fair value of options granted on each grant date, determined using the Black-Scholes option-pricing model.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements and do not have any holdings in variable interest entities.

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

We are exposed to market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily the result of interest rate sensitivities.

Interest Rate Sensitivity

As of September 30, 2020 and December 31, 2019, we had cash and cash equivalents of $ million and $7.0 million, respectively. Our exposure to interest rate sensitivity is impacted by changes in the underlying U.S. bank interest rates. Our surplus cash has been invested in money market fund accounts as well as interest-bearing savings accounts from time to time. We have not entered into investments for trading or speculative purposes. Due to the conservative nature of our investment portfolio, which is predicated on capital preservation of investments with short-term maturities, we do not believe an immediate one percentage point change in interest rates would have a material effect on the fair market value of our portfolio, and therefore we

do not expect our operating results or cash flows to be significantly affected by changes in market interest rates.

As of September 30, 2020 and December 31, 2019, we had no debt outstanding that is subject to interest rate variability, as our only debt is related to our lease incentive allowance. Therefore, we are not subject to interest rate risk related to debt.

Emerging Growth Company Status

In April 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" may take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Therefore, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected to avail ourselves of this extended transition period and, as a result, we will not adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

In addition, 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:

- reduced disclosure about the compensation paid to our executive officers;
- not being required to submit to our stockholders' advisory votes on executive compensation or golden parachute arrangements;
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002; and
- an exemption from new or revised financial accounting standards until they would apply to private companies and from compliance with any new requirements adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotation.

We may take advantage of these exemptions until December 31, 2025 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 (1) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (2) December 31, 2025; (3) the date on which we have issued more than $1.0 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 Securities and Exchange Commission. We may choose to take advantage of some but not all of these exemptions.

BUSINESS

Overview

We are a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel treatments for patients suffering from hematological and musculoskeletal disorders with high unmet medical need. We are a leader in understanding the role of the Transforming Growth Factor-Beta, or TGF-ß, family of proteins, which are master regulators of red blood cell and platelet production as well as of the growth, repair and maintenance of muscle and bone. We have leveraged this understanding and developed a discovery approach to generate large and small molecules to address diseases of these tissues. Targeting TGF-ß signaling pathways has been clinically proven to elicit robust changes in blood cells, muscle and bone, which we believe provides a precedent and strong rationale for our strategy. Our lead protein therapeutic product candidate, KER-050, is being developed for the treatment of low blood cell counts, or cytopenias, including anemia and thrombocytopenia, in patients with myelodysplastic syndromes, or MDS, and in patients with myelofibrosis. We have initiated a Phase 2 clinical trial in patients with MDS and expect to report initial data from Part 1 of this trial in mid-2021. We also plan to initiate a Phase 2 clinical trial in patients with myelofibrosis in 2021. Our lead small molecule product candidate, KER-047, is being developed for the treatment of anemia resulting from iron imbalance, as well as for the treatment of fibrodysplasia ossificans progressiva, or FOP, a rare musculoskeletal disorder. We have completed our expanded Phase 1 clinical trial of KER-047 and expect to report topline data from this trial by the end of 2020. Our third product candidate, KER-012, is being developed for the treatment of disorders associated with bone loss, such as osteoporosis and osteogenesis imperfecta, and for the treatment of pulmonary arterial hypertension, or PAH. We plan to progress KER-012 into a Phase 1 clinical trial in the second half of 2021. We believe KER-047 and KER-12 offer substantial opportunities for us to continue to apply our understanding of TGF-ß signaling pathways and expand our development programs in related hematological and musculoskeletal disorders with high unmet medical need.

KER-050 is an engineered ligand trap comprised of a modified ligand-binding domain of the TGF-ß receptor known as activin receptor type IIA, or ActRIIA, that is fused to the portion of the human antibody known as the Fc domain. KER-050 is designed to increase red blood cell and platelet production by inhibiting the signaling of a subset of the TGF-ß family of proteins to promote hematopoiesis. We believe KER-050 has the potential to provide benefit to patients suffering from red blood cell and platelet differentiation and maturation defects occurring across the spectrum from early through terminal stages of hematopoiesis, and consequently may be effective for many patients that have limited treatment options or are refractory to available therapies. We have completed a Phase 1 clinical trial evaluating the safety, tolerability and pharmacokinetics of KER-050 in healthy post-menopausal women. In this trial, we observed rapid and sustained increases in red blood cells, hemoglobin and reticulocytes, in addition to clinically meaningful increases in platelets after a single dose. Based on these findings and the results from preclinical studies, we believe KER-050 has a differentiated pharmacologic effect on red blood cells and platelets and has the potential to treat multiple cytopenias in diseases of ineffective hematopoiesis. In October 2020, we announced the dosing of the first two participants in our Phase 2 clinical trial evaluating KER-050 for the treatment of anemia and thrombocytopenia in very low-, low-, or intermediate-risk MDS. We expect to report initial data from Part 1 of this trial in mid-2021. Additionally, we plan to commence a Phase 2 clinical trial evaluating KER-050 for the treatment of patients with myelofibrosis-associated cytopenias in 2021.

KER-047 is designed to selectively and potently inhibit activin receptor-like kinase-2, or ALK2, a TGF-ß receptor. We believe that KER-047 has the potential to ameliorate excessive ALK2 signaling, which is directly implicated in anemias arising from iron imbalance and musculoskeletal disorders where the transformation of soft tissue into bone, referred to as heterotopic ossification, leads to devastating immobility. We are developing KER-047 for the treatment of anemia resulting from iron imbalance as a direct consequence of elevated ALK2 signaling, including our initial target, iron-refractory iron deficiency anemia, or IRIDA. We are also developing KER-047 as a treatment for FOP, a rare genetic disease resulting from mutations in the ALK2 receptor that results in gain-of-function activity. In these patients, soft tissue, including muscles and tendons, develops normally, but remodels into bone after injury. In August 2020, we announced the completion of our planned single and multiple ascending dose cohorts in a Phase 1 clinical trial of KER-047 in healthy volunteers, as well as the expansion of this trial to evaluate additional cohorts of healthy volunteers. In the planned cohorts of this trial, we observed dose-dependent increases in serum iron and increased reticulocyte hemoglobin,

which is a measure of hemoglobin content from newly-produced immature red blood cells, in the volunteers who received KER-047. We evaluated one additional cohort of healthy volunteers and terminated the trial after determining that the data from this cohort, in addition to the data from the planned cohorts of the trial, were sufficient to inform the design of the expected Phase 2 clinical trials of KER-047, and expect to report topline data by the end of 2020. As the data from this additional cohort was deemed sufficient to provide the necessary data, we currently do not plan to expand this trial into any additional cohorts of healthy volunteers. We also expect to commence two Phase 2 clinical trials, one in patients with iron deficiency anemia, or IDA, and one in patients with IRIDA, in 2021.

KER-012 is designed to bind to and inhibit the signaling of TGF-ß ligands, including activin A and activin B, which are key regulators of bone remodeling that act to suppress bone growth, to potentially increase bone mass. We believe that KER-012 has the potential to increase the signaling of bone morphogenic protein, or BMP, pathways through this inhibition of activin A and activin B signaling, and consequently treat diseases such as PAH that are associated with reduced BMP signaling due to inactivating mutations in the BMP receptors. We are developing KER-012 for the treatment of disorders associated with bone loss, such as osteoporosis and osteogenesis imperfecta, and for the treatment of PAH. In a rat model of PAH, rats receiving a rodent version of KER-012, or RKER-012, were protected from the thickening of the right ventricular wall. In addition, rats receiving a rodent version of KER-012 were protected from PAH-associated bone loss which we believe demonstrates proof-of-mechanism of KER-012 for the treatment of PAH and bone loss. We plan to advance KER-012 into a Phase 1 clinical trial in the second half of 2021.

Our strategy focuses on the role of members of the TGF-ß family of proteins in the development of blood cells, muscle and bone. Aged and damaged cells are routinely replaced by new cells in normally functioning organs. These new cells are derived from stem cells that have the ability to differentiate into cells with specialized function when appropriate signals are provided to maintain the homeostatic state of the tissue. Members of the TGF-ß family of proteins, including activins and bone morphogenetic proteins, or BMPs, provide the necessary signals for this process of self-renewal and repair.

We seek to address the limitations of current therapeutic approaches to treating diseases whose manifestations are linked to dysfunction of TGF-ß signaling pathways by:

- Leveraging our comprehensive insights into the TGF-ß signaling pathways to discover therapeutics to treat hematological and musculoskeletal disorders.
- Expanding our library of proprietary molecules that are engineered to induce desired biological effects, such as increased blood cell production, inhibit heterotopic ossification and increased muscle and bone mass.
- Engineering proprietary molecules to selectively target specific proteins in the TGF-ß signaling pathways to provide therapeutic benefit while potentially minimizing safety risks.
- Developing product candidates for the treatment of diseases where targeting the TGF-ß signaling pathways has clinical validation or biological rationale to improve our probability of success in the clinic.
- Targeting the TGF-ß family of proteins, which are highly conserved throughout evolution, permitting the use of animal models to potentially predict with high confidence the therapeutic benefit in patients.

We are led by a highly experienced management team and scientific advisory board who have more than 100 combined years of research and development on therapeutics in the TGF-ß family of proteins. Our team has collectively worked on marketed therapeutics such as Reblozyl, Tecfidera, Kalydeco and Waylivra, and led drug discovery and clinical development at companies including Acceleron Pharma Inc., Biogen Inc., Wyeth Pharmaceuticals Inc., Seres Therapeutics, Inc., Vertex Pharmaceuticals Incorporated and Akcea Therapeutics, Inc.

Our Pipeline

The following table sets forth our product candidates, their current development stages and anticipated upcoming milestones.

Program	Asset	Phase of Development				Status	Next Milestones*
		Preclinical	Phase 1	Phase 2	Phase 3		
Hematology	KER-050 (therapeutic protein)	Myelodysplastic syndromes (MDS)				Initiated Phase 2 clinical trial	**Initial data: mid-2021**
		Myelofibrosis (MF)				Completed Phase 1 clinical trial	Initiate Phase 2 clinical trial: 2021
Hematology / Musculoskeletal	KER-047 (small molecule)	Iron-deficiency anemia				Completed expanded Phase 1 clinical trial	Topline data: end of 2020
		Anemia from high hepcidin					
Musculoskeletal		Fibrodysplasia Ossificans Progressiva (FOP)					
Preclinical Pipeline	KER-012 (therapeutic protein)	Pulmonary Arterial Hypertension				Ongoing preclinical studies	Initiate Phase 1 clinical trial: H2 2021
		Bone Disorders					

* Anticipated clinical milestones are subject to the impact of COVID-19 on our business.

Our Strategy

Our mission is to deliver significant clinical benefit to patients suffering from hematological and musculoskeletal diseases by developing differentiated product candidates that are designed to alter TGF-ß signaling pathways. The key elements of our strategy include:

- *Rapidly advance the clinical development of KER-050 for the treatment of patients with MDS- and myelofibrosis-associated cytopenias.* We have generated preliminary data in our Phase 1 clinical trial of KER-050 in healthy post-menopausal women and have initiated a Phase 2 clinical trial evaluating KER-050 for the treatment of anemia and thrombocytopenia in participants with very low-, low-, or intermediate-risk MDS who either have or have not previously received treatment with an erythropoiesis-stimulating agent. We also plan to commence a Phase 2 clinical trial evaluating the treatment of patients with myelofibrosis-associated cytopenias in 2021.
- *Rapidly advance the clinical development of KER-047 for the treatment of anemias resulting from iron imbalance and musculoskeletal disorders where heterotopic ossification leads to devastating immobility.* We have generated preliminary topline data in a Phase 1 clinical trial of KER-047 in healthy volunteers, and expanded this trial to evaluate additional cohorts of healthy volunteers. We evaluated one additional cohort of healthy volunteers and terminated the trial after determining that the data from this cohort, in addition to the data from the planned cohorts, were sufficient to inform the design of the expected Phase 2 clinical trials of KER-047, and expect to report topline data by the end of 2020. We also expect to commence two Phase 2 clinical trials, one in patients with IDA and one in patients with IRIDA, in 2021. Following the completion of the expected Phase 2 clinical trial in patients with IDA, we plan to commence a Phase 2 clinical trial in patients with FOP. We also intend to develop KER-047 as a potential treatment option for patients who manifest anemia caused by iron imbalance as a secondary consequence of more common diseases.
- *Advance KER-012 into and through clinical development for the treatment of disorders associated with bone loss, such as osteoporosis and osteogenesis imperfecta, and for the treatment of PAH.* We have generated preclinical data that we believe demonstrated proof-of-mechanism of KER-012 for the treatment of disorders associated with bone loss, such as osteoporosis and osteogenesis imperfecta, and for the treatment of PAH. We plan to advance KER-012 into a Phase 1 clinical trial in the second half of 2021.

- *Pursue development and, if approved, commercialization of our product candidates in indications and regions where we believe we can maximize their value independently or through strategic collaborations.* We plan to independently advance our product candidates in indications and regions that we believe have clearly defined regulatory paths and commercialization strategies. We intend to opportunistically evaluate strategic collaborations to maximize the potential commercial value of our product candidates and discovery programs.
- *Leverage our proprietary discovery approach and knowledge base to develop new therapeutics.* Our discovery efforts are focused on expanding our pipeline of wholly-owned assets for the treatment of hematological and musculoskeletal diseases. Accordingly, we intend to identify and develop product candidates to treat diseases where targeting the TGF-ß signaling pathways has clinical validation or biological rationale.

Our Hematology Program

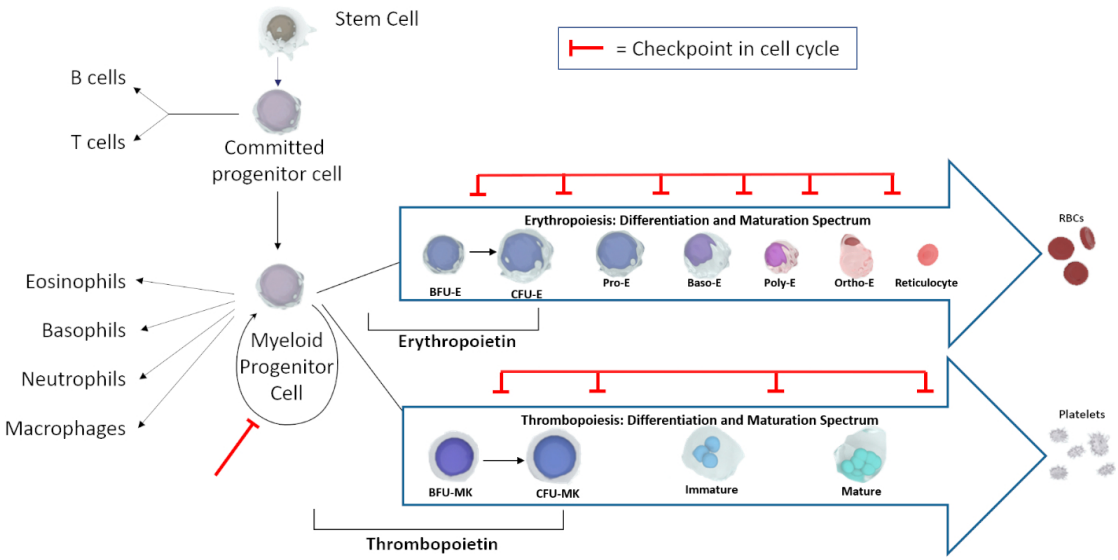
Our two lead product candidates, KER-050 and KER-047, are designed to target TGF-ß signaling pathways to address diseases that arise from ineffective hematopoiesis as well as anemias that result from iron imbalance.

Hematopoiesis

The primary cellular components of blood are red blood cells, white blood cells and platelets. The function of red blood cells is to distribute oxygen to tissues throughout the body and to carry waste carbon dioxide back to the lungs. White blood cells are responsible for the immune response through coordinated surveillance and targeting of pathogens, infected or aberrant cells and cell debris. Platelets are a key component of the coagulation system and are responsible for stopping bleeding by forming a blood clot.

Hematopoiesis is the production of red blood cells, white blood cells and platelets from common progenitor stem cells, or progenitor cells. This process begins when a hematopoietic progenitor cell becomes committed to a specific cellular lineage. These cells progress through a series of intermediate stages before becoming a mature cell with a specialized function. At any given time, pools of each progenitor cell are maintained and primed to rapidly respond to a reduction of red blood cells, white blood cells and platelets. The graphic below depicts the stages of hematopoiesis for red blood cells and platelets.

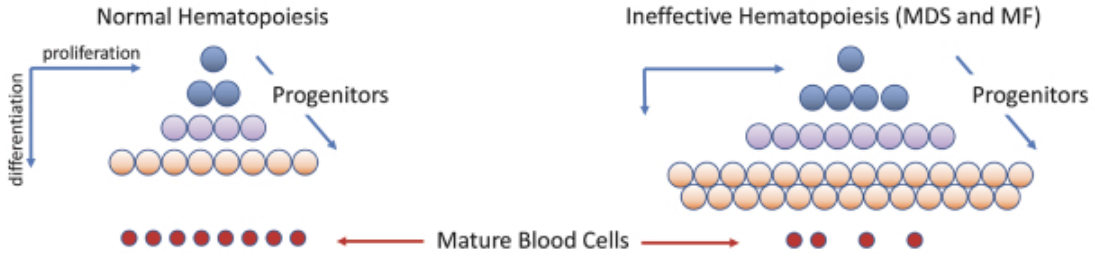
Stages of Hematopoiesis



TGF-ß signaling pathways involving activins prevent differentiation in order to maintain progenitor cells in a quiescent state while others involving BMPs promote differentiation of progenitor cells. Homeostasis of this process is essential to ensure all cell types are properly replenished in the blood.

In many hematological disorders, there is abnormal proliferation and differentiation of the progenitor cells for red blood cells, platelets and neutrophils. This failure to produce fully mature cells is termed ineffective hematopoiesis, and may be due to single or multiple defects that can lead to a hyperproliferation or a shortage of progenitor cells.

These changes have clinical consequences: a lack of red blood cells leads to anemia, a lack of platelets hampers clotting, resulting in increased incidence of bleeding events, and a lack of neutrophils increases susceptibility to infection. The failure of progenitor cells to differentiate can also lead to a build-up of these cells, resulting in bone marrow failure and fibrotic disease. The graphic below provides an illustration of the difference in the number of progenitor cells and mature bloods cells that are produced in normal hematopoiesis and in ineffective hematopoiesis.



Another critical component in red blood cell development is the production of hemoglobin, an iron-containing protein that delivers oxygen to cells and removes carbon dioxide. The synthesis of hemoglobin requires that sufficient levels of iron are present in the bone marrow and if iron levels are too low, it can result in a failure to produce sufficient numbers of red blood cells. Anemia is a common consequence of diseases where normal iron mobilization is hindered.

KER-050: For the Treatment of Ineffective Hematopoiesis to Address Cytopenias

We are developing KER-050, our lead protein therapeutic product candidate, for the treatment of cytopenias that occur due to ineffective hematopoiesis, including anemia and thrombocytopenia, in patients with MDS and in patients with myelofibrosis. KER-050 is designed to benefit patients suffering from defects in red blood cell and platelet differentiation and maturation across the spectrum from early through terminal stages of hematopoiesis. Consequently, KER-050 may be effective for many patients that have limited treatment options or are refractory to available therapies.

Myelodysplastic Syndromes

Myelodysplastic syndromes, or MDS, is a collection of bone marrow disorders characterized by ineffective hematopoiesis, often with a dramatic expansion of progenitor cells that are unable to mature into functioning blood cells. In the United States, there are 60,000 to 170,000 patients with MDS and 15,000 to 20,000 new cases of MDS reported each year. MDS predominantly affects older adults, with approximately 75% of patients aged 60 years or older at diagnosis. Median survival ranges from approximately nine years for very low-risk patients to less than a year for high-risk patients.

Cytopenias in MDS are caused by defects occurring across the various stages of hematopoiesis, from the self-renewal of progenitor cells to differentiation in early through terminal stages. Anemia is the most frequent consequence of ineffective hematopoiesis in patients with MDS due to low red blood cell production, and impacts 90% of MDS patients, with approximately 40% becoming transfusion dependent. Another consequence is thrombocytopenia, a deficiency of platelets in the blood, which is impaired blood clotting that can cause bleeding. The prevalence of thrombocytopenia in patients with MDS has been reported at 40% to 65%. A deficiency of neutrophils in the blood, or neutropenia, also increases the risk of serious infections in patients with MDS and has been reported to affect approximately 20% of patients with MDS.

To guide decisions on risk stratification and the treatment of patients with MDS, clinicians typically use the International Prognostic Scoring System-Revised, or the IPSS-R. The IPSS-R incorporates information on bone marrow blast percentage, karyotype and presence and severity of cytopenias in order to classify patients with MDS into groups based on the risk of progression to acute myeloid leukemia, ranging from very low-risk to high-risk. Patients are further classified into high transfusion burden and low transfusion burden categories based on the number of units of transfused red blood cells they receive.

A second classification system is the World Health Organization, or WHO, system, which is based on a combination of morphology, immunophenotype, genetics and clinical features. The WHO classification system includes a subgroup of patients with MDS that show the presence of iron deposits around the mitochondria, known as ring sideroblasts. These patients are commonly referred to as RS positive and comprise approximately 15% of incident patients with MDS, and splicing factor mutations, such as *SF3B1*, are highly correlated with these patients. Patients with splicing factor mutations often have been observed to have defects in the differentiation of red blood cells at the terminal stage. The majority of patients with MDS that develop cytopenias lack ring sideroblasts or a single, defining splicing factor mutation and are termed non-RS. These non-RS patients have differentiation and maturation defects occurring across the spectrum from early through terminal stages of hematopoiesis.

Limitations of Current Treatment Options for Cytopenias in Patients with MDS

Patients with MDS-associated anemia are generally treated with red blood cell transfusions and erythroid stimulating agents, or ESAs, which are not approved for such treatment. The treatment of MDS-associated thrombocytopenia is platelet transfusions and platelet-stimulating agents.

Severe cytopenia and transfusion dependence are independent predictors of poor prognosis for patients with MDS and are inversely correlated with quality of life. Red blood cell and platelet transfusions provide temporary benefits to patients with MDS, but are associated with both acute and chronic health risks, including risk of bacterial infection and allergic reactions to the donor blood, and place a significant burden on both the patient and the healthcare system. Red blood cell transfusions are also associated with iron overload, which can lead to organ dysfunction over time. Additionally, the benefit from a platelet transfusion is typically short-lived and availability is limited. Platelet-stimulating agents for the treatment of thrombocytopenia, which are not currently indicated for MDS, carry the risk of thromboembolic events and bone marrow fibrosis.

ESAs are a class of drugs that work on the proliferation stage of red blood cell development by expanding the pool of early-stage progenitor cells. While ESAs have been shown to alleviate anemia in a subset of patients with MDS, patients that have elevated endogenous erythropoietin levels are unlikely to respond. In two controlled Phase 3 clinical trials evaluating darbepoetin alfa (Aranesp) for the treatment of MDS-associated anemia, 15% to 31% of patients responded. However, this response was limited to patients with mildly elevated endogenous erythropoietin levels and to patients who largely did not require regular red blood cell transfusions. These treatment options also represent a significant burden to patients, as they must be administered up to three times a week. Additionally, the effect of ESAs is limited to the red blood cell lineage and, therefore, ESAs only treat MDS-associated anemia and do not provide benefit to cytopenia of other cell lineages, including thrombocytopenia and neutropenia.

Reblozyl, a TGF-ß-based erythroid maturation agent, is designed to promote the terminal differentiation of red blood cells through inhibition of selected endogenous TGF-ß superfamily ligands. The characteristics of response were defined in a Phase 2 clinical trial of Reblozyl in patients with MDS. Consistent with the mechanism of Reblozyl on the terminal stages of erythropoiesis, the majority of responders were determined to have an *SF3B1* splicing factor mutation. Additionally, the responders were characterized as having increased erythroid progenitor cells in the bone marrow, while patients with fewer erythroid progenitor cells in the bone marrow did not achieve hematological improvement. We believe this indicates that Reblozyl is limited to its effect on terminal differentiation of erythropoiesis and does not affect the early stages of differentiation.

Reblozyl received approval from the U.S. Food and Drug Administration, or the FDA, in April 2020 for the treatment of anemia in adult RS positive patients with very low- to intermediate-risk MDS that failed an erythropoiesis stimulating agent and required two or more units of red blood cells over eight weeks. The approval was based on a single Phase 3 clinical trial of Reblozyl that was conducted in RS positive, very low- to intermediate-risk patients with MDS. This trial included both patients with low transfusion dependence requiring

fewer than four units of red blood cells over eight weeks and patients with high transfusion dependence requiring four or more units of red blood cells over eight weeks. In this trial, 37.9% of the RS positive patients treated with Reblozyl achieved the primary endpoint of transfusion independence, compared to 13.2% of patients that received placebo. The highest proportion of responders to Reblozyl were those with low transfusion dependence, while only a few high transfusion burden patients achieved transfusion independence despite being RS positive patients.

Accordingly, we believe that additional treatment options will be needed to address anemia in the heterogeneous non-ring sideroblast MDS population, to provide clinical benefit to the RS positive population regardless of transfusion burden and to address other cytopenias, such as thrombocytopenia.

KER-050 is designed to alter TGF-ß signaling pathways at multiple stages of hematopoietic differentiation in both red blood cells and platelets. Consequently, we believe KER-050 has the potential to provide therapeutic benefit in a broader subset of patients with MDS that have varying defects in commitment, differentiation and maturation of multiple cell types found in blood.

Myelofibrosis

Myelofibrosis is a group of rare cancers of the bone marrow in which the marrow is replaced by scar tissue and is not able to produce healthy blood cells. Myelofibrosis is characterized by ineffective hematopoiesis, an enlarged spleen, bone marrow fibrosis and shortened survival. Patients often experience multiple disease-associated and treatment-emergent cytopenias, including anemia and thrombocytopenia.

The ineffective hematopoiesis in myelofibrosis is driven by molecular abnormalities in the Janus kinase 2, or JAK2, -signal transducers and activators of transcription, or JAK-STAT, signaling pathway of transcriptional activators. Specifically, JAK2 activation leads to proliferation of red blood cell progenitors and platelet progenitors, or megakaryocytes, that fail to mature to platelets. Additionally, megakaryocyte dysplasia/hyperplasia has been implicated in inducing bone marrow fibrosis in patients with myelofibrosis. The inability of megakaryocytes to fully differentiate leads to the release of pro-inflammatory and pro-fibrotic factors that results in scarring of the bone marrow, which further exacerbates the myelofibrosis-associated cytopenias.

Myelofibrosis is a relatively rare condition with an identified prevalence of 16,000 to 18,500 patients in the United States. Approximately 3,000 new patients are diagnosed with myelofibrosis each year, and the median age at diagnosis is approximately 60 years. Currently, there are limited therapeutic options to address the myelofibrosis-associated cytopenias. Within a year of diagnosis, 38% of patients with myelofibrosis are red blood cell transfusion dependent and eventually nearly all will develop transfusion dependence. Additionally, within a year of diagnosis, 26% of patients with myelofibrosis will develop thrombocytopenia and 51% will develop anemia.

Limitations of Current Treatment Options for Cytopenias in Patients with Myelofibrosis

There are no approved pharmacological treatments for myelofibrosis-associated cytopenias. The National Comprehensive Cancer Network describes all therapeutic options to address myelofibrosis-associated cytopenias, including transfusions, as only minimally effective.

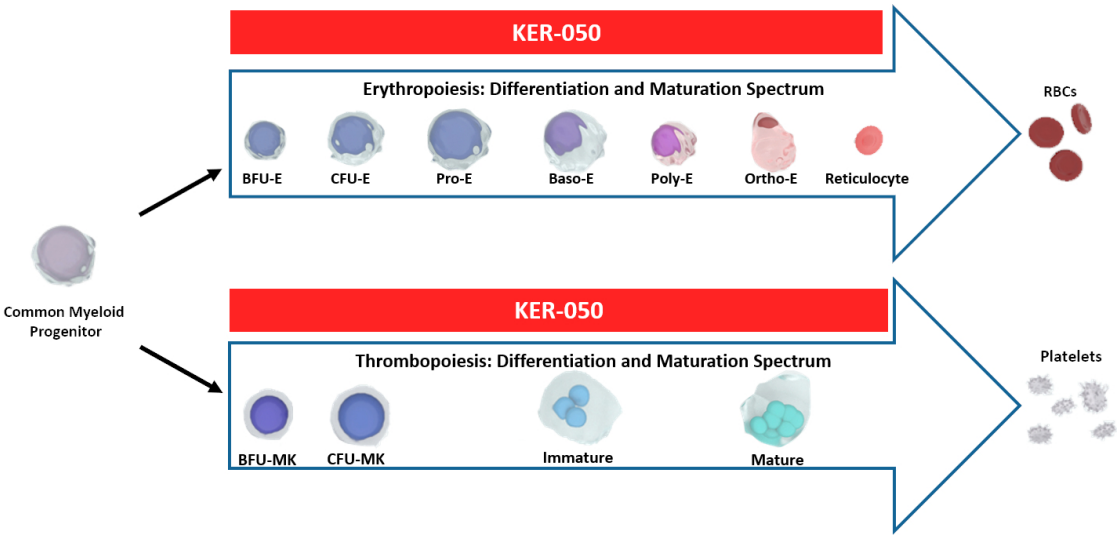
Currently approved products for the treatment of myelofibrosis, including JAK inhibitors ruxolitinib (Jakafi) and fedratinib (Inrebic), have been observed to exacerbate myelofibrosis-associated cytopenias. In a third-party Phase 3 clinical trial of Jakafi and a third-party Phase 3 clinical trial of Inrebic, treatment led to significant reductions in spleen volume and improvement in total symptom scores. However, JAK inhibitors interfere with normal hematopoiesis and treatment with Jakafi and Inrebic also resulted in clinically significant anemia and thrombocytopenia in these Phase 3 trials. Approximately 45% of patients in the Phase 3 clinical trial of Jakafi developed treatment-related grade 3 or 4 anemia. Grade 3 or higher adverse events of anemia and thrombocytopenia were observed in approximately 34% and 12%, respectively, of patients evaluated in the Phase 3 clinical trial of Inrebic. The treatment-related cytopenias led to severe complications, dose reductions and reduced compliance.

We believe KER-050 has the potential to ameliorate myelofibrosis-associated cytopenias.

Our Solution: KER-050

KER-050 is a ligand trap comprised of a modified ligand-binding domain of ActRIIA that is fused to the portion of the human antibody known as the Fc domain. KER-050 is designed to bind to and inhibit the signaling of TGF-ß ligands involved in the regulation of hematopoiesis, resulting in increased red blood cell and platelet production. Combined data from our preclinical studies and our Phase 1 clinical trial demonstrate that treatment with KER-050 increased red blood cell and platelet production. These data indicate that KER-050 is differentiated from available therapies because it appears to have both sustained and rapid effects on multiple cellular lineages in the hematopoietic pathway. We believe KER-050's promotion of differentiation of early- and terminal-stage progenitor cells contributes to these sustained and rapid effects, respectively, and consequently, KER-050 may be effective for many patients that are refractory to available therapies and may potentially provide benefit in multiple cytopenias simultaneously.

Mechanism of Action of KER-050



We intend to develop KER-050 for the treatment of both MDS- and myelofibrosis-associated cytopenias. We believe KER-050 has the potential to overcome limitations of current treatment options for MDS- and myelofibrosis-associated cytopenias. We believe the potential advantages of KER-050 compared to current treatment options include:

- *Dual mechanism affecting both the early and terminal stages of erythropoiesis.* Patients with MDS can have defects occurring anywhere along the differentiation and maturation spectrum of erythropoiesis, and often have multiple mutations that cause ineffective erythropoiesis. By acting on cell types throughout the erythropoiesis pathway, KER-050 may lead to robust responses in RS positive patients who have a characteristic defect in terminal maturation, and may also address anemia in the broader MDS population that has defects in earlier-stage erythroid cell development.
- *Increased platelet counts in blood.* Ineffective hematopoiesis in patients with MDS and in patients with myelofibrosis can result in thrombocytopenia, which can lead to an increased risk of bleeding events. We believe treatment with KER-050 has the potential to address the MDS- and myelofibrosis-associated thrombocytopenia.
- *Reduced accumulation of progenitor cells.* Ineffective hematopoiesis in patients with MDS and in patients with myelofibrosis can be caused by excessive production of blood cell progenitors that are unable to complete differentiation and ultimately become mature blood cells. We believe treatment with KER-050 will stimulate these progenitors to progress to maturation, ameliorating the accumulation of these cells that lead to MDS- and myelofibrosis-associated cytopenias.
- *Robust and sustained increase in red blood cells, hemoglobin and reticulocytes, supporting monthly or less frequent dosing.* ESAs can require dosing up to three times a week. We believe that treatment

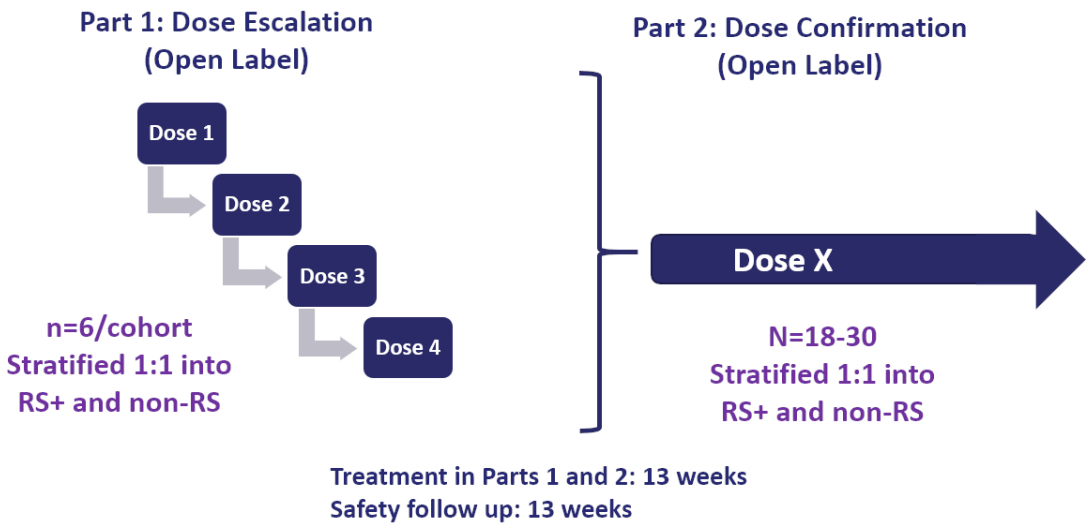
with KER-050 has the potential to reduce the frequency of dosing to every four weeks or less frequently, thereby decreasing the burden on patients and potentially improving compliance.

Ongoing Phase 2 Clinical Trial in Patients with Myelodysplastic Syndromes

We are conducting an open label, two-part, multiple ascending dose Phase 2 clinical trial to evaluate KER-050 in participants with very low-, low-, or intermediate-risk MDS who either have or have not previously received treatment with an ESA.

The primary objective of this trial is to assess the safety and tolerability of KER-050 in participants with MDS that either have ring sideroblasts (RS+) or do not have ring sideroblasts (non-RS). We expect to use the data from Part 1 of this trial to help define the dose level to be evaluated in Part 2 of this trial, in which the primary objective is confirmation of the safety and tolerability of the selected dose levels. The secondary objectives of this trial are to evaluate the pharmacokinetics, pharmacodynamics and efficacy of KER-050. The trial design is summarized in the figure below.

Phase 2 Clinical Trial Design



Clinical Development Strategy

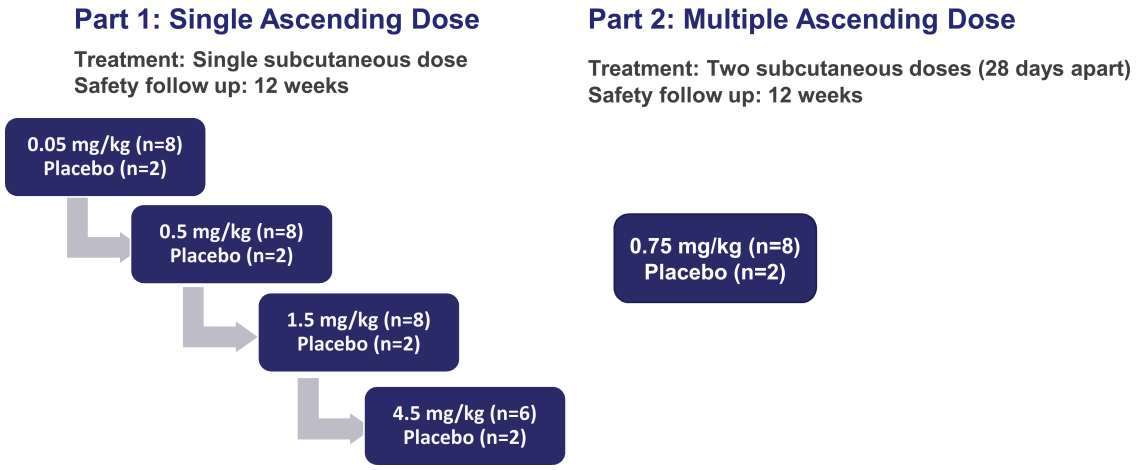
We expect to report initial data from Part 1 of the Phase 2 clinical trial in patients with MDS in mid-2021. We also expect to commence an open-label Phase 2 clinical trial evaluating the treatment of patients with myelofibrosis-associated cytopenias in 2021.

Completed Phase 1 Clinical Trial

In January 2020, we completed a randomized, double-blind, placebo-controlled, two-part, dose-escalation Phase 1 clinical trial of KER-050 in 48 healthy post-menopausal women. The primary objectives of this trial were safety, tolerability and pharmacokinetics. We also investigated changes in hematology and bone biomarkers in this clinical trial.

In Part 1 of this trial, 30 subjects received a single dose of KER-050 and eight subjects received a single dose of placebo, each administered subcutaneously with a 12-week safety follow-up. The subjects were enrolled in sequential single-ascending dose escalation cohorts of up to ten subjects each. In Part 2 of this trial, eight subjects received KER-050 and two received placebo, administered subcutaneously, on two occasions 28 days apart, with a 12-week safety follow-up after the second dose. In Part 2 of this trial, only one dose level was evaluated, as it was deemed to provide the necessary data, in addition to that from Part 1 of the trial, to inform the design of the Phase 2 clinical trials of KER-050 in patients with MDS and in patients with myelofibrosis.

The trial design is summarized in the figure below.



Observed tolerability data

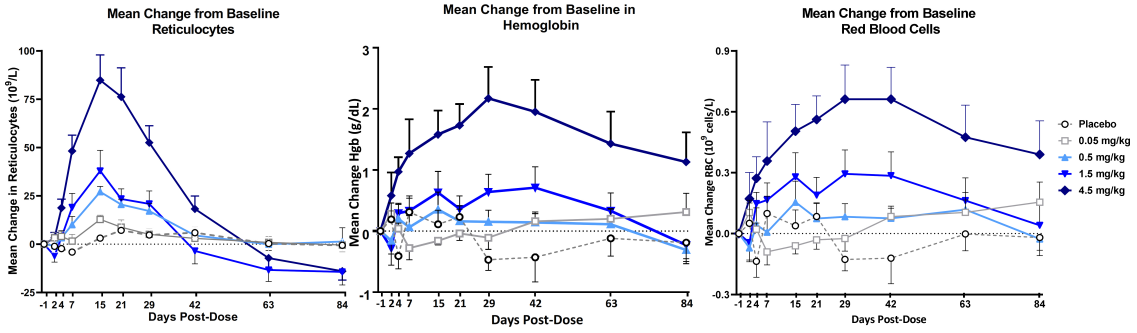
KER-050 was well tolerated in this Phase 1 clinical trial at dose levels up to 4.5 mg/kg, the highest dose level tested, and multiple doses of 0.75 mg/kg. While one subject in the placebo group withdrew consent, there were no discontinuations due to treatment-related adverse events. No treatment-related serious adverse events were reported. The most common adverse events observed in subjects in this trial were nausea, gastroenteritis, injection site erythema and, consistent with the mechanism of action of KER-050, increased hemoglobin and hypertension. The reversible, mild hypertension events were observed in subjects with an approximately 3 g/dL increase in hemoglobin.

Long half-life observed, potentially supporting monthly or less frequent dosing

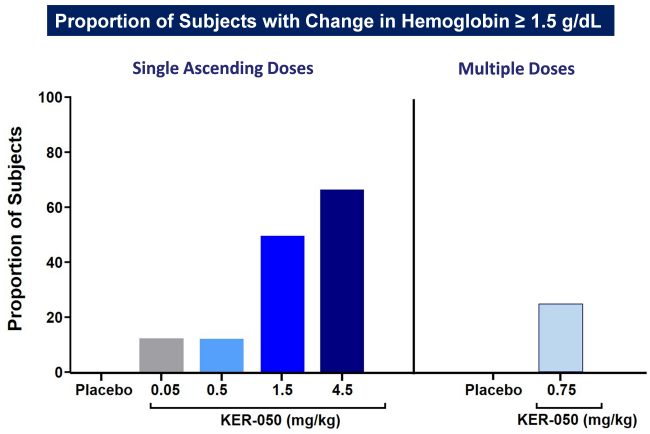
We observed that KER-050 drug levels were dose proportional in Part 1 of this trial, with a mean half-life of approximately ten to 12 days. The half-life coupled with the pharmacodynamic effect observed in the hematologic parameters support the potential for administration of monthly or less frequent dosing, which we believe will decrease the burden on patients and improve compliance.

