

Amendment No. 2 to Draft Registration Statement, as confidentially submitted to the Securities and Exchange Commission on November 3, 2020  
This draft registration statement has not been filed publicly with the Securities and Exchange Commission, and all information herein remains strictly confidential.

Registration No. 333-

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM S-1  
REGISTRATION STATEMENT**  
*Under  
The Securities Act of 1933*

**KINNATE BIOPHARMA INC.**

(Exact name of Registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

2834  
(Primary Standard Industrial  
Classification Code Number)

82-4566526  
(I.R.S. Employer  
Identification Number)

11975 El Camino Real, Suite 101  
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(858) 299-4699

(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

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**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, 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 statement 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 <input type="checkbox"/>	Accelerated filer <input type="checkbox"/>
Non-accelerated filer <input checked="" type="checkbox"/>	Smaller reporting company <input checked="" type="checkbox"/>
	Emerging growth company <input checked="" type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 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 <sup>(1)(2)</sup>	Amount of Registration Fee
Common Stock \$0.0001 par value	\$	\$

(1) Includes offering price of any additional shares of common stock that the underwriters have the option to purchase.

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

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 which 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 Commission, acting pursuant to said Section 8(a), may determine.

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The information contained 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

Shares



## Common Stock

This is the initial public offering of shares of common stock of Kinnate Biopharma Inc. We are offering \_\_\_\_\_ shares of common stock.

Prior to this offering, there has been no public market for our common stock. It is currently estimated that the initial public offering price will be between \$ \_\_\_\_\_ and \$ \_\_\_\_\_ per share.

We intend to apply to list our common stock on the \_\_\_\_\_ under the symbol "\_\_\_\_\_."

We are an "emerging growth company" and a "smaller reporting company" as defined under the federal securities laws and, as such, have elected to comply with certain reduced public company reporting requirements in this prospectus and may elect to do so in future filings.

See the section titled "Risk Factors" beginning on page [13](#) to read about factors you should consider before deciding to invest in shares of our common stock.

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

	Per Share	Total
Initial public offering price	\$ _____	\$ _____
Underwriting discounts and commissions <sup>(1)</sup>	\$ _____	\$ _____
Proceeds, before expenses, to Kinnate Biopharma Inc.	\$ _____	\$ _____

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

To the extent that the underwriters sell more than \_\_\_\_\_ shares of common stock, the underwriters have an option to purchase up to an additional \_\_\_\_\_ shares from us at the initial public offering price, less the underwriting discounts and commissions.

The underwriters expect to deliver the shares against payment in New York, New York on \_\_\_\_\_, 2020.

**Goldman Sachs & Co. LLC**

**SVB Leerink**

**Piper Sandler**

**Wedbush PacGrow**

Prospectus dated \_\_\_\_\_, 2020

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Through and including \_\_\_\_\_, 2020 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

Neither we nor the underwriters have authorized anyone to provide you any information or make any representations other than that contained in this prospectus or in any free writing prospectus 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. We and the underwriters are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside of 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 the United States. Persons outside of 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 of the United States.

## PROSPECTUS SUMMARY

*This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information investors should consider before investing in our common stock. Investors should read this entire prospectus carefully, especially the section titled "Risk Factors" and our financial statements and the related notes appearing elsewhere in this prospectus, before making an investment decision. As used in this prospectus, unless the context otherwise requires, references to "we," "us," "our," "our company," and "Kinnate" refer to Kinnate Biopharma Inc.*

### Overview

We are a biopharmaceutical company focused on the discovery and development of small molecule kinase inhibitors for difficult-to-treat, genomically defined cancers. Our mission is to expand the reach of targeted therapeutics by developing products for underserved populations. We utilize our deep expertise in structure-based drug discovery, translational research and patient-driven precision medicine, which we collectively refer to as our Kinnate Discovery Engine, to develop our targeted therapies. We focus our discovery and development efforts on three patient populations: (1) those with cancers that harbor known oncogenic drivers (gene mutations that cause cancers) with no currently available targeted therapies, (2) those with genomically well-characterized tumors that have intrinsic resistance to currently available treatments, and (3) those whose tumors have acquired resistance over the course of therapy to currently available treatments. We believe our unique approach may enable us to develop drugs with an increased probability of clinical success while reducing the cost and risk of drug development. Our most advanced product candidate is KIN002787, which is a Rapidly Accelerated Fibrosarcoma (RAF) inhibitor we are developing for the treatment of patients with lung cancer, melanoma and other solid tumors. Unlike currently available treatments that target only Class I B-Rapidly Accelerated Fibrosarcoma (BRAF) kinase mutations, we have designed KIN002787 to target Class II and Class III BRAF mutations, where it would be a first-line targeted therapy, in addition to covering Class I BRAF mutations. We anticipate filing an Investigational New Drug application (IND) for KIN002787 with the U.S. Food and Drug Administration (FDA) in the first half of 2021. Additionally, in our KIN003 program we are evaluating Fibroblast Growth Factor Receptors (FGFR) inhibitor candidates for the treatment of patients with intrahepatic cholangiocarcinoma (ICC), a cancer of the bile ducts in the liver, and urothelial carcinoma (UC), a cancer of the bladder lining. Our FGFR candidates are designed to address clinically observed genomic alterations in FGFR2 and FGFR3 that drive resistance to current therapies. We are also advancing a number of other small molecule research programs, including a Cyclin-Dependent Kinase 12 (CDK12) inhibitor in our KIN004 program. We anticipate filing an IND for one of our FGFR candidates in our KIN003 program with the FDA in the first half of 2022. Our RAF and FGFR candidates have demonstrated proof of concept in preclinical models and, subject to our planned IND submissions taking effect, we anticipate initiating a Phase 1 clinical trial for KIN002787 in 2021 and an additional Phase 1 clinical trial for our KIN003 program in the first half of 2022.