Rapid and sustained increases in mean reticulocyte counts, hemoglobin, red blood cell counts and platelet counts observed

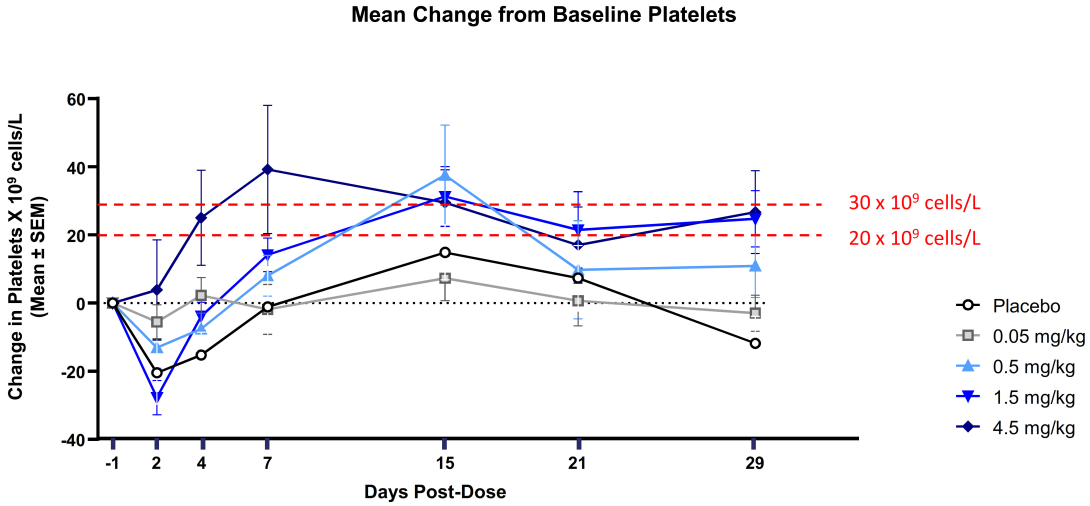
In Part 1 of this trial, we observed rapid and sustained increases in mean reticulocyte counts, hemoglobin, red blood cell counts and platelet counts. Consistent with the underlying biology, increases in reticulocytes were observed early with increases of hemoglobin following thereafter. Increases in reticulocytes were observed as early as Day 2 and reached a peak around Day 15. Increases in hemoglobin concentration were also observed as early as Day 2, reached a peak around Day 29 and remained elevated for several weeks.



We also observed a dose-dependent increase in the proportion of subjects with hemoglobin increases of 1.5 g/dL. We believe a 1.5 g/dL increase would be considered clinically meaningful in patients with low red blood cell counts.



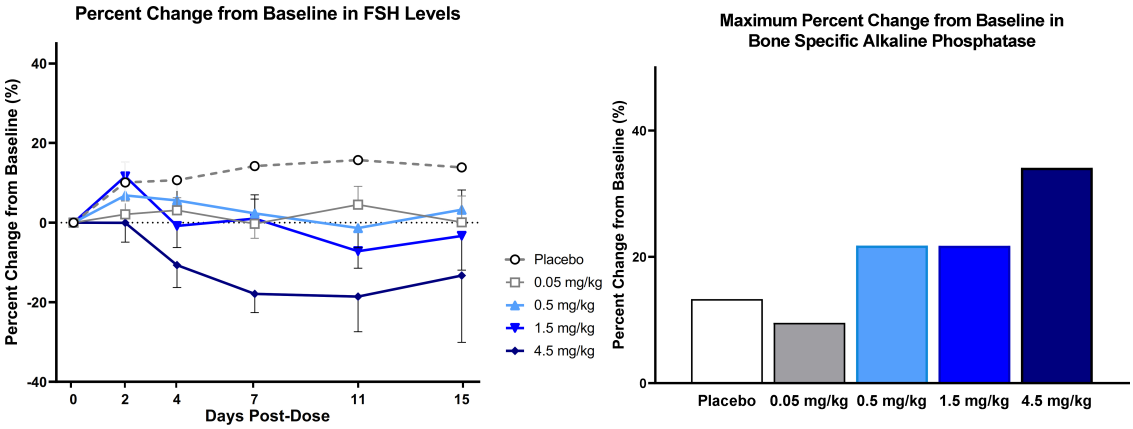
In addition to the changes in erythroid parameters, robust, dose-dependent increases in platelet count were observed after a single dose of KER-050. All subjects who received a 4.5 mg/kg dose of KER-050, the highest dose evaluated, demonstrated an increase of 30 x 109 cells/L or greater at any one point in the trial, which we believe would be considered clinically meaningful in patients with low platelet counts.



We believe the rapid onset and durability of increased hemoglobin and platelet count observed in our Phase 1 clinical trial supports the potential for a dual effect of KER-050 on both early-stage differentiation and terminal maturation.

Additionally, we observed reductions in follicle-stimulating hormone, a biomarker of activin inhibition, following administration of KER-050, which we believe is indicative of target engagement and activin inhibition. We also

observed an increase in bone-specific alkaline phosphatase, a biomarker of bone remodeling, which we believe demonstrates that KER-050 has the potential to increase bone mass.



Preclinical Data

KER-050 was observed to inhibit ligands that signal through activin receptors in *in vitro* assays, and to potently regulate hematopoiesis in *in vivo* studies. Specifically, KER-050 demonstrated in these studies:

- high affinity for and potent inhibition of ligands involved in the regulation of hematopoiesis;
- increased red blood cell production in mice and non-human primates; and
- increased maturation of early- and terminal-stage erythroid progenitors.

KER-050 observed to target ligands that signal through ActRIIA and ActRIIB

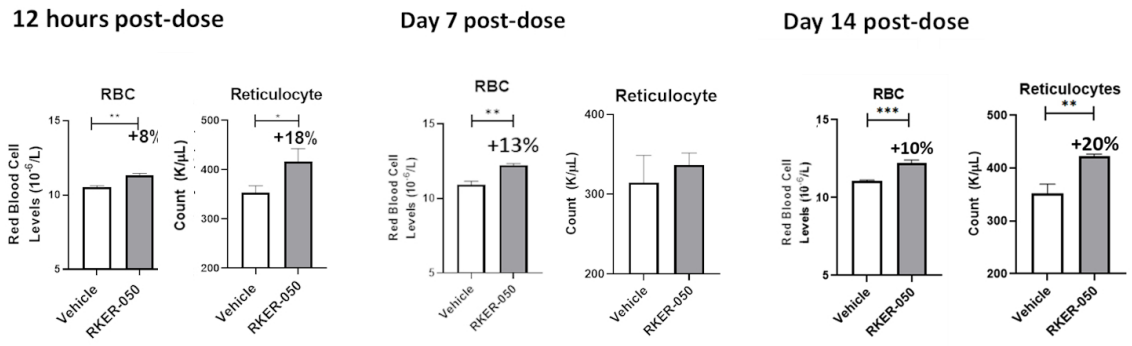
KER-050 is a modified ActRIIA ligand trap that contains sequences from both wild-type ActRIIA and wild-type activin receptor type IIB, or ActRIIB. KER-050 was observed to bind to and inhibit multiple ligands that signal through these cell surface receptors, including activin A, activin B and growth differentiation factor 11. These ligands are key regulators of hematopoiesis that restrict blood cell progenitors from continuing through differentiation and developing into mature cells with specialized function. The KER-050-mediated inhibition of these regulators stimulated the progenitors to progress to maturation and, consequently, increased the number of mature cells in the blood.

Mouse version of KER-050 observed to potently stimulate red blood cell parameters and to increase the populations of erythroid progenitors

In a preclinical study conducted in mice, a single, subcutaneous 10 mg/kg dose of a mouse version of KER-050, or RKER-050, increased red blood cell parameters, including red blood cell number and reticulocytes, as early as 12 hours and continuing to at least 14 days post-dose. We believe the rapid onset of the effect is consistent with terminal maturation of late-stage erythroid precursors. RKER-050 has been

modified to have a murine Fc domain in place of the human Fc domain present in KER-050, in order to minimize results confounded by the development of anti-drug antibodies in mice treated with a human protein.

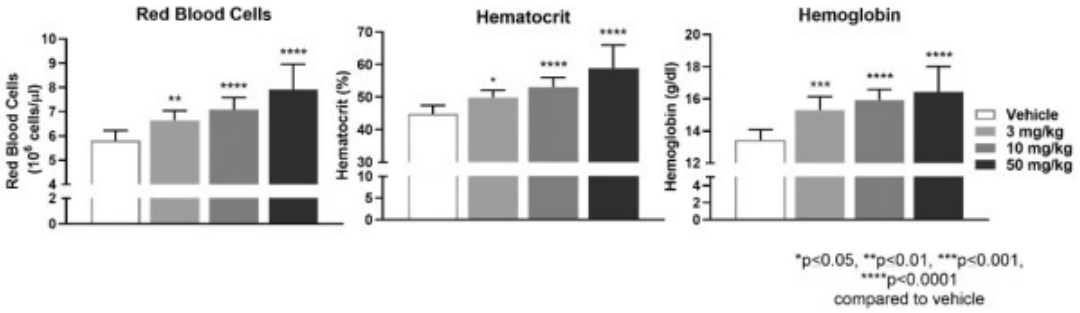
Increase in Red Blood Cells and Reticulocytes in Mice



KER-050 also observed to increase red blood cells in non-human primates

We believe that our observations in preclinical studies of KER-050 in non-human primates indicate that the red blood cell effects of KER-050 also translated to higher-order species. In this study, cynomolgus monkeys received subcutaneous administration every other week for three months of either vehicle or doses of 3 mg/kg, 10 mg/kg or 50 mg/kg of KER-050. Hematology was measured at baseline and on Day 92. Red cell mass, including red blood cell number, hematocrit and hemoglobin were dose-dependently increased in the cohorts receiving KER-050. These data demonstrate the translatability of red blood cell, hematocrit and hemoglobin increases observed in preclinical studies of KER-050 from mice to non-human primates.

Increase in Red Blood Cells, Hematocrit and Hemoglobin in Cynomolgus Monkeys

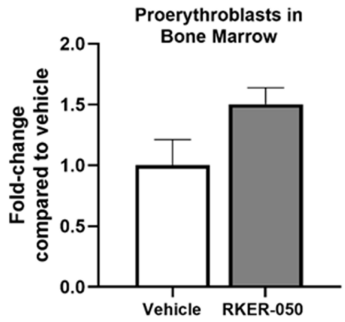


RKER-050 also observed to increase numbers of erythroid progenitors in mice

To evaluate the mechanism of action of RKER-050 in erythropoiesis, we collected and analyzed bone marrow from RKER-050-treated mice for erythroid progenitors. We observed a RKER-050-mediated increase in the

proerythroblast, or Pro-E, population in a flow cytometry analysis that used antibodies directed against cell surface markers to label-specific cell populations.

Increase in Overall Numbers of Proerythroblasts in Mice

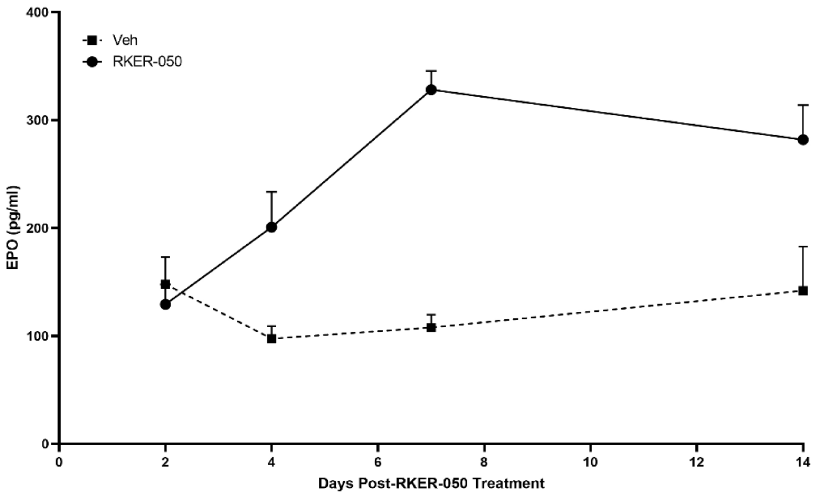


The rapid expansion of the Pro-E population also coincided with decreased numbers of erythroid burst-forming units and erythroid colony-forming units, the cells that give rise to Pro-E cells, which demonstrates that treatment with RKER-050 stimulated the erythroid burst-forming units and erythroid colony-forming units into erythroid differentiation. Since treatment with RKER-050 stimulated the earliest progenitors in the erythroid lineage to progress to maturation and increased the Pro-E pool, the first cells to start synthesis of hemoglobin, we believe KER-050 has the potential to affect the early stages of erythropoiesis.

RKER-050 also observed to increase serum erythropoietin and bone marrow erythropoietin receptor expression in mice

In a preclinical study conducted in mice, a single, subcutaneous 10 mg/kg dose of RKER-050 increased serum erythropoietin at days 4, 7 and 14 post-dose in mice. We believe the observed increase in erythropoietin could contribute to the durability in red blood cell production we observed in preclinical studies and supports the durability of the red blood cell increase we observed in our Phase 1 clinical trial of KER-050 in healthy post-menopausal women.

Observed Increase in Serum Erythropoietin in Mice



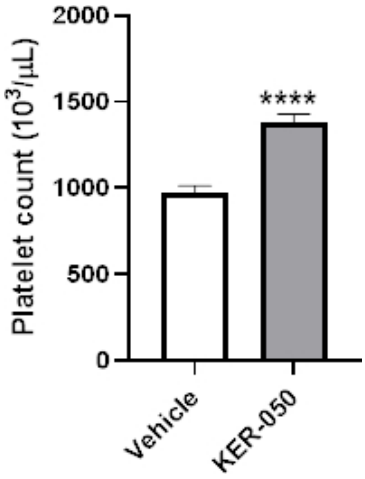
Given that KER-050 increased early erythroid precursor cell pools in this preclinical study and its effect on upregulating serum erythropoietin, we believe KER-050 has the potential to treat patients with MDS that have hypocellular bone marrow. We believe the observed increases in serum erythropoietin in mice that were dosed

with KER-050 support the potential of KER-050 as a therapy for patients with low serum erythropoietin across a diverse set of diseases, including chronic kidney diseases and polycythemia.

KER-050 observed to stimulate platelet release into circulation in wild-type mice

To evaluate the effect of KER-050 on blood cell types other than red blood cells, mice were administered a single, subcutaneous 7.5 mg/kg dose of KER-050 and had blood sampled and analyzed 4 days post-dose. Mice that received KER-050 were observed to have increased platelet counts compared to mice in the vehicle cohort.

Observed Increase in Platelet Count in Mice



**** P value <0.005

We believe that the findings from our preclinical studies and from our Phase 1 clinical trial of KER-050 in healthy post-menopausal women demonstrate the translation of biological action from rodents to humans. We also believe that data from our preclinical studies and clinical trials support that treatment with KER-050 has the potential to address ineffective hematopoiesis in diseases where multiple cytopenias arise from the blockage in progression of progenitor cells to mature blood cells, such as in MDS and myelofibrosis.

KER-047: For the Treatment of Anemia Arising from Iron Imbalance

We are developing KER-047, our lead small molecule product candidate, for the treatment of anemia resulting from iron imbalance. We believe KER-047 is a potent and selective inhibitor of ALK2, a receptor whose excessive signaling is the underlying cause of the elevated levels of hepcidin, the key regulator of iron absorption and recycling, that leads to low iron bioavailability and anemia in a broad range of diseases. In August 2020, we announced the completion of our planned single and multiple ascending dose cohorts in a Phase 1 clinical trial of KER-047 in healthy volunteers, as well as the expansion of this trial to evaluate additional cohorts of healthy volunteers. In the planned cohorts of this trial, we observed dose-dependent increases in serum iron and increased reticulocyte hemoglobin, which is a measure of hemoglobin content from newly-produced immature red blood cells, in the volunteers who received KER-047. We evaluated one additional cohort of healthy volunteers and terminated the trial after determining that the data from this cohort, in addition to the data from the planned cohorts, were sufficient to inform the design of the expected Phase 2 clinical trials of KER-047, and expect to report topline data by the end of 2020.

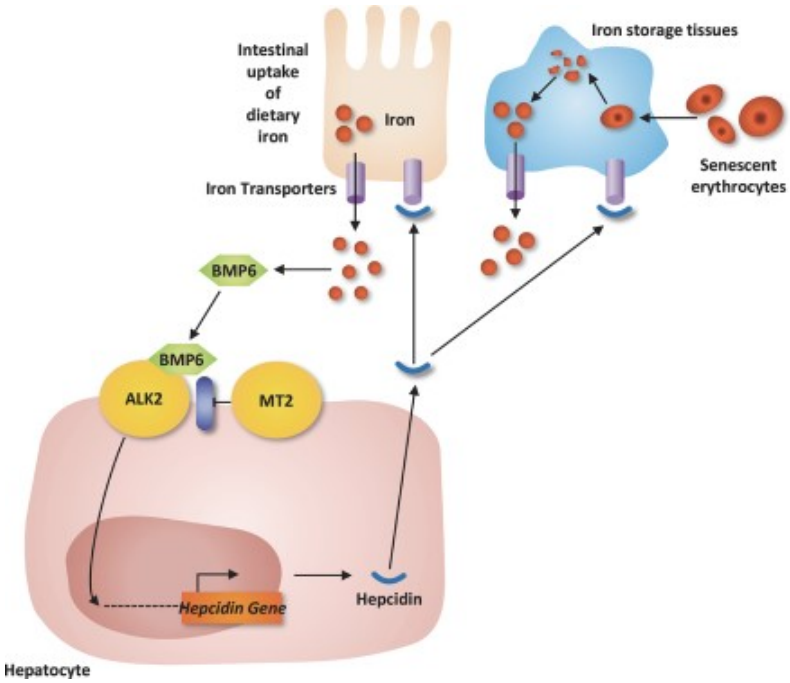
Hepcidin and Iron Homeostasis

Iron supply in the bone marrow is critical for erythropoiesis, as iron is an essential component of hemoglobin. Although iron is required for many functions in the body, including erythropoiesis, high iron levels are toxic, so circulating levels are regulated to avoid iron overload. To maintain this balance, absorption of dietary iron is tightly controlled and recycled iron is held in the liver and macrophages, which we refer to as the storage tissues, to be mobilized quickly when circulating iron levels are too low. These storage tissues also act to

sequester away iron when levels are too high. Hepcidin, a hormone produced by the liver, is the key regulator of iron absorption and recycling, and controls both the recirculation of iron from storage tissues as well as the absorption of dietary iron from the intestine.

Hepcidin levels are upregulated through activation of the ALK2 receptor, which is a BMP receptor belonging to the broader TGF-ß family of proteins. Hepcidin levels are tightly regulated by liver cells through BMP6 signaling via ALK2. High serum iron triggers the expression of BMP6, which then acts to increase hepcidin expression, resulting in iron sequestration, decreased iron absorption and reduced serum iron. Hepcidin is controlled by a feedback loop, and serum hepcidin levels are inversely related to serum iron levels. This feedback loop prevents this system from shifting out of balance. The system is down regulated through the activity of matriptase-2, or MT-2, a cell surface protease, which is encoded by the TMPRSS6 gene. This protein reduces the ability of BMP6 to signal through ALK2. The below graphic illustrates a normal functioning of the negative feedback loop.

Regulation of Iron in the Body



Anemia Arising from Iron Imbalance, including Iron Deficiency Anemia and IRIDA

Failure to suppress ALK2 signaling can result in elevated hepcidin levels, which are associated with decreased dietary iron absorption, increased iron sequestration in storage tissues and low iron bioavailability in the bone marrow. These effects culminate in a shortage of serum iron, which leads to insufficient red blood cell production that manifests as mild to moderate anemia.

Iron deficiency anemia, or IDA, is a common form of anemia that is caused by patients not having enough iron to manufacture healthy red blood cells. IDA is associated with fatigue, lethargy, decreased quality of life, cardiovascular complications, hospitalizations and increased mortality. IDA is prevalent in many different patient populations, including patients with IDA due to chronic kidney disease, chemotherapy-induced anemia and gastrointestinal diseases or disorders. It is estimated that approximately five million people in the United States have IDA and we estimate that a small fraction of the patients who are diagnosed with IDA regardless of the underlying cause are currently being treated with intravenous, or IV, iron. We estimate that the size of the total 2019 U.S. non-dialysis IV iron replacement therapy market was approximately 1.5 million grams.

Additionally, high hepcidin levels can be the result of genetic disease. Iron-refractory iron deficiency anemia, or IRIDA, is a rare, inherited form of IDA that results in loss of function of MT-2, resulting in elevated ALK2 signaling and high hepcidin levels. Patients with IRIDA have the typical symptoms of anemia, including fatigue, weakness and shortness of breath, in addition to other symptoms associated with low iron. These symptoms are most pronounced during childhood, although they tend to be mild.

The prevalence of IRIDA worldwide is estimated to be less than one person in 1,000,000. IRIDA was first described in 1981 with the observation that patients with anemia were refractory to treatment with oral iron. However, the association of mutations in the TMPRSS6 gene with IRIDA was not identified until 2008, and genetic testing for IRIDA is not widely available. Furthermore, affected individuals usually have normal growth and development, so IRIDA is poorly diagnosed. All these factors contribute to an inability to accurately determine the prevalence of IRIDA.

Proinflammatory cytokines can also result in inappropriately high ALK2 signaling, increased hepcidin expression and anemia. Patients with chronic inflammation have mild to moderate anemia resulting from low serum iron that is driven by abnormally high hepcidin levels through sustained cytokine-mediated ALK2 activation. Anemia of inflammation is the second most common cause of anemia worldwide. The prevalence of anemia varies among different inflammatory rheumatic diseases. In the United States, approximately 1,000,000 people older than age 65 suffer from diseases of chronic inflammation, including rheumatoid arthritis, systemic lupus erythematosus and ankylosing spondylitis. Anemia with high hepcidin levels has also been reported in patients with primary myelofibrosis.

Limitations of Current Treatment Options for Anemia Arising from Iron Imbalance, including IRIDA

There are no current treatments that address the underlying cause of anemia arising from iron imbalance, including in patients with IDA associated with co-morbidities and in patients with IRIDA.

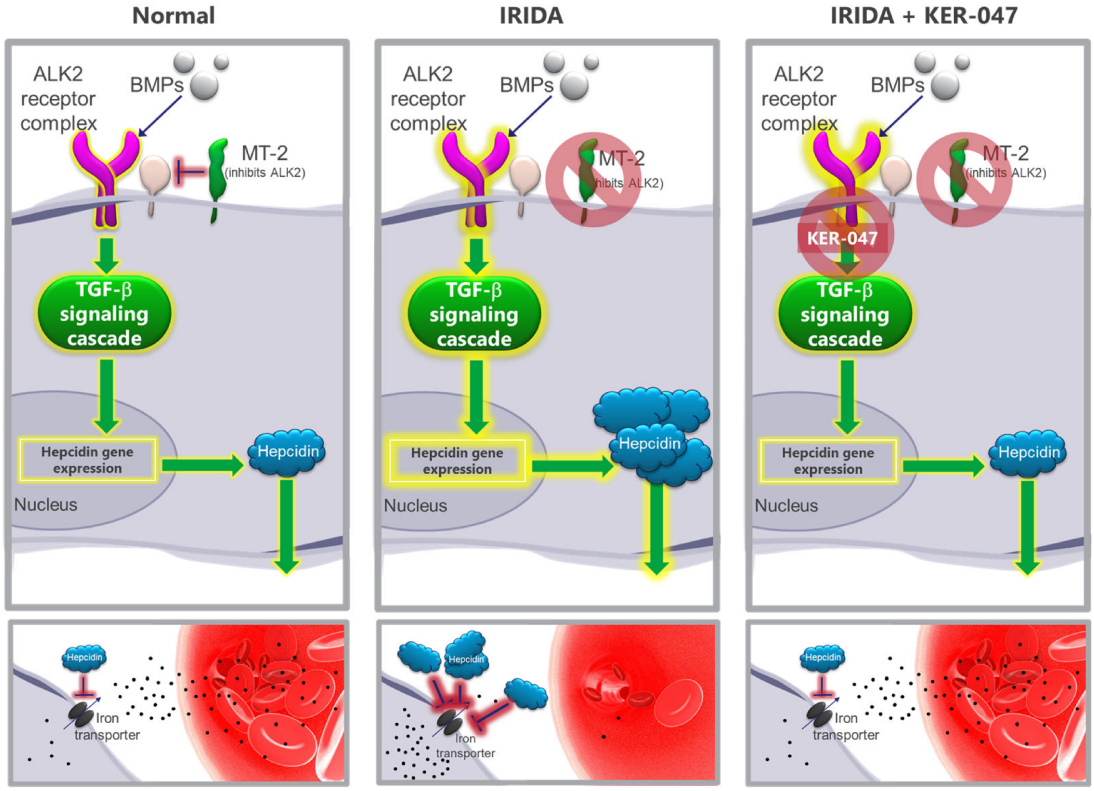
Currently, there are two common methods of iron therapy used to treat IDA: oral iron supplements and IV iron. While oral iron supplements are used as first-line iron replacement therapy for most patients, they are poorly absorbed and not well tolerated by some patients, which may adversely impact their effectiveness. The beneficial effect of oral iron supplements on increasing hemoglobin levels can require an extended treatment period, and, at times, treatment is inadequate to achieve the targeted hemoglobin levels. Conversely, iron administered by IV infusion allows larger amounts of iron to be delivered to patients in a shorter time frame, which can result in faster rises in hemoglobin levels. However, for patients with IDA associated with co-morbidities, neither of these treatments address the underlying cause of the disease. Additionally, these treatments can also cause mild side effects, such as constipation, diarrhea and cramping, and can increase the risk of very serious, life-threatening side effects, such as hypersensitivity reactions, opportunistic infections and the deposition of excess iron in organs in patients with co-morbidities such as chronic kidney disease.

Separately, patients with anemia due to ineffective erythropoiesis that require frequent red blood cell transfusions may have elevated levels of hepcidin with accompanying iron overload in multiple organ systems. This chronic iron overload can lead to multiple organ dysfunction, including in the liver, heart and endocrine. Accordingly, iron chelation therapy is used to reduce iron deposits in those organs. We believe that a treatment option that reestablishes normal iron homeostasis has the potential to benefit a broad range of patients, from patients with IDA to patients with anemia associated with iron overload.

Our Solution: KER-047

KER-047 is an orally-available small molecule ALK2 inhibitor designed to potently inhibit ALK2 signaling, with high selectivity for ALK2 relative to other structurally-similar TGF-ß receptors as well as other kinase families.

Mechanism of Action of KER-047



We believe that KER-047 has the potential to address the underlying cause of diseases arising from iron imbalance, including IDA, IRIDA and iron overload, by suppressing ALK2 signaling to normalize hepcidin expression and mobilizing iron out of tissues. We believe this effect will result in increased iron bioavailability, resulting in restoration of the production of red blood cells and a reversal of anemia in patients with IDA and patients with IRIDA. By ameliorating anemia arising from iron imbalance, we believe KER-047 can potentially eliminate the need for excessive supplementary iron or IV iron treatments and avoid the adverse events associated with those treatment options. In addition, we believe KER-047, if approved, has the potential to be beneficial in diseases of iron overload by mobilizing excess iron being stored in tissues into the serum. By ameliorating the excess iron in tissues, we believe KER-047 can potentially eliminate or reduce the need for phlebotomy and/or treatment with iron chelators, while allowing patients to avoid the adverse events associated with these treatments and providing benefit to patients where the current treatment options are largely ineffective.

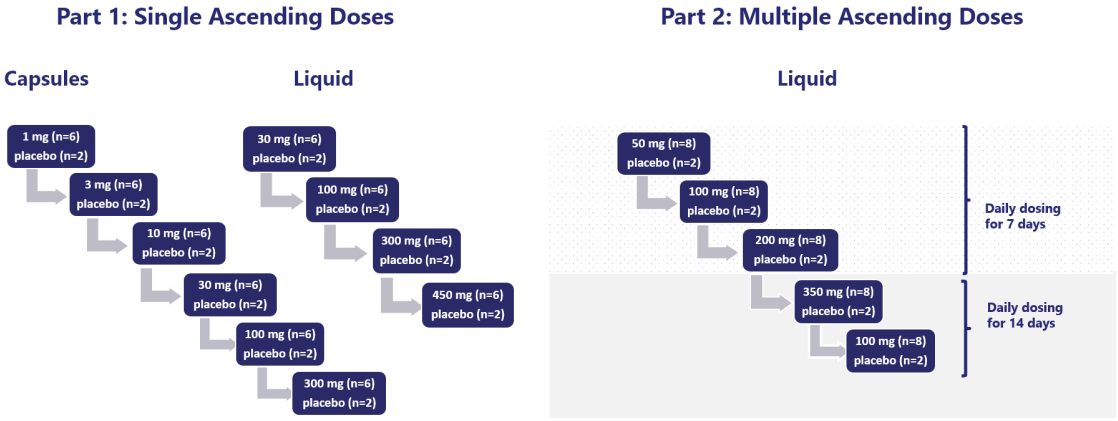
In August 2020, we announced the completion of our planned single and multiple ascending dose cohorts in a Phase 1 clinical trial of KER-047 in healthy volunteers, as well as the expansion of this trial to evaluate additional cohorts of healthy volunteers. We evaluated one additional cohort of healthy volunteers and terminated the trial after determining that the data from this cohort, in addition to the data from the planned cohorts, were sufficient to inform the design of the expected Phase 2 clinical trials of KER-047, and expect to report topline data by the end of 2020. We also expect to commence two Phase 2 clinical trials of KER-047, one in patients with IDA and one in patients with IRIDA, in 2021. Additionally, we intend to develop KER-047 as

a potential treatment for patients who manifest anemia caused by high hepcidin levels as a secondary consequence of more common diseases.

Expanded Phase 1 Clinical Trial

We conducted a randomized, double-blind, placebo-controlled, two-part Phase 1 clinical trial to evaluate single and multiple ascending doses of KER-047 in healthy volunteers. The primary objectives of this trial are to assess safety, tolerability and pharmacokinetics of KER-047. The trial design for the planned single and multiple ascending dose cohorts of KER-047 is summarized in the figure below.

Phase 1 Clinical Trial Design



Observed tolerability data

There were no serious adverse events reported in the planned single and multiple ascending dose cohorts of this Phase 1 clinical trial. The most common adverse events observed in healthy volunteers in the planned cohorts of this trial were headache, nausea, vomiting, diarrhea, gastroenteritis, chills, pyrexia, myalgia, decreased appetite, lymphopenia, neutropenia and liver enzyme increases. We also observed dose-related decreases in lymphocytes following peak increases in serum iron at the highest doses, which we believe is consistent with KER-047's mechanism of action and suggestive of excessive mobilization and subsequent depletion of iron.

Rapid mobilization of iron stores resulted in increased reticulocyte hemoglobin content of newly-produced immature red blood cells

In the planned cohorts of this trial, we observed rapid and dose-dependent increases in serum iron and transferrin saturation in the volunteers who received KER-047. We also observed a reduction in hepcidin at each dose level tested in Part 2 of this trial, which we believe is consistent with KER-047's mechanism of action. Importantly, we believe the iron mobilization led to increased iron bioavailability for incorporation into reticulocyte hemoglobin, a measure of hemoglobin content from newly-produced immature red blood cells. These erythroid precursors potentially would continue maturation into hemoglobin-rich red blood cells. We believe the data from this Phase 1 clinical trial support the potential for KER-047 to be developed as a treatment for diseases arising from iron imbalance.

Observed reductions in total cholesterol

Reductions in total cholesterol, low-density lipoproteins and high-density lipoproteins were observed in the multiple ascending dose cohorts. The reductions in total cholesterol were achieved rapidly with a mean reduction of greater than 20% at the highest dose, following seven days of dosing.

Clinical Development Strategy

We recently completed the planned single and multiple ascending dose cohorts in this trial. Based upon preliminary analysis, we expanded the Phase 1 trial to evaluate additional cohorts of healthy volunteers. We evaluated one additional cohort of healthy volunteers and terminated the trial after determining that the data

from this cohort, in addition to the data from the planned cohorts, were sufficient to inform the design of the expected Phase 2 clinical trials of KER-047, and expect to report topline data by the end of 2020. We expect to commence separate Phase 2 clinical trials in patients with IDA and in patients with IRIDA in 2021.

Preclinical Data

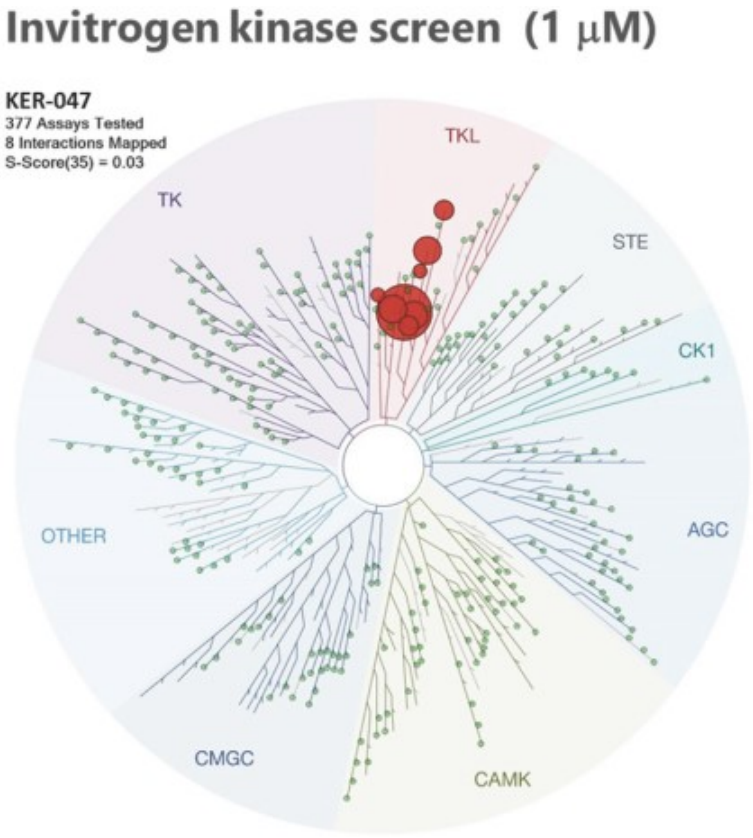
KER-047 was observed in preclinical studies to be a potent and highly selective ALK2 inhibitor and to change serum iron levels. Specifically, KER-047 demonstrated in these studies:

- selectivity for ALK2 compared to other structurally-related TGF-ß and non-TGF-ß kinases;
- increased serum iron levels in rat studies; and
- reversal of high hepcidin levels and low hemoglobin levels in a mouse model of IRIDA.

KER-047 observed to be a potent and highly selective ALK2 receptor inhibitor in a biochemical assay

In standard biochemical kinase screenings, KER-047 exhibited low nanomolar potency for ALK2. Under the conditions of this assay, KER-047 exhibited at least an eight-fold selectivity over the other structurally-related TGF-ß kinases. In a 370-member kinase panel, only two non-TGF-ß kinases were inhibited less than 75% at a KER-047 concentration of 1 µM. We believe these preclinical data further support the potency and selectivity of KER-047 for the ALK2 domain.

Highly Selective ALK2 Receptor Inhibitor



The kinase selectivity of KER-047 is shown in the dendrogram above. Compounds were screened at 1 µM against a panel of over 370 kinases and disease-relevant mutants. Each branch of the dendogram represents an individual human kinase. Kinases bound by the compound are indicated by red circles on the kinome tree. The degree of binding corresponds to the size of the circle. As illustrated by the largest red circle in the above

graphic, KER-047 was observed to be a potent ALK2 inhibitor and a weak inhibitor of other members of the TGF-ß family of receptors.

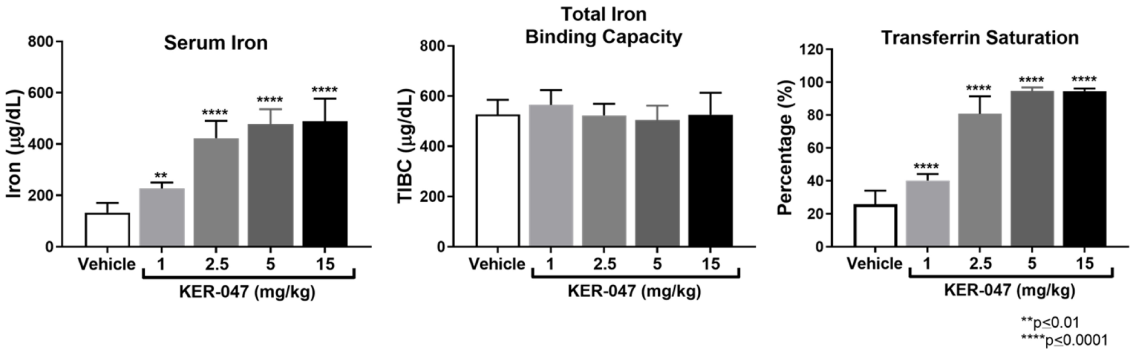
In cell-based assays that more directly tested the functional ability of KER-047 to suppress receptor signaling, KER-047 exhibited low nanomolar potency. In assays evaluating the effect of KER-047 on receptors with the highest structural homology to ALK2, KER-047 had at least 20-fold selectivity for ALK2, compared to ALK1 and ALK5, which have 77% and 65% homology to ALK2, respectively.

KER-047 inhibition of ALK2 signaling resulted in increased serum iron and transferrin saturation in multiple animal models

We believe that data from preclinical studies support a link between ALK2 signaling, hepcidin expression and serum iron across multiple preclinical species in both healthy and disease models. Serum iron is an indicator of whether there is adequate iron available in the body. Total iron binding capacity is the measure of the maximum amount of iron that can be bound by transferrin, an iron-binding protein, and is a surrogate measurement of serum transferrin levels. Transferrin saturation is calculated by dividing serum iron by total iron binding capacity and is an indicator of how well the body is transporting the iron in blood. Taken together, these values are an indication of the state of iron balance in the body.

We evaluated serum iron, total iron binding capacity and transferrin saturation in Sprague-Dawley rats that received daily, oral administration of either vehicle or doses of 1 mg/kg, 2.5 mg/kg, 5 mg/kg or 15 mg/kg of KER-047 for three months. Rats that were treated with KER-047 were observed to have a dose-dependent increase in serum iron levels and a concomitant increase in transferrin saturation, with no change in total iron binding capacity.

Increased Serum Iron, Total Iron Binding Capacity and Transferrin Saturation in Rats

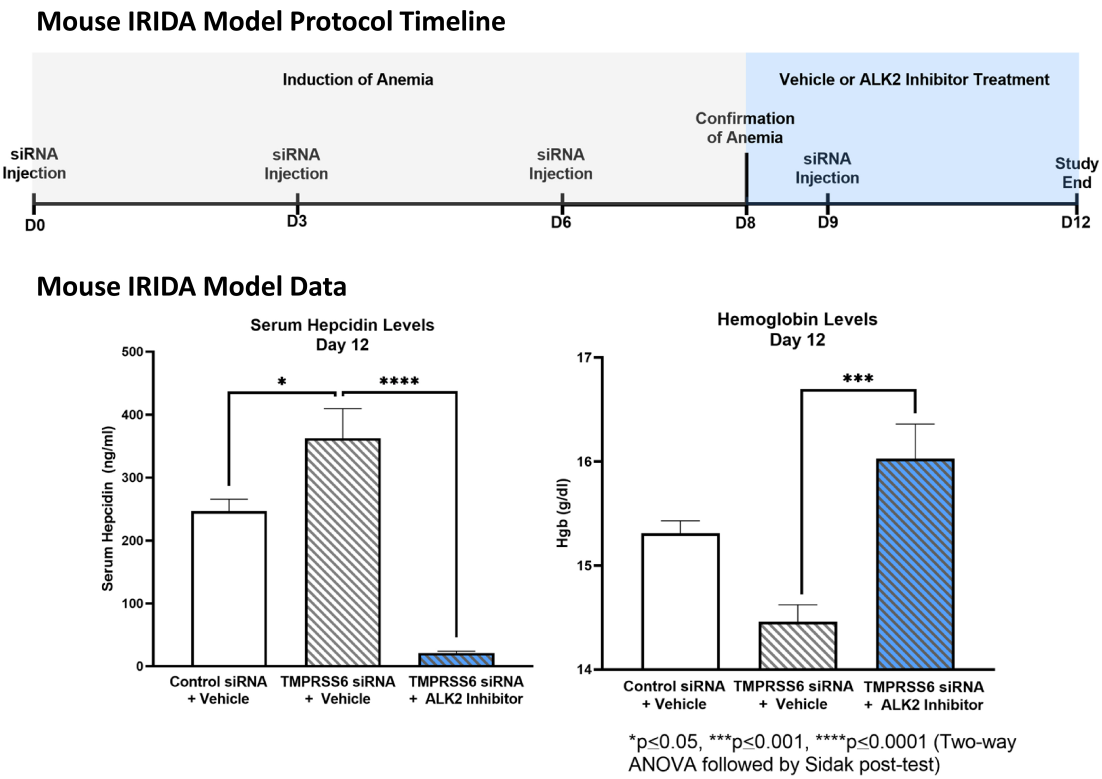


These data demonstrate that ALK2 inhibition resulted in increased serum iron and that KER-047 acts by releasing iron into blood without altering the expression or functionality of iron binding proteins. We believe that these data demonstrate that treatment with KER-047 has the potential to alter ALK2 signaling and release iron from storage tissue for transport to other tissues, including in the bone marrow.

Treatment with an ALK2 inhibitor closely related to KER-047 was also observed to reverse anemia in a mouse model of IRIDA. To generate this mouse model, we used an siRNA directed against TMPRSS6, the same gene that is defective in patients with IRIDA, to render the mice TMPRSS6-deficient. We confirmed that mice receiving the TMPRSS6 siRNA had a greater than 85% reduction of target gene expression relative to the control siRNA cohort. This model recapitulated the increased hepcidin levels and reduced hemoglobin that are characteristic of patients with IRIDA. Treatment of the mice receiving the TMPRSS6 siRNA with an ALK2 inhibitor normalized levels of both hepcidin gene expression and hemoglobin levels compared to the control

siRNA cohort receiving vehicle treatment, which we believe indicates that ALK2 inhibition can reverse anemia resulting from iron imbalance.

Serum Hepcidin and Hemoglobin Levels in Mice with siRNA-induced IRIDA



The sequence of the ALK2 receptor has been highly conserved through evolution, with greater than 98% amino acid sequence homology between mice and humans. Likewise, the finding that the mouse models with changes in ALK2 signaling recapitulate human disease also provides evidence that the function of the ALK2 receptor is conserved across species. For example, knockdown of the TMPRSS6 gene results in a phenocopy of the disease observed in patients with IRIDA. We believe that the conservation of biology provides confidence that treatments that are efficacious in preclinical models will have similar effects in humans.

Our Fibrodysplasia Ossificans Progressiva Program

We are also developing KER-047 for the treatment of fibrodysplasia ossificans progressiva, or FOP. FOP is a rare genetic disease resulting from gain-of-function mutations in the ALK2 receptor. In patients with FOP, soft tissue, including muscles and tendons, develops normally, but remodels into bone spontaneously or after injury. There are currently no approved treatments for FOP. We believe KER-047 has the potential to prevent progression of disease in these patients by normalizing ALK2 signaling.

Fibrodysplasia Ossificans Progressiva

FOP results from single amino acid mutations in the ALK2 receptor that result in gain-of-function activity of the receptor. An estimated 97% of patients with FOP have an R206H mutation that results in excessive ALK2 receptor signaling. Multiple processes drive this excessive signaling. The ALK2/R206H receptor is inappropriately activated by activins A and B, hyperresponsive to the endogenous BMP ligands and can be active in the absence of ligands. These changes all result in increased kinase-mediated signaling and upregulation of bone-forming cellular activity, such as heterotopic ossification.

Heterotopic ossification in patients with FOP can occur spontaneously or can be triggered by soft tissue trauma, such as from immunizations, falls, surgery or viral illnesses. The bony lesions from heterotopic ossification are painful and restrict movement. These lesions are permanent and their accumulation leads to progressive loss of function and immobility, eventually resulting in patients becoming wheelchair-dependent, making independent living difficult. Patients can have additional morbidity due to severe weight loss resulting from bone developing in and essentially locking the jaw, as well as respiratory problems due to constriction of the rib cage. Additionally, development of pneumonia and heart failure results in a high mortality rate, with a median age of death of 40 years. The International Fibrodysplasia Ossificans Progressiva Association estimates that there are 3,500 people worldwide with FOP, with approximately 800 patients identified. There are 285 known cases in the United States.

Limitations of Current Treatment Options for FOP

There are no therapies approved to treat FOP. Patients are administered anti-inflammatory agents to minimize tissue damage and alleviate pain, but these treatment options do not reduce or prevent bone formation. Surgical removal of the heterotopic ossification is performed in extreme cases, such as when the bony lesion is hindering jaw movement. However, this intervention only provides temporary benefit, as bone that is surgically removed is quickly replaced by a similar volume of new bone in its place.

Our Solution: KER-047

KER-047 is designed as an ALK2 inhibitor that is also designed to inhibit the ALK2/R206H mutant receptor, which we believe presents the potential to address the underlying cause of FOP as well as prevent the development of new, and the expansion of existing, heterotopic ossification. Additionally, we believe that KER-047 has the potential to prevent the regrowth of bone after surgical resection and *de novo* bone formation resulting from surgery-induced trauma.

FOP treatments currently in development, such as palovarotene, were observed to hamper the healing process in preclinical studies. We believe treatment with KER-047 would not interfere with a patient's ability to undergo and recover from surgery. Additionally, treatment with palovarotene has been observed in a Phase 2 clinical trial to cause premature closure of growth plates in pediatric patients. ALK2 signaling is not required for normal skeletal growth and development, and in our preclinical studies, we did not observe changes to normal bone growth when treating mice with dose levels of KER-047 that resulted in a reduction in the amount of heterotopic ossification. Based on these data, KER-047 would not be expected to affect normal skeletal development and could be used to treat patients with FOP of all ages.

Following the completion of our expected Phase 2 clinical trial of KER-047 in patients with IDA, we plan to commence a Phase 2 clinical trial in patients with FOP.

Preclinical Data

We have generated compelling biochemical and preclinical data that we believe demonstrated proof-of-mechanism of KER-047 for the treatment of FOP. Specifically, KER-047 demonstrated in these studies:

- potent ALK2/R206H mutant receptor inhibitor;
- dose-dependent reduction in the formation of heterotopic ossification in multiple mouse models; and
- no shortening of long bones in mice receiving the ALK2 inhibitor.

KER-047 observed to be a potent ALK2 receptor inhibitor and ALK2/R206H mutant receptor inhibitor

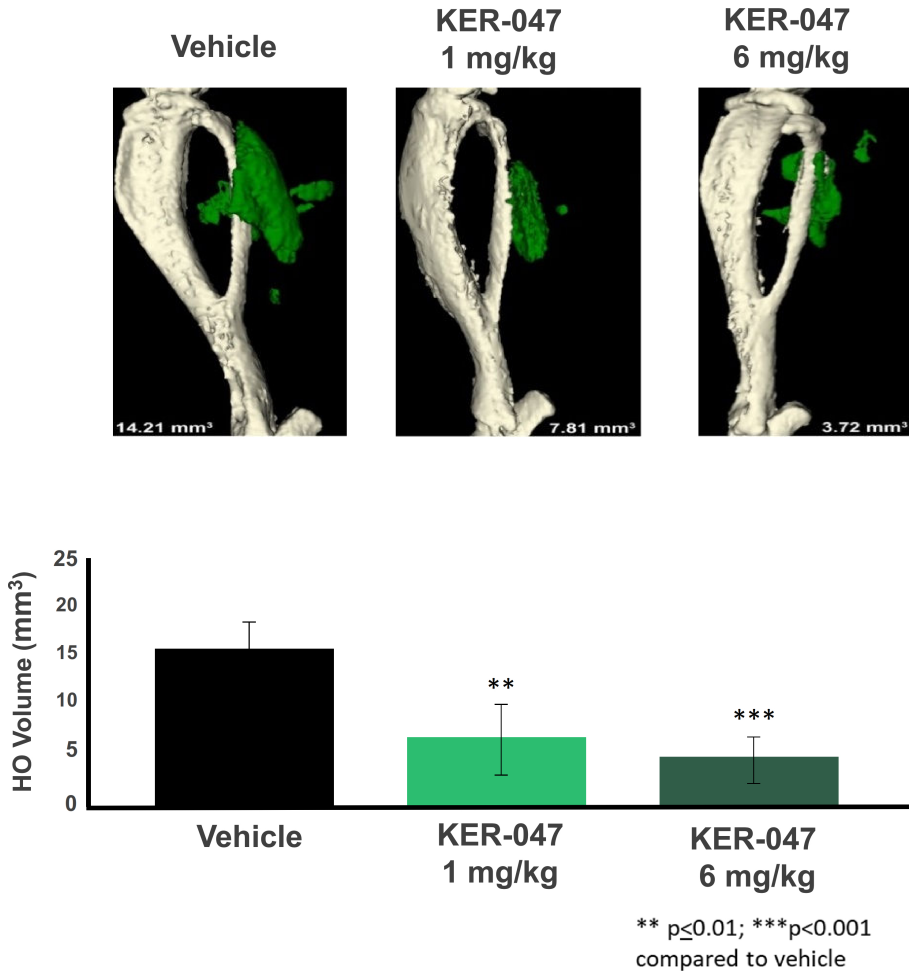
In an *in vitro* assay, KER-047 was observed to be a potent ALK2 receptor inhibitor. In cell-based reporter assays, KER-047 also exhibited low nanomolar potency against the ALK2/R206H mutant receptor.

KER-047 inhibited ALK2 signaling and was associated with reduced bone formation in a mouse model of heterotopic ossification

In patients with FOP, heterotopic ossification is driven by excessive signaling through a mutated ALK2 receptor. We evaluated treatment with KER-047 in an R206H mouse model of FOP and observed a dose-dependent reduction in heterotopic ossification. In our preclinical study, mice were treated with either vehicle or doses of 1 mg/kg or 6 mg/kg of KER-047, dosed daily by oral gavage, starting three days prior to mice receiving the pinch injury and continuing through 14 days post-injury. Micro-CT scans were analyzed for the presence of heterotopic ossification lesions in muscle. In mice with the ALK2/R206H mutant receptor receiving KER-047, a

statistically significant, dose-dependent reduction in the formation of heterotopic ossification after pinch injury was observed.

Reduced Formation of Heterotopic Ossification in a Mouse Model of FOP Representative MicroCT Images



Treatment with a selective ALK2 inhibitor did not affect skeletal development in young mice

Third-party reports have described how treatment of young mice with palovarotene, a RAR-gamma agonist, resulted in growth plate closure in the normal skeleton, which led to a shortening of the long bones. We dosed two-week old mice with a potent ALK2 inhibitor closely related to KER-047 and measured changes in length of the long bones. While ALK2 inhibition failed to alter the length of the long bone, we observed a statistically significant shortening of the long bones in mice treated with palovarotene.

Our Preclinical Pipeline

KER-012

KER-012 is a ligand trap comprised of a modified ligand-binding domain of ActRIIB that is fused to the portion of the human antibody known as the Fc domain. KER-012 is designed to bind to and inhibit the signaling of TGF-ß ligands, including activin A and activin B, which are key regulators of bone remodeling that act to suppress bone growth, to potentially increase bone mass. We believe that KER-012 has the potential to

increase the signaling of BMP pathways through this inhibition of activin A and activin B signaling, and consequently treat diseases such as PAH that are associated with reduced BMP signaling due to inactivating mutations in the BMP receptors. We are developing KER-012 for the treatment of disorders associated with bone loss, such as osteoporosis and osteogenesis imperfecta, and for the treatment of pulmonary arterial hypertension, or PAH.

Osteoporosis

Osteoporosis is a highly prevalent disease characterized by low bone mineral density and deterioration of bone structure, which leads to an increase in bone fractures. It is estimated that more than 200 million people worldwide, including approximately 30% of all post-menopausal women in the United States and Europe, suffer from osteoporosis. It is also estimated that 50% of women and 20% of men over the age of 50 will suffer at least one osteoporosis-related fracture in their remaining lifetime. These fractures can lead to increased morbidity and mortality. With the number of individuals over the age of 50 expected to increase, the incidence of osteoporosis-related fractures is predicted to double or triple in the upcoming decades.

Limitations of Current Treatment Options for Osteoporosis

Patients with osteoporosis are generally treated with anti-resorptive agents and anabolic agents. Anti-resorptive agents act to prevent further bone loss by inhibiting the breakdown of bone, while anabolic agents stimulate bone formation to build new, high-quality bone.

Bisphosphonate anti-resorptive agents, including Aredia (pamidronate), Fosamax (alendronate) and Reclast (zoledronic acid), are the current standard of care, and these treatments inhibit the cells that resorb or take away bone. However, bisphosphonates have limited efficacy for non-vertebral fractures, and gains in bone mineral density have been observed to plateau after a few years of treatment. Additionally, bisphosphonate use has been associated with infrequent but serious adverse events, such as osteonecrosis of the jaw and atypical femoral fractures. These side effects, although rare, have created increasing concern among physicians and patients. Accordingly, the number of bisphosphonate prescriptions has declined over 50% in the last decade and physicians are seeking alternatives.

There are several alternatives to bisphosphonates that are approved for the treatment of osteoporosis, including anti-resorptive agents and anabolic agents. The most potent anti-resorptive product that is approved for treatment is Prolia (denosumab). Given twice a year via subcutaneous injection by a physician, Prolia increases bone density and reduces hip, spine and non-vertebral fractures. However, in the past five years, there have been numerous reports about fractures, especially those of the spine, occurring after the cessation of Prolia, which we believe has caused many patients with osteoporosis to refrain from commencing treatment with Prolia.

Anabolic therapies approved for treatment of osteoporosis include Forteo (teriparatide) and Tymlos (abaloparatide). Delivered by daily subcutaneous injection, these products have been observed to improve bone density and reduce vertebral fractures, but have limited evidence for reduction of hip fracture, which is frequently a debilitating fracture for patients. Additionally, use of these products is restricted to two years and their labels include a black-box warning regarding the occurrence of bone cancer in rats treated with Forteo, which is a key deterrent to using these products for many patients.

Evenity (romosozumab-aqqg), an anabolic therapy, increases bone formation briefly while also reducing bone resorption. The reason for the short-term nature of the anabolic effect is unclear. Evenity is delivered via two subcutaneous injections monthly at a doctor’s office, with use restricted to 12 months. Although Evenity exhibited robust anti-fracture efficacy and large gains in bone mineral density in a third-party Phase 3 clinical trial, the Evenity label includes a black-box warning that the product may increase the risk of heart attack, stroke or death from a cardiovascular event.

We believe there is a large unmet need for patients with osteoporosis, as existing therapies have shortcomings in efficacy, tolerability, convenience and safety. Given these shortcomings, we believe there is a significant market opportunity for an anabolic agent such as KER-012, which is designed to be a potent and selective inhibitor of certain TGF-ß ligands, including activin A and activin B, that are key regulators of bone remodeling that act to suppress bone growth. Additionally, with a growing population of older adults, the number of patients with osteoporosis is predicted to expand in the coming years.

Osteogenesis Imperfecta

Osteogenesis imperfecta is a group of genetic disorders that mainly affect the bones. People with osteogenesis imperfecta have bones that fracture easily, often from mild trauma or with no apparent cause. Osteogenesis imperfecta affects approximately one out of every 10,000 to 20,000 people worldwide, while an estimated 25,000 to 50,000 people in the United States are living with the condition.

Limitations of Current Treatment Options for Osteogenesis Imperfecta

There are no approved therapies for the treatment of osteogenesis imperfecta in the United States or the European Union. Current treatment of osteogenesis imperfecta is directed towards the management of fractures with casting or surgical fixation, followed by physical therapy. Preventative surgeries, such as intramedullary, or in-bone, nailing fixation, in which a permanent nail or rod is placed into the center of the bone, are also undertaken. However, these surgical options do not treat the underlying cause of osteogenesis imperfecta. Additionally, bisphosphonates, which are not approved for osteogenesis imperfecta, are commonly used off-label in children. A meta-analysis of randomized trials demonstrated that there was no evidence that current treatments, including bisphosphonates, reduce fracture risk in patients with osteogenesis imperfecta. Controlled clinical trials also showed no improvement in bone pain, a key disability in children with osteogenesis imperfecta. Additionally, we are not aware of any long-term clinical trials demonstrating a reduction in fractures in adults, and the effect of long-term therapy with these existing products remains unclear.

Pulmonary Arterial Hypertension

PAH is a debilitating disorder characterized by elevated pulmonary vascular resistance due to severe constriction and progressive obliteration of the pulmonary vessels. PAH results in diminished oxygenation, impaired cardiac output and symptoms stemming from overload of the right ventricle, such as shortness of breath, fatigue, fainting, chest pain, palpitations and swelling of extremities and abdomen. We estimate that in the United States there are 750 to 2,000 new cases of PAH each year and 10,000 to 20,000 individuals living with this condition. Despite current treatment options, survival with PAH remains only slightly above 50% at five years, with mortality typically resulting from right ventricle failure.

Loss-of-function mutations in the gene encoding the BMP type II receptor, or BMPR2, are present in over 70% of cases of heritable PAH, or HPAH, while loss-of-function mutations in certain BMPR2 co-receptors are present in other cases of HPAH and idiopathic PAH. Histology and gene expression studies from the lungs of human and experimental PAH showed diminished BMPR2 expression and BMP signaling even in the absence of loss-of-function mutations, as well as enhanced TGF-ß signaling. Consistent with an imbalance in the signaling of these families of ligands, it was recently found that PAH due to cirrhosis and portal hypertension is marked by a severe deficiency of circulating BMP9, while circulating TGF-ß, activin and growth differentiation factor, or GDF, ligands were found to be increased in PAH, even in the absence of causative mutations. Multiple experimental third-party models also demonstrated the efficacy of augmenting BMP signaling or suppressing TGF-ß, activin or GDF signaling, which we believe supports the notion that imbalanced homeostatic BMP and pathogenic TGF-ß, activin and GDF signaling drive the development and progression of pulmonary vascular disease.

Limitations of Current Treatment Options for PAH

All of the currently-approved therapies for PAH are vasodilators, which are medications that dilate blood vessels. These vasodilators fall into one of three categories: (i) prostanoids, which are agonists of the prostacyclin signaling pathway; (ii) endothelin receptor antagonists, or ERAs; or (iii) (a) phosphodiesterase 5 inhibitors, or PDE5i, which are agents that enhance nitric oxide metabolism, or (b) soluble guanylate cyclase activators, which cause downstream cGMP signaling.

One common approach to treating early-stage or mild PAH is an oral combination therapy using ERA and PDE5i medications. More severe PAH generally requires the addition of prostanoid, via oral or inhaled administration, while advanced PAH typically requires continuous parenteral administration. Each of these individual therapies may modestly improve a patient's functional status and in some cases survival, but is limited by systemic hypotension, systemic side effects and tachyphylaxis, which is an acute, sudden decrease in response to a product after its administration. Additionally, combination therapy is limited by the combined

side effect profiles. Although existing treatments may modestly slow the progression of PAH, none appear to halt or reverse the disease's progression.

While the key physiologic and pathologic features of PAH include vasoconstriction, scar tissue and vascular smooth muscle cell proliferation and inflammation, the main pharmacological effect for all currently approved therapies is believed to be vasodilation. Accordingly, we believe there is a significant unmet need for a treatment that primarily targets the proliferative pathological processes and can be used alone or in combination with other PAH therapies. We believe that potent therapies that do not exhibit tachyphylaxis, are orally bioavailable or do not require continuous infusion therapy would have advantages over the currently available treatments for PAH.

Therapies that arrest pulmonary vascular remodeling could have a long-term clinical stabilizing effect in PAH, or reverse vascular obliteration. We believe that KER-012 has the potential to increase the signaling of BMP pathways through the inhibition of activin A and activin B signaling, and consequently treat diseases such as PAH that are associated with reduced BMP signaling due to inactivating mutations in the BMP receptors.

Preclinical Data

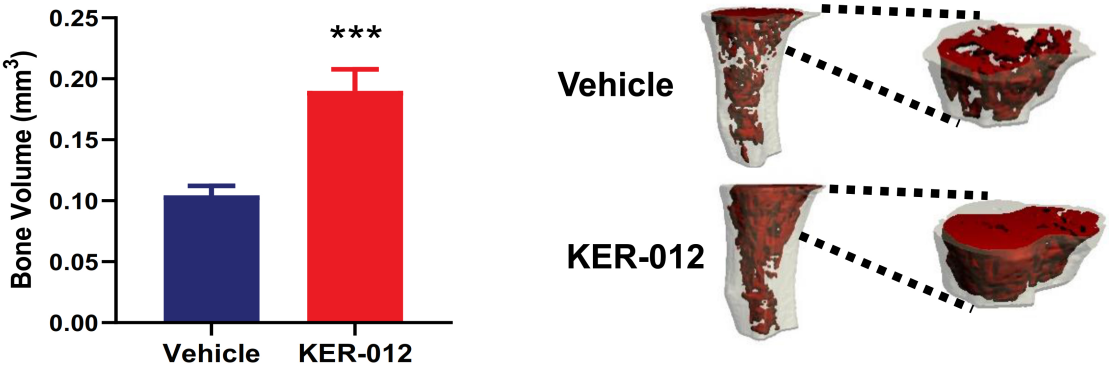
We have generated preclinical data that we believe demonstrated proof-of-mechanism of KER-012 for the treatment of disorders associated with bone loss, such as osteoporosis and osteogenesis imperfecta, and for the treatment of PAH. Specifically, in preclinical studies, KER-012:

- showed high affinity for and potent inhibition of ligands involved in the regulation of bone homeostasis;
- lacked binding to BMP9, a ligand critical in vascular remodeling, vascular stability and vascular quiescence;
- increased bone mineral density and trabecular bone volume in wild-type mice and mice with established osteoporosis; and
- did not increase red blood cell production in cynomolgus monkeys.

KER-012 targeted ligands that signal through ActRIIA and ActRIIB in preclinical studies

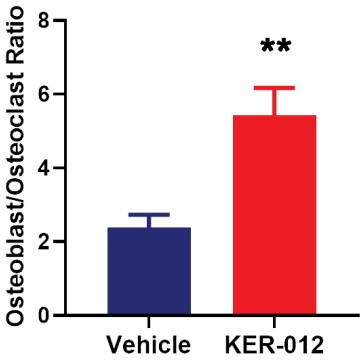
KER-012 is a modified ActRIIB ligand trap that contains sequences from both wild-type ActRIIB and wild-type ActRIIA. In preclinical studies, KER-012 bound to and inhibited multiple ligands that signal through these cell surface receptors, including activin A, activin B and growth differentiation factor 11. These ligands are key regulators of bone remodeling that act to suppress bone growth. BMP9 is a ligand capable of signaling through the ActRIIB and bone morphogenetic receptor II. Inhibition of BMP9 results in disruption of vascular remodeling, which can lead to the development of epistaxis and telangiectasias. KER-012 did not bind BMP9 or inhibit BMP9 signaling in preclinical studies. Consequently, we believe KER-012 has the potential to avoid negative effects on vascular remodeling.

Treatment with KER-012 increased bone mineral density



*** P value <0.001

In preclinical studies conducted in wild-type mice, twice weekly intraperitoneal 20 mg/kg dosing of KER-012 increased bone mineral density compared to vehicle-treated mice 31 days post-treatment. Additionally, we observed that treatment with KER-012 statistically significantly increased trabecular bone formation and mineral apposition rate, which we believe is consistent with an anabolic effect on bone.



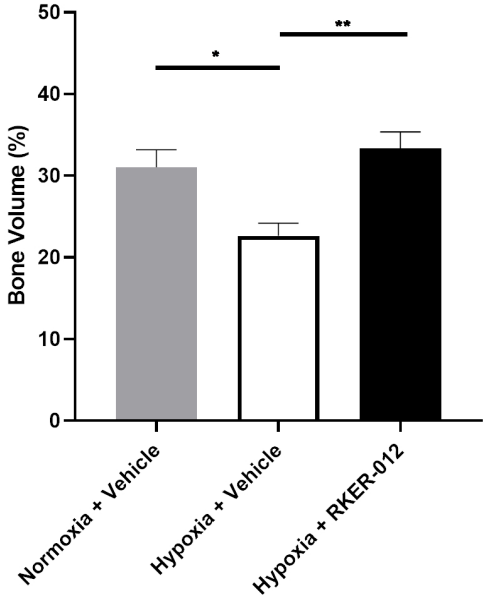
** P value <0.01

In a separate preclinical study, we observed that treatment with KER-012 increased the ratio of osteoblasts, which are bone forming cells, to osteoclasts, which are bone resorbing cells, which further supports that KER-012 acts via an anabolic effect on bone. We also observed in preclinical studies conducted in mice with established osteoporosis that twice weekly intraperitoneal 20 mg/kg dosing of KER-012 increased bone mass compared to vehicle-treated mice 46 days post-treatment.

Treatment with RKER-012 prevented cardiac hypertrophy in a rat model of PAH

To generate a rat model of PAH, we combined SUGEN5416, a tyrosine kinase inhibitor of vascular endothelial growth factor receptors 1/2, with exposure to chronic hypoxia to recapitulate the biology in PAH. In this model, remodeling of the arterial wall results in wall thickening, increased arterial pressure and impairment of heart function through a thickening of the right ventricle. Treatment with twice weekly subcutaneous 25 mg/kg dosing of the rodent version of KER-012, or RKER-012, was observed to protect against a thickening of the right ventricular wall, which we believe demonstrates that KER-012 has the potential to treat PAH.

Treatment with RKER-012 prevented bone loss from hypoxia in the rat model of PAH



* P value <0.05; **P value <0.01

In the rat model of PAH, chronic hypoxia induced a catabolic state that resulted in wasting of tissue, including bone and muscle. Treatment with a subcutaneous 25 mg/kg dose of RKER-012 was observed to prevent bone loss in the rat model of PAH.

CKER-012 did not increase red blood cells in non-human primates

In a preclinical study, cynomolgus monkeys received subcutaneous administration every other week for one month of either vehicle or a 10 mg/kg dose of CKER-012, a monkey form of KER-012 comprised of the same modified ActRIIB fused to a cynomolgus Fc that has a ligand binding profile similar to that of KER-012. We measured hematology at baseline and on Day 35. Changes in red blood cells, hematocrit and hemoglobin over the 35-day study were not statistically significantly different compared to changes observed in the vehicle-treated cohort. Based on these findings that CKER-012 did not increase red blood cell production in monkeys, we believe KER-012 has the potential not to increase red blood cell production in humans.

Based on the findings from our preclinical studies, we believe KER-012 has the potential to treat disorders associated with bone loss, such as osteoporosis and osteogenesis imperfecta. Additionally, inhibition of BMP9 signaling can result in endothelial cell apoptosis, remodeling and arterial occlusion in diseases such as PAH. We believe that KER-012 has the potential to increase the signaling of BMP pathways through this inhibition of activin A and activin B signaling, and consequently treat diseases such as PAH that are associated with reduced BMP signaling due to inactivating mutations in the BMP receptors.

Our Proprietary Discovery Approach

We believe, based on our previous experience with ActRII ligand traps using the endogenous and wild-type sequences, that observations in preclinical rodent models have the potential to translate to humans in the clinic. Specifically:

- Wild-type ActRIIA-Fc was associated with increased bone growth and red blood cell production in rodents and non-human primates. In a third-party clinical trial of ActRIIA-Fc, increased bone mineral density and red blood cell production was reported in healthy post-menopausal women. In this clinical trial, it was also reported that lower doses elicited the effect on red blood cells compared to bone, and

thus, the dominant effect on red blood cell production prevented development in diseases with bone loss.
- In third-party preclinical studies in rodents and non-human primates, ActRIIB-Fc was associated with increased bone mineral density and lean muscle mass, but was not associated with changes in red blood cells. However, ActRIIB-Fc was also observed to cause nose and gum bleeding, which we believe is due to its effect of disrupting normal vascular remodeling. BMP9 signaling is required for normal vascular remodeling, but is not involved in regulation of muscle or bone tissues. ActRIIB-Fc potently inhibits BMP9 signaling, which is the mechanism behind the bleeding events observed with ActRIIB-Fc treatment.

We have developed a proprietary library of ActRII ligand traps by combining sequences from ActRIIA and ActRIIB. We have engineered molecules that are designed to have the therapeutic properties of either or both parent molecules without the dose-limiting effect on red blood cells observed with ActRIIA-Fc or the negative effect on blood vessels observed with wild-type ActRIIB-Fc. Our ActRII program has produced a broader pipeline of engineered ligand traps and currently contains more than 20 unique variants in preclinical development. These include:

- Molecules designed to increase bone mass without the dose-limiting effect on red blood cells observed with wild-type ActRIIA-Fc; and
- Molecules designed to increase muscle and bone mass with reduced BMP9 binding without impacting vascular remodeling that leads to weak blood vessels observed with the wild-type ActRIIB-Fc.

Our discovery approach has built on these initial observations to generate product candidates designed to target ActRII receptors without the liabilities observed in third-party preclinical studies and clinical trials of ActRIIA-Fc and ActRIIB-Fc.

We believe that we are well positioned to advance our product candidates and realize the commercial opportunities in diseases where muscle and bone loss result in a debilitating impact on survival and quality of life, if our product candidates are successfully developed and approved. Our deep knowledge and expertise of the TGF-ß family of proteins provides a streamlined approach to screen and develop novel product candidates for hematological and musculoskeletal diseases.

Manufacturing

We rely, and expect to continue to rely for the foreseeable future, on third-party contract manufacturing organizations, or CMOs, to produce our product candidates for preclinical and clinical testing, as well as for commercial manufacture if our product candidates receive marketing approval. We require that our CMOs produce bulk drug substances and finished drug products in accordance with current Good Manufacturing Practices, or cGMPs, and all other applicable laws and regulations. We maintain agreements with our manufacturers that include confidentiality and intellectual property provisions to protect our proprietary rights related to our product candidates.

We have engaged CMOs to manufacture supply for preclinical and clinical use. Additional CMOs are used to label, package and distribute drug product for preclinical and clinical use. We obtain our supplies from these CMOs on a purchase order basis and do not have any long-term supply arrangements in place. We do not currently have arrangements in place for redundant supply. We are closely monitoring the impact of the COVID-19 pandemic on our ability to procure sufficient supplies for the development of our product candidates. The magnitude of any potential impact will depend on the severity and duration of the spread of the virus, and the actions undertaken to contain COVID-19 or treat its effects. We are working with our CMOs to manage this process. However, we could be unable to find alternative suppliers of acceptable quality, in the appropriate volumes and at an acceptable cost, if needed. As our development programs expand and we build new process efficiencies, we expect to continually evaluate this strategy with the objective of satisfying demand for registration trials and, if approved, the manufacture, sale and distribution of commercial products.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary rights. While we believe that our product candidates,

discovery programs, technology, knowledge, experience and scientific resources provide us with competitive advantages, we compete in the highly competitive markets and face significant competition from many sources, including pharmaceutical and biotechnology companies, as well as academic institutions, governmental agencies and private and public research institutions.

We compete in the segments of the biotechnology, pharmaceutical and other related industries that develop and market therapies for the treatment of hematological and musculoskeletal disorders. There are many other companies, including large biotechnology and pharmaceutical companies, that have commercialized and/or are developing therapies for the same therapeutic areas that our product candidates target. For example, FibroGen Inc., Astellas Pharma Inc. are developing product candidates for the treatment of anemia, and Acceleron Pharma Inc., or Acceleron, Bristol-Myers Squibb Company and Disc Medicine are developing product candidates targeting diseases associated with MDS and myelofibrosis, including chronic anemia. Additionally, in April 2020, Acceleron received FDA approval of its product, Reblozyl, for the treatment of anemia failing an erythropoiesis stimulating agent and requiring two or more red blood cell units over eight weeks in adult patients with very low- to intermediate-risk MDS with ring sideroblasts or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis. In June 2020, Acceleron further announced that the European Commission approved Reblozyl for the treatment of transfusion-dependent anemia in adult patients with MDS or beta thalassemia and in September 2020, Acceleron announced that Health Canada approved Reblozyl for the treatment of adult patients with red blood cell transfusion-dependent anemia associated with beta thalassemia. Sierra Oncology, Inc. is developing momelotinib as a treatment for myelofibrosis. Additionally, Constellation Pharmaceutics, Inc. is also developing a product candidate as a treatment for myelofibrosis.

Other companies that are developing product candidates that are designed to target the TGF-ß signaling pathways include Scholar Rock Holding Corporation, Biogen Inc. and Regeneron Pharmaceuticals, Inc.

There are currently no approved drugs for the treatment of FOP. However, Ipsen, through its subsidiary Clementia Pharmaceuticals Inc. and pursuant to a collaboration with Blueprint Medicines Corporation, as well as Regeneron Pharmaceuticals, Inc., BioCryst Pharmaceuticals, Inc. and Incyte Corporation are developing product candidates for the treatment of FOP that are intended to work, at least in part, through inhibition of aberrant ALK2 signaling.

Many of the companies against which we are competing or against which we may compete in the future, either alone or with their strategic collaborators, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies or universities and research institutions. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and enrolling patients for our clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We could see a reduction or elimination of our commercial opportunity if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. The availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Collaborations and License Agreement

2016 Exclusive Patent License Agreement with The General Hospital Corporation

In April 2016, we entered into an exclusive patent license agreement with The General Hospital Corporation, or MGH, which was subsequently amended in May 2017 and February 2018. Under the license agreement with MGH, or the MGH Agreement, we obtained an exclusive, worldwide license, with the right to sublicense, under certain patents and technical information of MGH, to make, have made, use, have used, sell, have sold, lease,

have leased, import, have imported or otherwise transfer licensed products and processes for use in the treatment, diagnosis, palliation and prevention of diseases and disorders in humans and animals. We are required to use commercially reasonable efforts to develop and commercialize licensed products and processes, and must achieve certain required diligence milestones.

Under the terms of the MGH Agreement, we made an initial license payment of $100,000 and reimbursed MGH approximately $280,000 of prior patent prosecution expenses related to the licensed patents. We also issued MGH an aggregate of 358,674 shares of our common stock. Additionally, we are required to pay a low-five digit to mid-five digit annual maintenance fee prior to the first commercial sale of our first product or process, a mid-five digit annual maintenance fee after the first commercial sale of our first product or process that is creditable against royalties, certain clinical and regulatory milestone payments for the first three products or indications to achieve such milestones, which milestone payments are $8.6 million in the aggregate, and certain commercial milestone payments for the first three products or indications to achieve such milestones, which milestone payments are $18.0 million in the aggregate. In 2020, we made a single payment of $50,000 with respect to achievement of the clinical and regulatory milestone of filing of an IND in the first country. We are also obligated to pay tiered royalties on net sales of licensed products ranging in the low-single digits to mid-single digits. The royalty rates are subject to up to a maximum 50% reduction for lack of a valid claim, in the event that it is necessary for us to obtain a license to any third-party intellectual property related to the licensed products, and generic competition. The obligation to pay royalties under the MGH Agreement expires on a licensed product-by-licensed product and country-by-country basis upon the later of expiry of the last valid claim of the licensed patents that cover such licensed product in such country and ten years from the first commercial sale of such product in such country. We are also obligated to pay a percentage of non-royalty related payments received by us from sublicensees ranging in the sub-teen double digits and a change of control fee equal to a low-single digit percentage of the payments received as part of any completed transaction up to a low-seven digit amount.

The MGH Agreement expires upon expiry of the last remaining royalty obligation for a licensed product or process. Under the MGH Agreement, MGH may terminate the agreement upon our uncured material breach or insolvency, a challenge by us of the licensed patents and certain other specified breaches of the MGH Agreement. We may terminate the agreement for any reason upon specified prior written notice to MGH.

Termination of 2017 Research Collaboration and Exclusive License Agreement with Novo Nordisk

In December 2017, we entered into a research collaboration and exclusive license agreement with Novo Nordisk A/S, or Novo Nordisk. Under the agreement with Novo Nordisk, or the Novo Nordisk Agreement, we are collaborating with Novo Nordisk on research and development of fusion molecules consisting of a ligand binder present as part of a larger molecule, or ligand traps. Pursuant to the Novo Nordisk Agreement, Novo Nordisk had the right to select a prespecified number of ligand traps for further development and commercialization by Novo Nordisk. Following execution, Novo Nordisk selected one existing ligand trap to further develop and commercialize and prior to the completion of the two-year research program, selected a second ligand trap arising from the collaboration.

Upon selection by Novo Nordisk of each ligand trap, we transferred the selected ligand trap to Novo Nordisk for further development and commercialization. We are able to further develop and commercialize all other remaining declined ligand traps, subject to certain limitations as described below.

Under the Novo Nordisk Agreement, we granted Novo Nordisk an exclusive, worldwide, royalty bearing license, with the right to sublicense, under certain of our background intellectual property and collaboration intellectual property to develop, manufacture and commercialize products that contain the initial ligand trap and any selected ligand trap, whether alone or as a combination product, for use in the treatment of diabetes (including diabetes related complications of cardiovascular disease, or CVD, and chronic kidney disease, or CKD), obesity, (including obesity related complications of CVD, CKD and sarcopenic obesity), non-alcoholic steatohepatitis and cachexia, and, solely as a combination product for use in CVD and CKD.

Under the terms of the Novo Nordisk Agreement, during the term of the agreement, we are not permitted, directly or indirectly, to research, develop or commercialize any ligand trap or ligand binder for use in the licensed field or any selected ligand trap outside of the licensed field, except that we may research, develop, or commercialize any declined ligand trap for use in CVD and CKD. Under the terms of the Novo Nordisk

Agreement, we received an initial license payment of $16.0 million in 2018. Novo Nordisk has paid us $4.0 million in research funding over the two-year research program.

On October 26, 2020, Novo Nordisk gave written notice of termination of the Novo Nordisk Agreement, effective six months following the delivery of notice, on April 26, 2021. Upon termination, all worldwide rights to all ligand traps selected under the Novo Nordisk Agreement, along with all rights to develop our molecules in the fields of diabetes, obesity, nonalcoholic steatohepatitis and cachexia, will revert to us. Under the terms of the Novo Nordisk Agreement, Novo Nordisk is obligated to continue to reimburse the Company for certain research and development costs through April 26, 2021. Upon effectiveness of the termination, such reimbursements will cease.

Intellectual Property

Overview

We strive to protect the proprietary technology, inventions and improvements that we believe are commercially important to our business, including obtaining, maintaining, enforcing and defending our intellectual property rights, including patent rights, whether developed internally or licensed from third parties. We rely, in part, on trade secrets and know-how relating to our proprietary technology and drug candidates and continuing innovation to develop, strengthen and maintain our proprietary position. We also plan to rely, in part, on data exclusivity, market exclusivity and patent term extensions if and when available. Our commercial success will depend in part on our ability to obtain and maintain patent and other intellectual property protection for our technology, inventions and improvements; to preserve the confidentiality of our trade secrets; to defend and enforce our proprietary rights, including any patents that we own or may obtain in the future; and to operate without infringing, misappropriating or otherwise violating the valid and enforceable patents and other intellectual property rights of third parties. Intellectual property rights may not address all potential threats to our competitive advantage

As of September 30, 2020, our patent portfolio consisted of five issued U.S. patents, 19 pending U.S. patent applications, three issued ex-U.S. patents and 47 pending ex-U.S. applications, with expected expiry dates not earlier than between March 13, 2029 and April 30, 2041. Of these, 52 patent applications relate to KER-050, KER-047 and KER-012, and eight issued patents and 14 patent applications relate to other technologies, in each case as described in more detail below. Each of our pending international patent applications has been filed under the Patent Cooperation Treaty and has not yet entered any national jurisdictions. Our policy is to file patent applications to protect technology, inventions and improvements to inventions that may be commercially important to the development of our business.

We seek U.S. and international patent protection for a variety of technologies, and own patent applications with claims directed to ActRIIA ligand traps, ActRIIB ligand traps, ActRII chimera ligand traps, GDNF fusion polypeptides, ALK2 antibodies, and crystal forms of an ALK2 inhibitor. We also intend to seek patent protection or rely upon trade secret rights to protect other technologies that may be used to discover and validate targets, and that may be used to manufacture and develop novel products. We are a party to license agreements that give us rights to use specific technologies in our products and in manufacturing our products.

Patent applications directed to our most advanced programs are summarized below.

KER-050

KER-050 is a modified ActRIIA ligand trap that is designed to bind to different TGF-ß ligands that signal through a TGF-ß signaling pathway. We own six pending U.S. patent applications and 26 pending ex-U.S. applications that contain claims or supporting disclosure directed to ActRIIA ligand traps and use thereof to treat muscle disease, bone disease, metabolic disease, anemia, fibrosis, pulmonary hypertension, thrombocytopenia, and neutropenia. Any patents issuing from these applications will have expiration dates between November 9, 2037 and March 20, 2041, absent any patent term adjustments or extensions.

KER-047

KER-047 is an orally available small molecule ALK2 inhibitor designed to potently and selectively inhibit ALK2 signaling. We own two pending U.S. patent applications that contain claims or supporting disclosure directed to crystal forms of an ALK2 inhibitor and uses thereof. Any patents issuing from these applications will have

expiration dates between October 25, 2039 and April 30, 2041, absent any patent term adjustments or extensions.

We have exclusively licensed from The General Hospital Corporation rights in one patent family related to novel ALK2 inhibitors. Patents in this family are expected to expire on April 26, 2038, absent any patent term adjustments or extensions.

KER-012

KER-012 is a modified ActRIIB ligand trap that is designed to bind to different TGF-ß ligands that signal through a TGF-ß signaling pathway. We own four pending U.S. patent applications and nine pending ex-U.S. applications that contain claims or supporting disclosure directed to ActRIIB ligand traps and use thereof to treat muscle disease, bone disease, anemia, fibrosis, pulmonary hypertension, metabolic disease, thrombocytopenia, and neutropenia. Any patents issuing from these applications will have expiration dates between January 11, 2039 and March 20, 2041, absent any patent term adjustments or extensions.

Other

We plan to seek United States and international patent protection for a variety of additional technologies. We own six pending U.S. patent applications and eight pending ex-U.S. applications that contain claims or supporting disclosure directed to GDNF fusion polypeptides, ALK2 antibodies, and ActRII chimera ligand traps. Any patents issuing from these applications will have expiration dates between November 9, 2037 and March 20, 2041, absent any patent term adjustments or extensions.

Intellectual Property Protection

Individual patents extend for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, patents issued for regularly filed applications in the United States are granted a term of 20 years from the earliest effective non-provisional filing date. In addition, in certain instances, a patent term can be extended to recapture a portion of the U.S. Patent and Trademark Office, or the USPTO, delay in issuing the patent as well as a portion of the term effectively lost as a result of the FDA regulatory review period. However, as to the FDA component, the restoration period cannot be longer than five years and the total patent term including the restoration period must not exceed 14 years following FDA approval. The duration of patents outside of the United States varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective filing date. However, the actual protection afforded by a patent varies on a product by product basis, from country to country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

Furthermore, we rely upon trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements with our collaborators, employees and consultants and invention assignment agreements with our employees. We also have confidentiality agreements or invention assignment agreements with our collaborators and consultants. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, or our product candidates or processes, obtain licenses or cease certain activities. Our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop or commercialize our future product candidates may have an adverse impact on us. If third parties have prepared and filed patent applications prior to March 16, 2013 in the United States that also claim technology to which we have rights, we may have to participate in interference proceedings in the USPTO, to

determine priority of invention. For more information, please see "Risk Factors—Risks Related to Intellectual Property."

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, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of drug and biological products such as those we are developing.