### Background of Kinase Inhibitors

Kinase inhibition is a proven approach to fighting cancer, and for nearly two decades, has addressed an increasing number of oncology indications. Kinases are enzymes that regulate the biological activity of proteins. Mutated kinases can result in deregulated activity that results in cancerous cell proliferation. Currently approved drugs that inhibit the activity of mutated oncogenic kinases (kinase inhibitors) have demonstrated significant clinical benefit to hundreds of thousands of cancer patients globally. The worldwide sales of small molecule kinase inhibitors in oncology were reported to be \$23 billion in 2019 and are estimated to grow to more than \$50 billion in 2024. However, because of the limitations of currently approved drugs, it is estimated that only 10% of all patients with advanced or metastatic cancer today are eligible for these treatments. This low penetration of targeted therapies demonstrates a substantial unmet patient need and market opportunity.

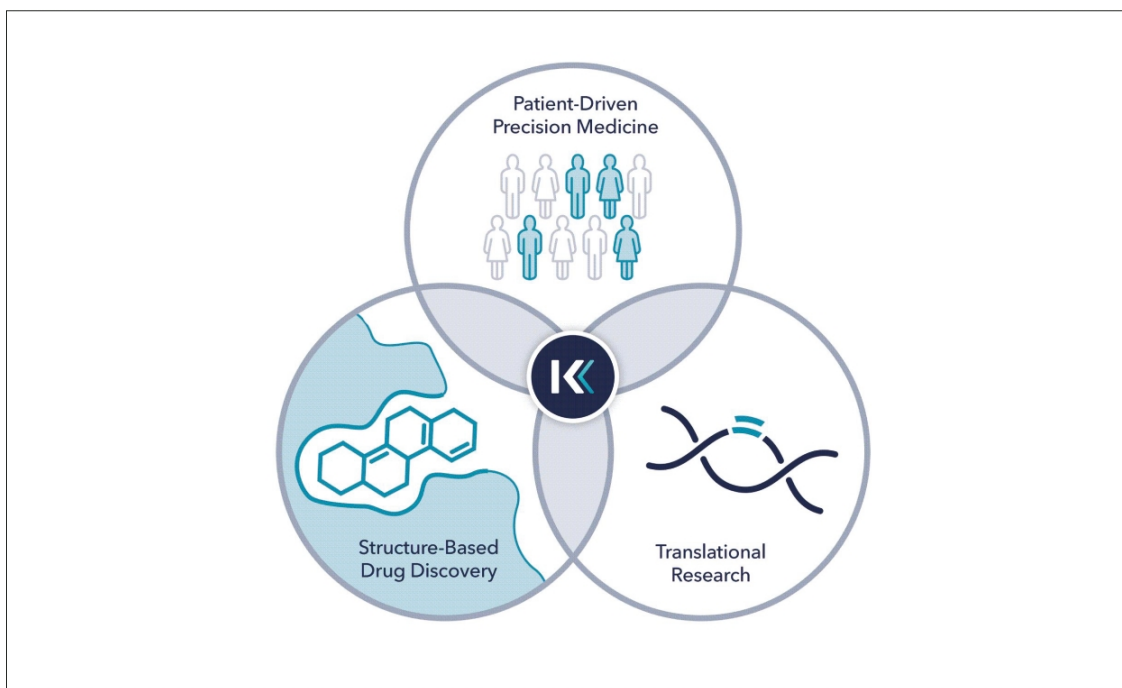
Of the 10% of all patients with advanced or metastatic cancer eligible for targeted therapeutics, where a defined genomic driver is matched with a currently approved targeted therapy, only up to 50% (5% of all patients) will respond to the therapy (the responders), while the remainder gain no clinical benefit due to intrinsic resistance (the non-responders). Furthermore, among the responders, the majority

(conservatively estimated at 50% to 80%) will eventually develop acquired resistance, lose their beneficial response to the therapy and experience disease progression despite continued treatment with the targeted therapy. Therefore, it is estimated that only 2% to 3% of current patients with advanced or metastatic cancer will have durable responses to currently available targeted therapeutics.

RAF kinases are a family of proteins that are involved in growth signaling, and include ARAF, BRAF and CRAF. BRAF mutations, which increase signaling, are divided into three classes: mutations where BRAF signals as a monomer (Class I), as a dimer of BRAF molecules (Class II) and as a dimer of BRAF and CRAF molecules (Class III). BRAF mutations occur in approximately 6% of all human cancers but there are only three BRAF-targeted kinase inhibitor drugs approved by the FDA for use in Class I BRAF mutation driven cancers. Further, no targeted therapies have been approved for Class II or Class III BRAF mutation-driven cancers. Genomic alterations in the FGFR gene family occur in approximately 7% of human cancers. Approximately 30% to 35% of patients with urothelial cancers and cholangiocarcinoma whose tumors are driven by FGFR-dependent driver genes will respond to the two currently FDA-approved FGFR-targeting drugs. However, the duration of response (DoR) of such inhibitors is limited due to acquired mutational resistance, which is estimated to occur in the majority of patients. Taken together, this represents a substantial opportunity for developing novel and potentially transformative drugs for underserved patient populations with difficult-to-treat, genomically defined cancers.

### Our Kinnate Discovery Engine

The key elements of our strategy come together to form our Kinnate Discovery Engine, which seeks to leverage our team's significant industry expertise to drive towards accelerated clinical development, regulatory review, and ultimately, potential new drug approval. We are led by a management team of precision oncology experts with decades of collective experience in the discovery, development and commercialization of novel therapeutics who have held leadership positions at four of the top global oncology companies: Amgen Inc., AstraZeneca plc, Novartis AG, and Pfizer Inc. This expertise extends to our established collaborations with leaders at experienced precision medicine cancer centers and research institutions.



We believe our expertise and the foundational principles driving our highly productive Kinnate Discovery Engine offer an opportunity to identify and develop precision oncology solutions for populations that are currently underserved. Our Kinnate Discovery Engine encompasses:

- **Structure-based drug discovery.** Through our integrated biology and chemistry approach led by experts in small molecule kinase inhibitors, we identify compounds with a high probability of success in inhibiting selective kinase targets.
- **Translational research.** We employ a biomarker-driven approach to predict and increase the likelihood of therapeutic response to our product candidates in patients.
- **Patient-driven precision medicine.** Capitalizing on next-generation sequencing technologies and guidance from leaders at experienced precision medicine cancer centers, we define emerging patient populations for our product candidates.

Leveraging our Kinnate Discovery Engine, to date we have generated more than 3,300 new chemical entities (NCEs), conducted more than 4,000 Drug Metabolism and Pharmacokinetics (DMPK) studies, developed more than 170 unique *in vitro* assays and completed more than 80 *in vivo* pharmacology studies, while profiling 30 compounds for kinome selectivity.

### Our Approach

We employ a consistent, systematic approach to identify kinases that drive difficult-to-treat, genomically defined cancers. Through this approach, we aim to develop kinase inhibitor product candidates with therapeutic windows that provide durable and meaningful clinical responses to benefit patients in three patient populations:

- those with cancers that harbor known oncogenic drivers with no currently available targeted therapies;
- those with genomically well-characterized tumors that have intrinsic resistance to currently available treatments (non-responders); and
- those whose tumors have acquired resistance over the course of therapy to currently available treatments.

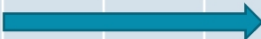
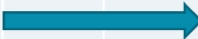

By focusing on these three well-characterized patient populations, we believe that we will have a more efficient development path with potentially improved response rates in these populations. Due to advancements in genomic profiling and our collaborations with leaders at experienced precision medicine cancer centers and research institutions, we have established and continue to develop a deep expertise and understanding of specific oncogenic drivers. Our collaborations allow us to:

- define emerging patient populations;
- demonstrate selective *in vitro* and *in vivo* activity and define dose-exposure pharmacodynamic relationships in clinically relevant models;
- test prioritized compounds against specific mutations and fusions;
- investigate mechanism of action—the specific biochemical interaction through which a drug substance produces its pharmacological effect—to support the refinement of strategies for patient selection and patient stratification for both monotherapy and rationale combinations; and
- develop biomarker-based development strategies that will drive patient selection in our clinical programs.

The combination of these defined patient populations, our deep understanding of oncogenic drivers and our Kinnate Discovery Engine allows us to target known kinases that have previously been difficult to inhibit selectively and also to identify, characterize and develop product candidates for novel kinase targets with clearly validated paths to early clinical signals.

## Our Programs

Our lead preclinical programs include small molecule inhibitors targeting specific classes of BRAF kinase mutations (Class II and Class III BRAF mutations) and specific alterations of FGFR2 and FGFR3 that aim to overcome the genomic resistance commonly limiting the efficacy of existing therapies. We are also advancing a number of other small molecule research programs, including a CDK12 inhibitor in lead optimization and several other undisclosed targets with compounds at the lead identification stage.

Target, Program	Discovery	Lead Optimization	IND-Enabling	Phase 1	Phase 2	Phase 3	Next Anticipated Milestones
RAF KIN002787							IND H1 2021 Initiate Phase 1 in 2021
FGFR2/3 KIN003							IND H1 2022 Initiate Phase 1 in H1 2022
CDK12 KIN004							

### RAF Program: KIN002787

In our most advanced program, we are developing KIN002787, a small molecule kinase inhibitor targeting specific classes of BRAF kinase mutations (Class II and Class III BRAF mutations) that characterize subsets of lung cancer, melanoma and other solid tumors. No targeted therapies have currently been approved for Class II or Class III BRAF mutation-driven cancers, unlike the Class I BRAF mutations where three BRAF-targeted kinase inhibitor drugs have been approved by the FDA. Patients with cancers driven by Class II or Class III BRAF mutations have not responded to existing targeted therapies and have few treatment options currently available to them. Initially, we plan to develop our RAF inhibitor product candidate, KIN002787, for the treatment of patients with non-small cell lung cancer (NSCLC) and melanoma subpopulations with Class II or Class III BRAF mutations that include specific BRAF point mutations (other than BRAF V600E), BRAF insertions/deletions (indels) and BRAF gene fusion events. We believe KIN002787 may provide substantial clinical benefit to these cancer patients who are inadequately served by current therapies.