Our product candidates are subject to regulation under the Food, Drug, and Cosmetic Act and the Public Health Service Act, and other federal, state, local and foreign statutes and regulations. We, along with third-party contractors, will be required to navigate the various preclinical, 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. Drug and Biological Product Regulation

Our product candidates must be approved by the FDA through either a New Drug Application, or NDA, or a Biologics License Application, or BLA. The process required by the FDA before biopharmaceutical product candidates may be marketed in the United States generally involves the following:

- completion of extensive preclinical laboratory tests and animal studies performed in accordance with applicable regulations, including the FDA's Good Laboratory Practice, or GLP, requirements;
- submission to the FDA of an Investigational New Drug, or IND, application which must become effective before human clinical trials may begin;
- approval 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 in accordance with applicable IND regulations, good clinical practice, or GCP, requirements and other clinical trial-related regulations to establish the safety and efficacy of the investigational drug product for each proposed indication and to establish the safety, purity and potency of the investigational biologic product candidate for each proposed indication;
- preparation of and submission to the FDA of an NDA for a small molecule product candidate or a BLA for a biologic after completion of all pivotal clinical trials;
- payment of user fees for FDA review of the NDA or BLA;
- a determination by the FDA within 60 days of its receipt of the NDA or BLA to file the application for review;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities at which the proposed product will be produced to assess compliance with current Good Manufacturing Practice, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the product's continued identity, strength, quality and purity;
- potential FDA audit of the preclinical study and/or clinical trial sites that generated the data in support of the NDA or BLA;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- FDA review and approval of an NDA or licensure of a BLA, including consideration of the views of any FDA Advisory Committee, prior to any commercial marketing or sale of the product for particular indications for use in the United States; and
- compliance with any post-approval requirements, including the potential requirement to conduct post-approval studies.

Preclinical and Clinical Development

Before testing any drug or biologic candidate in humans in the United States, the product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as *in vitro* and animal studies to assess safety and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal and state regulations and requirements, including GLP regulations for safety/toxicology studies.

Prior to beginning the first clinical trial with a product candidate, we must submit the results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The IND submission contains the general investigational plan and the protocol or protocols for preclinical studies and clinical trials, as well as results of in vitro and animal studies assessing the toxicology, pharmacokinetics, pharmacology and pharmacodynamic characteristics of the product, chemistry, manufacturing and controls information, and any available human data or literature to support the use of the investigational product. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day period, raises safety concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

The clinical stage of development involves the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. These investigators are generally physicians who are not employed by or under the trial sponsor's control. 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 and assessing efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the existing IND. Furthermore, each clinical trial must be reviewed and approved by an independent IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative, 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 preclinical studies and clinical trials 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 an NDA. The FDA will accept a well-designed and well-conducted foreign clinical trial not conducted under an IND if the trial was conducted in accordance with GCP requirements and the FDA is able to validate the data through an onsite inspection, if deemed necessary, and the practice of medicine in the foreign country is consistent with the United States.

Human clinical trials in the United States are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1 clinical trials generally involve a small number of healthy volunteers or patients with the target disease or condition. 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.
- Phase 2 clinical trials involve studies in a limited population of disease-affected patients to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks.
- Phase 3 clinical trials generally involve a large number of patients at multiple geographically dispersed clinical trial sites and are designed to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety. 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.

When these phases overlap or are combined, the trials may be referred to as Phase 1/2 or Phase 2/3. A Phase 1/2 clinical trial is a human trial that investigates both safety and preliminary efficacy of an investigational therapy. A Phase 2/3 clinical trial is a human trial that investigates both preliminary and confirmatory efficacy and safety to potentially support submission of a marketing application with the applicable regulatory authorities.

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, are used to gain additional experience from the treatment of patients in the intended therapeutic indication and are commonly intended to generate additional safety data regarding use of the product in a clinical setting. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition to FDA approval of an NDA or BLA.

Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the chemistry and physical 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.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical study investigators. The FDA or the sponsor or its data safety monitoring board may suspend a clinical study 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 study at its institution if the clinical study is not being conducted in accordance with the IRB's requirements or if the biological product candidate has been associated with unexpected serious harm to patients. There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Sponsors of clinical trials of FDA-regulated products, including biologics, are required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov.

FDA Review Process

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 an NDA or BLA. The NDA or BLA is a request for approval to market the drug or biologic for one or more specified indications and must contain proof of safety and efficacy for a drug or safety, purity and potency for a biologic. The application must include all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results of preclinical studies and clinical trials, as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of FDA.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each submission of an NDA or BLA requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs or BLAs for products designated as orphan drugs, unless the product application also includes a non-orphan indication.

The FDA reviews all submitted NDAs and BLAs before it accepts them for filing, and may request additional information rather than accepting the NDA or BLA for filing. The FDA must make a decision on accepting an NDA or BLA for filing within sixty days of receipt. Such decision could include either issue a refusal to file letter or acceptance of the NDA or BLA for filing, indicating that it is sufficiently complete to permit substantive review.

Once an NDA or BLA has been accepted for filing, the FDA begins an in-depth review of the NDA or BLA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA aims to review standard applications within ten months from the filing date, during which it will complete its initial review of a new molecular entity NDA or original BLA and respond to the applicant, or within six months from the filing date of a new molecular entity NDA or original BLA designated for 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. The FDA reviews the application to determine, among other things, whether a product is safe and effective, or for a biologic, safe, pure and potent for its intended use, and whether the facility in which it is manufactured, processed, packed or held meets standards designed to assure and preserve the product's identity, safety, strength, quality, potency and purity.

The FDA generally accepts data from foreign clinical trials in support of an NDA or BLA if the trials were conducted under an IND, and the IND requirements, unless waived, were met. If a foreign clinical trial is not conducted under an IND, the FDA nevertheless may accept the data in support of an NDA or BLA if the trial was conducted in accordance with GCPs and the FDA is able to validate the data through an on-site inspection, if deemed necessary. Although the FDA generally requests that marketing applications be supported by some data from domestic clinical studies, the FDA may accept foreign data as the sole basis for marketing approval if (1) the foreign data are applicable to the U.S. population and U.S. medical practice, (2) the trials were performed by clinical investigators with recognized competence, and (3) the data may be considered valid without the need for an on-site inspection or, if the FDA considers the inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means.

Before approving an NDA or BLA, the FDA will conduct a pre-approval inspection of the manufacturing facility or facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve an application 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. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel products or products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by recommendations of the advisory committee, but it considers such recommendations when making decisions on approval. Additionally, before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs. 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 an NDA or BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be manufactured, the FDA will 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 indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response letter usually describes all of the specific deficiencies that the FDA has identified in the NDA or 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 application in condition for approval, including requests for additional information or clarification, which may include the potential requirement for additional clinical studies, including the potential requirement to conduct additional clinical trial(s) and/or to complete other significant and time-consuming requirements related to clinical trials, or to conduct additional preclinical studies or manufacturing activities. If a Complete Response Letter is issued, the applicant may either resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing. Even if such data and information are submitted, the FDA may decide that the NDA or BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

Orphan Drug Designation

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

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full NDA or BLA, to market the same product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the application fee.

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

Post-Approval Requirements

Following approval of a new product, the manufacturer and the approved product are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to monitoring and record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, compliance with advertising and promotion requirements, which include restrictions on promoting the product for unapproved uses or patient populations, known as “off-label use,” and limitations on industry-sponsored scientific and educational activities. Further, after approval, if there are any changes or modifications to the approved product, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA review and approval of a new NDA/BLA or NDA/BLA supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may also place other conditions on approvals including the requirement for a Risk Evaluation and Mitigation Strategy, or REMS, to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS. 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 will not approve the NDA or BLA without an approved REMS, if required. 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. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

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 the product, complete withdrawal of the product from the market or product recalls;
- fines, warning or untitled letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of drugs and biologics. Drugs and biologics may be promoted only for the approved indications and in accordance with the provisions of the approved label. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. 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.

Biosimilars and Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCI Act, which created an abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product. To date, only a handful of biosimilars have been licensed under the BPCIA, although 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 and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structure of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation that are still being worked out by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing

the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

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

Foreign Regulation

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety, and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable foreign regulatory authorities before we can commence clinical trials or marketing of the product in foreign countries and jurisdictions.

Australia

Our Phase 1 trial for KER-047 and our Phase 1 trial for KER-050 were both conducted in Australia. The Therapeutic Goods Administration, or the TGA, and the National Health and Medical Research Council set the GCP requirements for clinical research in Australia, and compliance with these codes is mandatory. Australia has also adopted international codes, such as those promulgated by the International Council for Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, or the ICH. The ICH guidelines must be complied with across all fields of clinical research, including those related to pharmaceutical quality, nonclinical and clinical data requirements and trial designs. The basic requirements for preclinical data to support a first-in-human trial under ICH guidelines are applicable in Australia. Requirements related to adverse event reporting in Australia are similar to those required in other major jurisdictions.

Clinical trials conducted using "unapproved therapeutic goods" in Australia, being those which have not yet been evaluated by the TGA for quality, safety and efficacy must occur pursuant to either the Clinical Trial Notification Scheme, or the CTN Scheme, or the Clinical Trial Exemption Scheme, or the CTX Scheme. In each case, the trial is supervised by a Human Research Ethics Committee, or HREC, an independent review committee set up under guidelines of the Australian National Health and Medical Research Council that ensures the protection of rights, safety and well-being of human subjects involved in a clinical trial. A HREC does this by reviewing, approving and providing continuing examination of trial protocols and amendments, and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

The CTN Scheme broadly involves:

- completion of preclinical laboratory and animal testing;
- submission to a HREC, of all material relating to the proposed clinical trial, including the trial protocol;
- the institution or organisation at which the trial will be conducted, referred to as the "Approving Authority", giving final approval for the conduct of the trial at the site, having regard to the advice from the HREC; and
- the investigator submitting a 'Notification of Intent to Conduct a Clinical Trial' form, or CTN Form, to the TGA. The CTN form must be signed by the sponsor, the principal investigator, the chairman of the HREC and a person responsible from the Approving Authority. The TGA does not review any data relating to the clinical trial however CTN trials cannot commence until the trial has been notified to the TGA.

Under the CTX Scheme:

- a sponsor submits an application to conduct a clinical trial to the TGA for evaluation and comment; and
- a sponsor must forward any comments made by the TGA Delegate to the HREC(s) at the sites where the trial will be conducted.

A sponsor cannot commence a trial under the CTX Scheme until written advice has been received from the TGA regarding the application and approval for the conduct of the trial has been obtained from an ethics committee and the institution at which the trial will be conducted.

Approval for inclusion in the Australian Register of Therapeutic Goods, or ARTG, is required before a pharmaceutical product may be marketed (or imported, exported or manufactured) in Australia. In order to obtain registration of the product on the ARTG, it is required that:

- adequate and well-controlled clinical trials demonstrate the quality, safety and efficacy of the therapeutic product;
- evidence is compiled which demonstrates that the manufacture of the therapeutic product complies with the principles of cGMP;
- manufacturing and clinical data is derived to submit to the Advisory Committee on Prescription Medicines, which makes recommendations to the TGA as to whether or not to grant approval to include the therapeutic product in the ARTG; and
- an ultimate decision is made by the TGA whether to include the therapeutic product in the ARTG.

Other Healthcare Laws and Compliance Requirements

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation: the U.S. federal Anti-Kickback Statute, the civil False Claims Act, U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, and similar foreign, federal and state fraud and abuse, transparency and privacy laws.

The U.S. federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, to induce, or in return for, either the referral of an individual, or the purchase or recommendation of an item or service for which payment may be made under any federal healthcare program. The term remuneration has been interpreted broadly to include anything of value, including stock options. The U.S. federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and others on the other hand. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but they are drawn narrowly, and practices that involve remuneration, such as consulting agreements, 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 U.S. 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 in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. 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, a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act.

Civil and criminal false claims laws, including the civil False Claims Act, which can be enforced through civil whistleblower or *qui tam* actions, and civil monetary penalty laws prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment to the federal government, including federal healthcare programs, that are false or fraudulent. For example, the civil False Claims Act prohibits any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes “any request or demand” for money or property presented to the U.S. government. 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.

HIPAA created additional federal civil and criminal liability for, among other things, executing a scheme to defraud any healthcare benefit program, including private third-party payors, and making false statements relating to healthcare matters. Similar to the U.S. federal Anti-Kickback Statute, 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, HIPAA, as amended by HITECH, and their implementing regulations, impose certain requirements on HIPAA covered entities, which include certain healthcare providers, healthcare clearing houses and health plans, and individuals and entities that provide services on their behalf that involve individually identifiable health information, known as business associates, as well as their covered subcontractors, relating to the privacy, security and transmission of individually identifiable health information.

The U.S. federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to certain payments and other transfers of value made in the prior year to physicians, as defined under such law, and teaching hospitals, as well as ownership and investment interests held by such physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding their relationships with physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives during the previous year.

We are also subject to additional similar U.S. state and foreign law equivalents of each of the above federal laws, such as 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, or that apply regardless of payor, state laws which require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, state and local laws which require pharmaceutical companies to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, state laws which require the reporting of information related to drug pricing, state and local laws requiring the registration of pharmaceutical sales representatives, and state and foreign laws governing the privacy and security of health information which, in some cases, differ from each other in significant ways, and may not have the same effect, thus complicating compliance efforts. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply, we may be subject to penalties, including, without limitation, significant civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical or biological product for which we obtain regulatory approval. Sales of any product, if approved, depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement, if any, for such product by third-party payors. No uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Decisions regarding whether to cover any of our product candidates, if approved, the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical or biological products, medical devices and medical services, in addition to questioning safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product that receives approval. Decreases in third-party reimbursement for any product or a decision by a third party not to cover a product could reduce physician usage and patient demand for the product. No regulatory authority has granted approval for a personalized cancer immunotherapy based on a vaccine approach, and there is no model for reimbursement of this type of product.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of reform proposals to change the healthcare system. There is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by federal and state legislative initiatives, including those designed to limit the pricing, coverage, and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded healthcare programs, and increased governmental control of drug pricing.

The ACA, which was enacted in March 2010, substantially changed the way healthcare is financed by both governmental and private insurers in the United States, and significantly affected the pharmaceutical industry. The ACA contains a number of provisions of particular import to the pharmaceutical and biotechnology industries, including, but not limited to, those governing enrollment in federal healthcare programs, 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, and annual fees based on pharmaceutical companies' share of sales to federal healthcare programs. Since its enactment, there have been judicial, Congressional and executive branch challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties, which started on January 1, 2019, for not complying with ACA's individual mandate to carry health insurance, delaying the implementation of certain ACA-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. On December 14, 2018, a U.S. District Court Judge in Texas ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit ruled that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year and reduced payments to several types of Medicare providers. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through December 31, 2020, unless additional action is taken by Congress.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking

to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses and place limits on pharmaceutical price increases. Further, the Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained 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 Department of Health and Human Services, or HHS, has solicited feedback on certain of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. On July 24, 2020, the Trump administration announced four executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals, including a policy that would tie certain Medicare Part B drug prices to international drug prices, the details of which were released on September 13, 2020 and expanded the policy to cover certain Part D drugs; one that directs HHS to finalize the Canadian drug importation proposed rule previously issued by HHS and makes other changes allowing for personal importation of drugs from Canada; one that directs HHS to finalize the rulemaking process on modifying the anti-kickback law safe harbors for discounts for plans, pharmacies, and pharmaceutical benefit managers; and one that reduces costs of insulin and epipens to patients of federally qualified health centers. The FDA also recently released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Although a number of these and other 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 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, it is possible that additional governmental action is taken in response to the COVID-19 pandemic. For example, on August 6, 2020, the Trump administration issued another executive order that instructs the federal government to develop a list of "essential" medicines and then buy them and other medical supplies from U.S. manufacturers instead of from companies around the world, including China. The order is meant to reduce regulatory barriers to domestic pharmaceutical manufacturing and catalyze manufacturing technologies needed to keep drug prices low and the production of drug products in the United States.

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservation and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern the use, handling and disposal of various biologic, chemical and radioactive substances used in, and wastes generated by, 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. Equivalent laws have been adopted in other countries that impose similar obligations.

U.S. Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act, or FCPA, prohibits U.S. corporations and individuals from engaging in certain activities to obtain or retain business abroad or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. The scope of the FCPA includes interactions with certain healthcare professionals in many countries. Equivalent laws have been adopted in other foreign countries that impose similar obligations.

Employees and Human Capital Resources

As of September 30, 2020, we had 32 full-time employees, including ten who hold Ph.D. or M.D. degrees. Of these full-time employees, 22 employees are engaged in research and development and ten employees are engaged in management or general and administrative activities. None of our employees are subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relationship with our employees to be good.

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

Facilities

Our principal office is located at 99 Hayden Avenue, Suite 120, Building E, Lexington, Massachusetts 02421, where we lease approximately 10,400 square feet of office and laboratory space under a lease that terminates in 2022. We believe that these facilities will be adequate for our near-term needs. If required, we believe that suitable additional or substitute space will be available in the future on commercially reasonable terms to accommodate any such expansion of our operations.

Legal Proceedings

From time to time, we may be involved in various other claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any material legal proceedings.

MANAGEMENT

Executive Officers and Directors

The following table sets forth information concerning our executive officers and directors as of October 15, 2020:

NAME	AGE	POSITION(S)
Executive Officers		
Jasbir Seehra, Ph.D.	65	Chief Executive Officer and Director
Keith Regnante	51	Chief Financial Officer
Jennifer Lachey, Ph.D.	48	Chief Scientific Officer
Claudia Ordonez, M.D.	54	Chief Medical Officer
Non-Employee Directors		
Nima Farzan	44	Director
Carl Gordon, Ph.D., C.F.A.	55	Director
Tomer Kariv	59	Director
Julius Knowles	57	Director
Alon Lazarus, Ph.D.	45	Director
Ran Nussbaum	47	Director

Executive Officers

Jasbir Seehra, Ph.D., has served as our Chief Executive Officer and as a member of our board of directors since December 2015. Prior to joining us, Dr. Seehra served as the Chief Scientific Officer at Ember Therapeutics, Inc. from December 2011 to April 2015. From February 2004 to November 2010, Dr. Seehra served as the Co-Founder and Chief Scientific Officer of Acceleron Pharma Inc. Dr. Seehra serves on the board of directors of Eloxx Pharmaceuticals, Inc. He has also served as Vice President of Biological Chemistry at Wyeth Pharmaceuticals Inc. and led the small molecule lead discovery effort at Genetics Institute, Inc., where he helped build the institute's small molecule drug discovery capabilities, including medicinal chemistry, high throughput screening and structural biology. Dr. Seehra received a B.Sc. and a Ph.D. in Biochemistry from the University of Southampton in England. He completed his postdoctoral work at the Massachusetts Institute of Technology. Our board of directors believes that Dr. Seehra's extensive experience in the pharmaceutical industry and executive leadership experience provides him with the qualifications to serve on our board of directors.

Keith Regnante has served as our Chief Financial Officer since February 2020. Prior to joining us, from August 2016 to January 2020, Mr. Regnante served as Chief Financial Officer at Wave Life Sciences Ltd. From February 2014 to August 2016, Mr. Regnante served as Vice President of Finance at Shire Pharmaceuticals, or Shire, a global biopharmaceutical company. Mr. Regnante also served on the Financial Leadership Team and the R&D Leadership Team while he was at Shire. From September 2013 to February 2014, he served as Head of R&D Finance for ARIAD Pharmaceuticals, Inc. From January 1999 to August 2013, Mr. Regnante held multiple finance positions at Biogen Inc., including Senior Director of Corporate Finance from 2011 to 2013, Senior Director of Worldwide R&D Finance from 2008 to 2011 and several other positions dating back to 1999. Prior to these roles, Mr. Regnante worked as a consultant at The Boston Consulting Group. He holds a B.A. in Economics from Tufts University and an M.B.A. from the MIT Sloan School of Management.

Jennifer Lachey, Ph.D., has served as our Chief Scientific Officer since June 2019, and as our Vice President of Biology and Pharmacology since July 2016. Prior to joining us, Dr. Lachey served as a Senior Director at Seres Therapeutics, Inc. from March 2015 to July 2016. From July 2012 to January 2015, Dr. Lachey served as the Senior Director of Preclinical Pharmacology at Ember Therapeutics, Inc. From January 2008 to July 2012, Dr. Lachey served as the Associate Director of Preclinical Pharmacology at Acceleron Pharma Inc. Dr. Lachey

received a B.Sc. in Biology from Indiana University, and a Ph.D. in Neurobiology from the University of Cincinnati. Dr. Lachey completed her post-doctoral training at Beth Israel Deaconess Medical Center.

Claudia Ordonez, M.D., has served as our Chief Medical Officer since September 2019. Prior to joining us, Dr. Ordonez served as vice president of Akcea Therapeutics, Inc. from November 2018 to September 2019. From October 2015 to October 2018, Dr. Ordonez served as Chief Medical Officer of Flatley Discovery Lab. From July 2012 to October 2015, Dr. Ordonez served as Senior Medical Director at Biogen Inc. (formerly Biogen Idec Inc.). From July 2006 to June 2012, Dr. Ordonez served as Senior Medical Director at Vertex Pharmaceuticals, Inc. Dr. Ordonez also served as a full-time attending physician at Boston Children's Hospital from August 1998 to July 2006, maintaining the position on a part-time basis to April 2013. Dr. Ordonez received a B.A. in Biology from the University of Maryland, Baltimore County, and received an M.D. in Medicine and fellowship training at University of California, San Francisco.

Non-Employee Directors

Nima Farzan has served as a member of our board of directors since March 2020. Mr. Farzan has served as the Chief Executive Officer and director of Kinnate Biopharma Inc. since March 2020. Mr. Farzan served as an advisor for a number of life sciences companies from October 2018 to February 2020. From 2011 to October 2018, Mr. Farzan was employed by PaxVax Corporation, serving as its President and Chief Executive Officer from April 2015 until the company's acquisition by Emergent Biosolutions Inc. in October 2018. Prior to PaxVax, Mr. Farzan held positions of increasing seniority at Novartis AG from 2003 to 2011. From 1999 to 2002, Mr. Farzan served in various marketing and business development positions at DoubleTwist, Inc. and from 1997 to 1999, Mr. Farzan served as an associate at The Boston Consulting Group. Nima has a bachelor's degree in Human Biology from Stanford University and an M.B.A. from the Harvard Business School. Our board of directors believes that Mr. Farzan's significant industry experience and corporate management experience qualify him to serve on our board of directors.

Carl Gordon, Ph.D., C.F.A., has served as a member of our board of directors since March 2020. Dr. Gordon is a founding member, Managing Partner and Co-Head of Global Private Equity at OrbiMed Advisors LLC, an investment firm. Dr. Gordon currently serves on the boards of directors of Adicet Bio, Inc., ORIC Pharmaceutics, Inc., Prevail Therapeutics Inc. and Turning Point Therapeutics, Inc., as well as several private companies. Dr. Gordon previously served on the boards of directors of several biopharmaceutical companies, including Alector Inc., ARMO BioSciences, Inc., Intellia Therapeutics, Inc., Passage Bio Inc., Selecta Biosciences, Inc., SpringWorks Therapeutics, Inc. and X4 Pharmaceuticals, Inc. (formerly Arsanis, Inc.), . Dr. Gordon received a B.A. in Chemistry from Harvard College, a Ph.D. in Molecular Biology from the Massachusetts Institute of Technology and was a Fellow at The Rockefeller University. Our board of directors believes that Dr. Gordon's medical expertise, extensive business experience and experience in venture capital and the life science industry qualify him to serve on our board of directors.

Tomer Kariv has served as a member of our board of directors since January 2020. Mr. Kariv has served as Managing Partner and Co-Founder of The Pontifax Group, or Pontifax, a group of Israeli-based life sciences venture funds focusing on investments in development stage bio-pharmaceutical and med-tech technologies, since December 2004. Mr. Kariv currently serves on the boards of Eloxx Pharmaceuticals, Inc. and LogicBio Therapeutics, Inc., and he previously served on the boards of 89bio, Inc., Arno Therapeutics, Inc., Check-Cap Ltd., Macrocure Ltd. and VBI Vaccines Inc. Mr. Kariv also serves as a member of the boards of several private life sciences companies. Mr. Kariv received a B.A. in Economics from Harvard University and a J.D. from Harvard Law School. Our board of directors believes Mr. Kariv's extensive experience as a venture capital investor, financial executive and board member qualifies him to serve on our board of directors.

Julius Knowles has served as a member of our board of directors since April 2016. Since January 2014, Mr. Knowles has served as a Partner at Partners Innovation Fund, the venture arm of Partners HealthCare. From March 2012 to January 2014, Mr. Knowles served as the Chief Executive Officer of X-BODY BioSciences Inc. (acquired by Juno Therapeutics, Inc.). From October 2006 to February 2012, Mr. Knowles was responsible for global technology and drug discovery collaborations at Novartis, including as the Head of the Platforms team for Strategic Alliances at Novartis Institute of Biomedical Research. From March 2002 to June 2006, Mr. Knowles served as the President of Novalar Pharmaceuticals, Inc. Mr. Knowles previously served as the Vice President of Business Development of Novacea, Inc. (acquired by Transcept Pharmaceuticals, Inc.) from June 2001 to March 2002, the Vice President of Business Development of SGX Pharmaceuticals, Inc. from October

1999 to June 2001 and the Director of Research and Development Planning at Vertex Pharmaceuticals, Inc. from June 1993 to October 1999. Mr. Knowles also serves on the board of several private life science companies. Mr. Knowles received a B.A. with distinction in Chemistry from Carleton College, an M.B.A. from the University of Pennsylvania and an M.Sc. in Chemistry from UC Berkeley. Our board of directors believes Mr. Knowles' significant industry experience and corporate management experience qualify him to serve on our board of directors.

Alon Lazarus, Ph.D., has served as a member of our board of directors since April 2016. Dr. Lazarus has held the position of Biotech Investment Manager of the Pharma Division of Arkin Holdings, which focuses mainly on investments in the healthcare and pharmaceutical sectors, since August 2013. Prior to joining Arkin Holdings, Ltd., Dr. Lazarus worked for the Healthcare Business Development Department of Yissum Research Development Company of the Hebrew University of Jerusalem from January 2012 until August 2013, and as an Analyst for Integra Holdings, Ltd., an Israel-based healthcare investment company. Dr. Lazarus serves as a member of the board of directors of several private life science companies. Dr. Lazarus holds a Ph.D. in Molecular Biology from the Hadassah Medical School of Hebrew University of Jerusalem in Israel, an M.B.A. from the School of Business Administration of Hebrew University of Jerusalem in Israel and a B.Sc. in Biology from Hebrew University of Jerusalem in Israel. Our board of directors believes Dr. Lazarus' experience as a member of the board of directors of several biotechnology companies and his comprehensive understanding of the industry qualifies him to serve on our board of directors.

Ran Nussbaum has served as a member of our board of directors since April 2016. Since January 2004, Mr. Nussbaum has served as a Managing Partner and the Co-Founder of Pontifax. He also serves as a board member on many of Pontifax's portfolio companies, including ArQule, Inc. (acquired by Merck & Co., Inc.), Eloxx Pharmaceuticals Ltd., Prevail Therapeutics, Inc. and UroGen Pharma Ltd. Mr. Nussbaum previously served as a director of BioBlast Pharma Ltd., VBI Vaccines Inc. and Kite Pharma, Inc. until its acquisition by Gilead Sciences, Inc. Our board of directors believes Mr. Nussbaum's investment experience in the life sciences industry provides him with the qualifications to serve on our board of directors.

Family Relationships

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

Board Composition

Our business and affairs are managed under the direction of our board of directors, which currently consists of seven members. In accordance with our amended and restated certificate of incorporation, our board of directors is divided into three classes with staggered three-year terms. At each annual general meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors are divided among the three classes as follows:

- Class I, which consists of Jasbir Seehra, Nima Farzan and Julius Knowles, and has a term that expires at our annual meeting of stockholders to be held in 2021;
- Class II, which consists of Alon Lazarus and Ran Nussbaum, and has a term that expires at our annual meeting of stockholders to be held in 2022; and
- Class III, which consists of Tomer Kariv and Carl Gordon, and has a term that expires at our annual meeting of stockholders to be held in 2023.

Our amended and restated bylaws provides that the authorized number of directors may be changed only by resolution approved by a majority of our board of directors.

We expect that any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control.

Director Independence

Our board of directors has undertaken a review of the independence of our directors and considered whether any director has a relationship that, in the opinion of the board of directors, would interfere with the exercise of

independent judgment in carrying out the responsibilities of a member of our board. Based upon information requested from and provided by each director concerning such director's background, employment and affiliations, including family relationships, our board of directors has determined that all of our directors other than Dr. Seehra, representing six of our seven directors, are "independent directors" as defined under the standards of the Nasdaq Stock Market, or Nasdaq. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company 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 and the transactions involving them described in the section of this prospectus titled "Certain Relationships and Related Party Transactions."

Board Committees

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. From time to time, the board may establish other committees to facilitate the management of our business.

Audit Committee

Our audit committee consists of three directors, Mr. Farzan, Mr. Knowles and Dr. Lazarus. Our board of directors has determined that each of these individuals meets the requirements for independence under current rules and regulations of the SEC and the listing standards of Nasdaq. Each member of our audit committee meets the financial literacy requirements of the listing standards of Nasdaq. Mr. Farzan serves as the chairman of the audit committee and our board of directors has determined that Mr. Farzan is an "audit committee financial expert" as defined by Item 407(d) of Regulation S-K under the Securities Act. The principal duties and responsibilities of our audit committee include, among other things:

- selecting a qualified firm to serve as the independent registered public accounting firm to audit our financial statements;
- helping to ensure the independence and performance of the independent registered public accounting firm;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and the independent accountants, our interim and year-end operating results;
- developing procedures for employees to submit concerns anonymously about questionable accounting or audit matters;
- reviewing our policies on risk assessment and risk management;
- reviewing related party transactions;
- obtaining and reviewing a report by the independent registered public accounting firm at least annually, that describes our internal quality-control procedures, any material issues with such procedures, and any steps taken to deal with such issues when required by applicable law; and
- approving (or, as permitted, pre-approving) all audit and all permissible non-audit services, other than de minimis non-audit services, to be performed by the independent registered public accounting firm.

Our audit committee operates under a written charter, which satisfies the applicable rules and regulations of the SEC and the listing standards of Nasdaq.

Compensation Committee

Our compensation committee consists of three directors, Mr. Nussbaum, Dr. Gordon and Dr. Lazarus, each of whom is a non-employee member of our board of directors as defined in Rule 16b-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our board of directors has determined that each of these individuals meets the requirements for independence under current rules and regulations of the SEC and the listing standards of Nasdaq. Mr. Nussbaum serves as the chairman of the compensation committee. The principal duties and responsibilities of our compensation committee include, among other things:

- reviewing and recommending to our board of directors the compensation of our executive officers, including evaluating the performance of our chief executive officer and, with his assistance, that of our other executive officers;
- reviewing and recommending to our board of directors the compensation of our directors;

- reviewing and approving, or recommending that our board of directors approve, the terms of compensatory arrangements with our executive officers;
- administering our equity and non-equity incentive plans;
- reviewing and approving, or recommending that our board of directors approve, incentive compensation and equity plans; and
- reviewing and establishing general policies relating to compensation and benefits of our employees and reviewing our overall compensation philosophy.

Our compensation committee operates under a written charter, which satisfies the applicable rules and regulations of the SEC and the listing standards of Nasdaq.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of three directors, Messrs. Kariv, Farzan and Knowles. Our board of directors has determined that each of these individuals meets the requirements for independence under current rules and regulations of the SEC and the listing standards of Nasdaq. Mr. Kariv serves as the chairman of the nominating and corporate governance committee. The nominating and corporate governance committee's responsibilities include, among other things:

- identifying, evaluating and selecting, or recommending that our board of directors approve, nominees for election to our board of directors and its committees;
- evaluating the performance of our board of directors and of individual directors;
- considering and making recommendations to our board of directors regarding the composition of our board of directors and its committees;
- reviewing developments in corporate governance practices;
- evaluating the adequacy of our corporate governance practices and reporting;
- developing and making recommendations to our board of directors regarding corporate governance guidelines and matters; and
- overseeing an annual evaluation of the board's performance.

Our nominating and governance committee operates under a written charter, which satisfies the applicable rules and regulations of the SEC and the listing standards of Nasdaq.

Code of Business Conduct and Ethics

We maintain a Code of Business Conduct and Ethics, or the Code of Conduct, applicable to all of our employees, executive officers and directors. The Code of Conduct is available on our website at www.kerostx.com. The nominating and corporate governance committee of our board of directors is responsible for overseeing the Code of Conduct and must approve any waivers of the Code of Conduct for employees, executive officers and directors. We expect that any amendments to the Code of Conduct, or any waivers of its requirements, will be disclosed on our website. Information contained in, or accessible through, our website does not constitute a part of, and is not incorporated into, this prospectus.

Compensation Committee Interlocks and Insider Participation

None of our executive officers currently serves, or in our last completed fiscal year has served, as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any entity that has one or more executive officers that has served or is planning to serve on our board of directors or compensation committee. None of the members of our compensation committee is an officer or employee of our company, nor have they ever been an officer or employee of our company.

Non-Employee Director Compensation

During the fiscal year ended December 31, 2019, we did not pay cash or equity-based compensation to any of our non-employee directors for service on our board of directors. We have reimbursed and will continue to reimburse all of our non-employee directors for their reasonable out-of-pocket expenses incurred in attending board of directors and committee meetings.

Dr. Seehra, our Chief Executive Officer, who is also a member of our board of directors, did not receive any additional compensation for service as a director. Dr. Seehra's compensation as a named executive officer is set forth below under "Executive Compensation—Summary Compensation Table."

As of December 31, 2019, none of the non-employee directors held any outstanding option awards or other stock awards to purchase or to be issued our common stock.

On May 29, 2020, our board of directors granted an option to purchase 8,500 shares of our common stock to Nima Farzan, one of our non-employee directors. The shares subject to the option have an exercise price of $28.74 and will vest in equal quarterly installments over the 12 months following the vesting commencement date, subject to Mr. Farzan's continuous service with us as of each such vesting date.

Non-Employee Director Compensation Policy

Our board of directors maintains a non-employee director compensation policy, pursuant to which each of our directors who is not an employee or consultant of our company is eligible to receive compensation for service on our board of directors and committees of our board of directors. In March 2020, following market research and advice from its compensation consultant, our board of directors adopted the non-employee director compensation policy, which became effective on April 7, 2020.

Cash Compensation

Under this policy, we will pay each of our non-employee directors a cash retainer for service on our board of directors and committees of our board of directors. Our non-employee chair also receives an additional cash retainer. These retainers will be payable in arrears in four equal quarterly installments on the last day of each fiscal quarter in which the service occurred, provided that the amount of such payment will be prorated for any portion of such quarter that the director is not serving on our board.

Non-employee directors will be eligible to receive cash compensation as follows:

	ANNUAL CASH RETAINER ($)
Annual retainer	35,000
Additional retainer for chair	30,000
Additional retainer for audit committee chair	15,000
Additional retainer for audit committee member	7,500
Additional retainer for compensation committee chair	10,000
Additional retainer for compensation committee member	5,000
Additional retainer for nominating and corporate governance committee chair	8,000
Additional retainer for nominating and corporate governance committee member	4,000

Equity Compensation

In addition to cash compensation, each non-employee director will be eligible to receive options under the 2020 Equity Incentive Plan. Any options granted under this policy will have a term of ten years from the date of grant, subject to earlier termination in connection with a termination of service. Vesting schedules for equity awards will be subject to the non-employee director's continuous service on each applicable vesting date, provided that each option will vest in full upon a change in control of the company.

Upon the termination of service of the non-employee director for any reason other than death, disability or cause, his or her options granted under this policy shall remain exercisable for 12 months following his or her date of termination.

Initial Award

Each new non-employee director elected or appointed to our board of directors will be granted an initial, one-time option to purchase 16,587 shares of our common stock, which will vest in equal quarterly installments such that the option is fully vested on the third anniversary of the grant date.

Annual Awards

On the date of each annual meeting of stockholders of our company after the effective date of the policy, each non-employee director that continues to serve will be granted an option to purchase 8,293 shares of our common stock, each of which will vest in equal quarterly installments over the 12 months following the grant date, provided that such option will in any case be fully vested on the date of our next annual stockholder meeting.

EXECUTIVE COMPENSATION

The following table summarizes information regarding the compensation awarded to, earned by, or paid to our principal executive officer and the next two most highly compensated executive officers during 2019. We refer to these individuals in this prospectus as our named executive officers. Our named executive officers for 2019 who appear in the 2019 Summary Compensation Table are:

- Jasbir Seehra, Ph.D., Chief Executive Officer and Director;
- Jennifer Lachey, Ph.D., Chief Scientific Officer; and
- Claudia Ordonez, M.D., Chief Medical Officer.

In February 2020, we hired Keith Regnante as our Chief Financial Officer. Although Mr. Regnante commenced services with us in 2020, we have included information in the following narrative regarding his compensation where it may be material to an understanding of our executive compensation program.

Summary Compensation Table

The following table sets forth information concerning the compensation of our named executive officers for the year ended December 31, 2019.

NAME AND PRINCIPAL POSITION	YEAR	SALARY ($)	BONUS ($)	OPTION AWARDS ($)(1)	NON-EQUITY INCENTIVE PLAN COMP. ($)(2)	ALL OTHER COMP. ($)	TOTAL ($)
Jasbir Seehra, Ph.D.(3) *Chief Executive Officer and Director*	2019	485,100	—	15,379	194,040	—	694,519
Jennifer Lachey, Ph.D. *Chief Scientific Officer*	2019	294,255	—	27,039	93,000	—	414,294
Claudia Ordonez, M.D.(4) *Chief Medical Officer*	2019	106,458	30,000 (5)	32,650	32,100	700 (6)	201,908

(1) This column reflects the aggregate grant date fair value of option awards granted during the year measured pursuant to Financial Accounting Standard Board Accounting Standards Codification Topic 718, the basis for computing stock-based compensation in our consolidated financial statements. This calculation assumes that the named executive officer will perform the requisite service for the award to vest in full as required by SEC rules. The assumptions we used in valuing options are described in Note 10 to our consolidated financial statements appearing at the end of this prospectus. These amounts do not reflect the actual economic value that will be realized by the named executive officer upon vesting of the stock options, the exercise of the stock options, or the sale of the common stock underlying such stock options.
(2) This column reflects the amount of performance-based incentive compensation earned by our named executive officers for 2019. For more information, see below under "—Non-Equity Incentive Plan Compensation."
(3) Dr. Seehra is also a member of our board of directors, but does not receive any additional compensation in his capacity as a director.
(4) Dr. Ordonez commenced employment with us in September 2019.
(5) In connection with her commencement of employment, Dr. Ordonez received a one-time signing bonus, which was paid in 2019.
(6) This reflects a monthly payment of $200 that we make to Dr. Ordonez in exchange for her opting not to participate in our health insurance plans.

Narrative to Summary Compensation Table

The compensation committee of our board of directors has historically determined our executives' compensation and determines the compensation of our named executive officers. Our compensation committee typically reviews and discusses management's proposed compensation with the Chief Executive Officer for all executives other than the Chief Executive Officer. Based on those discussions and its discretion, the compensation committee then approves the compensation of each executive officer after discussions without members of management present. We generally do not provide perquisites or personal benefits except in limited circumstances, and we did not provide any perquisites or personal benefits to our named executive officers in 2019.

Annual Base Salary

The annual base salaries of our named executive officers are generally reviewed, determined and approved by the board of directors periodically upon the recommendation of the compensation committee in order to

compensate our named executive officers for the satisfactory performance of duties to our company. Annual base salaries are intended to provide a fixed component of compensation to our named executive officers, reflecting their skill sets, experience, roles and responsibilities. Base salaries for our named executive officers have generally been set at levels deemed necessary to attract and retain individuals with superior talent.

The following table sets forth the annual base salaries for each of our named executive officers for 2019 and 2020:

NAME	2019 BASE SALARY ($)	2020 BASE SALARY ($)(4)
Jasbir Seehra, Ph.D.(1) *Chief Executive Officer and Director*	485,100	525,300
Jennifer Lachey, Ph.D.(2) *Chief Scientific Officer*	310,000	380,000
Claudia Ordonez, M.D(3) *Chief Medical Officer*	365,000	385,000

(1) Dr. Seehra's 2019 base salary was approved by the compensation committee in December 2018.
(2) Dr. Lachey's base salary was increased from $267,842 to $310,000 in June 2019 by the board of directors in connection with Dr. Lachey's promotion to Chief Scientific Officer.
(3) Dr. Ordonez's 2019 base salary was approved by the compensation committee in August 2019 in connection with her commencement of employment.
(4) Amounts reflect current base salaries pursuant to the employment agreements entered into between us and each of our named executive officers in March 2020, as described below under "—Agreements with Our Named Executive Officers."

Non-Equity Incentive Plan Compensation

We seek to motivate and reward our executives for achievements relative to our corporate goals and expectations for each fiscal year. Each of our named executive officers is eligible to receive an annual performance bonus based on the achievement of company-wide annual performance goals as determined by our board of directors upon recommendation by our compensation committee. For 2019, these goals included research and clinical objectives and corporate objectives. Each officer is assigned a target bonus expressed as a percentage of his or her base salary. The target bonus amounts for Dr. Seehra, Dr. Lachey and Dr. Ordonez for 2019 were set at 40%, 30% and 30%, respectively. In December 2019, the board of directors determined that the 2019 corporate goals were achieved at 100% and, as a result, approved annual performance bonuses for Dr. Seehra, Dr. Lachey and Dr. Ordonez in the amounts of $194,040, $93,000 and $32,100, respectively, as reflected in the "Non-Equity Incentive Plan Compensation" column of the Summary Compensation Table above. Dr. Ordonez's 2019 annual bonus amount was prorated to reflect her partial year of employment.

Equity-Based Incentive Awards

In June 2019, in connection with Dr. Lachey's promotion to Chief Scientific Officer, our board of directors granted an option to purchase 48,380 shares to Dr. Lachey. The shares subject to the option have an exercise price per share of $0.48 and vest over a four-year period, with 25% of the shares subject to the option vesting on the first anniversary of the vesting commencement date and 6.25% of the shares subject to the option vesting at the end of each successive three-month period following the first anniversary of the vesting commencement date, subject to Dr. Lachey's continuous service with us as of each such vesting date.

Also in June 2019, our board of directors granted options to purchase 49,087 shares to Dr. Seehra and 36,861 shares to Dr. Lachey. The shares subject to each of the options have an exercise price of $0.48 and vest over a four-year period, with 25% of the shares subject to the option vesting on the first anniversary of the vesting commencement date and 6.25% of the shares subject to the option vesting at the end of each successive three-month period following the first anniversary of the vesting commencement date, subject to the executive's continuous service with us as of each such vesting date.