In our *in vitro* and *in vivo* preclinical studies evaluating KIN002787, we observed kinase inhibition selectivity and a reduction in the size of tumors from drug treated models of human cancer. In internal *in vitro* and *in vivo* head-to-head comparisons, we have seen improved kinase inhibition selectivity and pharmaceutical properties compared to a number of currently approved drugs and in-development drug candidates. Importantly, KIN002787 demonstrated inhibition of RAF dimer signaling while minimizing mitogen-activated protein kinase (MAPK) pathway rebound, potentially resulting in a broad therapeutic index. We anticipate filing an IND for KIN002787 with the FDA in the first half of 2021 and, subject to such submission taking effect, initiating a Phase 1 clinical trial in 2021. We are designing our first in human clinical trial primarily to assess the safety and tolerability of KIN002787 in patients with advanced or metastatic solid tumors driven by specific classes of BRAF mutations, while also characterizing pharmacological and anti-cancer properties of our candidate.

### FGFR Program: KIN003

We are developing small-molecule kinase inhibitors that target cancer-associated alterations in FGFR2 and FGFR3 genes, which (together with BRAF mutations) are among the most commonly identified oncogenic drivers detected in solid tumor cancers. Our KIN003 program aims to address the initial alteration and clinically-observed and predicted mutations in FGFR2 fusion gene-positive ICC and FGFR3-altered UC that drive resistance to current FGFR2- and FGFR3-targeted therapies. We believe this will translate to deeper, more sustained and more clinically impactful cancer responses than those observed with either of the two currently FDA-approved FGFR inhibitors, or other targeted drugs that, to our knowledge, are currently in development.



We are evaluating our FGFR inhibitor candidates for the treatment of patients with ICC and UC. In preclinical studies, we have observed inhibitory activity across a broad range of clinically-relevant genomic alterations in FGFR2 and FGFR3 that drive resistance to current therapies. Because our preclinical studies demonstrated our candidates' ability to cover the initial alterations and preemptively address these resistance mutations, we believe we may be able to meaningfully increase the DoR for certain patients by addressing these alterations. We plan to develop our candidates initially for patients whose tumors have acquired resistance to therapies targeting FGFR2 or FGFR3 alterations, which limits the durability of response. As with other precision oncology approaches, addressing resistance mutations may also ultimately enable us to develop a first-line therapy. In this program, we plan to adopt many of the same principles as our RAF program but to primarily focus on cancers that are driven by alterations in FGFR2 and FGFR3. We plan to nominate a lead product candidate in our KIN003 program in 2021, file an IND with the FDA in the first half of 2022 and, subject to such submission taking effect, initiate a Phase 1 clinical trial in the first half of 2022.

#### ***CDK12 Inhibitor Program (KIN004) and Other Research Programs***

Through the broad applicability of our Kinnate Discovery Engine, we are also advancing a number of other small molecule research programs, including a CDK12 inhibitor in our KIN004 program. CDK12 is an essential regulator of DNA damage response genes for which no targeted therapies are currently approved or, to our knowledge, in clinical development. We expect to develop a CDK12 inhibitor candidate to target the treatment of ovarian carcinoma (OC), metastatic castration-resistant prostate cancer (mCRPC) and triple-negative breast cancer (TNBC). CDK12 and our other small molecule research programs are aimed at addressing cancer cases not covered by existing targeted therapies.

#### **Our Strategy**

Our mission is to expand the reach of targeted therapeutics by developing products for underserved populations. The key elements of our strategy are to:

- Rapidly advance the development of our lead targeted therapy RAF and FGFR candidates.
- Develop a pipeline of product candidates focused on overcoming the limitations of current targeted oncology therapeutics.
- Increase our probability of clinical success by prioritizing known oncogenic drivers for development and incorporating biomarkers into preclinical and clinical development.
- Leverage our existing relationships, collaborations and experience to efficiently develop and expand our product portfolio.
- Maximize the clinical impact and value of our portfolio.

#### **Our Team and Investors**

Our management team includes:

- **Precision oncology and kinase inhibitor experts** who have held leadership positions at four of the top global oncology companies: Amgen Inc., AstraZeneca plc, Novartis AG, and Pfizer Inc. Our team includes one of the inventors of Inlyta (axitinib), Lorbrena (lorlatinib) and Xalkori (crizotinib), the research co-lead for LXH254 and the translational co-lead for PLX8394. Our team members have also been involved with the development of Mektovi (binimetinib), Cabometyx (cabozantinib), Tavegyl (crizotinib), Zykadia (ceritinib), Braftovi (encorafenib), Rozlytrek (entrectinib) and EGF816.
- **Functional experts across domains such as biomarkers and toxicology** who have developed their expertise at companies including AstraZeneca plc, Exelixis, Inc., GRAIL, Inc., Puma Biotechnology, Inc. and WuXi NextCODE Genomics USA, Inc. (now known as Genuity Science, Inc.).
- **Senior leaders with a track record of success** who have built and operated drug development businesses from research and development to commercial-stage operations at companies including Audentes Therapeutics, Inc., Biogen Inc., Novartis AG, PaxVax, Inc. (now part of Emergent BioSolutions Inc.), and Qanticeal Pharmaceuticals, Inc.



We intend to leverage the experience of our leadership team to efficiently advance our pipeline. In addition to our strong leadership team, our scientific advisors include researchers who publish widely-cited research on topics relevant to the study and treatment of cancer, lead clinical units at experienced precision medicine cancer centers in the United States and are actively involved in our drug development process and programs. Our scientific advisory board includes leaders at Massachusetts General Hospital Cancer Center, Memorial Sloan Kettering Cancer Center and Moores Cancer Center at UCSD, including Keith Flaherty, M.D. (co-founder of Loxo Oncology, Inc.), who is also on our board of directors.