In September 2019, in connection with Dr. Ordonez's commencement of employment, our board of directors granted an option to purchase 103,211 shares to Dr. Ordonez. The shares subject to the option have an exercise price of $0.48 and vest over a four-year period, with 25% of the shares subject to the option vesting on the first anniversary of the vesting commencement date and 6.25% of the shares subject to the option vesting

at the end of each successive three-month period following the first anniversary of the vesting commencement date, subject to Dr. Ordonez's continuous service with us as of each such vesting date.

In March 2020, in connection with Mr. Regnante's commencement of employment, our board of directors approved an option to Mr. Regnante to purchase 133,622 shares of our common stock, which was granted in April 2020 and has an exercise price of $16.00 per share. The shares subject to the option vest over a four-year period, with 25% of the shares subject to the option vesting on the first anniversary of the vesting commencement date and 6.25% of the shares subject to the option vesting at the end of each successive three-month period following the first anniversary of the vesting commencement date, subject to Mr. Regnante's continuous service with us as of each such vesting date.

In March 2020, our board of directors, based on the recommendation of our compensation committee, approved option grants to each of our named executive officers and Mr. Regnante in the amounts of 696,569 shares to Dr. Seehra, 241,222 shares to Dr. Lachey, 18,430 shares to Dr. Ordonez and 18,430 shares to Mr. Regnante (in addition to his new hire award described above), which were granted in April 2020 and have an exercise price of $16.00 per share. These options vest over a four-year period, with 25% of the shares subject to the option vesting on the first anniversary of the vesting commencement date and 6.25% of the shares subject to the option vesting at the end of each successive three-month period following the first anniversary of the vesting commencement date, subject to the executive officer's continuous service with us as of each such vesting date. The options are eligible to accelerate under certain circumstances in accordance with the named executive officer's or Mr. Regnante's employment agreement. See "—Potential Payments upon Termination or Change of Control" below for a description of vesting acceleration applicable to stock options held by our named executive officers and Mr. Regnante.

Outstanding Equity Awards as of December 31, 2019

The following table sets forth certain information about equity awards granted to our named executive officers that remained outstanding as of December 31, 2019.

	OPTION AWARDS(1)					
NAME	GRANT DATE	VESTING COMMENCEMENT DATE	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS (#) EXERCISABLE	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS (#) UNEXERCISABLE	OPTION EXERCISE PRICE PER SHARE ($)	OPTION EXPIRATION DATE
Jasbir Seehra, Ph.D.	4/3/2017 (2)	1/1/2017	3,455	3,455	0.11	4/2/2027
	3/26/2018 (3)	12/18/2017	301,811	—	0.30	3/25/2028
	3/26/2018 (2)	12/18/2017	27,645	13,822	0.30	3/25/2028
	6/19/2019 (4)	12/1/2018	12,271	36,816	0.48	6/18/2029
Jennifer Lachey, Ph.D.	2/6/2017 (4)	7/1/2016	30,237	12,959	0.11	2/5/2027
	4/3/2017 (2)	1/1/2017	5,529	691	0.11	4/2/2027
	3/26/2018 (3)	12/18/2017	150,905	—	0.30	3/25/2028
	3/26/2018 (2)	12/18/2017	5,529	2,764	0.30	3/25/2028
	6/12/2019 (4)	5/13/2019	—	48,380	0.48	6/11/2029
	6/19/2019 (4)	12/1/2018	9,215	27,645	0.48	6/18/2029
Claudia Ordonez, M.D.	9/19/2019 (4)	9/16/2019	—	103,211	0.48	9/18/2029

(1) All of the option awards were granted under the 2017 Incentive Stock Plan, the terms of which are described below under "—Equity Incentive Plans."
(2) Each option award vests as follows: 8.33% of the shares subject to the option vest at the end of each successive three (3) month period following the vesting commencement date until the third anniversary of the vesting commencement date.
(3) Each option award vests as follows: 50% of the shares subject to the option are fully vested and 6.25% of the shares subject to the option vest at the end of each successive three (3) month period following the vesting commencement date until the second anniversary of the vesting commencement date.
(4) Each option award vests as follows: 25% of the shares subject to the option vest on the first anniversary of the vesting commencement date and 6.25% of the shares subject to the option vest at the end of each successive three (3) month period following the first anniversary of the vesting commencement date until the fourth anniversary of the vesting commencement date.

In September 2019, Dr. Seehra exercised a portion of his April 2017 option and acquired 34,557 shares. We did not make any material modifications to options held by our named executive officers in 2019.

Agreements with Our Named Executive Officers

We have employment agreements or offer letters with each of our named executive officers. The material terms of each of these agreements are described below. These agreements provide for base salaries and incentive compensation, and each component reflects the scope of each named executive officer's anticipated responsibilities and the individual experience they bring to our company. The employment of each of our named executive officers is "at will" and may be terminated at any time. In addition, each of our named executive officers has executed a form of our standard proprietary information and inventions agreement.

Jasbir Seehra, Ph.D. We entered into an offer letter agreement with Dr. Seehra in December 2015, which was amended and restated by an employment agreement entered into in March 2020 and effective on April 13, 2020. Pursuant to his April 2020 agreement, Dr. Seehra is entitled to an annual base salary of $525,300, an annual discretionary bonus with a target amount equal to 50% of his annual base salary and certain severance benefits, as described below under "—Potential Payments upon Termination or Change of Control." Dr. Seehra is eligible to participate in the employee benefit plans generally available to our employees, and is subject to customary confidentiality covenants, as well as a non-competition and non-solicitation covenant for a period of twelve months following termination of his employment.

Jennifer Lachey, Ph.D. We entered into an offer letter agreement with Dr. Lachey in April 2016, which was amended and restated by an employment agreement entered into in March 2020 and effective on April 13, 2020. Pursuant to her April 2020 agreement, Dr. Lachey is entitled to an annual base salary of $380,000, an annual discretionary bonus with a target amount equal to 40% of her annual base salary and certain severance benefits, as described below under "—Potential Payments upon Termination or Change of Control." Dr. Lachey is eligible to participate in the employee benefit plans generally available to our employees, and is subject to customary confidentiality covenants, as well as a non-competition and non-solicitation covenant for a period of 12 months following her termination of employment.

Claudia Ordonez, M.D. We entered into an offer letter agreement with Dr. Ordonez in August 2019, which was amended and restated by an employment agreement entered into in March 2020 and effective on April 13, 2020. Pursuant to the offer letter agreement, Dr. Ordonez was entitled to an initial annual base salary of $365,000, a one-time signing bonus of $30,000 and an annual incentive bonus based on a target amount of 30% of her base salary. In addition, Dr. Ordonez was eligible to receive a stock option to purchase up to 103,211 shares of our common stock, which was granted to Dr. Ordonez in September 2019. Pursuant to her April 2020 agreement, Dr. Ordonez is entitled to an annual base salary of $385,000, an annual discretionary bonus with a target amount equal to 40% of her annual base salary and certain severance benefits, as described below under "—Potential Payments upon Termination or Change of Control." Dr. Ordonez is eligible to participate in the employee benefit plans generally available to our employees, and is subject to customary confidentiality covenants, as well as a non-competition and non-solicitation covenant for a period of 12 months following her termination of employment.

Keith Regnante. We entered into an offer letter agreement with Mr. Regnante in February 2020, which was amended and restated by an employment agreement entered into in March 2020 and effective on April 13, 2020. Pursuant to the offer letter agreement, Mr. Regnante was entitled to an initial annual base salary of $362,000. In addition, Mr. Regnante was eligible to receive a stock option to purchase up to 133,622 shares of our common stock, which was approved by our board of directors in March 2020 and granted in April 2020. Pursuant to his April 2020 agreement, Mr. Regnante is entitled to an annual base salary of $382,200, an annual discretionary bonus with a target amount equal to 40% of his annual base salary and certain severance benefits, as described below under "–Potential Payments upon Termination or Change of Control." Mr. Regnante is eligible to participate in the employee benefit plans generally available to our employees, and is subject to customary confidentiality covenants, as well as a non-competition and non-solicitation covenant for a period of 12 months following his termination of employment.

Potential Payments upon Termination or Change of Control

Regardless of the manner in which a named executive officer's service terminates, each named executive officer, as well as Mr. Regnante, is entitled to receive amounts earned during his or her term of service,

including unpaid salary and unused vacation. Pursuant to the employment agreements entered into with each of our named executive officers and Mr. Regnante in March 2020 and effective on April 13, 2020, our named executive officers and Mr. Regnante are entitled to certain severance benefits, subject to specific requirements, including signing and not revoking a separation agreement and release of claims. Cause, change of control, disability and good reason are defined in the April 2020 agreements.

If the executive is terminated by the company involuntarily without cause (and not due to death or disability) or the executive resigns for good reason, in each case, not in connection with a change of control then:

- With respect to Dr. Seehra and Dr. Lachey, the executive shall be entitled to cash severance equal to continued base salary payments for 12 months; continued vesting of the executive's options for a period of 12 months; a lump sum payment equal to 100% of the executive's target bonus pro-rated for the year of termination, only if the executive is terminated on or after July 1 of the calendar year; and payment of COBRA premiums for up to 12 months for Dr. Seehra or up to 9 months for Dr. Lachey.
- With respect to Dr. Ordonez and Mr. Regnante, the executive will be entitled to cash severance equal to continued base salary payments for nine months and payment of COBRA premiums for up to nine months.

If immediately before or within 12 months following a change of control, the executive is terminated by the company or successor involuntarily without cause (and not due to death or disability) or the executive resigns for good reason, the executive shall be entitled to cash severance equal to continued base salary payments for 18 months for Dr. Seehra or for 12 months for our other named executive officers and Mr. Regnante; acceleration of all of the executive's unvested and outstanding equity awards; a lump sum payment equal to 100% of the executive's target bonus for the year of termination; and payment of COBRA premiums for up to 18 months for Dr. Seehra or up to 12 months for our other named executive officers and Mr. Regnante.

Each of our named executive officers' stock options granted prior to April 7, 2020 are subject to the terms of the 2017 Stock Incentive Plan, or 2017 Plan; a description of the termination and change in control provisions in the 2017 Plan and stock options granted thereunder is provided below under "—Equity Incentive Plans."

Equity Incentive Plans

The principal features of our equity incentive plans are summarized below. These summaries are qualified in their entirety by reference to the actual text of the plans, which are filed as exhibits to the registration statement of which this prospectus is a part.

2020 Equity Incentive Plan

In March 2020, our board of directors adopted and our stockholders approved our 2020 Plan. The 2020 Plan became effective on April 7, 2020. After such time, no further grants have been or will be made under our 2017 Plan, as described in "—2017 Stock Incentive Plan." As of September 30, 2020, there were outstanding stock options covering a total of 1,419,504 shares of our common stock that were granted under our 2020 Plan.

Awards. Our 2020 Plan provides for the grant of stock options qualifying as incentive stock options, or ISOs, within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended, or the Code, to our employees and for the grant of nonstatutory stock options, or NSOs, restricted stock awards, restricted stock unit awards, stock appreciation rights, performance stock awards and other forms of stock compensation to our employees, consultants and directors. Our 2020 Plan also provides for the grant of performance cash awards to our employees, consultants and directors. We have only granted stock options under the 2020 Plan.

Authorized Shares. The number of shares of our common stock initially reserved for issuance under our 2020 Plan is the sum of (i) 1,002,874 new shares of our common stock, plus (ii) an additional number of shares not to exceed 2,104,937 shares, consisting of (A) the number of shares remaining available for issuance under our 2017 Plan when the 2020 Plan became effective and (B) the number of shares of our common stock subject to outstanding awards under our 2017 Plan when the 2020 Plan became effective that thereafter expire or are forfeited, canceled, withheld to satisfy tax withholding or to purchase or exercise an award, reacquired by us or are otherwise terminated. The number of shares of our common stock reserved for issuance under our 2020 Plan will automatically increase on January 1 of each year, for a period of ten years, from January 1, 2021 continuing through January 1, 2030, by 4.0% of the total number of shares of our common stock outstanding on

December 31 of the preceding calendar year, or a lesser number of shares as may be determined by our board of directors. The maximum number of shares that may be issued pursuant to the exercise of ISOs under the 2020 Plan is 9,323,434.

Shares issued under our 2020 Plan may be authorized but unissued or reacquired shares of our common stock. Shares subject to stock awards granted under our 2020 Plan that expire or terminate without being exercised in full, or that are paid out in cash rather than in shares, will not reduce the number of shares available for issuance under our 2020 Plan. Additionally, shares issued pursuant to stock awards under our 2020 Plan that we repurchase or that are forfeited, as well as shares reacquired by us as consideration for the exercise or purchase price of a stock award or to satisfy tax withholding obligations related to a stock award, will become available for future grant under our 2020 Plan.

Administration. Our board of directors, or a duly authorized committee thereof, has the authority to administer our 2020 Plan. Our board of directors has delegated its authority to administer our 2020 Plan to our compensation committee under the terms of the compensation committee's charter. The administrator may also delegate to one or more of our officers the authority to (i) designate employees other than officers to receive specified stock awards and (ii) determine the number of shares of our common stock to be subject to such stock awards. Subject to the terms of our 2020 Plan, the administrator has the authority to determine the terms of awards, including recipients, the exercise price or strike price of stock awards, if any, the number of shares subject to each stock award, the fair market value of a share of our common stock, the vesting schedule or performance criteria applicable to the awards, together with any vesting acceleration, the form of consideration, if any, payable upon exercise or settlement of the stock award and the terms and conditions of the award agreements for use under our 2020 Plan.

The administrator has the power to modify outstanding awards under our 2020 Plan. Subject to the terms of our 2020 Plan, the administrator has the authority to reprice any outstanding stock award, cancel and re-grant any outstanding stock award in exchange for new stock awards, cash or other consideration, or take any other action that is treated as a repricing under generally accepted accounting principles, with the consent of any adversely affected participant.

Stock Options. ISOs and NSOs are granted under stock option agreements adopted by the administrator. The administrator determines the exercise price for stock options, within the terms and conditions of the 2020 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2020 Plan vest at the rate specified in the stock option agreement, as determined by the administrator.

The administrator determines the term of stock options granted under the 2020 Plan, up to a maximum of ten years. Unless the terms of an optionholder's stock option agreement provide otherwise, if an optionholder's service relationship with us or any of our affiliates ceases for any reason other than disability, death or cause, the optionholder may generally exercise any vested options for a period of three months following the cessation of service. This period may be extended in the event that exercise of the option is prohibited by applicable securities laws. If an optionholder's service relationship with us or any of our affiliates ceases due to death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of 24 months following the date of death. If an optionholder's service relationship with us or any of our affiliates ceases due to disability, the optionholder may generally exercise any vested options for a period of 12 months following the cessation of service. In the event of an optionholder's termination for cause, options generally terminate upon the termination date. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of our common stock issued upon the exercise of a stock option will be determined by the administrator and may include (1) cash, check, bank draft or money order, (2) a broker-assisted cashless exercise, (3) the tender of shares of our common stock previously owned by the optionholder subject to certain limitations set forth in the 2020 Plan, (4) a net exercise of the option if it is an NSO or (5) other legal consideration approved by the administrator.

Unless the administrator provides otherwise, options generally are not transferable except by will or the laws of descent and distribution. Subject to approval of the administrator or a duly authorized officer, an option may be

transferred pursuant to a domestic relations order, official marital settlement agreement or other divorce or separation instrument.

Tax Limitations on ISOs. The aggregate fair market value, determined at the time of grant, of our common stock with respect to ISOs that are exercisable for the first time by an award holder during any calendar year under all of our stock plans may not exceed $100,000. Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless (1) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant and (2) the term of the ISO does not exceed five years from the date of grant.

Restricted Stock Unit Awards. Restricted stock unit awards are granted under restricted stock unit award agreements adopted by the administrator. Restricted stock unit awards may be granted in consideration for any form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. A restricted stock unit award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the administrator or in any other form of consideration set forth in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit award. Except as otherwise provided in the applicable award agreement, restricted stock unit awards that have not vested will be forfeited once the participant's continuous service ends for any reason.

Restricted Stock Awards. Restricted stock awards are granted under restricted stock award agreements adopted by the administrator. A restricted stock award may be awarded in consideration for cash, check, bank draft or money order, past or future services to us or any other form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. The administrator determines the terms and conditions of restricted stock awards, including vesting and forfeiture terms. If a participant's service relationship with us ends for any reason, we may receive any or all of the shares of our common stock held by the participant that have not vested as of the date the participant terminates service with us through a forfeiture condition or a repurchase right.

Stock Appreciation Rights. Stock appreciation rights are granted under stock appreciation right agreements adopted by the administrator. The administrator determines the purchase price or strike price for a stock appreciation right, which generally cannot be less than 100% of the fair market value of our common stock on the date of grant. A stock appreciation right granted under the 2020 Plan vests at the rate specified in the stock appreciation right agreement as determined by the administrator. Stock appreciation rights may be settled in cash or shares of our common stock, or in any other form of payment, as determined by the administrator.

The administrator determines the term of stock appreciation rights granted under the 2020 Plan, up to a maximum of ten years. If a participant's service relationship with us or any of our affiliates ceases for any reason other than cause, disability or death, the participant may generally exercise any vested stock appreciation right for a period of three months following the cessation of service. This period may be further extended in the event that exercise of the stock appreciation right following such a termination of service is prohibited by applicable securities laws. If a participant's service relationship with us, or any of our affiliates, ceases due to disability or death, or a participant dies within a certain period following cessation of service, the participant or a beneficiary may generally exercise any vested stock appreciation right for a period of 12 months in the event of disability and 24 months in the event of death. In the event of a termination for cause, stock appreciation rights generally terminate immediately upon the occurrence of the event giving rise to the termination of the individual for cause. In no event may a stock appreciation right be exercised beyond the expiration of its term.

Performance Awards. The 2020 Plan permits the grant of performance awards that may be settled in stock, cash or other property. Performance awards may be structured so that the stock or cash will be issued or paid only following the achievement of certain pre-established performance goals during a designated performance period. Performance awards that are settled in cash or other property are not required to be valued in whole or in part by reference to, or otherwise based on, our common stock.

The performance goals may be based on any measure of performance selected by the board of directors. The performance goals may be based on company-wide performance or performance of one or more business units, divisions, affiliates or business segments, and may be either absolute or relative to the performance of

one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise by the board of directors at the time the performance award is granted, the board will appropriately make adjustments in the method of calculating the attainment of performance goals as follows: (i) to exclude restructuring and/or other nonrecurring charges; (ii) to exclude exchange rate effects; (iii) to exclude the effects of changes to generally accepted accounting principles; (iv) to exclude the effects of any statutory adjustments to corporate tax rates; (v) to exclude the effects of items that are "unusual" in nature or occur "infrequently" as determined under generally accepted accounting principles; (vi) to exclude the dilutive effects of acquisitions or joint ventures; (vii) to assume that any business divested by us achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; (viii) to exclude the effect of any change in the outstanding shares of our common stock by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (ix) to exclude the effects of stock-based compensation and the award of bonuses under our bonus plans; (x) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles; and (xi) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles.

Other Stock Awards. The administrator may grant other awards based in whole or in part by reference to our common stock. The administrator will set the number of shares under the stock award (or cash equivalent) and all other terms and conditions of such awards.

Limitation on Grants to Non-Employee Directors. The maximum number of shares of our common stock subject to awards granted under our 2020 Plan or otherwise to any of our non-employee directors with respect to any period commencing on the date of our annual meeting of stockholders for a particular year and ending on the day immediately prior to the date of our annual meeting of stockholders for the next subsequent year, taken together with any cash fees paid by us to such non-employee director with respect to such period for serving on our board, will not exceed $500,000 in total value (the value of any such stock awards to be based on their grant date fair market value for financial reporting purposes), or, with respect to such period in which a non-employee director is first appointed or elected to our board, $700,000.

Changes to Capital Structure. In the event there is a specified type of change in our capital structure, such as a stock split, reverse stock split or recapitalization, appropriate and proportionate adjustments will be made to (1) the class and maximum number of shares reserved for issuance under the 2020 Plan, (2) the class and maximum number of shares by which the share reserve may increase automatically each year, (3) the class and maximum number of shares that may be issued on the exercise of ISOs and (4) the class and number of shares and exercise price, strike price or purchase price of outstanding stock awards.

Corporate Transactions. The following applies to stock awards under the 2020 Plan in the event of a corporate transaction, unless otherwise provided in a participant's stock award agreement or other written agreement with us or one of our affiliates or unless otherwise expressly provided by the administrator at the time of grant. In the event of a corporate transaction, any stock awards outstanding under the 2020 Plan may be assumed, continued or substituted for by any surviving or acquiring corporation (or its parent company), and any reacquisition or repurchase rights held by us with respect to the stock award may be assigned to the successor (or its parent company). If the surviving or acquiring corporation (or its parent company) does not assume, continue or substitute for such stock awards, then (i) with respect to any such stock awards that are held by participants whose continuous service has not terminated prior to the effective time of the corporate transaction, or current participants, the vesting (and exercisability, if applicable) of such stock awards will be accelerated in full (meaning at 100% of target level for certain performance awards, unless the administrator or relevant award agreement provides otherwise) to a date prior to the effective time of the corporate transaction (contingent upon the effectiveness of the corporate transaction), and such stock awards will terminate if not exercised (if applicable) at or prior to the effective time of the corporate transaction, and any reacquisition or repurchase rights held by us with respect to such stock awards will lapse (contingent upon the effectiveness of the corporate transaction), and (ii) any such stock awards that are held by persons other than current participants will terminate if not exercised (if applicable) prior to the effective time of the corporate transaction, except that any reacquisition or repurchase rights held by us with respect to such stock awards will not terminate and may continue to be exercised notwithstanding the corporate transaction.

In the event a stock award will terminate if not exercised prior to the effective time of a corporate transaction, the administrator may provide, in its sole discretion, that the holder of such stock award may not exercise such stock award but instead will receive a payment equal in value to the excess (if any) of (i) the value of the property the holder would have received upon the exercise of the stock award, over (ii) any per share exercise price payable by such holder provided in the stock award. In addition, any escrow, holdback, earn out or similar provisions in the definitive agreement for the corporate transaction may apply to such payment to the same extent and in the same manner as such provisions apply to the holders of our common stock.

Under the 2020 Plan, a corporate transaction is generally the consummation of: (1) a sale of all or substantially all of our assets, (2) the sale or disposition of more than 50% of our outstanding securities, (3) a merger, consolidation or similar transaction where we do not survive the transaction or (4) a merger, consolidation or similar transaction where we do survive the transaction but the shares of our common stock outstanding immediately before such transaction are converted or exchanged into other property by virtue of the transaction.

Change in Control. The administrator may provide, in an individual award agreement or in any other written agreement between us and the participant, that the stock award will be subject to additional acceleration of vesting and exercisability in the event of a change in control (as defined in the 2020 Plan). In the absence of such a provision, no such acceleration of the stock award will automatically occur, except as described above.

Under the 2020 Plan, a change in control is generally (1) the acquisition by any person or company of more than 50% of the combined voting power of our then-outstanding stock, (2) a consummated merger, consolidation or similar transaction in which our stockholders immediately before the transaction do not own, directly or indirectly, more than 50% of the combined voting power of the surviving entity (or the parent of the surviving entity) in substantially the same proportions as their ownership immediately prior to such transaction, (3) a sale, lease, exclusive license or other disposition of all or substantially all of our assets other than to an entity more than 50% of the combined voting power of which is owned by our stockholders in substantially the same proportions as their ownership of our outstanding voting securities immediately prior to such transaction or (4) when a majority of our board of directors becomes comprised of individuals who were not serving on our board of directors on the date the 2020 Plan was adopted by the board of directors, or the incumbent board, or whose nomination, appointment, or election was not approved by a majority of the incumbent board still in office.

Amendment or Termination. Our board has the authority to amend, suspend, or terminate our 2020 Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. No ISOs may be granted after the tenth anniversary of the date our board of directors adopts our 2020 Plan.

2017 Stock Incentive Plan

Our board of directors adopted the 2017 Plan in February 2017, and our stockholders approved the 2017 Plan in March 2017. The 2017 Plan was most recently amended in March 2020. As of September 30, 2020, there were outstanding stock options covering a total of 1,064,648 shares of our common stock that were granted under the 2017 Plan. In April 2020, upon the effective date of the 2020 Plan, the 2017 Plan ceased to be available for new grants of equity awards, and any shares remaining available for issuance under the 2017 Plan became available for issuance under the 2020 Plan.

Stock Awards. The 2017 Plan provided for the grant of ISOs within the meaning of Section 422 of the Code to our employees, including employees of any parent or subsidiary, and for the grant of NSOs, restricted stock, restricted stock units and other forms of stock-based awards to our employees, officers, directors, consultants and advisors, including employees, officers, directors, consultants and advisors of any parent or subsidiary. We only granted stock options under the 2017 Plan.

Authorized Shares. Subject to certain capitalization adjustments, the aggregate number of shares of our common stock that could be issued pursuant to stock awards under the 2017 Plan could not exceed 2,283,618 shares.

Effective as of April 7, 2020, shares that would otherwise return to the 2017 Plan will become available under the 2020 Plan, as described above under "—2020 Equity Incentive Plan."

Plan Administration. Our board of directors, or a duly authorized committee of our board of directors to which the board delegates its administrative authority, administers the 2017 Plan and is referred to as the "plan administrator" herein. The plan administrator may also delegate to one or more of our officers the authority powers under the 2017 Plan as the plan administrator may determine.

Under the 2017 Plan, the plan administrator has the authority to, among other things, (1) construe and interpret the terms of the 2017 Plan and any stock award agreements entered into under it, (2) adopt, amend and repeal administrative rules, guidelines and practices relating to the 2017 Plan, (3) correct any defect, supply any omission or reconcile any inconsistency in the 2017 Plan or any stock award and (4) accelerate stock awards in full or in part.

The plan administrator also has the authority to amend, modify or terminate any outstanding stock award, including but not limited to, substituting another stock award of the same or a different type, changing the date of exercise or realization, and converting an ISO into an NSO. The participant's consent to such action is required unless (1) the plan administrator determines that the action would not materially and adversely affect the participant's rights under the 2017 Plan, (2) the change is permitted under the terms of the 2017 Plan governing changes in our capital structure and reorganization events or (3) the change is to ensure that a stock option intended to qualify as an ISO qualifies as such. Additionally, the plan administrator has the authority to, without stockholder approval, (1) amend any outstanding stock award granted under the 2017 Plan to provide an exercise price per share that is lower than the then-current exercise price per share of such outstanding stock award and (2) cancel any outstanding stock award and grant in substitution new stock awards under the 2017 Plan covering the same or a different number of shares of our common stock and having an exercise price per share that is lower than the then-current exercise price per share of the cancelled award.

Stock Options. ISOs and NSOs are generally granted under stock option agreements adopted by the plan administrator. The plan administrator determined the number of shares covered by each stock option and the applicable exercise price, within the terms and conditions of the 2017 Plan, provided that the exercise price of an NSO (for California residents) or an ISO (except as described below) generally cannot be less than 85% or 100%, respectively, of the fair market value of our common stock on the date of grant. Subject to the provisions of the 2017 Plan, stock options granted under the 2017 Plan are exercisable at such times and subject to such terms and conditions as the plan administrator has specified in the applicable stock option agreement.

The plan administrator determined the term of stock options granted under the 2017 Plan, which is generally a maximum of ten years. If an optionholder's service relationship with us (or any parent or subsidiary) ceases for any reason other than death, disability or cause, the optionholder may generally exercise any exercisable options for a period of up to three months following the cessation of service. If an optionholder's service relationship with us (or any parent or subsidiary) ceases due to death or disability, the optionholder or an authorized transferee, in the event of death, may generally exercise any exercisable options for a period of up to one year following the date of death or disability. In the event of a termination for cause, options generally terminate upon the termination date. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of our common stock issued upon the exercise of a stock option will be determined by the plan administrator and may include: (1) cash or check payable to us; (2) a broker-assisted cashless exercise; (3) the tender of shares of our common stock previously owned by the optionholder; (4) delivery of a promissory note of the optionholder to us on terms determined by the plan administrator; (5) payment of other lawful consideration as the plan administrator may determine; or (6) any combination of the foregoing permitted forms of payment.

Transferability. Unless the plan administrator provides otherwise, stock options granted under the 2017 Plan generally may not be sold, assigned, transferred, pledged or otherwise encumbered by the optionholder to whom they are granted, except by will or the laws of descent and distribution or, other than in the case of an ISO, pursuant to a qualified domestic relations order. During the lifetime of the optionholder, stock options are exercisable only by the optionholder.

Tax Limitations on ISOs. The aggregate fair market value, determined at the time of grant, of our common stock with respect to ISOs that are exercisable for the first time by an optionholder during any calendar year under all of our stock plans may not exceed $100,000. Stock options or portions thereof that exceed such limit will be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is

deemed to own stock possessing more than 10% of our total combined voting power or that of any of our parent or subsidiary corporations unless (1) the exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant, and (2) the term of the ISO does not exceed five years from the date of grant.

Changes to Capital Structure. In the event of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any dividend or distribution to holders of our common stock other than an ordinary cash dividend, the plan administrator, in its discretion, will make equitable adjustments to (1) the number and class of securities available under the 2017 Plan and (2) the number and class of securities and exercise price per share of each outstanding stock option.

Reorganization Events. The 2017 Plan provides that, in the event of a "reorganization event," the plan administrator may take any one or more of the following actions as to all or any outstanding stock options on such terms as the plan administrator determines:

- provide for the assumption or substitution of a stock option by an acquiring or succeeding corporation (or any affiliate thereof);
- upon written notice to the participant, provide that a participant's unexercised stock options will terminate immediately prior to the consummation of such reorganization event unless exercised by the participant within a specified period following the date of such notice;
- provide that outstanding stock options will become exercisable, realizable or deliverable, as applicable, or restrictions applicable to a stock option will lapse, in whole or in part, prior to or upon such reorganization event;
- in the event of a reorganization event under the terms of which holders of our common stock will receive a cash payment for each share surrendered in the reorganization event upon its consummation (the "acquisition price"), make or provide for a cash payment equal to the excess, if any, of (A) the acquisition price times the number of shares of our common stock subject to the participant's stock options (to the extent the exercise price does not exceed the acquisition price) over (B) the aggregate exercise price of all such outstanding stock options and any applicable tax withholdings, in exchange for the termination of such stock options;
- provide that, in connection with our liquidation or dissolution, stock options will convert into the right to receive liquidation proceeds; or
- any combination of the foregoing.

The plan administrator is not obligated to treat all stock options or all stock options held by a participant.

Under the 2017 Plan, a "reorganization event" is generally defined as: (1) our merger or consolidation with or into another entity, resulting in all of our common stock being (i) converted into or exchanged for the right to receive cash, securities or other property or (ii) cancelled; (2) any exchange of all of our common stock for cash, securities or other property pursuant to a share exchange transaction; or (3) our liquidation or dissolution.

Plan Amendment or Termination. The plan administrator has the authority to amend, suspend or terminate the 2017 Plan or any portion of it at any time, provided (i) that any such amendment does not materially and adversely affect the rights of participants under the 2017 Plan and (ii) that if at any time the approval of our stockholders is required as to any modification or amendment under Section 422 of the Code with respect to ISOs, our plan administrator may not effect such modification or amendment without such approval. Once the 2020 Plan became effective on April 7, 2020, no further grants have been or will be made under the 2017 Plan.

2020 Employee Stock Purchase Plan

In March 2020, our board of directors adopted and our stockholders approved our 2020 Employee Stock Purchase Plan, or ESPP. The ESPP became effective on April 7, 2020. The purpose of the ESPP is to secure the services of new employees, to retain the services of existing employees and to provide incentives for such individuals to exert maximum efforts toward our success. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Code.

Share Reserve. The ESPP authorizes the issuance of shares of our common stock pursuant to purchase rights granted to our employees or to employees of any of our designated affiliates. The ESPP initially provides

participating employees with the opportunity to purchase up to an aggregate of 182,341 shares of our common stock. The number of shares of our common stock reserved for issuance will automatically increase on January 1 of each calendar year, from January 1, 2021 through January 1, 2030, by the lesser of (i) 1.0% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, and (ii) 455,852 shares; provided, that prior to the date of any such increase, our board of directors may determine that such increase will be less than the amount set forth in clauses (i) and (ii). If purchase rights granted under the ESPP terminate without having been exercised, the shares of our common stock not purchased under such purchase rights will again become available for issuance under the ESPP.

Administration. Our board of directors has delegated concurrent authority to administer the ESPP to our compensation committee. The ESPP is implemented through a series of offerings under which eligible employees are granted purchase rights to purchase shares of our common stock on specified dates during such offerings. Under the ESPP, we may specify offerings with durations of not more than 27 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our common stock will be purchased for employees participating in the offering. An offering under the ESPP may be terminated under certain circumstances.

Payroll Deductions. Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, may participate in the ESPP and may contribute, normally through payroll deductions, up to 15% of their earnings (as defined in the ESPP) for the purchase of our common stock under the ESPP. Unless otherwise determined by our board of directors, common stock will be purchased for the accounts of employees participating in the ESPP at a price per share that is at least the lesser of (i) 85% of the fair market value of a share of our common stock on the first trading date of an offering or (ii) 85% of the fair market value of a share of our common stock on the date of purchase.

Limitations. Employees may have to satisfy one or more of the following service requirements before participating in the ESPP, as determined by our board of directors, including: (i) being customarily employed for more than 20 hours per week; (ii) being customarily employed for more than five months per calendar year; or (iii) continuous employment with us or one of our affiliates for a period of time (not to exceed two years). No employee may purchase shares under the ESPP at a rate in excess of $25,000 worth of our common stock based on the fair market value per share of our common stock at the beginning of an offering for each year such a purchase right is outstanding. Finally, no employee will be eligible for the grant of any purchase rights under the ESPP if immediately after such rights are granted, such employee has voting power over 5% or more of our outstanding capital stock measured by vote or value pursuant to Section 424(d) of the Code.

Changes to Capital Structure. In the event that there occurs a change in our capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or similar transaction, the board of directors will make appropriate adjustments to (i) the maximum number of shares reserved under the ESPP, (ii) the maximum number of shares by which the share reserve may increase automatically each year, (iii) the number of shares and purchase price applicable to all outstanding offerings and purchase rights and (iv) the number of shares that are subject to purchase limits under ongoing offerings.

Corporate Transactions. In the event of certain significant corporate transactions, including (i) the consummation of a sale of all or substantially all of our assets, (ii) the consummation of a sale or disposition of more than 50% of our outstanding securities, (iii) the consummation of a merger or consolidation where we do not survive the transactions and (iv) the consummation of a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction, any then-outstanding rights to purchase our stock under the ESPP may be assumed, continued or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue or substitute for such purchase rights, then the participants' accumulated payroll contributions will be used to purchase shares of our common stock within ten business days prior to such corporate transaction, and such purchase rights will terminate immediately after such purchase.

Amendments or Termination. Our board of directors has the authority to amend or terminate our ESPP, provided that except in certain circumstances such amendment or termination may not materially impair any

outstanding purchase rights without the holder's consent. We will obtain stockholder approval of any amendment to our ESPP, as required by applicable law or listing requirements.

401(k) Plan

We maintain a 401(k) plan intended to qualify as a tax-qualified plan under Section 401 of the Code, with the 401(k) plan's related trust intended to be tax exempt under Section 501(a) of the Code. The 401(k) plan provides that each participant may contribute up to the lesser of 100% of his or her compensation or the statutory limit, which was $19,000 for calendar year 2019 and $19,500 for calendar year 2020 (each subject to catch-up contributions for individuals aged 50 and over). We have the ability to make discretionary contributions to the 401(k) plan but have not done so to date. Employees' pre-tax contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participant's directions. Employees are immediately and fully vested in their contributions. As a tax-qualified retirement plan, contributions to the 401(k) plan and earnings on those contributions are not taxable to the employees until distributed from the 401(k) plan.

Rule 10b5-1 Sales Plans

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from the director or officer. It is also possible that the director or officer could amend or terminate the plan when not in possession of material, nonpublic information. In addition, our directors and executive officers may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material, nonpublic information.

Limitations on Liability and Indemnification Matters

Our amended and restated certificate of incorporation contains provisions that limit the liability of our current and former directors for monetary damages to the fullest extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to the corporation or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not apply to liabilities arising under federal securities laws and do not affect the availability of equitable remedies, such as injunctive relief or rescission.

We have entered into separate indemnification agreements with each of our directors and officers, in addition to the indemnification provided for in our bylaws. These indemnification agreements provide, among other things, that we will indemnify our directors and officers for certain expenses, including damages, judgments, fines, penalties, settlements and costs and attorneys' fees and disbursements, incurred by a director or officer in any claim, action or proceeding arising in his or her capacity as a director or officer of our company or in connection with service at our request for another corporation or entity. The indemnification agreements also provide for procedures that will apply in the event that a director or officer makes a claim for indemnification.

We also maintain a directors' and officers' insurance policy pursuant to which our directors and officers are insured against liability for actions taken in their capacities as directors and officers. We believe that these indemnification provisions and insurance are useful to attract and retain qualified directors and officers.

The limitation of liability and indemnification provisions that are contained in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder's investment may be harmed to the extent we pay the costs of settlement and

damage awards against directors and officers pursuant to these indemnification provisions. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Other than compensation arrangements, we describe below transactions and series of similar transactions, since January 1, 2017, to which we were a party or will be a party, in which:

- the amount involved exceeded or will exceed the lesser of $120,000 and one percent of the average of our total assets at year-end for the last two completed fiscal years; and
- any of our directors, executive officers or holders of more than 5% of any class of our capital stock at the time of such transaction, or any member of the immediate family of the foregoing persons, which we refer to as our related parties, had or will have a direct or indirect material interest.

We have entered into various employment-related agreements and compensatory arrangements with our directors and executive officers that, among other things, provide for compensatory benefits. For a description of these agreements and arrangements, see the sections titled "Management" and "Executive Compensation."

Participation in Our Initial Public Offering

In connection with our initial public offering, or IPO, certain of our related parties purchased shares of our common stock from the underwriters at the IPO price of $16.00 per share, and on the same terms as other investors in our IPO. The following table summarizes purchases of shares of our common stock in our IPO by our related parties:

RELATED PARTY	SHARES OF COMMON STOCK	TOTAL PURCHASE PRICE
Entities affiliated with OrbiMed(1)	562,500	$ 9,000,000
Entities affiliated with Pontifax(2)	437,499	$ 6,999,984
Foresite Capital Fund IV, L.P.(3)	125,000	$ 2,000,000
Arkin Bio Ventures Limited Partnership(4)	120,000	$ 1,920,000
Jasbir Seehra, Ph.D.(5)	20,000	$ 320,000

(1) Represents (i) 375,200 shares of common stock purchased by OrbiMed Private Investments VII, LP, or OPI VII and (ii) 187,300 shares of common stock purchased by The Biotech Growth Trust PLC, or BIOG. OPI VII and BIOG are collectively referred to as the OrbiMed Entities. OrbiMed Capital GP VII, or OrbiMed GP VII, is the general partner of OPI VII and OrbiMed Advisors LLC. OrbiMed Advisors, is the managing member of OrbiMed GP VII. OrbiMed Capital LLC, or OrbiMed Capital, is the investment advisor of BIOG. OrbiMed Capital is a relying adviser of OrbiMed Advisors. Carl Gordon, Ph.D., C.F.A., a member of our board of directors, is a managing partner of OrbiMed Advisors and, as a result, may be deemed to share voting and investment power with respect to the shares held by each of the OrbiMed Entities. The OrbiMed Entities collectively hold more than 5% of our capital stock prior to this offering.

(2) Represents (i) 194,203 shares of common stock purchased by Pontifax (Israel) IV, L.P., or Pontifax Israel, (ii) 94,546 shares of common stock purchased by Pontifax (Cayman) IV, L.P., or Pontifax Cayman, (iii) 105,000 shares of common stock purchased by Pontifax (China) IV, L.P., or Pontifax China, and (iv) 43,750 shares of common stock purchased by Pontifax Late Stage Fund L.P., or Pontifax Late Stage. Pontifax Israel, Pontifax Cayman and Pontifax China are collectively referred to as the Pontifax IV Funds. The Pontifax IV Funds and Pontifax Late Stage are collectively referred to as the Pontifax Entities. Tomer Kariv and Ran Nussbaum, both members of our board of directors, are the Managing Partners of Pontifax Management 4 G.P. (2015) Ltd., or Pontifax Management, the general partner of each of the Pontifax IV Funds, and, as a result, may be deemed to share voting and investment power with respect to the shares held by each of the Pontifax IV Funds. Pursuant to Strategic Alliance Agreement, dated August 9, 2018, between Pontifax Late Stage and the Pontifax IV Funds, Pontifax Late Stage invests side-by-side with the Pontifax IV Funds. By virtue of the strategic relationship, each of Pontifax Management, Mr. Kariv and Mr. Nussbaum may be deemed to share voting and dispositive power with respect to the shares held by Pontifax Late Stage in a manner similar to the voting and investment power with respect to the shares held by each of the Pontifax IV Funds. The Pontifax Entities collectively hold more than 5% of our capital stock prior to this offering.

(3) Foresite Capital Fund IV, L.P. is a holder of more than 5% of our capital stock prior to this offering.

(4) Alon Lazarus, Ph.D., a member of our board of directors, is the Biotech Investment Manager of the Pharma Division of Arkin Holdings and, as a result, may be deemed to share voting and investment power with respect to the shares held by Arkin Bio Ventures Limited Partnership. Arkin Bio Ventures Limited Partnership is a holder of more than 5% our capital stock prior to this offering.

(5) Dr. Seehra is our Chief Executive Officer and a member of our board of directors.

Massachusetts General Hospital Exclusive Patent License Agreement

In April 2016, we entered into an exclusive patent license agreement with The General Hospital Corporation, or MGH, as subsequently amended in May 2017 and February 2018, or the MGH Agreement, pursuant to which we obtained an exclusive, worldwide license of certain intellectual property owned by MGH. MGH is an affiliate of Partners Innovation Fund, LLC, a 5% holder of our capital stock. For a more detailed description of the MGH Agreement, see "Business—Collaborations and License Agreements—2016 Exclusive Patent License Agreement with The General Hospital Corporation."

Private Placements of Securities

Series A Preferred Stock Financing

In April 2016, April 2017 and November 2017, we sold an aggregate of 4,607,652 shares of our Series A preferred stock in multiple closings at a purchase price of $2.17 per share for an aggregate amount of $10.0 million. Upon the closing of our IPO in April 2020, all 4,607,652 shares of our Series A preferred stock automatically converted into our common stock on a one-for-one basis.

The following table summarizes purchases of our Series A preferred stock by related parties:

RELATED PARTY	SHARES OF SERIES A PREFERRED STOCK	TOTAL PURCHASE PRICE
Entities affiliated with Pontifax(1)	2,764,593	$ 6,000,000
Arkin Bio Ventures Limited Partnership(2)	1,382,295	$ 3,000,000
Entities affiliated with Partners Innovation Fund(3)	460,764	$ 1,000,000

(1) Represents (i) 1,363,542 shares of Series A preferred stock purchased by Pontifax Israel, (ii) 663,825 shares of Series A preferred stock purchased by Pontifax Cayman, and (iii) 737,226 shares of Series A preferred stock purchased by Pontifax China. Tomer Kariv and Ran Nussbaum, both members of our board of directors, are the Managing Partners of Pontifax Management, the general partner of each of the Pontifax IV Funds, and, as a result, may be deemed to share voting and investment power with respect to the shares held by each of the Pontifax IV Funds. The Pontifax Entities collectively hold more than 5% of our capital stock prior to this offering.

(2) Alon Lazarus, Ph.D., a member of our board of directors, is the Biotech Investment Manager of the Pharma Division of Arkin Holdings and, as a result, may be deemed to share voting and investment power with respect to the shares held by Arkin Bio Ventures Limited Partnership. Arkin Bio Ventures Limited Partnership is a holder of more than 5% our capital stock prior to this offering.

(3) Represents (i) 276,459 shares of Series A preferred stock purchased by Partners Innovation Fund, LLC, or PIF I, and (ii) 184,305 shares of Series A preferred stock purchased by Partners Innovation Fund II, L.P., or PIF II. PIF I and PIF II are collectively referred to as the Partners Entities. Julius Knowles, a member of our board of directors, is a partner of each of Partners Innovation Fund, LLC, or Partners GP I, the ultimate general partner of PIF I, and Partners Innovation Fund II, LLC, or Partners GP II, the ultimate general partner of PIF II, and, as a result, may be deemed to share voting and investment power with respect to the shares held by each of the Partners Entities. The Partners Entities collectively hold more than 5% of our capital stock prior to this offering.

Series B-1 and Series B-2 Preferred Stock Financing

In November 2018, we sold an aggregate of 1,579,043 shares of our Series B-1 preferred stock at a purchase price of $7.28 per share for an aggregate amount of approximately $11.5 million. Upon the closing of our IPO in April 2020, all 1,579,043 shares of our Series B-1 preferred stock automatically converted into our common stock on a one-for-one basis.

The following table summarizes purchases of our Series B-1 preferred stock by related parties:

RELATED PARTY	SHARES OF SERIES B-1 PREFERRED STOCK	TOTAL PURCHASE PRICE
Entities affiliated with Pontifax(1)	411,924	$ 3,000,000
Arkin Bio Ventures Limited Partnership(2)	343,270	$ 2,500,000
Entities affiliated with Partners Innovation Fund(3)	343,270	$ 2,500,000

(1) Represents (i) 169,307 shares of Series B-1 preferred stock purchased by Pontifax Israel, (ii) 82,425 shares of Series B-1 preferred stock purchased by Pontifax Cayman, (iii) 91,538 shares of Series B-1 preferred stock purchased by Pontifax China and (iv) 68,654 shares of Series B-1 preferred stock purchased by Pontifax Late Stage. Tomer Kariv and Ran Nussbaum, both members of our board of directors, are the Managing Partners of Pontifax Management, the general partner of each of the Pontifax IV Funds, and, as a result, may be deemed to share voting and investment power with respect to the shares held by each of the Pontifax Entities, and, as a result, may be deemed to share voting and investment power with respect to the shares held by each of the Pontifax Entities. The Pontifax Entities collectively hold more than 5% of our capital stock prior to this offering.

(2) Alon Lazarus, Ph.D., a member of our board of directors, is the Biotech Investment Manager of the Pharma Division of Arkin Holdings and, as a result, may be deemed to share voting and investment power with respect to the shares held by Arkin Bio Ventures Limited Partnership. Arkin Bio Ventures Limited Partnership is a holder of more than 5% our capital stock prior to this offering.

(3) Represents (i) 205,962 shares of Series B-1 preferred stock purchased by PIF I and (ii) 137,308 shares of Series B-1 preferred stock purchased by PIF II. Julius Knowles, a member of our board of directors, is a partner of each of Partners GP I, the ultimate general partner of PIF I, and Partners GP II, the ultimate general partner of PIF II, and, as a result, may be deemed to share voting and investment power with respect to the shares held by each of the Partners Entities. The Partners Entities collectively hold more than 5% of our capital stock prior to this offering.

In addition to our Series B-1 preferred stock financing described above, certain investors committed to purchase up to 1,411,275 shares of Series B-2 preferred stock in a separate closing upon the achievement of a specified clinical development milestone. In March 2020, we and the investors agreed to terminate and waive any future issuance and sale of shares of Series B-2 preferred stock and the related purchase of the shares of Series B-2 preferred stock by such investors.

Series C Preferred Stock Financing

In March 2020, we sold an aggregate of 4,169,822 shares of our Series C preferred stock at a purchase price of $13.43 per share for an aggregate amount of approximately $56.0 million. Upon the closing of our IPO in April 2020, all 4,169,822 shares of our Series C preferred stock automatically converted into our common stock on a one-for-one basis.

The following table summarizes purchases of our Series C preferred stock by related parties:

RELATED PARTY	SHARES OF SERIES C PREFERRED STOCK	TOTAL PURCHASE PRICE
Foresite Capital Fund IV, L.P.(1)	1,303,071	$ 17,500,004
Entities affiliated with OrbiMed(2)	1,116,917	$ 15,000,015
Entities affiliated with Pontifax(3)	368,583	$ 4,950,016
Arkin Bio Ventures Limited Partnership(4)	167,537	$ 2,250,000
Entities affiliated with Partners Innovation Fund(5)	111,691	$ 1,500,002
Jasbir Seehra, Ph.D.(6)	11,169	$ 150,003

(1) Foresite Capital Fund IV, L.P. is a holder of more than 5% of our capital stock prior to this offering.

(2) Represents (i) 744,612 shares of Series C preferred stock purchased by OPI VII, (ii) 223,383 shares of Series C preferred stock purchased by BIOG, and (iii) 148,922 shares of Series C preferred stock purchased by OrbiMed Genesis Master Fund, L.P., or Genesis. OPI VII, BIOG and Genesis are collectively referred to as the OrbiMed Entities. OrbiMed GP VII is the general partner of OPI VII and OrbiMed Advisors LLC. OrbiMed Advisors, is the managing member of OrbiMed GP VII. OrbiMed Genesis GP LLC, or Genesis GP, is the general partner of Genesis. OrbiMed Advisors is the managing member of Genesis GP. OrbiMed Capital is the investment advisor of BIOG. OrbiMed Capital is a relying adviser of OrbiMed Advisors. Carl Gordon, Ph.D., C.F.A., a member of our board of directors, is a managing partner of OrbiMed Advisors and, as a result, may be deemed

to share voting and investment power with respect to the shares held by each of the OrbiMed Entities. The OrbiMed Entities collectively hold more than 5% of our capital stock prior to this offering.

(3) Represents (i) 163,612 shares of Series C preferred stock purchased by Pontifax Israel, (ii) 88,460 shares of Series C preferred stock purchased by Pontifax Cayman, (iii) 79,653 shares of Series C preferred stock purchased by Pontifax China and (iv) 36,858 shares of Series C preferred stock purchased by Pontifax Late Stage. Tomer Kariv and Ran Nussbaum, both members of our board of directors, are the Managing Partners of Pontifax Management, the general partner of each of the Pontifax Entities, and, as a result, may be deemed to share voting and investment power with respect to the shares held by each of the Pontifax Entities. The Pontifax Entities collectively hold more than 5% of our capital stock prior to this offering.

(4) Alon Lazarus, Ph.D., a member of our board of directors, is the Biotech Investment Manager of the Pharma Division of Arkin Holdings and, as a result, may be deemed to share voting and investment power with respect to the shares held by Arkin Bio Ventures Limited Partnership. Arkin Bio Ventures Limited Partnership is a holder of more than 5% our capital stock prior to this offering.

(5) Represents (i) 67,015 shares of Series C preferred stock purchased by PIF I and (ii) 44,676 shares of Series C preferred stock purchased by PIF II. Julius Knowles, a member of our board of directors, is a partner of Partners GP, the ultimate general partner of the Partners Entities, and, as a result, may be deemed to share voting and investment power with respect to the shares held by each of the Partners Entities. The Partners Entities collectively hold more than 5% of our capital stock prior to this offering.

(6) Dr. Seehra is our Chief Executive Officer and a member of our board of directors.

Transactions with HepatoChem, Inc.

We have, from time to time, purchased goods and services from HepatoChem, Inc., or HepatoChem, a contract research organization providing bioanalytical support and drug metabolite identification and characterization. Approximately 70% of the capital stock of HepatoChem is held by Marc Bazin, the husband of our Chief Scientific Officer, Jennifer Lachey, Ph.D. The aggregate amount of all goods and services we have purchased from HepatoChem since January 1, 2017 is approximately $182,500.

Investors' Rights, Voting and Stockholders Agreements

In connection with our convertible preferred stock financings, we entered into investors' rights, voting and stockholder agreements containing registration rights, information rights, voting rights and rights of first refusal, among other things, with certain holders of our convertible preferred stock and certain holders of our common stock including the Pontifax Entities, Arkin Bio Ventures Limited Partnership, Foresite Capital Fund IV, L.P., the Partners Entities and the OrbiMed Entities. These stockholder agreements terminated upon the closing of our IPO in April 2020, except for the registration rights granted under our amended and restated investors' rights agreement, as more fully described in the section of this prospectus titled "Description of Capital Stock—Registration Rights."

Employment Arrangements

We have entered into employment agreements or offer letter agreements with certain of our executive officers. For more information regarding these agreements with our named executive officers, see "Executive Compensation—Agreements with our Named Executive Officers."

Indemnification Agreements

We have entered, and intend to continue to enter, into indemnification agreements with each of our directors and executive officers. The indemnification agreements and our amended and restated bylaws require us to indemnify our directors and executive officers to the fullest extent permitted by Delaware law. For more information regarding these agreements, see "Executive Compensation—Limitations on Liability and Indemnification Matters."

Executive and Director Compensation

We have granted stock options to certain of our executive officers and directors. See the section titled "Executive Compensation" for a description of these stock options.

On May 29, 2020, our board of directors granted an option to purchase 8,500 shares of our common stock to Nima Farzan, one of our non-employee directors. The shares subject to the option have an exercise price of $28.74 and will vest in equal quarterly installments over the 12 months following the vesting commencement date, subject to Mr. Farzan's continuous service with us as of each such vesting date.

Related Party Transaction Policy

We maintain a related party transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related party transactions. The policy became effective on April 7, 2020. For purposes of our policy only, a related party transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and any related party are, were or will be participants and in which the amount involved exceeds the lesser of $120,000 and one percent of the average of our total assets at year-end for the last two completed fiscal years. Transactions involving compensation for services provided to us as an employee or director are not covered by this policy. A related party is any executive officer, director or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related party transaction, including any transaction that was not a related party transaction when originally consummated or any transaction that was not initially identified as a related party transaction prior to consummation, our management must present information regarding the related party transaction to our audit committee, or, if audit committee approval would be inappropriate, to another independent body of our board of directors, for review, consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related parties, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each director, executive officer and, to the extent feasible, significant stockholder to enable us to identify any existing or potential related-person transactions and to effectuate the terms of the policy.

In addition, under our Code of Conduct, our employees and directors have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest.

In considering related party transactions, our audit committee, or other independent body of our board of directors, will take into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event that the related party is a director, immediate family member of a director or an entity with which a director is affiliated;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy requires that, in determining whether to approve, ratify or reject a related party transaction, our audit committee, or other independent body of our board of directors, must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our stockholders, as our audit committee, or other independent body of our board of directors, determines in the good faith exercise of its discretion.

All of the transactions described above were entered into prior to the adoption of this policy, but all were approved by our board of directors considering similar factors to those described above.

PRINCIPAL STOCKHOLDERS

The following table sets forth the beneficial ownership of our common stock as of September 30, 2020, as adjusted to reflect the sale of common stock offered by us in this offering, for:

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

The percentage ownership information shown in the table prior to this offering is based on 20,185,730 shares of common stock outstanding as of September 30, 2020. The percentage ownership information shown in the table after this offering is based on shares outstanding, after giving effect to the sale of shares of our common stock by us in this offering and assuming no exercise of the underwriters' option to purchase additional shares.

We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to the exercise of stock options that are exercisable on or before November 29, 2020, which is 60 days after September 30, 2020. These shares are deemed to be outstanding and beneficially owned by the person holding those options for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Except as otherwise noted below, the address for persons listed in the table is c/o Keros Therapeutics, Inc., 99 Hayden Avenue, Suite 120, Building E, Lexington, Massachusetts 02421.

NAME OF BENEFICIAL OWNER	NUMBER OF SHARES BENEFICIALLY OWNED	PERCENTAGE OF SHARES BENEFICIALLY OWNED	
		BEFORE OFFERING	AFTER OFFERING
5% or greater stockholders:			
Entities affiliated with Pontifax(1)	4,734,507	23.5 %	%
Arkin Bio Ventures Limited Partnership(2)	2,013,102	10.0	
Entities affiliated with OrbiMed(3)	1,679,417	8.3	
Foresite Capital Fund IV, L.P.(4)	1,428,071	7.1	
Logos Global Master Fund LP(5)	1,350,000	6.7	
Entities affiliated with Partners Innovation Fund(6)	1,146,107	5.7	
Named executive officers and directors:			
Jasbir Seehra, Ph.D.(7)	577,509	2.8	
Jennifer Lachey, Ph.D.(8)	270,181	1.3	
Claudia Ordonez, M.D.(9)	25,802	*	
Nima Farzan(10)	4,250	*	
Carl Gordon, Ph.D., C.F.A.(3)	1,679,417	8.3	
Tomer Kariv(1)	4,734,507	23.5	
Julius Knowles(6)	1,146,107	5.7	
Alon Lazarus, Ph.D.(11)	2,036,140	10.1	
Ran Nussbaum(1)	4,734,507	23.5	
All current executive officers and directors as a group (10 persons)(1)(2)(3)(6)(12)	1,0473,913	50.4	

* Represent beneficial ownership of less than 1%.

(1) The information shown is based, in part, upon disclosures filed on a Schedule 13D filed on April 23, 2020 by (i) Pontifax (Israel) IV L.P., or Pontifax Israel, (ii) Pontifax (Cayman) IV L.P., or Pontifax Cayman, (iii), Pontifax (China) IV L.P., or Pontifax China, (iv) Pontifax Late Stage Fund, L.P., or Pontifax Late Stage, (v) Pontifax Management 4 G.P. (2015) Ltd., or Pontifax Management and (vi) Pontifax Late Stage GP Ltd., or Pontifax Late Stage GP. Consists of (i) 2,261,517 shares of common stock held by Pontifax Israel, (ii) 1,109,802 shares of common stock held by Cayman, (iii) 1,213,926 shares of common stock held by Pontifax China and (iv) 149,262 shares of common stock held by Pontifax Late Stage. Pontifax Israel, Pontifax Cayman and Pontifax China are collectively referred to as the Pontifax IV Funds, and together with Pontifax Late Stage are collectively referred to as the Pontifax Entities. Pontifax Management is the ultimate general partner of each of the Pontifax IV Funds. Ran Nussbaum and Tomer Kariv, both members of our board of directors, are the Managing Partners of Pontifax Management and, as a result, may be deemed to share voting and investment power with respect to the shares held by each of the Pontifax IV Funds. Pontifax Late Stage GP is the general partner of Pontifax Late Stage and the sole shareholder of Pontifax Late Stage GP is Mr. Shlomo Karako. Pursuant to Strategic Alliance Agreement, dated August 9, 2018, between Pontifax Late Stage and the Pontifax IV Funds, Pontifax Late Stage invests side-by-side with the Pontifax IV Funds. By virtue of the strategic relationship, each of Pontifax Management, Mr. Kariv and Mr. Nussbaum may be deemed to share voting and dispositive power with respect to the shares held by Pontifax Late Stage in a manner similar to the voting and investment power with respect to the shares held by each of the Pontifax IV Funds. The address of each of the Pontifax Entities is c/o The Pontifax Group, 14 Shenkar Street, Beit Ofek, Herzliya Pituach, 46140 Israel.

(2) Arkin Bio Venture Partners Ltd. is the general partner of Arkin Bio Ventures Limited Partnership and the sole shareholder and chairman of the board of Arkin Bio Venture Partners Ltd. is Moshe Arkin. As a result, Mr. Arkin may be deemed to share voting and investment power with respect to the shares held by Arkin Bio Ventures Limited Partnership. Alon Lazarus, Ph.D., a member of our board of directors, is the Biotech Investment Manager of the Pharma Division of Arkin Holdings and, as a result, may be deemed to share voting and investment power with respect to the shares held by Arkin Bio Ventures Limited Partnership. The address of Arkin Bio Ventures Limited Partnership is 6 Ha'Choshlim Street, Building C, Herzliya, 46724 Israel. Mr. Lazarus disclaims beneficial ownership of the shares held by Arkin Bio Ventures Limited Partnership.

(3) The information shown is based, in part, upon disclosures filed on a Schedule 13D filed on April 17, 2020 by (i) OrbiMed Advisors LLC, or OrbiMed, (ii) OrbiMed Capital GP VII LLC, or OrbiMed GP VII, (iii), OrbiMed Genesis GP LLC, or Genesis GP, and (iv) OrbiMed Capital LLC, or OrbiMed Capital. Consists of (i) 1,119,812 shares of common stock held by OrbiMed Private Investments VII, LP, or OPI, (ii) 410,683 shares of common stock held by The Biotech Growth Trust PLC, or BIOG, and (iii) 148,922 shares of common stock held by OrbiMed Genesis Master Fund, L.P., or Genesis. OPI VII, BIOG and Genesis are collectively referred to as the OrbiMed Entities. OrbiMed GP VII is the general partner of OPI VII and Advisors, is the managing member of OrbiMed GP VII. By virtue of such relationships, OrbiMed GP VII and OrbiMed Advisors may be deemed to have

voting and investment power over the securities held by OPI VII and as a result may be deemed to have beneficial ownership over such securities. Genesis GP is the general partner of Genesis. OrbiMed Advisors is the managing member of Genesis GP. By virtue of such relationships, Genesis GP and OrbiMed Advisors may be deemed to have voting and investment power over the securities held by Genesis and as a result may be deemed to have beneficial ownership over such securities. OrbiMed Capital is the investment advisor of BIOG. OrbiMed Capital is a relying adviser of OrbiMed Advisors. OrbiMed Advisors and OrbiMed Capital exercise voting and investment power through a management committee comprised of Carl L. Gordon, Sven H. Borho, and Jonathan T. Silverstein, each of whom disclaims beneficial ownership of the shares held by the OrbiMed Entities. Carl Gordon, Ph.D., C.F.A., a member of OrbiMed Advisors, is a member of our board of directors. The business address of each of the OrbiMed Entities is 601 Lexington Avenue, 54th Floor, New York, NY 10022.

(4) The information shown is based, in part, upon disclosures filed on a Schedule 13G filed on April 15, 2020 by (i) Foresite Capital Fund IV, L.P., or FCF IV, (ii) Foresite Capital Management IV, LLC, or FCM IV, and (iii) James Tananbaum. FCM IV, the sole general partner of FCF IV, may be deemed to have sole voting and dispositive power over these shares. James B. Tananbaum, in his capacity as managing member of FCM IV, may be deemed to have sole voting and dispositive power over these shares. The address of Mr. Tananbaum and each of the entities identified in this footnote is c/o Foresite Capital Management, 600 Montgomery Street, Suite 4500, San Francisco, CA 94111.

(5) The information shown is based solely upon disclosures filed on a Schedule 13G filed on August 31, 2020 by (i) Logos Global Management LP, or Logos Global, (ii) Logos Global Management GP LLC, or Logos Global GP, (iii) Arsani William, (iv) Logos Global Master Fund LP, or Global Fund, and (v) Logos GP LLC, or Logos GP. Logos Global GP is the general partner of Logos Global. Logos Global is the investment advisor of Logos Global Fund. Arsani William is a control person of Logos Global and Logos Global GP. The business address for Global Fund is One Letterman Drive, Building D, Suite D3-700, San Francisco, California 94129.

(6) Consists of (i) 687,665 shares of common stock held by Partners Innovation Fund, LLC, or PIF I and (ii) 458,442 shares of common stock held by Partners Innovation Fund II, L.P., or PIF II. PIF I and PIF II are collectively referred to as the Partners Entities. Partners Innovation Fund, LLC, or Partners GP I, is the ultimate general partner of PIF I, and Partners Innovation Fund II, LLC, or Partners GP II, is the ultimate general partner of PIF II. Julius Knowles, a member of our board of directors, is a partner of each of Partners GP and Partners GP II, and, as a result, may be deemed to share voting and investment power with respect to the shares held by each of the Partners Entities. The address of each of the Partners Entities is 215 First Street, Suite 500, Cambridge, Massachusetts 02142.

(7) Consists of (i) 243,856 shares of common stock held by Dr. Seehra and (ii) 333,653 shares issuable upon the exercise of options granted to Dr. Seehra that are exercisable within 60 days of September 30, 2020.

(8) Consists of (i) 27,991 shares of common stock held by Dr. Lachey and (ii) 242,190 shares issuable upon the exercise of options granted to Dr. Lachey that are exercisable within 60 days of September 30, 2020.

(9) Consists of shares issuable upon the exercise of options granted to Dr. Ordonez that are exercisable within 60 days of September 30, 2020.

(10) Consists of shares issuable upon the exercise of options granted to Mr. Farzan that are exercisable within 60 days of September 30, 2020.

(11) Consists of (i) 23,038 shares of common stock held by Dr. Lazarus and (ii) 2,013,102 shares of common stock held by Arkin Bio Ventures Limited Partnership referred to in footnote (2) above. Dr. Lazarus is the Biotech Investment Manager of Arkin Holdings and, as a result, may be deemed to share voting and investment power with respect to the shares held by Arkin Bio Ventures Limited Partnership.

(12) Consists of (i) 9,868,018 shares of common stock and (ii) 605,895 shares issuable upon the exercise of options granted to our executive officers and directors that are exercisable within 60 days of September 30, 2020. The shares held by the Pontifax Entities referred to in footnote (1) above of which Mr. Kariv and Mr. Nussbaum may be deemed to share voting and investment power with respect to have been counted once for purposes of calculating the number of shares beneficially owned by all current executive officers and directors as a group.

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock, certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws and certain provisions of Delaware law are summaries. You should also refer to the amended and restated certificate of incorporation and the amended and restated bylaws, which are filed as exhibits to the registration statement of which this prospectus is part. We refer in this section to our amended and restated certificate of incorporation and amended and restated bylaws as our certificate of incorporation and bylaws, respectively.

General

Our certificate of incorporation authorizes us to issue up to 200,000,000 shares of common stock, $0.0001 par value per share, and 10,000,000 shares of preferred stock, $0.0001 par value per share, all of which shares of preferred stock are undesignated. Our board of directors may establish the rights and preferences of the preferred stock from time to time.

As of September 30, 2020, there were 20,185,730 shares of common stock issued and outstanding held of record by 52 stockholders.

As of September 30, 2020, there were 2,484,152 shares of our common stock issuable upon the exercise of outstanding options.

Common Stock

Voting Rights

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Under our certificate of incorporation and bylaws, our stockholders will not have cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

Dividends

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

Liquidation

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

Rights and Preferences

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

Preferred Stock

Our board of directors may, without further action by our stockholders, fix the rights, preferences, privileges and restrictions of up to an aggregate of 10,000,000 shares of preferred stock in one or more series and authorize their issuance. 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 any series or the designation of such series, any or all of which may be greater than the rights of our common stock. The issuance of our preferred stock could adversely affect the voting power of holders of our common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change of

control or other corporate action. Upon the closing of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

Registration Rights

Certain holders of shares of our common stock, including all of our former preferred stockholders prior to our IPO, are entitled to certain rights with respect to registration of their respective shares of common stock under the Securities Act pursuant to the terms of an amended and restated investors' rights agreement by and among us and certain of our stockholders. These shares are collectively referred to herein as registrable securities.

The amended and restated investors' rights agreement provides the holders of registrable securities with demand, piggyback and S-3 registration rights as described more fully below. Under the terms of the investor's rights agreement, holders of registrable securities will have equivalent registration rights with respect to any additional shares of our common stock acquired by these holders.

Demand Registration Rights

At any time beginning October 4, 2020, the holders of at least a majority of the registrable securities then outstanding have the right to make up to two demands that we file a registration statement under the Securities Act, subject to specified conditions and exceptions.

Piggyback Registration Rights

If we register any securities for public sale, the holders of our registrable securities then outstanding will each be entitled to notice of the registration and will have the right to include their shares in the registration statement, subject to specified exceptions. The underwriters of any underwritten offering will have the right to limit the number of shares having registration rights to be included in such registration statement, but not below 30% of the total amount of securities included in such registration.

Registration on Form S-3

If we are eligible to file a registration statement on Form S-3, the holders of at least 20% of our registrable securities then outstanding have the right to demand that we file registration statements on Form S-3, provided that the aggregate amount of securities to be sold under the registration statement is at least $3.0 million, net of underwriting discounts and commissions and specified expenses. We are not obligated to effect a demand for registration on Form S-3 by holders of our registrable securities more than two times during any 12-month period. The right to have such shares registered on Form S-3 is further subject to other specified conditions and limitations.

Expenses of Registration

We will pay all expenses relating to any demand, piggyback or Form S-3 registration, other than underwriting discounts and commissions, subject to specified conditions and limitations.

Termination of Registration Rights

The demand, piggyback and Form S-3 registration rights described above will terminate on the earliest to occur of (1) the closing of a deemed liquidation event, as defined in our certificate of incorporation, (2) April 13, 2025 and (3) with respect to each stockholder, at such time as Rule 144 under the Securities Act or another similar exemption is available for the sale of all of such holder's shares without limitation during a three-month period without registration.

Anti-Takeover Provisions

Anti-Takeover Statute

We are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a publicly held Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

- upon completion of the transaction that 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 began, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, those shares owned (1) by persons who are directors and also officers and (2) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66-2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a “business combination” to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an “interested stockholder” as an entity or person who, together with the person’s affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

Anti-Takeover Effects of Certain Provisions of our Certificate of Incorporation and Bylaws

Our certificate of incorporation provides for our board of directors to be divided into three classes with staggered three-year terms. Only one class of directors is elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because our stockholders do not have cumulative voting rights, our stockholders holding a majority of the voting power of our shares of common stock outstanding will be able to elect all of our directors. The directors may be removed by the stockholders only for cause upon the vote of holders of 66 2/3% of the shares then entitled to vote at an election of directors. Furthermore, the authorized number of directors may be changed only by resolution of our board of directors, and vacancies and newly created directorships on our board of directors may, except as otherwise required by law or determined by our board, only be filled by a majority vote of the directors then serving on the board, even though less than a quorum. Our certificate of incorporation and bylaws provide that all stockholder actions must be effected at a duly called meeting of stockholders and not by a consent in writing. A special meeting of stockholders may be called only by a majority of our whole board of directors, the chair of our board of directors or our chief executive officer. Our bylaws also provide that stockholders seeking to present proposals before a meeting of stockholders to nominate candidates for election as directors at a meeting of stockholders must provide timely advance notice in writing, and will specify requirements as to the form and content of a stockholder’s notice.

Our certificate of incorporation further provides that the affirmative vote of holders of at least 66 2/3% of the voting power of all of the then outstanding shares of voting stock, voting as a single class, is required to amend certain provisions of our certificate of incorporation, including provisions relating to the structure of our board of directors, the size of the board, removal of directors, special meetings of stockholders, actions by written consent and cumulative voting. The affirmative vote of holders of at least 66 2/3% of the voting power of all of the then outstanding shares of voting stock, voting as a single class, is required to amend or repeal our bylaws, although our bylaws may be amended by a simple majority vote of our whole board of directors.

The foregoing provisions will make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of our company by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the

authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change the control of our company.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage certain types of transactions that may involve an actual or threatened acquisition of our company. These provisions are also designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy rights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of deterring hostile takeovers or delaying changes in control of our company or our management. As a consequence, these provisions also may inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts.

Choice of Forum

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for: (1) any derivative action or proceeding brought on our behalf; (2) any action or proceeding asserting a breach of fiduciary duty owed by any of our current or former directors, officers or employees to us or our stockholders; (3) any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees, arising out of or pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws; (4) any action or proceeding to interpret, apply, enforce or determine the validity of our certificate of incorporation or our by-laws; or (5) any action or proceeding asserting a claim against us that is governed by the internal affairs doctrine, provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Securities Act, the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. It is possible that a court of law could rule that the choice of forum provision contained in our amended and restated certificate of incorporation is inapplicable or unenforceable if it is challenged in a proceeding or otherwise.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. The transfer agent’s address is 250 Royall Street, Canton, Massachusetts 02021.

Listing

Our common stock is listed on the Nasdaq Global Market under the trading symbol “KROS.”

MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS

The following discussion is a summary of the material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the ownership and disposition of our common stock issued pursuant to this offering. This discussion is not a complete analysis of all potential U.S. federal income tax consequences relating thereto, does not address the potential application of the Medicare contribution tax on net investment income or the alternative minimum tax, and does not address any estate or gift tax consequences or any tax consequences arising under any state, local or foreign tax laws, or any other U.S. federal tax laws. This discussion is based on the Internal Revenue Code of 1986, as amended, or the Code, Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the Internal Revenue Service, or the IRS, all as in effect on the date of this prospectus. These authorities are subject to differing interpretations and may change, possibly retroactively, resulting in U.S. federal income tax consequences different from those discussed below. We have not requested a ruling from the IRS with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS or a court will agree with such statements and conclusions.

This discussion is limited to non-U.S. holders who purchase our common stock pursuant to this offering and who hold 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 of the U.S. federal income tax consequences that may be relevant to an individual holder in light of such holder's particular circumstances. This discussion also does not consider any specific facts or circumstances that may be relevant to holders subject to special rules under the U.S. federal income tax laws, including:

- certain former citizens or long-term residents of the United States;
- partnerships or other pass-through entities (and investors therein);
- "controlled foreign corporations";
- "passive foreign investment companies";
- corporations that accumulate earnings to avoid U.S. federal income tax;
- banks, financial institutions, investment funds, insurance companies, brokers, dealers or traders in securities;
- tax-exempt organizations and governmental organizations;
- tax-qualified retirement plans;
- persons subject to special tax accounting rules under Section 451(b) of the Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- "qualified foreign pension funds" as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds;
- persons that own or have owned, actually or constructively, more than 5% of our common stock;
- persons who have elected to mark securities to market; and
- persons holding our common stock as part of a hedging or conversion transaction or straddle, or a constructive sale, or other risk reduction strategy or integrated investment.

If an entity or arrangement that is classified as a partnership for U.S. federal income tax purposes holds our common stock, the U.S. federal income tax treatment of a partner in the partnership will generally depend on the status of the partner and the activities of the partnership. Partnerships holding our common stock and the partners in such partnerships are urged to consult their tax advisors about the particular U.S. federal income tax consequences to them of holding and disposing of our common stock.

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES TO THEM OF ACQUIRING, OWNING AND DISPOSING OF OUR COMMON STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL OR FOREIGN TAX LAWS AND ANY OTHER U.S. FEDERAL TAX LAWS.

Definition of Non-U.S. Holder

For purposes of this discussion, a non-U.S. holder is any beneficial owner of our common stock that is not a "U.S. person" or a partnership (including any entity or arrangement treated as a partnership) for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation (including any entity treated as a corporation for U.S. federal income tax purposes) created or organized under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust (1) whose administration is subject to the primary supervision of a U.S. court and which has one or more U.S. persons who have the authority to control all substantial decisions of the trust or (2) that has a valid election in effect under applicable Treasury Regulations to be treated as a U.S. person.

Distributions on Our Common Stock

As described in the section entitled "Dividend Policy," we do not anticipate declaring or paying dividends to holders of our common stock in the foreseeable future. However, if we distribute cash or other property on our common stock, such distributions 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. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and will first be applied against and reduce a holder's tax basis in our common stock, but not below zero. Any excess amount distributed will be treated as gain realized on the sale or other disposition of our common stock and will be treated as described under "—Gain On Disposition of Our Common Stock" below.

Subject to the discussion below regarding effectively connected income, backup withholding and FATCA (as defined below), dividends paid to a non-U.S. holder of our common stock generally will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends or such lower rate specified by an applicable income tax treaty. To receive the benefit of a reduced treaty rate, a non-U.S. holder must furnish us or our withholding agent with a valid IRS Form W-8BEN or IRS Form W-8BEN-E (or applicable successor form) certifying such holder's qualification for the reduced rate. This certification must be provided to us or our withholding agent before the payment of dividends and must be updated periodically. If the non-U.S. holder holds our common stock through a financial institution or other agent acting on the non-U.S. holder's behalf, the non-U.S. holder will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or our withholding agent, either directly or through other intermediaries.

If a non-U.S. holder holds our common stock in connection with the conduct of a trade or business in the United States, and dividends paid on our common stock are effectively connected with such holder's U.S. trade or business (and are attributable to such holder's permanent establishment or fixed base in the United States if required by an applicable tax treaty), the non-U.S. holder will be exempt from U.S. federal withholding tax. To claim the exemption, the non-U.S. holder must generally furnish a valid IRS Form W-8ECI (or applicable successor form) to the applicable withholding agent, certifying that the dividends are effectively connected with the non-U.S. holder's conduct of trade or business within the United States.

However, any such effectively connected dividends paid on our common stock generally will be subject to U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items.

Non-U.S. holders that do not provide the required certification on a timely basis, but that qualify for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Gain on Disposition of Our Common Stock

Subject to the discussion below regarding backup withholding and FATCA, a non-U.S. holder generally will not be subject to U.S. federal income tax on any gain realized on the sale or other disposition of our common stock, unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States and, if required by an applicable income tax treaty, is attributable to a permanent establishment or fixed base maintained by the non-U.S. holder in the United States;
- the non-U.S. holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition, and certain other requirements are met; or
- our common stock constitutes a "United States real property interest" by reason of our status as a United States real property holding corporation, or a USRPHC, for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding the disposition or the non-U.S. holder's holding period for our common stock, and our common stock is not regularly traded on an established securities market during the calendar year in which the sale or other disposition occurs.

Determining whether we are a USRPHC depends on the fair market value of our U.S. real property interests relative to the fair market value of our other trade or business assets and our foreign real property interests. We believe that we are not currently and we do not anticipate becoming a USRPHC for U.S. federal income tax purposes, although there can be no assurance we will not in the future become a USRPHC.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items. Gain described in the second bullet point above will be subject to U.S. federal income tax at a flat 30% rate (or such lower rate specified by an applicable income tax treaty), but may be offset by certain U.S.-source capital losses (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. Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules. Gain described in the third bullet point above will generally be subject to U.S. federal income tax in the same manner as gain that is effectively connected with the conduct of a U.S. trade or business (subject to any provisions under an applicable income tax treaty), except that the branch profits tax generally will not apply.

Information Reporting and Backup Withholding

Annual reports are required to be filed with the IRS and provided to each non-U.S. holder indicating the amount of distributions on our common stock paid to such holder and the amount of any tax withheld with respect to those dividends. These information reporting requirements apply even if no withholding was required because the distributions were effectively connected with the holder's conduct of a U.S. trade or business, or withholding was reduced or eliminated by an applicable income tax treaty and regardless of whether the distributions constituted dividends. This information also may be made available under a specific treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides or is established. Backup withholding, currently at a 24% rate, generally will not apply to payments to a non-U.S. holder of dividends on or the gross proceeds of a disposition of our common stock provided the non-U.S. holder furnishes the required certification for its non-U.S. status, such as by providing a valid IRS Form W-8BEN, IRS Form W-8BEN-E or IRS Form W-8ECI, or certain other requirements are met. Backup withholding may apply if the payor has actual knowledge, or reason to know, that the holder is a U.S. person who is not an exempt recipient.

Backup withholding is not an additional tax. If any amount is withheld under the backup withholding rules, the non-U.S. holder should consult with a U.S. tax advisor regarding the possibility of and procedure for obtaining a refund or a credit against the non-U.S. holder's U.S. federal income tax liability, if any.

Withholding on Foreign Entities

Sections 1471 through 1474 of the Code, which are commonly referred to as FATCA, impose a U.S. federal withholding tax of 30% on certain payments made to a "foreign financial institution" (as specially defined under

these rules) unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding certain U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or an exemption applies. FATCA also generally will impose a U.S. federal withholding tax of 30% on certain payments made to a non-financial foreign entity unless such entity provides the withholding agent a certification identifying certain direct and indirect U.S. owners of the entity or an exemption applies. An intergovernmental agreement between the United States and an applicable foreign country may modify these requirements. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. FATCA currently applies to dividends paid on our common stock. FATCA will also apply to gross proceeds from sales or other dispositions of our common stock after December 31, 2018. However, the Treasury Department has recently proposed regulations which, if finalized in their present form, would eliminate the federal withholding tax of 30% applicable to gross proceeds from a disposition of our common stock. In its preamble to such proposed regulations, the Treasury Department stated that taxpayers may generally rely on the proposed regulations until final regulations are issued.

Prospective investors are encouraged to consult with their own tax advisors regarding the possible implications of this legislation on their investment in our common stock.

Confidential Treatment Requested by Keros Therapeutics, Inc.
Pursuant to 17 C.F.R. § 200.83

UNDERWRITING

Subject to the terms and conditions set forth in the underwriting agreement, dated , 2020, among us and Jefferies LLC, SVB Leerink LLC and Piper Sandler & Co., as the representatives of the underwriters named below and the joint book-running managers of this offering, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the respective number of shares of common stock shown opposite its name below:

UNDERWRITER	NUMBER OF SHARES
Jefferies LLC	
SVB Leerink LLC	
Piper Sandler & Co.	
H.C. Wainwright & Co., LLC	
Total	

The underwriting agreement provides that the obligations of the several underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers' certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the shares of common stock if any of them are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated. We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The underwriters have advised us that, following the completion of this offering, they currently intend to make a market in the common stock as permitted by applicable laws and regulations. However, the underwriters are not obligated to do so, and the underwriters may discontinue any market-making activities at any time without notice in their sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for the common stock, that you will be able to sell any of the common stock held by you at a particular time or that the prices that you receive when you sell will be favorable.

The underwriters are offering the shares of common stock subject to their acceptance of the shares of common stock from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part. In addition, the underwriters have advised us that they do not intend to confirm sales to any account over which they exercise discretionary authority.

Commission and Expenses

The underwriters have advised us that they propose to offer the shares of common stock to the public at the public offering price set forth on the cover page of this prospectus and to certain dealers, which may include the underwriters, at that price less a concession not in excess of $ per share of common stock. The underwriters may allow, and certain dealers may reallow, a discount from the concession not in excess of $ per share of common stock to certain brokers and dealers. After the offering, the public offering price, concession and reallowance to dealers may be reduced by the representatives. No such reduction will change the amount of proceeds to be received by us as set forth on the cover page of this prospectus.

The following table shows the public offering price, the underwriting discounts and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection with this offering. Such amounts

are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	PER SHARE		TOTAL	
	WITHOUT OPTION TO PURCHASE ADDITIONAL SHARES	WITH OPTION TO PURCHASE ADDITIONAL SHARES	WITHOUT OPTION TO PURCHASE ADDITIONAL SHARES	WITH OPTION TO PURCHASE ADDITIONAL SHARES
Public offering price	$	$	$	$
Underwriting discounts and commissions paid by us	$	$	$	$
Proceeds to us, before expenses	$	$	$	$

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately $. We will agree to reimburse the underwriters for certain of their expenses incurred in connection with this offering in an amount not to exceed $.

Listing

Our common stock is listed on The Nasdaq Global Market under the trading symbol "KROS".

Stamp Taxes

If you purchase shares of common stock offered in this prospectus, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus.

Option to Purchase Additional Shares

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase, from time to time, in whole or in part, up to an aggregate of shares from us at the public offering price set forth on the cover page of this prospectus, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to specified conditions, to purchase a number of additional shares proportionate to that underwriter's initial purchase commitment as indicated in the table above.

No Sales of Similar Securities

We, our executive officers and directors have agreed, subject to specified exceptions, not to directly or indirectly:

- sell, offer, contract or grant any option to sell (including any short sale), pledge, transfer, establish an open "put equivalent position" within the meaning of Rule 16a-l(h) under the Exchange Act;
- otherwise dispose of any shares of common stock, options or warrants to acquire shares of common stock, or securities exchangeable or exercisable for or convertible into shares of common stock currently or hereafter owned either of record or beneficially; or
- publicly announce an intention to do any of the foregoing for a period of 90 days after the date of this prospectus without the prior written consent of Jefferies LLC, SVB Leerink LLC and Piper Sandler & Co.

This restriction terminates after the close of trading of the common stock on and including the 90th day after the date of this prospectus.

Jefferies LLC, SVB Leerink LLC and Piper Sandler & Co. may, in their sole discretion and at any time or from time to time before the termination of the 90-day period, release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our shareholders who will execute a lock-up agreement, providing consent to the sale of shares prior to the expiration of the lock-up period.