Since our inception, we have raised over \$190 million from a syndicate of leading life sciences investors that includes Foresite Capital, OrbiMed, RA Capital Management, Nextech Invest, Vida Ventures, Viking Global Investors, Venrock Healthcare Capital Partners, Fidelity Management & Research Company, LLC, Boxer Capital of Tavistock Group, Janus Henderson Investors, Surveyor Capital (a Citadel company) and Logos Capital.

### **Risks Associated with Our Business**

Our ability to execute on our business strategy is subject to a number of risks, which are discussed more fully in the section titled “Risk Factors.” Investors should carefully consider these risks before making an investment in our common stock. These risks include, among others, the following:

- We are very early in our development efforts, have a limited operating history, have not initiated or completed any clinical trials, have no products approved for commercial sale and have not generated any revenue, which may make it difficult for investors to evaluate our current business and likelihood of success and viability.
- We have incurred significant net losses in each period since our inception, and we expect to continue to incur significant net losses for the foreseeable future.
- Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve our objectives relating to the discovery, development and commercialization of our product candidates.
- Even if this offering is successful, we will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce or eliminate one or more of our research and drug development programs, future commercialization efforts, product development or other operations.
- We are very early in our development efforts and are substantially dependent on our RAF and FGFR programs. If we are unable to advance any product candidates from our RAF or FGFR programs through preclinical and clinical development, obtain regulatory approval and ultimately commercialize such product candidates, or experience significant delays in doing so, our business will be materially harmed.
- Our preclinical studies and clinical trials may fail to adequately demonstrate the safety and efficacy of any of our product candidates, which would prevent or delay development, regulatory approval and commercialization.
- Our discovery and preclinical development activities are focused on the development of targeted therapeutics for patients with genomically defined cancers, which is a rapidly evolving area of science, and the approach we are taking to discover and develop drugs is novel and may never lead to approved or marketable products.
- The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, European Medicines Agency (EMA) or other comparable foreign regulatory authorities.
- In addition to our RAF and FGFR programs, our prospects depend in part upon discovering, developing and commercializing product candidates from our CDK12 and other research programs, which may fail in development or suffer delays that adversely affect their commercial viability.

- Our approach to the discovery and development of product candidates is unproven, and we may not be successful in our efforts to use and expand our Kinnate Discovery Engine to build a pipeline of product candidates with commercial value.
- The regulatory approval processes of the FDA, EMA and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval of our product candidates, we will be unable to generate product revenue and our business will be substantially harmed.
- We have no experience as a company in conducting clinical trials.
- The COVID-19 pandemic could adversely impact our business, including our planned clinical trials and ongoing and planned preclinical studies.
- We face substantial competition which may result in others discovering, developing or commercializing products before or more successfully than we do.
- Our success depends on our ability to protect our intellectual property and our proprietary technologies.

### **Corporate Information**

We were incorporated in Delaware in January 2018. Our principal executive offices are located at 11975 El Camino Real, Suite 101, San Diego, CA 92130. Our telephone number is (858) 299-4699. Our website address is [www.kinnate.com](http://www.kinnate.com). Information contained on the website is not incorporated by reference into this prospectus and should not be considered to be part of this prospectus. The inclusion of our website address in this prospectus is an inactive textual reference only.

### **Trademarks and Service Marks**

We use the Kinnate logo and other marks as trademarks in the United States and other countries. This prospectus contains references to our trademarks and service marks and to those belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without a trademark symbol, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other entities' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

### **Implications of Being an Emerging Growth Company and a Smaller Reporting Company**

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended (JOBS Act). We will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have more than \$1.07 billion in annual revenue; (ii) the date we qualify as a "large accelerated filer," with at least \$700 million of equity securities held by non-affiliates; (iii) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period; and (iv) the last day of the fiscal year ending after the fifth anniversary of our initial public offering. As a result of this status, we have taken advantage of reduced reporting requirements in this prospectus and may elect to take advantage of other reduced reporting requirements in our future filings with the U.S. Securities and Exchange Commission. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies. We have elected to use the extended transition period to enable us to comply with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date on which we (1) are no longer an emerging growth company and (2) affirmatively and irrevocably opt out of the extended transition

period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We are also a “smaller reporting company,” meaning that the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than \$700 million and our annual revenue was less than \$100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after this offering if either (i) the market value of our stock held by non-affiliates is less than \$250 million or (ii) our annual revenue was less than \$100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than \$700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

The Offering	
Common stock offered by us	shares.
Option to purchase additional shares	We have granted the underwriters an option for a period of 30 days to purchase up to additional shares of our common stock.
Common stock to be outstanding immediately after this offering	shares (or shares if the underwriters exercise in full their option to purchase additional shares).
Use of proceeds	<p>We estimate that the net proceeds from this offering will be approximately \$ million, or \$ million if the underwriters exercise in full their option to purchase additional shares of common stock, assuming an initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.</p> <p>We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, to fund the continued development of our most advanced product candidate, KIN002787, to fund the continued development of candidates in our FGFR program, and to fund the continued development of our other research programs, as well as for working capital and other general corporate purposes. See the section titled "Use of Proceeds" for more information.</p>
Risk factors	See the section titled "Risk Factors" for a discussion of factors investors should carefully consider before deciding to invest in shares of our common stock.
Proposed trading symbol	" "
<p>The number of shares of our common stock to be outstanding after this offering is based on 36,452,278 shares of our common stock outstanding as of September 30, 2020 (including our convertible preferred stock on an as-converted basis), and excludes:</p> <ul style="list-style-type: none"> <li>• 7,037,046 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2020 with a weighted-average exercise price of \$2.49 per share;</li> <li>• shares of common stock issuable upon the exercise of options granted after September 30, 2020 with a weighted-average exercise price of \$ per share;</li> <li>• 1,379,209 shares of common stock reserved for future issuance under our 2018 Equity Incentive Plan, as amended, as of September 30, 2020, which shares will be added to the shares to be reserved for future issuance under our 2020 Equity Incentive Plan (2020 Plan);</li> <li>• shares of common stock reserved for future issuance under our 2020 Plan, which will become effective on the business day immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan; and</li> </ul>	

- shares of common stock reserved for future issuance under our 2020 Employee Stock Purchase Plan (2020 ESPP), which will become effective on the business day immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan.