Stabilization

The underwriters have advised us that, pursuant to Regulation M under the Exchange Act, certain persons participating in the offering may engage in short sale transactions, stabilizing transactions, syndicate covering transactions or the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintaining the market price of the common stock at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either "covered" short sales or "naked" short sales.

"Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares of our common stock in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares of our common stock or purchasing shares of our common stock in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option to purchase additional shares.

"Naked" short sales are sales in excess of the option to purchase additional shares of our common stock. The underwriters must close out any naked short position by purchasing shares in the open market. 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 shares of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of shares of common stock on behalf of the underwriters for the purpose of fixing or maintaining the price of the common stock. A syndicate covering transaction is the bid for or the purchase of shares of common stock on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering. Similar to other purchase transactions, the underwriter's purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the common stock originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. The underwriters are not obligated to engage in these activities and, if commenced, any of the activities may be discontinued at any time.

The underwriters may also engage in passive market making transactions in our common stock on The Nasdaq Global Market in accordance with Rule 103 of Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, that bid must then be lowered when specified purchase limits are exceeded.

Electronic Distribution

A prospectus in electronic format may be made available by e-mail or on the web sites or through online services maintained by one or more of the underwriters or their affiliates. In those cases, prospective investors may view offering terms online and may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares of common stock for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' web sites and any information contained in any other web site maintained by any of the underwriters is not part of this prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors.

Other Activities and Relationships

The underwriters and certain of their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and certain of their respective affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and certain of their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments issued by us and our affiliates. If the underwriters or certain of their respective affiliates have a lending relationship with us, they routinely hedge their credit exposure to us consistent with their respective customary risk management policies. The underwriters and certain of their respective affiliates may hedge such exposure by entering into transactions which consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the common stock offered hereby. Any such short positions could adversely affect future trading prices of the common stock offered hereby. The underwriters and certain of their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Selling Restrictions

Notice to Prospective Investors in the EEA and the United Kingdom

In relation to each Member State of the EEA and the United Kingdom, each, a Relevant State, no offer of the shares may be made to the public in that Relevant State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that offers of shares may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

- to any legal entity which is a “qualified investor” as defined in the Prospectus Regulation;
- to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Regulation), subject to obtaining the prior consent of the representatives; or
- in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of ordinary shares referred to above shall result in a requirement for the Company or any representative to publish a prospectus pursuant to Article 3 of the Prospectus Regulation, or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

Each person in a Relevant State who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged, and agreed to and with the Company and the underwriters that it is a qualified investor within the meaning of the Prospectus Regulation.

In the case of any shares being offered to a financial intermediary as that term is used in Article 5(1) of the Prospectus Regulation, 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 nondiscretionary 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 to the public other than their offer or resale in a Relevant State to qualified investors, in circumstances in which the prior consent of the underwriters has been obtained to each such proposed offer or resale.

The Company, the underwriters and their affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements, and agreements.

For the purposes of this provision, the expression an "offer to the public" in relation to any shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

References to the Prospectus Regulation includes, in relation to the United Kingdom, the Prospectus Regulation as it forms part of U.K. domestic law by virtue of the European Union (Withdrawal) Act 2018.

The above selling restriction is in addition to any other selling restrictions set out below.

Notice to Prospective Investors in the United Kingdom

This document is for distribution only to persons who (i) have professional experience in matters relating to investments and who qualify as investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the Financial Promotion Order; (ii) are persons falling within Article 49(2)(a) to (d) ("high net worth companies, unincorporated associations etc.") of the Financial Promotion Order; (iii) are outside the United Kingdom; or (iv) are persons to whom an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000, as amended) in connection with the issue or sale of any securities may otherwise lawfully be communicated or caused to be communicated (all such persons together being referred to as "relevant persons"). This document is directed only at relevant persons and must not be acted on or relied on by persons who are not relevant persons. Any investment or investment activity to which this document relates is available only to relevant persons and will be engaged in only with relevant persons.

Notice to Prospective Investors in Bermuda

Securities 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 Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission, or the ASIC, in relation to this offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001, or the Corporations Act, and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons, or the Exempt Investors, who are "sophisticated investors" (within the meaning of section 708(8) of the Corporations Act), "professional investors" (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under this offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Notice to Prospective Investors in Hong Kong

The shares have not been 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 thereunder 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 of Hong Kong and any rules made under that Ordinance.

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, neither 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 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 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, or the SFA, (ii) to a relevant person pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA 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 shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- 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
- 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:

- 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;
- where no consideration is or will be given for the transfer;
- where the transfer is by operation of law;
- as specified in Section 276(7) of the SFA; or
- as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

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 prospectus 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 prospectus 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 prospectus nor any other offering or marketing material relating to the offering, the Company or the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority, 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 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 hereto) 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.

LEGAL MATTERS

The validity of the shares of common stock being offered by this prospectus will be passed upon for us by Cooley LLP, Boston, Massachusetts. As of the date of this prospectus, an entity comprised of partners and associates of Cooley LLP beneficially own an aggregate of 3,722 shares of our common stock. Certain legal matters will be passed upon for the underwriters by Latham & Watkins LLP.

EXPERTS

The consolidated financial statements as of December 31, 2019 and 2018 and for each of the two years in the period ended December 31, 2019 included in this prospectus, have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report appearing herein (which report expresses an unqualified opinion on the consolidated financial statements and includes an explanatory paragraph referring to our ability to continue as a going concern). Such consolidated financial statements have been so included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act, with respect to the shares of common stock being offered by this prospectus, which constitutes a part of the registration statement. This prospectus, which constitutes part of the registration statement, does not contain all of the information in the registration statement and its exhibits. For further information with respect to us and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference. You can read our SEC filings, including the registration statement, over the internet at the SEC's website at www.sec.gov.

We are subject to the information reporting requirements of the Exchange Act, and we file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available over the internet at the SEC's web site referred to above. We also maintain a website at www.kerostx.com, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. **However, the information contained in or accessible through our website is not part of this prospectus or the registration statement of which this prospectus forms a part, and investors should not rely on such information in making a decision to purchase our common stock in this offering.**

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Keros Therapeutics, Inc. and its subsidiary (the "Company") as of December 31, 2018 and 2019, the related consolidated statements of operations, convertible preferred stock and stockholders' deficit, and cash flows, for each of the years then ended, 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 2019, and the results of its operations and its cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company's recurring losses from operations incurred since inception, expectation of continuing operating losses for the foreseeable future, and the need to raise additional capital to finance its future operations raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Deloitte & Touche LLP

Boston, Massachusetts

February 26, 2020 (April 1, 2020, as to the subsequent events described in Note 15)

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

KEROS THERAPEUTICS, INC.

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

	DECEMBER 31,		PRO FORMA DECEMBER 31,
	2018	2019	2019
			(Unaudited)
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents	$ 23,259	$ 7,020	$ 7,020
Prepaid expenses and other current assets	2,272	381	381
Deferred IPO costs	—	604	604
Research and development incentive receivable	—	922	922
Total current assets	25,531	8,927	8,927
Operating lease right-of-use assets	735	1,205	1,205
Property and equipment, net	645	708	708
Research and development incentive receivable	370	—	—
Restricted cash	131	115	115
TOTAL ASSETS	$ 27,412	$ 10,955	$ 10,955
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT			
CURRENT LIABILITIES:			
Accounts payable	$ 501	$ 2,088	$ 2,088
Current portion of operating lease liabilities	166	376	376
Deferred revenue	10,000	—	—
Accrued expenses and other current liabilities	802	2,022	2,022
Total current liabilities	11,469	4,486	4,486
Operating lease liabilities, net of current portion	622	899	899
Preferred stock tranche liability	2,392	4,956	—
Other liabilities	171	119	119
Total liabilities	14,654	10,460	5,504
COMMITMENTS AND CONTINGENCIES (Note 13)			
Series A convertible preferred stock, par value of $0.0001 per share; 10,000,000 shares authorized as of December 31, 2018 and 2019; 4,607,652 shares issued and outstanding as of December 31, 2018 and 2019; liquidation and redemption value of $12,271 as of December 31, 2019; no shares authorized, issued or outstanding, pro forma as of December 31, 2019 (unaudited)	9,891	9,891	—
Series A-1 convertible preferred stock, par value of $0.0001 per share; 800,000 shares authorized as of December 31, 2018 and 2019; 368,612 shares issued and outstanding as of December 31, 2018 and 2019; liquidation and redemption value of $1,171 as of December 31, 2019; no shares authorized, issued or outstanding, pro forma as of December 31, 2019 (unaudited)	944	944	—
Series B-1 convertible preferred stock, par value of $0.0001 per share; 3,427,004 shares authorized as of December 31, 2018 and 2019; 1,579,043 shares issued and outstanding as of December 31, 2018 and 2019; liquidation and redemption value of $12,596 as of December 31, 2019; no shares authorized, issued or outstanding, pro forma as of December 31, 2019 (unaudited)	9,106	9,106	—

STOCKHOLDERS' DEFICIT:			
Common stock, par value of $0.0001 per share; 27,000,000 shares authorized as of December 31, 2018 and 2019; 2,243,648 and 2,429,705 shares issued and outstanding as of December 31, 2018 and 2019, respectively; 8,985,012 shares issued and outstanding, pro forma as of December 31, 2019 (unaudited)	1	1	2
Additional paid-in capital	130	203	25,099
Accumulated deficit	(7,314)	(19,650)	(19,650)
Total stockholders' deficit	(7,183)	(19,446)	5,451
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT	$ 27,412	$ 10,955	$ 10,955

See notes to consolidated financial statements.

KEROS THERAPEUTICS, INC.

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

	YEAR ENDED DECEMBER 31,	
	2018	2019
REVENUE:		
Research collaboration revenue	$ 10,000	$ 10,000
Total revenue	10,000	10,000
OPERATING EXPENSES:		
Research and development	(10,111)	(17,379)
General and administrative	(1,580)	(3,184)
Total operating expenses	(11,691)	(20,563)
LOSS FROM OPERATIONS	(1,691)	(10,563)
OTHER INCOME, NET:		
Interest income (expense), net	6	(8)
Research and development incentive income	370	558
Change in fair value of preferred stock tranche obligation	(43)	(2,564)
Other income, net	280	241
Total other income (expense), net	613	(1,773)
Loss before income taxes	(1,078)	(12,336)
Income tax provision	(257)	—
Net loss	$ (1,335)	$ (12,336)
Net loss attributable to common stockholders—basic and diluted (Note 12)	$ (2,346)	$ (14,136)
Net loss per share attributable to common stockholders—basic and diluted	$ (1.08)	$ (6.08)
Weighted-average common stock outstanding—basic and diluted	2,174,514	2,326,857
Pro forma net loss per share attributable to common stockholders—basic and diluted (unaudited)		$ (1.39)
Pro forma weighted average common shares outstanding—basic and diluted (unaudited)		8,882,168

See notes to consolidated financial statements.

KEROS THERAPEUTICS, INC.

Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit
(In thousands, except share and per share data)

	CONVERTIBLE PREFERRED STOCK										
	$0.0001 PAR VALUE SERIES A		$0.0001 PAR VALUE SERIES A-1		$0.0001 PAR VALUE SERIES B-1		COMMON STOCK $0.0001 PAR VALUE		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	TOTAL STOCKHOLDERS' DEFICIT
	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT			
BALANCE, January 1, 2018	4,607,652	$ 9,891	368,612	$ 944	—	$ —	2,088,387	$ 1	$ 41	$ (5,979)	$ (5,937)
Issuance of Series B-1 convertible preferred stock, net of issuance costs of $45 and net of $2,349 discount associated with preferred stock tranche rights	—	—	—	—	1,579,043	9,106	—	—	—	—	—
Exercise of common stock options	—	—	—	—	—	—	51,591	—	8	—	8
Vesting of restricted stock	—	—	—	—	—	—	103,670	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	81	—	81
Net loss	—	—	—	—	—	—	—	—	—	(1,335)	(1,335)
BALANCE, December 31, 2018	4,607,652	$ 9,891	368,612	$ 944	1,579,043	$ 9,106	2,243,648	$ 1	$ 130	$ (7,314)	$ (7,183)
Exercise of common stock options	—	—	—	—	—	—	82,387	—	14	—	14
Vesting of restricted stock	—	—	—	—	—	—	103,670	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	59	—	59
Net loss	—	—	—	—	—	—	—	—	—	(12,336)	(12,336)
BALANCE, December 31, 2019	4,607,652	$ 9,891	368,612	$ 944	1,579,043	$ 9,106	2,429,705	$ 1	$ 203	$ (19,650)	$ (19,446)

See notes to consolidated financial statements.

KEROS THERAPEUTICS, INC.

Consolidated Statements of Cash Flows
(In thousands)

	YEAR ENDED DECEMBER 31,	
	2018	2019
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (1,335)	$ (12,336)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation expense	153	208
Stock-based compensation expense	81	59
Non-cash lease expense	151	230
Changes in fair value of preferred stock tranche obligation	43	2,565
Changes in operating assets and liabilities:		
Research and development incentive receivable	(370)	(552)
Prepaid expenses and other current assets	(2,210)	1,891
Deferred IPO costs	—	(300)
Accounts payable	(2)	1,312
Operating lease liabilities	(147)	(213)
Proceeds from Novo Nordisk A/S collaboration and license agreement	20,000	—
Deferred revenue	(10,000)	(10,000)
Accrued expenses and other current liabilities	506	1,191
Other liabilities	172	(53)
Net cash provided by (used in) operating activities	7,042	(15,998)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(217)	(271)
Net cash used in investing activities	(217)	(271)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of Series B1 preferred stock	11,500	—
Payment of issuance costs	(45)	—
Proceeds from exercise of stock options	8	14
Net cash provided by financing activities	11,463	14
NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	18,288	(16,255)
Cash, cash equivalents and restricted cash at beginning of year	5,102	23,390
Cash, cash equivalents and restricted cash at end of year	$ 23,390	$ 7,135
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid for taxes	$ —	$ 256
Preferred stock tranche obligation in connection with the issuance of Series B-1 convertible preferred stock	$ 2,349	$ —
Right-of-use assets obtained in exchange for operating lease obligation	$ —	$ 700
Deferred IPO costs in accounts payable and accrued expenses	$ —	$ 304

The following table provides a reconciliation of the cash and cash equivalents and restricted cash as of each of the periods shown above:

	YEAR ENDED DECEMBER 31,	
	2018	2019
Cash and cash equivalents	$ 23,259	$ 7,020
Restricted cash	131	115
Total cash, cash equivalents and restricted cash	$ 23,390	$ 7,135

See notes to consolidated financial statements.

KEROS THERAPEUTICS, INC.

Notes to Consolidated Financial Statements

1. NATURE OF BUSINESS AND BASIS OF PRESENTATION

Keros Therapeutics, Inc. (“Keros” or the “Company”) was incorporated in 2015 as a Delaware corporation. Its principal offices are in Lexington, Massachusetts. The Company is a clinical stage company dedicated to the discovery and development of breakthrough therapeutics for neuromuscular diseases.

The accompanying consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States of America (“U.S. GAAP”) and include the accounts of the Company and its wholly owned Australian subsidiary, Keros Therapeutics Australia Pty Ltd (“Keros Australia”).

Going Concern

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 financial statements are issued.

Since its inception in 2015, the Company has devoted the majority of its resources on business planning, research and development of its product candidates, including by conducting clinical trials and preclinical studies, raising capital and recruiting management and technical staff to support these operations. To date, the Company has not generated any revenue from product sales as none of its product candidates have been approved for commercialization. The Company has historically financed its operations primarily through the sale of convertible preferred stock and through its collaboration agreement.

The Company has incurred recurring losses since its inception, including net losses of $1.3 million and $12.3 million for the years ended December 31, 2018 and 2019, respectively. In addition, as of December 31, 2019, the Company had an accumulated deficit of $19.7 million. The Company expects to continue to generate operating losses and negative operating cash flows for the foreseeable future as it continues to develop its product candidates. As of February 21, 2020, the Company expects that its then-existing cash and cash equivalents of $3.6 million will be sufficient to fund its operating expenses and capital expenditure requirements into the second quarter of 2020.

The Company will not generate any revenue from product sales unless and until it successfully completes clinical development and obtains regulatory approval for one or more of its product candidates. If the Company obtains regulatory approval for any of its product candidates, it expects to incur significant expenses related to developing its internal commercialization capability to support product sales, marketing and distribution.

As a result, the Company will need substantial additional funding to support its operating activities as it advances its product candidates through clinical development, seeks regulatory approval and prepares for and, if any of its product candidates are approved, proceeds to commercialization. Until such time as the Company can generate significant revenue from product sales, if ever, the Company expects to finance its operating activities through a combination of equity offerings, debt financings, and license and development agreements in connection with any future collaborations. Adequate funding may not be available to the Company on acceptable terms, or at all.

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.

Based on its recurring losses from operations incurred since inception, expectation of continuing operating losses for the foreseeable future, and need to raise additional capital to finance its future operations, the Company has concluded that there is substantial doubt about its ability to continue as a going concern within one year after the date that the consolidated financial statements are issued.

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. These financial statements do not include any adjustments that might result from the outcome of this uncertainty.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and Keros Australia. All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, and expenses, and the disclosure of contingent assets and liabilities as of and during the reporting period. The Company bases its estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. This process may result in actual results differing materially from those estimated amounts used in the preparation of the financial statements if these results differ from historical experience, or other assumptions do not turn out to be substantially accurate, even if such assumptions are reasonable when made. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, useful lives assigned to property and equipment, the fair values of common and preferred stock and the fair value of the preferred stock tranche obligation. The Company assesses estimates on an ongoing basis; however, actual results could materially differ from those estimates.

Fair Value Measurements

Certain assets and liabilities are reported on a recurring basis at fair value. 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 and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

An entity may choose to measure many financial instruments and certain other items at fair value at specified election dates. Subsequent unrealized gains and losses on items for which the fair value option has been elected will be reported in earnings.

Cash, Cash Equivalents, and Restricted Cash

Cash and cash equivalents consist of standard checking accounts and money market funds. The Company considers all highly liquid investments with an original maturity of 90 days or less at the date of purchase to be cash equivalents.

The Company's cash equivalents, which are funds held in a money market account, are measured at fair value on a recurring basis. The carrying amount of cash equivalents was $18.4 million and $5.0 million as of

December 31, 2018 and 2019, respectively, which approximates fair value and was determined based upon Level 1 inputs. The money market account is valued using quoted market prices with no valuation adjustments applied and is categorized as Level 1.

The Company had restricted cash of $0.1 million in the form of a certificate of deposit related to its operating leases in Lexington, Massachusetts as of December 31, 2018 and 2019.

Concentrations of Credit Risk

Financial instruments that potentially subject us to significant concentration of credit risk consist primarily of cash and cash equivalents. The Company may maintain deposits in financial institutions in excess of government insured limits. The Company believes that it is not exposed to significant credit risk as its deposits are held at financial institutions that management believes to be of high credit quality and the Company has not experienced any losses on these deposits. As of December 31, 2018 and 2019, the Company's cash and cash equivalents were held with three financial institutions. The Company believes that the market risk arising from its holdings of these financial instruments is mitigated based on the fact that many of these securities are either government-backed or of high credit rating.

Property and Equipment

Property and equipment are recorded at cost. Expenditures for repairs and maintenance are expensed as incurred. When assets are retired or disposed of, the assets and related accumulated depreciation are derecognized from the accounts, and any resulting gain or loss is included in the determination of net loss. Depreciation is calculated using the straight-line method over the estimated useful lives of the related assets as follows:

	ESTIMATED USEFUL LIFE
Computer equipment and software	3 years
Laboratory equipment	5 years
Office furniture	5 years
Leasehold improvements	lesser of useful life or remaining lease term

Impairment of Long-Lived Assets

The Company evaluates its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceed the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell. To date, no impairments have been recognized for these assets.

Leases

The Company accounts for its leases under ASC Topic 842, Leases ("ASC 842"). At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present in the arrangement. Leases with a term greater than 12 months are recognized on the balance sheet as ROU assets and current and non-current lease liabilities, as applicable. The Company has elected not to recognize on the balance sheet leases with terms of 12 months or less. The Company typically only includes an initial lease term in its assessment of a lease arrangement. Options to renew a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew. The Company monitors its material leases on a quarterly basis.

Operating lease liabilities and their corresponding ROU assets are recorded based on the present value of future lease payments over the expected remaining lease term. Lease cost for operating leases is recognized on a straight-line basis over the lease term as an operating expense. Certain adjustments to the ROU asset may be required for items such as lease prepayments or incentives received. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the

lease payments in the same currency, for a similar term, in a similar economic environment. In transition to ASC 842, the Company utilized the remaining lease term of its lease in determining the appropriate incremental borrowing rate.

For all asset classes of its leases, the Company has elected to account for the lease and non-lease components together for existing classes of underlying assets.

Guarantees and Indemnifications

As permitted under Delaware law, the Company indemnifies its officers, directors, consultants and employees for certain events or occurrences that happen by reason of the relationship with, or position held at, the Company. Through December 31, 2019, the Company had not experienced any losses related to these indemnification obligations, and no claims were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related liabilities have been established.

Research and Development Costs

Research and development costs are charged to expense as incurred. Research and development costs consist of expenses incurred in performing research and development activities, including salaries and benefits, materials and supplies, preclinical expenses, stock-based compensation expense, depreciation of equipment, contract services, facilities, and other outside expenses. Costs for external development activities are recognized based on an evaluation of the progress to completion of specific tasks using information provided to the Company by its vendors. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the consolidated financial statements as prepaid expense or accrued research and development expense.

Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses and expensed as the related goods are delivered or the services are performed.

Research and Development Incentive

The Australian research and development tax incentive program provides tax offsets to eligible companies that engage in research and development activities and has two core components:

- 43.5% refundable tax offset for certain eligible research and development entities with an aggregated turnover of less than $20.0 million per annum; and
- 38.5% non-refundable tax offset for all other eligible research and development entities. Unused offset amounts may be able to be carried forward for use in future income years.

The Company is eligible to participate in an Australian research and development tax incentive program under which the Company is eligible to receive a cash refund from the Australian Taxation Office for a percentage of the research and development costs expended by the Company in Australia.

The Company's estimate of the cash refund it expects to receive related to the Australian research and development tax incentive program is included in other assets in the accompanying consolidated balance sheet and such amounts are recorded as research and development incentive income in the statement of operations. The Company recognizes research and development incentive income when there is reasonable assurance that the income will be received, the relevant expenditure has been incurred, and the consideration can be reliably measured. The Company has recorded a research and development incentive receivable of $0.4 million and $0.9 million and other income from Australian research and development incentives of $0.4 million and $0.6 million for the years ended December 31, 2018 and 2019, respectively, related to refundable research and development incentive program payments in Australia.

Revenue Recognition

To date, the Company has earned revenue solely under the license agreement with Novo Nordisk A/S.

The Company recognizes revenue in accordance with ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). The Company enters into certain agreements that are within the scope of ASC 606, under which

the Company licenses, may license or grants an option to license rights to certain of the Company's product candidates and performs research and development services in connection with such arrangements. The terms of these arrangements typically include payment of one or more of the following: non-refundable, upfront fees; reimbursement of research and development costs; development, clinical, regulatory and commercial sales milestone payments, and royalties on net sales of licensed products.

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of ASC 606, the Company performs the following five steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect consideration it is entitled to in exchange for the goods or services it transfers to the customer.

The promised goods or services in the Company's arrangements typically consist of a license, or option to license, rights to the Company's intellectual property or research and development services. The Company provides options to additional items in such arrangements, which are accounted for as separate contracts when the customer elects to exercise such options, unless the option provides a material right to the customer. Performance obligations are promised goods or services in a contract to transfer a distinct good or service to the customer and are considered distinct when (i) the customer can benefit from the good or service on its own or together with other readily available resources and (ii) the promised good or service is separately identifiable from other promises in the contract. In assessing whether promised goods or services are distinct, the Company considers factors such as the stage of development of the underlying intellectual property, the capabilities of the customer to develop the intellectual property on its own or whether the required expertise is readily available and whether the goods or services are integral or dependent to other goods or services in the contract.

The Company estimates the transaction price based on the amount expected to be received for transferring the promised goods or services in the contract. The consideration may include fixed consideration and variable consideration. At the inception of each arrangement that includes variable consideration, the Company evaluates the amount of potential payment and the likelihood that the payments will be received. The Company utilizes either the most likely amount method or expected value method to estimate the amount expected to be received based on which method best predicts the amount expected to be received. The amount of variable consideration that is included in the transaction price may be constrained and is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period.

The Company's contracts often include development and regulatory milestone payments that are assessed under the most likely amount method and constrained if it is probable that a significant revenue reversal would occur. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. At the end of each reporting period, the Company re-evaluates the probability of achievement of such development and clinical milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration and other research and development revenue in the period of adjustment.

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from any of the Company's collaboration or strategic alliance arrangements.

The Company allocates the transaction price based on the estimated standalone selling price. The Company must develop assumptions that require judgment to determine the stand-alone selling price for each

performance obligation identified in the contract. The Company utilizes key assumptions to determine the stand-alone selling price, which may include other comparable transactions, pricing considered in negotiating the transaction and the estimated costs. Variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration relate to the satisfaction of the performance obligation and the resulting amounts allocated are consistent with the amounts the Company would expect to receive for the satisfaction of each performance obligation.

The consideration allocated to each performance obligation is recognized as revenue when control is transferred for the related goods or services. For performance obligations which consist of licenses and other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

The Company receives payments from its customers based on billing schedules established in each contract. Upfront payments and fees are recorded as deferred revenue upon receipt or when due until the Company performs its obligations under these arrangements. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional.

Foreign Currency Transactions

The functional currency for the Company's wholly owned foreign subsidiary, Keros Australia, is the United States dollar. All foreign currency transaction gains and losses are recognized in the consolidated statement of operations.

Segment Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is made available for evaluation by the chief operating decision maker ("CODM") in making decisions regarding resource allocation and assessing performance. The CODM is the Company's chief executive officer. The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company's singular concentration is focused on the discovery and development of breakthrough therapeutics for neuromuscular diseases.

Common Stock Valuation

Due to the absence of an active market for the Company's common stock, the Company utilized methodologies in accordance with the framework of the American Institute of Certified Public Accountants Technical Practice Aid (*Valuation of Privately-Held Company Equity Securities Issued as Compensation*) to estimate the fair value of its common stock. In determining the exercise prices for options granted, the Company has considered the estimated fair value of the common stock as of the measurement date. The estimated fair value of the common stock has been determined at each grant date based upon a variety of factors, including the illiquid nature of the common stock, arm's-length sales of the Company's capital stock (including convertible preferred stock), the effect of the rights and preferences of the preferred stockholders, and the prospects of a liquidity event. Among other factors are the Company's financial position and historical financial performance, the status of technological developments within the Company's research, the composition and ability of the current research and management team, an evaluation or benchmark of the Company's competition, and the current business climate in the marketplace. Significant changes to the key assumptions underlying the factors used could result in different fair values of common stock at each valuation date.

Convertible Preferred Stock

The Company has classified convertible preferred stock, referred to as preferred stock, as temporary equity in the accompanying consolidated balance sheet due to terms that allow for redemption of the shares in cash upon certain change in control events that are outside of the Company's control, including sale or transfer of control of the Company as holders of the preferred stock could cause redemption of the shares in these situations. The Company did not accrete the carrying values of the preferred stock to the redemption values since a liquidation event was not considered probable as of December 31, 2019. Subsequent adjustments of the carrying values to the ultimate redemption values will be made only when it becomes probable that such a liquidation event will occur.

Stock-Based Compensation

The Company accounts for all stock-based payment awards granted to employees and non-employees as stock-based compensation expense at fair value. The Company's stock-based payments include stock options and grants of common stock, including common stock subject to vesting. The measurement date for employee awards is the date of grant, and stock-based compensation costs are recognized as expense over the employees' requisite service period, which is the vesting period, on a straight-line basis. Prior to the adoption of Accounting Standards Update ("ASU") No. 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* ("ASU No. 2018-07") as discussed below under "Recently Adopted Accounting Pronouncements", the measurement date for non-employee awards was generally the date the services were completed, resulting in financial reporting period adjustments to stock-based compensation during the vesting terms for changes in the fair value of the awards. Since the adoption of ASU 2018-07, the measurement date for non-employee awards is the date of grant without changes in the fair value of the award. Stock-based compensation costs for non-employees are recognized as expense over the vesting period on a straight-line basis. Stock-based compensation expense is classified in the accompanying consolidated statement of operations based on the function to which the related services are provided. The Company recognizes stock-based compensation expense for the portion of awards that have vested. Forfeitures are recorded as they occur.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The Company has historically been a private company and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of 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 stock price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. 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.

Income Taxes

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the Company's consolidated financial statements and tax returns. Deferred tax assets and liabilities are determined based upon the differences between the financial statement carrying amounts and the tax bases of existing assets and liabilities and for loss and credit carryforwards, using enacted tax rates expected to be in effect in the year in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that these assets may not be realized. The Company determines whether it is more likely than not that a tax position will be sustained upon examination. If it is not more likely than not that a position will be sustained, none of the benefit attributable to the position is recognized. The tax benefit to be recognized for any tax position that meets the more-likely-than-not recognition threshold is calculated as the largest amount that is more than 50% likely of being realized upon resolution of the contingency. The Company accounts for interest and penalties related to uncertain tax positions as part of its provision for income taxes.

Comprehensive Loss

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss is equal to net loss for all periods presented.

Net Loss Per Share

Basic net loss per share and diluted net loss per share are computed using the weighted-average number of shares of common stock outstanding for the period. Net loss per share attributable to common stockholders is calculated using the two-class method, which is an earnings allocation formula that determines net loss per share for the holders of shares of the Company's common stock and participating securities. The Company's preferred stock contains participation rights in any dividend paid by the Company and is deemed to be a participating security. The participating securities do not include a contractual obligation to share in losses of

the Company and are not included in the calculation of net loss per share in the periods in which a net loss is recorded.

Diluted net loss per share is computed using the more dilutive of (a) the two-class method or (b) the if-converted method. The Company allocates earnings first to preferred stockholders based on dividend rights and then to common and preferred stockholders based on ownership interests. The weighted-average number of shares of common stock included in the computation of diluted net loss gives effect to all potentially dilutive common stock equivalent shares, including outstanding stock options and preferred stock.

Common stock equivalent shares are excluded from the computation of diluted net loss per share if their effect is antidilutive. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is generally 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 net losses attributable to common stockholders for the years ended December 31, 2018 and 2019.

Unaudited Pro Forma Financial Information

The accompanying unaudited pro forma consolidated balance sheet as of December 31, 2019 has been prepared to give effect, upon the closing of a qualified initial public offering ("IPO"), to the automatic conversion of all outstanding preferred stock into 6,555,307 shares of common stock.

The unaudited pro forma basic and diluted weighted-average common shares outstanding used in the calculation of unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2019 have been prepared to give effect, upon a qualified IPO, to the automatic conversion of all outstanding shares of preferred stock into common stock as if the proposed IPO had occurred on the later of the beginning of each period or the issuance date of the preferred stock.

Recently Adopted Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, Revenue from Contracts with Customers (Topic 606) ("ASU No. 2014-09"), which modifies how all entities recognize revenue, and supersedes the current guidance found in ASC Topic 605, and various other revenue accounting standards for specialized transactions and industries. In August 2015, the FASB issued ASU No. 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of Effective Date* ("ASU No. 2015-14"), which defers the effective date of ASU No. 2014-09 by one year and was issued in contemplation of ASU No. 2014-09. ASU No. 2014-09 outlines a comprehensive five-step revenue recognition model based on the principle that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU No. 2014-09 may be applied using either a full retrospective approach, under which all years included in the financial statements will be presented under the revised guidance, or a modified retrospective approach, under which financial statements will be prepared under the revised guidance for the year of adoption, but not for prior years. Under the latter method, entities will recognize a cumulative catch-up adjustment to the opening balance of retained earnings at the effective date for contracts that still require performance by the entity at the date of adoption. The Company early adopted this guidance on January 1, 2018, applying the full retrospective method to all contracts that were not completed as of January 1, 2018. As such, there is no impact to the Company's audited consolidated financial statements as a result of this adoption. To date, the Company has earned revenue solely under the collaboration and license agreement with Novo Nordisk A/S. For greater detail around the accounting for the revenue related to this agreement refer to Note 14.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*. These amendments expand the scope of Topic 718, *Compensation—Stock Compensation* 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 public companies for annual periods beginning after December 15, 2018, including interim periods within those fiscal years, with early adoption permitted as long as ASU No. 2014-09 has been adopted by the Company. The new standard was early adopted by the Company on

January 1, 2018. Adoption of ASU No. 2018-07 did not have a material impact on the Company's consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirement for Fair Value Measurement*, which changes the disclosure requirements on fair value measurements in Topic 820. The guidance eliminates certain disclosure requirements that are no longer considered cost beneficial and adds new disclosure requirement for Level 3 fair value measurements. The ASU is effective for fiscal years beginning after December 15, 2019 and interim periods within those fiscal years. The Company is currently evaluating whether or not the guidance will have an impact on its consolidated financial statements.

In November 2018, FASB issued Accounting Standards Update No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*. The ASU amends ASC 808 to clarify ASC 606 should apply in entirety to certain transactions between collaborative arrangement participants. The amendments for ASU No. 2018-18 are effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. As the Company does not have any arrangements accounted for as collaborative arrangements it has determined that this guidance will not have a material impact on the its consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes-Simplifying the Accounting for Income Taxes* ("ASU No. 2019-12"). ASU No. 2019-12 eliminates certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new guidance also simplifies aspects of the accounting for franchise taxes, enacted changes in tax laws or rates and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. The standard is effective for annual periods beginning after December 15, 2020 and interim periods within those fiscal years, with early adoption permitted. Adoption of the standard requires certain changes to be made prospectively and certain others to be made retrospectively. The Company is currently assessing the impact of this standard on its financial condition and results of operations.

3. FAIR VALUE MEASUREMENTS

The following table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicates the level of the fair value hierarchy utilized to determine such fair values (in thousands):

DESCRIPTION	DECEMBER 31, 2018	QUOTED PRICES ACTIVE MARKETS FOR IDENTICAL ASSETS (LEVEL 1)	SIGNIFICANT OTHER OBSERVABLE INPUTS (LEVEL 2)	SIGNIFICANT OTHER OBSERVABLE INPUTS (LEVEL 3)
Asset				
Money market funds	$ 18,356	$ 18,356	$ —	$ —
Total financial assets	$ 18,356	$ 18,356	$ —	$ —
Liability				
Preferred stock tranche obligation	$ (2,392)	$ —	$ —	$ (2,392)
Total financial liabilities	$ (2,392)	$ —	$ —	$ (2,392)

DESCRIPTION	DECEMBER 31, 2019	QUOTED PRICES ACTIVE MARKETS FOR IDENTICAL ASSETS (LEVEL 1)	SIGNIFICANT OTHER OBSERVABLE INPUTS (LEVEL 2)	SIGNIFICANT OTHER OBSERVABLE INPUTS (LEVEL 3)
Asset				
Money market funds	$ 4,972	$ 4,972	$ —	$ —
Total financial assets	$ 4,972	$ 4,972	$ —	$ —
Liability				
Preferred stock tranche obligation	$ (4,956)	$ —	$ —	$ (4,956)
Total financial liabilities	$ (4,956)	$ —	$ —	$ (4,956)

There have been no transfers between fair value levels during the years ended December 31, 2018 and 2019. The Company's Preferred Stock Tranche Obligation (defined below) is carried at fair value determined according to Level 3 inputs in the fair value hierarchy as described below. The carrying values of other current assets, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities.

Preferred Stock Tranche Obligation

The Company determined that its obligation to issue, and the Company's investors' obligation to purchase additional shares of convertible preferred stock at a fixed price (i.e. the issuance price) in subsequent tranches following the initial closings of the series A, series A-1, and series B-1 convertible preferred stock ("Series A Preferred Stock," "Series A-1 Preferred Stock," "Series B-1 Preferred Stock", referred to collectively with the "Series B-2 Preferred Stock" as the "Preferred Stock") financings represented a freestanding financial instrument (the "Preferred Stock Tranche Obligation"). The freestanding financial instrument was classified as a liability on the Company's consolidated balance sheets and initially recorded at fair value, with changes in fair value for each reporting period recognized in other income, net in the consolidated statement of operations (see Note 8).

In connection with the Company's initial issuances of Series A Preferred Stock, Series A-1 Preferred Stock and Series B-1 Preferred Stock in April 2016, April 2017 and November 2018, respectively (see Note 8) the Company recognized the Preferred Stock Tranche Obligation at the fair value related to each issuance, which was determined based on significant inputs not observable in the market, which represented a Level 3 measurement within the fair value hierarchy. The initial fair value of each obligation was estimated based on results of a valuation performed. The obligation is remeasured prior to the issuance of subsequent tranches, and at each subsequent reporting period, as well as immediately prior to when the obligation is settled.

The Preferred Stock Tranche Obligation was determined using the binomial pricing model, which takes into account the probability of achievement and failure of tranche milestones and issuance of subsequent shares. The Preferred Stock Tranche Obligation is calculated as the difference between the future value of the Series B-2 Preferred Stock at the time the tranche milestone is met, estimated using the binomial pricing model, and the contractual purchase price for the Series B-2 Preferred Stock. The future value of the Series B-2 Preferred Stock was estimated by back-solving the future price of the Series B-2 Preferred Stock such that the initial proceeds of the Series B-1 Preferred Stock financing equaled the value of the Preferred Stock Tranche Obligation plus the standalone price paid for Series B-1 Preferred Stock.

The Preferred Stock Tranche Obligation value is discounted back to the initial issuance date and adjusted for probability of the tranche milestone achievement. In determining the fair values of the tranche obligations, estimates and assumptions impacting fair value include the estimated future values of the Company's Series B-2 Preferred Stock, discount rates, estimated time to liquidity, and probability of tranche closing/milestone achievement. The Company remeasured each tranche obligation at each reporting period and prior to settlement. Upon issuance of tranches two and three of Series A Preferred Stock and Series A-1 Preferred Stock, the Preferred Stock Tranche Obligation associated with Series A Preferred Stock and Series A-1 Preferred Stock were settled in 2017. The following reflects the significant quantitative inputs used in the

valuation of the Preferred Stock Tranche Obligation at issuance on November 9, 2018 and as of December 31, 2018 and 2019:

	NOVEMBER 9, 2018	DECEMBER 31, 2018	DECEMBER 31, 2019
Stand-alone Series B-1 Preferred Stock price (spot price)	$ 7.28	$ 7.28	$ 7.28
Estimated future value of Series B-2 Preferred Stock	$ 8.14	$ 8.14	$ 8.14
Discount rate	17.00 %	17.50 %	15.50 %
Time to liquidity (years)	1.14	1.00	0.16
Probability of tranche closing	25 %	25 %	80 %

A change in the assumptions related to the valuation of the Preferred Stock Tranche Obligation could have a significant impact on the value of the obligation. The purchase price of the Preferred Stock at initial issuance, and all subsequent issuances was higher than the fair value of the Company's common stock.

The following table sets forth a summary of changes in the fair value of the Company's Preferred Stock Tranche Obligation for which fair value is determined by Level 3 inputs (in thousands):

	PREFERRED STOCK TRANCHE OBLIGATION
Balance as of January 1, 2018	$ —
Issuance	2,349
Change in fair value	43
Balance as of December 31, 2018	2,392
Change in fair value	2,564
Balance as of December 31, 2019	$ 4,956

Fluctuations in the fair value of the Company's Preferred Stock is the primary cause for the significant changes in fair value of the Preferred Stock Tranche Obligation. In 2018 and 2019, the enterprise value of the Company was determined using the Market Approach, specifically the Subject Company Transaction Method, which considers all share class rights and preferences, as of the date of the most recent financing. During 2018, the Company closed the Series B-1 Preferred Stock financing, and as part of the Company's strategy, began considering the pursuit of longer-term liquidity options including a potential initial public offering, which caused an increase in the value of the Series B-1 Preferred Stock while reducing the value of the Preferred Stock Tranche Obligation, which relates to the future closing of Series B-2 Preferred Stock. During 2019, the Preferred Stock Tranche Obligation increased to $5.0 million as of December 31, 2019 from $2.4 million as of December 31, 2018, due to the increase in the probability of the Company achieving certain research and development milestones necessary to issue Series B-2 Preferred Stock, the increase in the value of the Series B-1 Preferred Stock and the consideration of an IPO scenario in the Company's valuation of its common and preferred stock.

4. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets as of December 31, 2018 and 2019 consisted of the following (in thousands):

	DECEMBER 31,	
	2018	2019
Prepaid service contracts	2,018	21
Prepaid professional services	126	5
Prepaid tax	44	65
Prepaid rent	—	64
Other	84	226
Total prepaid expenses and other current assets	$ 2,272	$ 381

5. PROPERTY AND EQUIPMENT, NET

Property and equipment, net as of December 31, 2018 and 2019 consisted of the following (in thousands):

	DECEMBER 31,	
	2018	2019
Computer equipment and software	$ 35	$ 35
Laboratory equipment	610	843
Office furniture	27	42
Leasehold improvements	219	241
Total	891	1,161
Less: Accumulated depreciation	(246)	(453)
Property and equipment, net	$ 645	$ 708

Depreciation expense was $0.2 million for each of the years ended December 31, 2018 and 2019.

6. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities as of December 31, 2018 and 2019 consisted of the following (in thousands):

	DECEMBER 31,	
	2018	2019
Accrued studies	$ 431	$ 1,123
Accrued compensation and benefits	41	749
Accrued tax	284	43
Other	46	107
Total accrued expenses and other current liabilities	$ 802	$ 2,022

Accrued compensation and benefits consists primarily of accrued vacation and accrued 401k withholding.

7. LICENSE AGREEMENTS

Massachusetts General Hospital

On April 5, 2016, the Company entered into an exclusive patent license agreement with The General Hospital Corporation d/b/a Massachusetts General Hospital (“MGH”). Under the license agreement with MGH (as amended in May 2017 and February 2018, the “MGH Agreement”), the Company obtained an exclusive, worldwide license, with the right to sublicense, under certain patents and technical information of MGH, to

make, have made, use, have used, sell, have sold, lease, have leased, import, have imported or otherwise transfer licensed products and processes for use in the treatment, diagnosis, palliation and prevention of diseases and disorders in humans and animals. The Company is required to use commercially reasonable efforts to develop and commercialize licensed products and processes and must achieve certain required diligence milestones.