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

- a 1-for- reverse stock split of our capital stock, which was effected on ;
- no exercise of the outstanding options referred to above;
- no exercise by the underwriters of their option to purchase additional shares of common stock from us in this offering;
- the automatic conversion of all outstanding shares of our convertible preferred stock as of September 30, 2020 into an aggregate of 31,824,284 shares of our common stock immediately prior to the completion of this offering; and
- the filing and effectiveness of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws, each of which will occur immediately prior to the completion of this offering.

### Summary Financial Data

The following tables set forth a summary of our financial data for the periods and as of the dates indicated. We have derived the summary statements of operations for the period from January 4, 2018 (inception) to December 31, 2018 and for the year ended December 31, 2019 from our audited financial statements appearing elsewhere in this prospectus. We have derived the summary statements of operations data for the nine months ended September 30, 2019 and 2020, and the summary balance sheet data as of September 30, 2020, from our unaudited interim financial statements appearing elsewhere in this prospectus. Our unaudited interim financial statements have been prepared on a basis consistent with our audited financial statements and, in the opinion of management, reflect all adjustments, consisting solely of normal recurring adjustments, necessary for the fair presentation of the financial information in those statements. Investors should read the following summary financial data together with our financial statements and the related notes appearing elsewhere in this prospectus and the information in the sections titled "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our historical results are not necessarily indicative of our future results, and the results for any interim period are not necessarily indicative of the results to be expected for the full year or any other period. The summary financial data in this section are not intended to replace the financial statements and the related notes appearing elsewhere in this prospectus.

	Period from January 4, 2018 (inception) through December 31, 2018	Year Ended December 31, 2019	Nine Months Ended September 30,	
			2019	2020
			(unaudited)	
(in thousands, except share and per share amounts)				
Statements of Operations Data:				
Operating expenses:				
Research and development (includes related party amounts of \$1,454, \$2,301, \$1,551, and \$0, respectively)	\$ 5,675	\$ 8,955	\$ 5,896	\$ 17,261
General and administrative (includes related party amounts of \$1,600, \$2,609, \$1,827, and \$92, respectively)	1,955	3,057	2,131	\$ 5,021
Total operating expenses	7,630	12,012	8,027	22,282
Loss from operations	(7,630)	(12,012)	(8,027)	(22,282)
Other income:				
Interest income	—	43	—	228
Total other income	—	43	—	228
Net loss and comprehensive loss	\$ (7,630)	\$ (11,969)	\$ (8,027)	\$ (22,054)
Gain on extinguishment of Series A convertible preferred stock	—	2,031	2,031	
Net loss attributable to common stockholders	\$ (7,630)	\$ (9,938)	\$ (5,996)	\$ (22,054)
Weighted-average shares outstanding, basic and diluted	4,504,024	4,517,713	4,517,500	4,578,904
Net loss attributable to common stockholders per share, basic and diluted	\$ (1.69)	\$ (2.20)	\$ (1.33)	\$ (4.82)
Pro forma weighted-average shares outstanding, basic and diluted (unaudited)		13,333,894		28,743,251
Pro forma net loss attributable to common stockholders per share, basic and diluted (unaudited)		\$ (0.75)		\$ (0.77)

As of September 30, 2020			
	Actual	Pro Forma <sup>(1)</sup>	Pro Forma As Adjusted <sup>(2)(3)</sup>
		(unaudited)	
		(in thousands)	
<b>Balance Sheet Data:</b>			
Cash and cash equivalents	\$156,859	\$156,859	\$
Working capital <sup>(4)</sup>	150,780	150,780	
Total assets	159,197	157,479	
Current liabilities	6,699	6,699	
Total liabilities	6,699	6,699	
Convertible preferred stock	190,835	—	
Accumulated deficit	(39,622)	(39,622)	
Total stockholders' equity (deficit)	(38,337)	152,498	
<p>(1) The pro forma balance sheet data gives effect to the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 31,824,284 shares of our common stock which will occur immediately prior to the completion of this offering, resulting in an aggregate of 36,452,278 outstanding shares of our common stock.</p> <p>(2) The pro forma as adjusted column in the balance sheet data table above gives effect to (i) the pro forma adjustments described in footnote (1) above and (ii) the issuance and sale of shares of common stock in this offering at the assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.</p> <p>(3) Each \$1.00 increase or decrease in the assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, the pro forma as adjusted amount of each of our cash and cash equivalents, working capital, total assets and stockholders' equity (deficit) by \$ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1.0 million shares in the number of shares offered by us at the assumed initial public offering price would increase or decrease, as applicable, each of our cash and cash equivalents, working capital, total assets, and stockholders' equity (deficit) by \$ million. The pro forma as adjusted information set forth above is illustrative only and will depend on the actual initial public offering price and other terms of this offering determined at pricing.</p> <p>(4) We define working capital as current assets less current liabilities. See our financial statements appearing elsewhere in this prospectus for further details regarding our current assets and current liabilities.</p>			



## RISK FACTORS

*Investing in our common stock involves a high degree of risk. Investors should carefully consider the risks described below, as well as the other information in this prospectus, including our financial statements and the related notes appearing elsewhere in this prospectus and the section titled "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 investors may lose all or part of their investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations and the market price of our common stock.*

### **Risks Related to our Financial Position and Need for Additional Capital**

***We are very early in our development efforts, have a limited operating history, have not initiated or completed any clinical trials, have no products approved for commercial sale and have not generated any revenue, which may make it difficult for investors to evaluate our current business and likelihood of success and viability.***

We are a preclinical-stage biopharmaceutical company with a limited operating history upon which investors can evaluate our business and prospects. We commenced operations in January 2018, have never initiated or completed any clinical trials, have no products approved for commercial sale and have never generated any revenue. Drug development is a highly uncertain undertaking and involves a substantial degree of risk. To date, we have devoted substantially all of our resources to research and development activities, including with respect to our Rapidly Accelerated Fibrosarcoma (RAF) inhibitor and Fibroblast Growth Factor Receptors (FGFR) inhibitor programs and our CDK12 and other research programs, business planning, establishing and maintaining our intellectual property portfolio, hiring personnel, raising capital and providing general and administrative support for these operations.

We have not yet demonstrated our ability to successfully initiate and complete any clinical trials, obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. As a result, it may be more difficult for investors to accurately predict our likelihood of success and viability than it could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by early-stage biopharmaceutical companies in rapidly evolving fields. We also expect that, as we advance our product candidates, we will need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We have not yet demonstrated an ability to successfully overcome such risks and difficulties, or to make such a transition. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

***We have incurred significant net losses in each period since our inception, and we expect to continue to incur significant net losses for the foreseeable future.***

We have incurred significant net losses in each reporting period since our inception, have not generated any revenue to date and have financed our operations principally through private placements of our convertible preferred stock. Our net loss was \$12.0 million for the year ended December 31, 2019, and \$22.1 million for the nine months ended September 30, 2020. As of September 30, 2020, we had an accumulated deficit of \$39.6 million. We are still in the early stages of development of our product candidates and have not yet initiated or completed any clinical trials. As a result, we expect that it will be several years, if ever, before we have a commercialized product and generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses in order to discover, develop and market additional potential products.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. 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 working capital, our ability to fund the development of our product candidates and our ability to achieve and maintain profitability and the performance of our stock.

***Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve our objectives relating to the discovery, development and commercialization of our product candidates.***

We rely on our team's expertise in structure-based drug discovery, translational research and patient-driven precision medicine, which we collectively refer to as our Kinnate Discovery Engine, to develop our product candidates. Our business depends significantly on the success of this engine and the development and commercialization of the product candidates that we discover with this engine. We have no products approved for commercial sale and do not anticipate generating any revenue from product sales for the next several years, if ever. Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve several objectives, including:

- successful and timely completion of preclinical and clinical development of product candidates from our RAF and FGFR programs, our CDK12 and other research programs, and any other future programs;
- establishing and maintaining relationships with contract research organizations (CROs) and clinical sites for the clinical development of product candidates from our RAF and FGFR programs, our CDK12 and other research programs, and any other future programs;
- timely receipt of marketing approvals from applicable regulatory authorities for any product candidates for which we successfully complete clinical development;
- developing an efficient and scalable manufacturing process for our product candidates, including obtaining finished products that are appropriately packaged for sale;
- establishing and maintaining commercially viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet the market demand for our product candidates, if approved;
- successful commercial launch following any marketing approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;
- a continued acceptable safety profile following any marketing approval of our product candidates;
- commercial acceptance of our product candidates by patients, the medical community and third-party payors;
- satisfying any required post-marketing approval commitments to applicable regulatory authorities;
- identifying, assessing and developing new product candidates;
- obtaining, maintaining and expanding patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- defending against third-party interference or infringement claims, if any;
- entering into, on favorable terms, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- obtaining coverage and adequate reimbursement by third-party payors for our product candidates;
- addressing any competing therapies and technological and market developments; and
- attracting, hiring and retaining qualified personnel.

We may never be successful in achieving our objectives and, even if we do, 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 maintain or further our research and development efforts, raise additional necessary capital, grow our business and continue our operations.

***Even if this offering is successful, we will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce or eliminate one or more of our research and drug development programs, future commercialization efforts, product development or other operations.***

Since our inception, we have used substantial amounts of cash to fund our operations, and our expenses will increase substantially in the foreseeable future in connection with our ongoing activities, particularly as we continue the research and development of, initiate clinical trials of, and seek marketing approval for, our product candidates. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Even if one or more of our product candidates or any future product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with sales, marketing, manufacturing and distribution activities. Our expenses could increase beyond expectations if we are required by the FDA, the European Medicines Agency (EMA) or other regulatory agencies to perform clinical trials or preclinical studies in addition to those that we currently anticipate. Other unanticipated costs may also arise. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of our product candidates or any future product candidates that we develop. We have not yet met with the FDA to discuss any of our product candidates or development programs, and we are not permitted to market or promote any product candidate before we receive marketing approval from the FDA. Following this offering, we also expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to continue our operations.