Under the terms of the MGH Agreement, the Company paid an initial license payment of $0.1 million in 2016, and reimbursed MGH approximately $0.3 million of prior patent prosecution expenses related to the licensed patents in 2017. The Company also issued MGH an aggregate of 358,674 shares of its common stock. Additionally, the Company is required to pay a low-five digit to mid-five digit annual maintenance fee prior to the first commercial sale of its first product or process, a mid-five digit annual maintenance fee after the first commercial sale of its first product or process that is creditable against royalties, certain clinical and regulatory milestone payments for the first three products or indications to achieve such milestones, which milestone payments are $8.6 million in the aggregate, and certain commercial milestone payments for the first three products or indications to achieve such milestones, which milestone payments are $18.0 million in the aggregate. The Company is also obligated to pay tiered royalties on net sales of licensed products ranging in the low-single digits to mid-single digits. The royalty rates are subject to up to a maximum 50% reduction for lack of a valid claim, in the event that it is necessary for the Company to obtain a license to any third-party intellectual property related to the licensed products, and generic competition. The obligation to pay royalties under the MGH Agreement expires on a licensed product-by-licensed product and country-by-country basis upon the later of expiry of the last valid claim of the licensed patents that cover such licensed product in such country or ten years from the first commercial sale of such product in such country. The Company is also obligated to pay a percentage of non-royalty-related payments received by it from sublicensees ranging in the low-double digits and a change of control fee equal to a low-single digit percentage of the payments received as part of any completed transaction up to a low seven-digit amount.

The MGH Agreement expires upon expiry of the last remaining royalty obligation for a licensed product or process. Under the MGH Agreement, MGH may terminate the agreement upon the Company's uncured material breach or insolvency, a challenge by the Company of the licensed patents and certain other specified breaches of the MGH Agreement. The Company may terminate the agreement for any reason upon specified prior written notice to MGH.

Novo Nordisk A/S

In addition, on December 14, 2017, the Company entered into a research collaboration and exclusive license agreement with Novo Nordisk A/S. Refer to Note 14, Revenue from Contracts with Customers, for more information regarding this agreement.

LakePharma, Inc.

On April 22, 2019, the Company entered into an exclusive license agreement with LakePharma, Inc.

("LakePharma") whereby the Company licensed LakePharma's intellectual property for research and development efforts for a license fee of $0.3 million, which is recorded as research and development expense in the Company's consolidated statements of operations. The agreement will continue in perpetuity unless terminated by either party. LakePharma may terminate the agreement at any time.

8. CONVERTIBLE PREFERRED STOCK

On April 15, 2016, the Company authorized the sale and issuance of up to 10,000,000 shares of $0.0001 par value Series A Preferred Stock. The Series A Preferred Stock financing was structured to close in three tranches, each contingent upon the achievement of certain research and development milestones agreed upon by the Company's board of directors (the "Board"). On April 15, 2016, the Company issued 1,535,884 shares of Series A Preferred Stock at $2.17 per share for gross proceeds of $3.3 million. Issuance costs were $68,000. The second tranche was contingent upon the achievement of the first milestone. The first milestone was completed on April 15, 2017 and the Company issued 1,535,884 shares of Series A Preferred Stock at $2.17 per share for gross proceeds of $3.3 million. The third tranche was contingent upon achievement of the second milestone. The completion of a second milestone was unanimously waived by the Board on October 25, 2017,

and on November 3, 2017, the Company issued 1,535,884 shares of Series A Preferred Stock at $2.17 per share for gross proceeds of $3.3 million. Issuance costs related to the second and third tranches were $23,000.

On August 16, 2016, the Company authorized the sale and issuance of up to 800,000 shares of $0.0001 par value Series A-1 Preferred Stock. The Series A-1 Preferred Stock financing was structured to close in three tranches. On August 16, 2016, the Company issued 122,871 shares of Series A-1 Preferred Stock at $2.71 per share for gross proceeds of $0.3 million. The issuance costs were immaterial. The second tranche was contingent upon the achievement of the first milestone. The first milestone was completed on April 15, 2017 and the Company issued 122,871 shares of Series A-1 Preferred Stock at $2.71 per share for gross proceeds of $0.3 million. The third tranche was contingent upon achievement of the second milestone. The completion of a second milestone was unanimously waived by the Company's Board on October 25, 2017 and, on November 3, 2017, the Company issued 122,870 shares of Series A-1 Preferred Stock at $2.71 per share for gross proceeds of $0.3 million. Issuance costs related to the second and third tranches were $7,000.

On November 9, 2018, the Company authorized the sale and issuance of up to 3,427,004 shares of $0.0001 par value Series B-1 Preferred Stock and up to 3,062,891 shares of $0.0001 par value Series B-2 Preferred Stock. The Series B-1/B-2 Preferred Stock financing was structured to close in two tranches. On November 9, 2018, the Company issued 1,579,043 shares of Series B-1 Preferred Stock at $7.28 per share for gross proceeds of $11.5 million. Issuance costs were $45,000 and the Preferred Stock Tranche Obligation was $2.3 million. As part of the Company's Series B-1 Preferred Stock issuance, a portion of the shares were issued to entities affiliated with Pontifax, entities affiliated with Partners Innovation Fund, and Arkin Bio Ventures Limited Partnership, all of which are affiliates of members of our Board. There were no material transactions with these parties other than this purchase of preferred stock in 2018. The second tranche, referred to as the B-1/B-2 Milestone Closing, is contingent upon the Company successfully completing its first Phase I single ascending dose clinical trial in normal healthy volunteers. Upon the B-1/B-2 Milestone Closing, the Company will issue 1,411,275 shares of Series B-2 Preferred Stock at $8.14 per share for gross proceeds of $11.5 million.

As of December 31, 2018 and 2019, Preferred Stock consisted of the following (in thousands, except share data):

	DECEMBER 31, 2018				
	PREFERRED STOCK AUTHORIZED	PREFERRED STOCK ISSUED AND OUTSTANDING	CARRYING VALUE	LIQUIDATION VALUE	COMMON STOCK ISSUABLE UPON CONVERSION
Series A Preferred Stock	10,000,000	4,607,652	$ 9,891	$ 11,471	4,607,652
Series A1 Preferred Stock	800,000	368,612	944	1,091	368,612
Series B1 Preferred Stock	3,427,004	1,579,043	9,106	11,676	1,579,043
Series B2 Preferred Stock	3,062,891	—	—	—	—
	17,289,895	6,555,307	$ 19,941	$ 24,238	6,555,307

	DECEMBER 31, 2019				
	PREFERRED STOCK AUTHORIZED	PREFERRED STOCK ISSUED AND OUTSTANDING	CARRYING VALUE	LIQUIDATION VALUE	COMMON STOCK ISSUABLE UPON CONVERSION
Series A Preferred Stock	10,000,000	4,607,652	$ 9,891	$ 12,271	4,607,652
Series A1 Preferred Stock	800,000	368,612	944	1,171	368,612
Series B1 Preferred Stock	3,427,004	1,579,043	9,106	12,596	1,579,043
Series B2 Preferred Stock	3,062,891	—	—	—	—
	17,289,895	6,555,307	$ 19,941	$ 26,038	6,555,307

The following is a summary of the rights and privileges of the Preferred Stockholders as of December 31, 2018 and 2019.

Conversion: Shares of Preferred Stock are convertible, at the option of the holder, at any time, into shares of common stock. The number of shares is determined by dividing the original issuance price by the conversion price. As such, the shares of Preferred Stock effectively convert on a one-for-one basis. These rights terminate in the event of a liquidation or winding up of the Company. No fractional shares will be issued.

Liquidation Preference: While the Preferred Stock is not redeemable, the shares are redeemable for cash in certain change of control events that are beyond the control of the Company. In the event of any liquidation or Deemed Liquation Event (as defined in the Company's articles of incorporation), the Preferred Stockholders are entitled to the greater of (i) the original issue price of the Preferred Stock plus any accrued dividends not yet paid plus any other dividends declared and unpaid or ii) the amount payable had all classes of shares been converted to common stock. In the event of a Deemed Liquidation Event, if the assets of the Company available for distribution are insufficient to pay the Preferred Stockholders in the full amount to which they are entitled, the Preferred Stockholders shall share ratably in any distribution of the assets available for distribution in proportion to the number of shares of Preferred Stock that they hold. Note that in relation to the above, the holders of Series B-1/B-2 Preferred Stock are entitled to be paid out prior to the holders of common stock, Series A Preferred Stock and Series A-1 Preferred Stock.

Dividends: Dividends accrue at a rate of $0.17, $0.21, $0.582630 and $0.651888 per share, per year on the anniversary of the issuance date for Series A Preferred Stock, Series A-1 Preferred Stock, Series B-1 Preferred Stock and Series B-2 Preferred Stock, respectively. Dividends are cumulative; however, accrued dividends will be payable only if and when declared by the Board. Dividends on other classes of the Company's stock may not be declared or paid unless the Preferred Stockholders are first paid (i) all dividends accrued and not yet paid plus (ii) the product of (a) dividends declared on an as converted basis and (b) Preferred Stock on an as converted basis. That is, if the Company declared dividends on outstanding common stock, Preferred Stockholders would receive both the dividends owed for the Preferred Stock plus that which would be owed if the Preferred Stock were converted to common stock. No dividends have been declared through December 31, 2019.

Voting Rights: Each holder of outstanding shares of Preferred Stock shall be entitled to cast the number of votes equal to the number of whole shares of common stock into which the shares of Preferred Stock held by such holder are convertible as of the record date for determining stockholders entitled to vote on such matter. Preferred Stockholders and common stockholders vote together as a single class.

9. COMMON STOCK

As of December 31, 2018 and 2019, the Company's certificate of incorporation authorized the Company to issue 27,000,000 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 preference of the holders of the Preferred Stock set forth above.

Each share of common stock entitles the holder to one vote, together with the holders of Preferred Stock, on all matters submitted to the stockholders for a vote. As of December 31, 2018 and 2019, no cash dividends have been declared or paid.

As of December 31, 2018 and 2019, the Company has reserved the following shares of common stock for potential conversion of outstanding Preferred Stock, the vesting of restricted stock and exercise of stock options:

	DECEMBER 31,	
	2018	2019
Preferred Stock	6,555,307	6,555,307
Unvested restricted stock	138,227	34,557
Options to purchase common stock	849,039	1,164,017
Total	7,542,573	7,753,881

10. STOCK-BASED COMPENSATION

2017 Plan

The Company adopted the Keros Therapeutics, Inc. 2017 Stock Incentive Plan (the "2017 Plan") on February 2, 2017 for the issuance of stock options and other stock-based awards. On January 2, 2018, the 2017 Plan was amended to increase the number of shares of common stock authorized to be issued from 691,444 to 895,102. On October 9, 2018, the 2017 Plan was amended to increase the number of shares of common stock authorized to be issued to 931,963, and on March 4, 2019, the 2017 Plan was amended such that the number of shares of common stock authorized to be issued was increased to 1,362,087. Shares that are expired, terminated, surrendered or canceled under the 2017 Plan without having been fully exercised will be available for future awards. In addition, shares of common stock that are tendered to the Company by a participant to exercise an award are added to the number of shares of common stock available for the grant of awards. There were 31,333 and 64,088 shares available for future grant under the 2017 Plan as of December 31, 2018 and 2019, respectively.

The 2017 Plan is administered by the Board. The exercise prices, vesting and other restrictions are determined at the discretion of the Board, except that the exercise price per share of incentive stock options may not be less than 100% of the fair market value of the common stock on the date of grant. Stock options awarded under the 2017 Plan expire ten years after the grant date, unless the Board sets a shorter term. Vesting periods for awards under the plans are determined at the discretion of the Board. Incentive stock options granted to employees and shares of restricted stock awards granted to employees, officers, members of the Board, advisors, and consultants of the Company typically vest over four years. Non-statutory options and shares of restricted stock awards granted to employees, officers, members of the Board, advisors, and consultants of the Company typically vest over three or four years.

The Company granted options to purchase 722,992 and 470,909 shares of common stock during the years ended December 31, 2018 and 2019, respectively. The Company recorded stock-based compensation expense for options granted of $0.1 million during each of the years ended December 31, 2018 and 2019. During the years ended December 31, 2018 and 2019, the Company granted no shares of restricted stock. The Company recorded stock-based compensation expense for restricted stock of less than $1,000 during each of the years ended December 31, 2018 and 2019.

Stock Option Valuation

The assumptions that the Company used in Black-Scholes option-pricing model to determine the grant-date fair value of stock options granted for the years ended December 31, 2018 and 2019 were as follows:

	YEAR ENDED DECEMBER 31,	
	2018	2019
Weighted-average risk-free interest rate	2.70 %	1.99 %
Expected term (in years)	5.49	6.05
Expected volatility	74.55 %	74.71 %
Expected dividend yield	0.00 %	0.00 %
Fair value of underlying common stock	$ 0.19	$ 0.32

A summary of option activity under the 2017 Plan during the years ended December 31, 2018 and 2019 is as follows (in thousands except share and per share data):

	NUMBER OF OPTIONS	WEIGHTED-AVERAGE EXERCISE PRICE	WEIGHTED-AVERAGE REMAINING CONTRACTUAL TERM (IN YEARS)	AGGREGATE INTRINSIC VALUE
Outstanding as of December 31, 2017	193,511	$ 0.10	9.20	$ 37,800
Granted	722,992	0.30		
Exercised	(51,591)	0.16		$ 7,189
Cancelled or forfeited	(13,288)	0.30		
Expired	(2,585)	0.30		
Outstanding as of December 31, 2018	849,039	$ 0.26	9.10	$ 30,611
Granted	470,909	0.47		
Exercised	(82,387)	0.16		$ 25,756
Cancelled or forfeited	(73,544)	0.36		
Outstanding as of December 31, 2019	1,164,017	$ 0.35	8.64	$ 143,801
Options exercisable as of December 31, 2018	424,279	$ 0.27	9.08	$ 12,105
Options exercisable as of December 31, 2019	608,156	$ 0.29	8.17	$ 111,638

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 of options granted during each of the years ended December 31, 2018 and 2019 was $0.1 million. As of December 31, 2018 and 2019, respectively, there was $0.1 million of unrecognized stock-based compensation expense related to unvested stock options. The unrecognized stock-based compensation expense is estimated to be recognized over a period of 3.0 years as of December 31, 2019.

The total fair value of options vested during the years ended December 31, 2018 and 2019, was $0.1 million and less than $0.1 million, respectively.

Shares of Restricted Common Stock

The Company has granted shares of restricted common stock with time-based vesting conditions. A summary of restricted stock activity under the 2017 Plan during the years ended December 31, 2018 and 2019 is as follows:

	YEAR ENDED DECEMBER 31,	
	2018	2019
Unvested at the beginning of the year	241,897	138,227
Vested or released	(103,670)	(103,670)
Unvested at the end of the year	138,227	34,557

As of December 31, 2018 and 2019, respectively, there was less than $1,000 of unrecognized stock-based compensation expense related to unvested restricted stock. The unrecognized stock-based compensation expense is estimated to be recognized over a period of 0.3 years as of December 31, 2019.

The total fair value of restricted stock vested during the years ended December 31, 2018 and 2019 was de minimis.

Stock-Based Compensation Expense

Total stock-based compensation expense recorded as research and development and general and administrative expenses, respectively, for employees, directors and non-employees during the years ended December 31, 2018 and 2019 is as follows (in thousands):

	YEAR ENDED DECEMBER 31,	
	2018	2019
Research and development	$ 30	$ 31
General and administrative	51	28
Total stock-based compensation expense	$ 81	$ 59

11. INCOME TAXES

Loss before provision for (benefit from) income taxes for the years ended December 31, 2018 and 2019 consisted of the following (in thousands):

	YEAR ENDED DECEMBER 31,	
	2018	2019
United States	$ (1,286)	$ (5,563)
Foreign	208	(6,773)
Loss before provision for (benefit from) income taxes	$ (1,078)	$ (12,336)

The components of income tax expense for the years ended December 31, 2018 and 2019 consisted of the following (in thousands):

	YEAR ENDED DECEMBER 31,	
	2018	2019
Current income tax expense:		
United States	$ 257	$ —
Total income tax expense	$ 257	$ —
Total deferred income tax expense	$ —	$ —
Total income tax expense	$ 257	$ —

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate for the years ended December 31, 2018 and 2019 was as follows:

	YEAR ENDED DECEMBER 31,	
	2018	2019
Federal income tax (benefit) at statutory rate	21.0 %	21.0 %
Permanent Differences	(2.5)	(0.9)
Preferred stock tranche obligation remeasurement	—	(4.4)
Research and development credits	56.5	(2.1)
State income tax, net of federal benefit	28.5	3.9
Impact of Foreign Operations	(3.3)	3.6
Other	(0.4)	—
Change in valuation allowance	(123.6)	(21.1)
Effective tax rate	(23.8)%	0.0 %

Net deferred tax assets as of December 31, 2018 and 2019 consisted of the following (in thousands):

	YEAR ENDED DECEMBER 31,	
	2018	2019
Net operating loss carryforwards	$ —	$ 3,127
Research and development credits	541	1,325
Accrueds	227	525
Other	3	1,180
Deferred revenue	2,732	—
Intangibles	108	151
Total deferred tax assets	$ 3,611	$ 6,308
Valuation allowance	(3,322)	(5,923)
Net deferred tax assets	$ 289	$ 385
Deferred tax liability		
Depreciation	(289)	(385)
Net deferred tax assets (liability)	$ —	$ —

As of December 31, 2018, the Company did not have any U.S. federal, state and foreign net operating loss carryforwards. As of December 31, 2019, the Company had U.S. federal, state and foreign net operating loss carryforwards of $11.5 million, $11.1 million and $4.3 million, respectively. The state net operating loss carryforwards begin to expire in 2039.

As of December 31, 2018, the Company had U.S. federal and state research and development tax credit carryforwards of $0.3 and $0.3 million, respectively. As of December 31, 2019, the Company had U.S. federal and state research and development tax credit carryforwards of $0.7 million and $0.7 million, respectively. The tax credits begin to expire in 2038.

Management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which are comprised principally of research and development credits and deferred revenue. Under the applicable accounting standards, management has considered the Company's history of losses and concluded that it is more likely than not that the Company will not recognize the benefits of federal and state deferred tax assets. Accordingly, a full valuation allowance was maintained as of December 31, 2018 and 2019. A change in the Company's valuation allowance was recorded in 2018 and 2019, in the amount of $1.3 million and $2.6 million, respectively, due primarily to the generation of additional net deferred tax assets.

The calculation of the Company's tax liabilities involves dealing with uncertainties in the application of complex tax laws and regulations for both federal taxes and the many states in which it operates or does business in. A tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, on the basis of the technical merits.

The Company records tax positions as liabilities and adjusts these liabilities when its judgement changes as a result of the evaluation of new information not previously available. Because of the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from the Company's current estimate of the recognized tax benefit liabilities. These differences will be reflected as increases or decreases to income tax expense in the period in which new information is available. As of December 31, 2019, the Company has not recorded any uncertain tax positions in its financial statements.

The Company recognize interest and penalties related to unrecognized tax benefits on the income tax expense line in the accompanying consolidated statement of operations. As of December 31, 2019, no accrued interest or penalties are included on the related tax liability line in the consolidated balance sheet.

The Company files tax returns 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's tax years are still open under statute from December 31, 2015, to the present. There are currently no pending income tax examinations. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service and state tax authorities to the extent utilized in a future period.

12. LOSS PER SHARE

Basic and diluted loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average common shares outstanding (in thousands, except share and per share data):

	YEAR ENDED DECEMBER 31,	
	2018	2019
Numerator:		
Net loss	$ (1,335)	$ (12,336)
Less: Accruals of dividends of preferred stock	(1,011)	(1,800)
Net loss attributable to common stockholders—basic and diluted	$ (2,346)	$ (14,136)
Denominator:		
Weighted-average common stock outstanding	2,174,514	2,326,857
Net loss per share attributable to common stockholders—basic and diluted	$ (1.08)	$ (6.08)

The Company's potentially dilutive securities, which include Preferred Stock, restricted stock, and stock options, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of 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 from the computation of diluted net loss per share attributable to common stockholders at December 31, 2018 and 2019 because including them would have had an anti-dilutive effect:

	DECEMBER 31,	
	2018	2019
Preferred stock	6,555,307	6,555,307
Unvested restricted stock	138,227	34,557
Options to purchase common stock	849,039	1,164,017
	7,542,573	7,753,881

Pro forma net loss per share was calculated as follows:

	YEAR ENDED DECEMBER 31, 2019 (Unaudited)
Numerator:	
Net loss attributable to common stockholders—basic and diluted	$ (14,136)
Plus: accruals of dividends of preferred stock	1,800
Pro forma net loss attributable to common stockholders—basic and diluted	$ (12,336)
Denominator:	
Weighted-average common stock outstanding—basic and diluted	2,326,857
Pro forma adjustment to reflect automatic conversion of convertible preferred stock to common stock upon the completion of the proposed initial public offering	6,555,307
Pro forma weighted-average common stock outstanding—basic and diluted	8,882,168
Pro forma net loss per share attributable to common stockholders—basic and diluted	$ (1.39)

13. COMMITMENTS AND CONTINGENCIES

Leases

The Company has historically entered into lease arrangements for its facilities and certain equipment. As of December 31, 2019, the Company had one operating lease with required future payments, related to its real estate. In applying the transition guidance under ASU No. 2016-02, *Leases (Topic 842)* ("ASC 842"), early adopted by the Company effective March 1, 2017, the Company determined the classification of its real estate lease to be operating and recorded a ROU asset and lease liability as of the effective date.

Operating Leases

In March 2017, the Company entered into a lease agreement (the "Lexington Lease") for its headquarters located in Lexington, Massachusetts. In July and August 2019, the Company entered into the first and second amendment, respectively, to its Lexington Lease to expand the rental space to 10,417 square feet. As required under the term of the lease agreement as collateral for the facility lease, the Company had restricted cash of $0.1 million in the form of a certificate of deposit as of December 31, 2018 and 2019. The Lexington Lease provides for scheduled annual rent increases throughout the lease term and does not include termination or purchase options.

From time to time, leases may include options to renew the lease after the expiration of the initial lease term. A renewal period is included in the lease term only when it is reasonably certain that the Company will exercise such renewal options. As of December 31, 2019, no renewal options existed that the Company believed were reasonably certain of being exercised.

The following table contains a summary of the lease costs recognized under ASC 842 and other information pertaining to the Company's operating lease for the years ended December 31, 2018 and 2019 (in thousands):

	FOR THE YEARS ENDED DECEMBER 31,	
	2018	2019
Lease cost		
Operating lease cost	$ 215	$ 278
Variable payments	—	—
Total lease cost	$ 215	$ 278
Other information		
Operating lease payments	$ 211	$ 278
Remaining lease term	4.0 years	2.9 years
Discount rate	8.44 %	8.02 %

The Lexington Lease does not include any variable payments. As the Lexington Lease does not provide an implicit rate, the Company utilized its incremental borrowing rate based on what it would normally pay to borrow on a collateralized basis over a similar term for an amount equal to the lease payments at the commencement date in determining the present value of lease payments. As of December 31, 2018 and 2019, the Company classified its short-term and long-term operating liabilities as short-term and long-term liabilities on the consolidated balance sheet, respectively.

As of December 31, 2019, future discounted lease payments under all lease arrangements accounted for under ASC 842 were as follows (in thousands):

MATURITY OF LEASE LIABILITY	
2020	$ 468
2021	482
2022	498
Total lease payments	1,448
Less: imputed interest	(173)
Total operating lease liabilities	$ 1,275
Included in the consolidated balance sheet:	
Current portion of lease liabilities	$ 376
Lease liabilities	899
Total operating lease liabilities	$ 1,275

Short-term Leases

The Company enters into short-term leasing arrangements related to storage of clinical trial materials. The Company did not have any expenses related to these arrangements for the year ended December 31, 2018, and had $1,544 related for the year ended December 31, 2019. As of December 31, 2018 and 2019, the Company classified its short-term operating lease liabilities within accrued expenses and other current liabilities, as the Company has elected the practical expedient whereby it will not recognize leases with terms of 12 months or less on the balance sheet.

Legal Proceedings

The Company is not a party to any litigation and does not have contingency reserves established for any litigation liabilities.

Other

In connection with the Lexington Lease, the Company received a loan from the landlord of $0.2 million related to its tenant improvement allowance, which is recorded as a non-current liability in the Company's consolidated balance sheets. The Company is required to repay interest only on the loan of 8.0% for the first 18 months of the lease and will then repay the full amount plus interest in installments over the remaining 3.5 year term of the lease, which expires in December 2022. The Company made payments totaling $32,337 related to the loan in 2019.

Future payments under the Company's loan obligation as of December 31, 2019, are as follows:

2020	$	65
2021		65
2022		65
Total payments	$	195

Refer to Note 7, License Agreements, for any potential future milestone or royalty payment amounts. These are not currently probable or estimable.

14. REVENUE FROM CONTRACTS WITH CUSTOMERS

The Company adopted ASC Topic 606 on January 1, 2018 applying the full retrospective method to all contracts that were not completed as of January 1, 2018. While the timing of future revenue under ASC Topic 606 may differ from the Company's historical accounting practices under ASC Topic 605, the cumulative effect recognized in the consolidated statement of stockholder's deficit was $0 because there was no change in timing or measurement of revenue for open contracts at January 1, 2018.

Novo Nordisk

On December 14, 2017, the Company entered into a research collaboration and exclusive license agreement with Novo Nordisk A/S ("Novo," agreement referred to as the "Novo Agreement"). The Novo Agreement stipulates that the two parties will work together on the discovery and development of new ligand traps for two years. Under the Novo Agreement, Keros granted Novo an exclusive license to develop and commercialize the licensed products listed as part of Keros' intellectual property and Novo granted Keros a non-exclusive license to Novo's intellectual property so that Keros could perform the activities for which it is responsible under the Novo Agreement. The Company does not share in the rights to the results of the Novo Agreement.

As consideration, the Company received an initial license payment in 2018 from Novo in the amount of $16.0 million. Novo has also paid the Company research collaboration budget funding payments of $2.0 million per each collaboration year, for $4.0 million total. Both of these research collaboration budget funding payments were received in 2018. Additionally, there are performance-based and sales-based milestone payments and sales-based royalties that have been determined to be variable consideration and constrained due to uncertainty of achievement. The sales-based royalties will be included in the transaction price and recognized as revenue once a sale occurs, and performance-based and sales-based milestone payments will be included in the transaction price and recognized as revenue if and when the cumulative revenue associated with the consideration is no longer probable of significant reversal.

The Company assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, Novo, is a customer. The Company identified the following material promises at the outset of the Novo Agreement: (1) an exclusive license to use the Company's intellectual property to conduct research activities; (2) research and development ("R&D") services for activities under the research plan; (3) an option to extend the Novo Agreement; (4) participation on the joint steering committee ("JSC"); and (5) technology transfer associated with the research and development outputs. The Company determined that these promises were not capable of being distinct from one another and were not distinct in the context of the contract, as the license has no true value without the performanceof the R&D activities and the technology transfer and JSC participation depend on these activities. Novo would not be able to use the license without the performance of R&D activities by the Company, as the research is novel in nature and could not be performed by another company. Additionally, the technology transfer is inherently dependent on the outcome of the Company's R&D

activities, and as such is not capable of being distinct. As indicated in number (3) above, Novo may elect to extend the term of the Novo Agreement to a third year on similar terms and conditions, subject to mutual written agreement of Novo and the Company. The Company assessed this option as a potential material right and determined that the additional work would be performed based on negotiated rates at the standalone selling price, and as such these services would not be provided at a significant or incremental discount and the option does not provide Novo with a material right. The Novo Agreement did not contain a significant financing component as of December 31, 2018 and 2019.

In accordance with the Company's ASC 606 assessment, the Novo Agreement was determined to contain a single combined performance obligation made up of the promises above, which does not require further allocation as the entire transaction price is allocated to this performance obligation. The Company determined the contract term of the Novo Agreement to be two years. The Company identified an appropriate measure of progress for the recognition of revenue and determined it would recognize the revenue over the term of the Novo Agreement using an input method based on full-time employee ("FTE") costs incurred, as this appropriately depicts the Company's performance in satisfaction of the performance obligation. As such, the Company is recognizing the transaction price for its single performance obligation as Novo uses the license and research and development services performed by the Company and as the Company participates on the JSC. Amounts received that have not yet been recognized as revenue are recorded in deferred revenue on the Company's consolidated balance sheet.

For the year ended December 31, 2018, the Company recognized $10.0 million as revenue in the consolidated statement of operations related to the Novo Agreement. The remaining $10.0 million of consideration was recorded as deferred revenue in the consolidated balance sheet as of December 31, 2018 and was recognized as revenue in the consolidated statements of operations according to costs incurred over the remaining term of the Novo Agreement in 2019. As the entire upfront payment and both collaboration funding payments were recognized as revenue in 2018 and 2019, the Company has no deferred revenue as of December 31, 2019.

15. SUBSEQUENT EVENTS

The Company has completed an evaluation of all subsequent events through February 26, 2020, the date these financial statements were available to be issued, and April 1, 2020 for the Series C preferred stock financing, the reverse stock split and the impact of COVID-19 referenced below. The Company has concluded that no subsequent events have occurred that require disclosure, except for those referenced below.

Series C Preferred Stock Financing

In March 2020, the Company sold an aggregate of 4,169,822 shares of its Series C preferred stock at a purchase price of $13.43 per share for an aggregate amount of approximately $56.0 million. Affiliates of the Board purchased 3,078,968 shares.

Reverse Stock Split

The Company's Board approved a one-for-2.1703 reverse stock split of its issued and outstanding common stock, stock options and preferred stock effective as of March 31, 2020. Accordingly, all share and per share amounts for all periods presented in the accompanying financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect the reverse stock split.

COVID-19

The impact of the COVID-19 coronavirus outbreak on the financial performance of the Company will depend on future developments, including the duration and spread of the outbreak and related governmental advisories and restrictions. These developments and the impact of COVID-19 on the financial markets and the overall economy are highly uncertain and cannot be predicted. If the financial markets and/or the overall economy are impacted for an extended period, the Company's results may be materially adversely affected. The Company is currently unable to determine the extent of the impact of the pandemic to its operations and financial condition.

Shares

Common Stock

PROSPECTUS

Joint Book-Running Managers

Jefferies **SVB Leerink** **Piper Sandler**

Co-Manager

H.C. Wainwright & Co.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth all costs and expenses, other than underwriting discounts and commissions, payable by us in connection with the sale of the common stock being registered. All amounts shown are estimates except for the SEC registration fee, the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee and the Nasdaq listing fee.

	AMOUNT TO BE PAID
SEC registration fee	$ *
FINRA filing fee	*
Nasdaq listing fee	*
Blue sky fees and expenses	*
Printing and engraving	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer agent and registrar fees	*
Miscellaneous fees and expenses	*
Total	$ *

* To be filed by amendment.

Item 14. Indemnification of Directors and Officers.

Section 145 of the Delaware General Corporation Law provides that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, other than an action by or in the right of the corporation, by reason of the fact that the person is or was a director, officer, employee or agent of the corporation or is or was serving at the corporation's request as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses, including attorneys' fees, judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with the action, suit or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe the person's conduct was unlawful. The power to indemnify applies to actions brought by or in the right of the corporation as well, but only to the extent of expenses, including attorneys' fees but excluding judgments, fines and amounts paid in settlement, actually and reasonably incurred by the person in connection with the defense or settlement of the action or suit if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation and except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that a court of competent jurisdiction shall determine that such indemnity is proper.

Section 145(g) of the Delaware General Corporation Law provides that a corporation shall have the power to purchase and maintain insurance on behalf of its officers, directors, employees and agents, against any liability asserted against and incurred by such persons in any such capacity.

Section 102(b)(7) of the General Corporation Law of the State of Delaware provides that a corporation may eliminate or limit the personal liability of a director to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, provided that such provision shall not eliminate or limit the liability of a director (i) for any breach of the director's duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under

Section 174 of the General Corporation Law of the State of Delaware or (iv) for any transaction from which the director derived an improper personal benefit. No such provision shall eliminate or limit the liability of a director for any act or omission occurring prior to the date when such provision becomes effective.

Our amended and restated certificate of incorporation provides that our directors shall not be liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director, except to the extent that the exculpation from liabilities is not permitted under the Delaware General Corporation Law as in effect at the time such liability is determined. In addition, our amended and restated certificate of incorporation provides that we may indemnify our directors, officers and other agents of the company to the fullest extent permitted by the laws of the State of Delaware and our amended and restated bylaws provide that we are required to indemnify our directors and executive officers to the fullest extent not prohibited by Delaware General Corporate Law. We have entered into indemnification agreements with each of our directors and officers. These indemnification agreements provide, among other things, that we will indemnify our directors and officers for certain expenses, including damages, judgments, fines, penalties, settlements and costs and attorneys' fees and disbursements, incurred by a director or officer in any claim, action or proceeding arising in his or her capacity as a director or officer of our company or in connection with service at our request for another corporation or entity. The indemnification agreements also provide for procedures that will apply in the event that a director or officer makes a claim for indemnification. We expect to enter into a similar agreement with any new directors or officers.

Our amended and restated bylaws provide that we may purchase and maintain insurance policies on behalf of our directors and officers against specified liabilities for actions taken in their capacities as such, including liabilities under the Securities Act. We have obtained directors' and officers' liability insurance to cover liabilities our directors and officers may incur in connection with their services to us, including matters arising under the securities laws.

In addition, the underwriting agreement related to this offering will provide for indemnification by the underwriters of us and our officers and directors for certain liabilities arising under the Securities Act or otherwise. Our amended and restated investors' rights agreement with certain stockholders also provides for cross-indemnification in connection with the registration of our common stock on behalf of such investors.

Item 15. Recent Sales of Unregistered Securities.

The following list sets forth information regarding all unregistered securities issued by us since January 1, 2017 through the date of the prospectus that is a part of this registration statement:

Issuances of Common Stock

In April 2017 and November 2017, we issued and sold an aggregate of 358,674 shares of our common stock to one accredited investor at $0.0002 per share for aggregate consideration of $77.84 in connection with a licensing transaction.

Issuances of Options to Purchase Common Stock

From January 1, 2017 through April 17, 2020, we granted stock options under our 2017 Stock Incentive Plan, as amended, or our 2017 Plan, to purchase up to an aggregate of 1,164,017 shares (net of expirations and cancellations) of our common stock to our employees, directors, and consultants, at a weighted average exercise price of $0.35 per share. From January 1, 2017 through April 17, 2020, 178,664 shares of our common stock were issued upon the exercise of these options and the payment of approximately $31,558.

On April 7, 2020, our 2020 Equity Incentive Plan, our 2020 Plan, became effective, and, as a result, no further awards were made under our 2017 Plan. From April 7, 2020, 2017 through April 17, 2020, we granted stock options under our 2020 Plan to purchase up to an aggregate of 1,147,436 shares (net of expirations and cancellations) of our common stock to our employees, directors, and consultants, at a weighted average exercise price of $16.00 per share.

Issuances of Preferred Stock

In November 2018, we issued and sold an aggregate of 1,579,043 shares of Series B-1 preferred stock to nine accredited investors at $7.2829 per share for aggregate consideration of approximately $11.5 million.

In March 2020, we issued and sold an aggregate of 4,169,822 shares of Series C preferred stock to 20 accredited investors at $13.43 per share for aggregate consideration of approximately $56.0 million.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. Unless otherwise specified above, we believe these transactions were exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act (and Regulation D or Regulation S promulgated thereunder) or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or under benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed on the share certificates issued in these transactions. All recipients had adequate access, through their relationships with us, to information about us. The sales of these securities were made without any general solicitation or advertising.

Item 16. Exhibits and Financial Statement Schedules.

Exhibits

EXHIBIT NO.	DESCRIPTION	FORM	FILE NO.	EXHIBIT	FILING DATE
1.1*	Form of Underwriting Agreement.				
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-39264	3.1	April 13, 2020
3.2	Amended and Restated Bylaws of the Registrant.	8-K	001-39264	3.2	April 13, 2020
4.1	Amended and Restated Investors' Rights Agreement by and among the registrant and certain of its stockholders, dated as of March 2, 2020.	S-1	333-237212	4.1	March 16, 2020
4.2	Form of Common Stock Certificate.	S-1/A	333-237212	4.2	April 1, 2020
5.1*	Opinion of Cooley LLP.				
10.1	Form of Indemnity Agreement between the registrant and its directors and officers.	S-1/A	333-237212	10.1	April 1, 2020
10.2+	2017 Stock Incentive Plan, as amended.	S-1	333-237212	10.2	March 16, 2020
10.3+	Form of Stock Option Grant Notice and Option Agreement for the 2017 Stock Incentive Plan, as amended.	S-1	333-237212	10.3	March 16, 2020
10.4+	2020 Equity Incentive Plan.	S-1/A	333-237212	10.4	April 1, 2020
10.5+	Forms of Stock Option Grant Notice, Option Agreement, Notice of Exercise, Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement for the 2020 Equity Incentive Plan.	S-1/A	333-237212	10.5	April 1, 2020
10.6+	2020 Employee Stock Purchase Plan.	S-1/A	333-237212	10.6	April 1, 2020
10.7+	Offer Letter Agreement by and between the registrant and Jasbir Seehra, dated as of December 14, 2015.	S-1	333-237212	10.7	March 16, 2020
10.8+	Offer Letter Agreement by and between the registrant and Jenn Lachey, dated as of April 20, 2016.	S-1	333-237212	10.8	March 16, 2020
10.9+	Offer Letter Agreement by and between the registrant and Claudia Ordonez, dated as of August 20, 2019.	S-1	333-237212	10.9	March 16, 2020

Confidential Treatment Requested by Keros Therapeutics, Inc.
Pursuant to 17 C.F.R. § 200.83

10.10#	Exclusive Patent License Agreement by and between the registrant and The General Hospital Corporation, d/b/a Massachusetts General Hospital, or MGH, dated as of April 5, 2016, as amended by Amendment #1 by and between the registrant and The Brigham and Women's Hospital, Inc. on May 12, 2017 and by Amendment #2 by and between the registrant and MGH on February 23, 2018.	S-1	333-237212	10.10	March 16, 2020
10.11#	Research Collaboration and Exclusive License Agreement by and between the registrant and Novo Nordisk A/S, dated as of December 14, 2017.	S-1	333-237212	10.11	March 16, 2020
10.12	Lease Agreement by and between the registrant and 128 Spring Street Lexington, LLC, dated March 20, 2017, as amended by the First Amendment to Lease Agreement by and between the registrant and 128 Spring Street Lexington, LLC, dated July 1, 2019 and by the Second Amendment to Lease Agreement by and between the registrant and 128 Spring Street Lexington, LLC, dated August 8, 2019.	S-1	333-237212	10.12	March 16, 2020
10.13+	Offer Letter Agreement by and between the registrant and Keith Regnante, dated as of February 7, 2020.	S-1	333-237212	10.13	March 16, 2020
10.14+	Employment Agreement by and between the registrant and Jasbir Seehra, dated as of March 31, 2020, to be effective upon the closing of this offering.	S-1/A	333-237212	10.14	April 1, 2020
10.15+	Employment Agreement by and between the registrant and Jenn Lachey, dated as of March 31, 2020, to be effective upon the closing of this offering.	S-1/A	333-237212	10.15	April 1, 2020
10.16+	Employment Agreement by and between the registrant and Claudia Ordonez, dated as of March 31, 2020, to be effective upon the closing of this offering.	S-1/A	333-237212	10.16	April 1, 2020
10.17+	Employment Agreement by and between the registrant and Keith Regnante, dated as of March 31, 2020, to be effective upon the closing of this offering.	S-1/A	333-237212	10.17	April 1, 2020
21.1	Subsidiaries of Keros Therapeutics, Inc.	S-1	333-237212	21.1	March 16, 2020
23.1*	Consent of Independent Registered Public Accounting Firm.				
23.2*	Consent of Cooley LLP (included in Exhibit 5.1)				
24.1*	Power of Attorney (see signature page to the registration statement).				

* To be filed by amendment.
\+ Indicates management contract or compensatory plan.
\# Certain portions of this exhibit (indicated by asterisks) have been omitted because they are not material and would likely cause competitive harm to Keros Therapeutics, Inc. if publicly disclosed.

Item 17. Undertakings.

The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the Underwriting Agreement, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 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 undersigned registrant hereby undertakes that:

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

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Lexington, Massachusetts, on the day of , 2020.

KEROS THERAPEUTICS, INC.

By: _____
Name: Jasbir Seehra, Ph.D.
Title: Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Jasbir Seehra, Ph.D. and Keith Regnante, and each of them, his true and lawful agent, proxy and attorney-in-fact, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to (1) act on, sign and file with the Securities and Exchange Commission any and all amendments (including post-effective amendments) to this registration statement together with all schedules and exhibits thereto and any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, together with all schedules and exhibits thereto, (2) act on, sign and file such certificates, instruments, agreements and other documents as may be necessary or appropriate in connection therewith, (3) act on and file any supplement to any prospectus included in this registration statement or any such amendment or any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and (4) take any and all actions which may be necessary or appropriate to be done, as fully for all intents and purposes as he might or could do in person, hereby approving, ratifying and confirming all that such agent, proxy and attorney-in-fact or any of his substitutes may lawfully do or cause to be done by virtue thereof.

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

NAME	POSITION	DATE
Jasbir Seehra, Ph.D.	Chief Executive Officer and Director *(Principal Executive Officer)*	, 2020
Keith Regnante	Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*	, 2020
Nima Farzan	Director	, 2020
Carl Gordon, Ph.D., C.F.A.	Director	, 2020
Tomer Kariv	Director	, 2020
Julius Knowles	Director	, 2020
Alon Lazarus, Ph.D.	Director	, 2020
Ran Nussbaum	Director	, 2020