Based on our current operating plan, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents as of the date of this prospectus, will be sufficient to fund our operating expenses and capital expenditures for at least the next months. Advancing the development of our RAF and FGFR programs, CDK12 and other research programs will require a significant amount of capital. The net proceeds from this offering, together with our existing cash and cash equivalents, will not be sufficient to fund any of our product candidates through regulatory approval, and we anticipate needing to raise additional capital to complete the development of and commercialize our product candidates. Our estimate as to how long we expect our existing cash and cash equivalents, together with the net proceeds from this offering, to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

We will be required to obtain further funding through public or private equity financings, debt financings, collaborative agreements, licensing arrangements or other sources of financing, which may dilute our stockholders or restrict our operating activities. We do not have any committed external source of funds. Adequate additional financing may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, each investor's ownership interests will be diluted, and the terms may include liquidation or other preferences that adversely affect each investor's rights as a stockholder. Debt financing may result in imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through upfront payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our product candidates or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research or drug development programs, clinical trials or future commercialization efforts.

#### **Risks Related to the Discovery, Development and Commercialization of our Product Candidates**

***We are very early in our development efforts and are substantially dependent on our RAF and FGFR programs. If we are unable to advance any product candidates from our RAF or FGFR programs through preclinical and clinical development, obtain regulatory approval and ultimately commercialize such product candidates, or experience significant delays in doing so, our business will be materially harmed.***

We are very early in our development efforts. All of our product candidates are still in preclinical development and have never been tested in humans. Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful preclinical and clinical development and eventual commercialization of one or more product candidates from our RAF or FGFR programs. We are not permitted to market or promote any product candidate before we receive marketing approval from the FDA, EMA or any comparable foreign regulatory authorities, and we may never receive such marketing approvals.

The success of our RAF and FGFR programs will depend on several factors, including the following:

- successful and timely completion of preclinical studies;
- approval of INDs for our planned clinical trials and future clinical trials;
- addressing any potential delays resulting from factors related to the COVID-19 pandemic;
- successful initiation and completion of clinical trials;
- successful and timely patient selection and enrollment in and completion of clinical trials;
- maintaining and establishing relationships with CROs and clinical sites for the clinical development of our product candidates both in the United States and internationally;
- the frequency and severity of adverse events in clinical trials;
- demonstrating efficacy, safety and tolerability profiles that are satisfactory to the FDA, EMA or any comparable foreign regulatory authority for marketing approval;
- the timely receipt of marketing approvals from applicable regulatory authorities;
- the timely identification, development and approval of companion diagnostic tests, if required;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- the maintenance of existing or the establishment of new supply arrangements with third-party drug product suppliers and manufacturers for clinical development and, if approved, commercialization of our product candidates;
- obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- the protection of our rights in our intellectual property portfolio;
- the successful launch of commercial sales following any marketing approval;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance by patients, the medical community and third-party payors; and
- our ability to compete with other therapies.

We do not have complete control over many of these factors, including certain aspects of preclinical and clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. 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 any product candidates from our lead programs, which would materially harm our business. If we do not receive marketing approvals for such product candidates, we may not be able to continue our operations.

***Our preclinical studies and clinical trials may fail to adequately demonstrate the safety and efficacy of any of our product candidates, which would prevent or delay development, regulatory approval and commercialization.***

Before obtaining marketing approval from the FDA, EMA or other comparable foreign regulatory authorities for the sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for use in each target indication. Preclinical and clinical testing is expensive, difficult to design and implement, can take many years to complete and its ultimate outcome is uncertain. Failure can occur at any time during the preclinical study and clinical trial processes, and, because our product candidates are in an early stage of development, there is a high risk of failure and we may never succeed in developing marketable products.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent receipt of marketing approval or our ability to commercialize our product candidates, including:

- failure of our product candidates in preclinical studies or clinical trials to demonstrate safety and efficacy;
- receipt of feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- negative or inconclusive clinical trial results that may require us to conduct additional clinical trials or abandon certain research and/or drug development programs;
- the number of patients required for clinical trials being larger than anticipated, enrollment in these clinical trials being slower than anticipated or participants dropping out of these clinical trials at a higher rate than anticipated;
- third-party contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- the suspension or termination of our clinical trials for various reasons, including non-compliance with regulatory requirements or a finding that our product candidates have undesirable side effects or other unexpected characteristics or risks;
- the cost of clinical trials of our product candidates being greater than anticipated;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates being insufficient or inadequate; and
- regulators revising the requirements for approving our product candidates.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing in a timely manner, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may incur unplanned costs, be delayed in seeking and obtaining marketing approval, if we receive such approval at all, receive more limited or restrictive marketing approval, be subject to additional post-marketing testing requirements or have the drug removed from the market after obtaining marketing approval.

***Our discovery and preclinical development activities are focused on the development of targeted therapeutics for patients with genomically defined cancers, which is a rapidly evolving area of science, and the approach we are taking to discover and develop drugs is novel and may never lead to approved or marketable products.***

The discovery and development of targeted therapeutics for patients with genomically defined cancers is an emerging field, and the scientific discoveries that form the basis for our efforts to discover and develop product candidates are relatively new. The scientific evidence to support the feasibility of developing product candidates based on these discoveries is both preliminary and limited. Although we believe, based on our preclinical work, that the genomic alterations targeted by our programs are oncogenic drivers, clinical results may not confirm this hypothesis or may only confirm it for certain alterations or certain tumor types. The patient populations for our product candidates are limited to those with specific target alterations and may not be completely defined but are substantially smaller than the general treated cancer population, and we will need to screen and identify these patients with targeted alterations. Successful identification of patients is dependent on several factors, including achieving certainty as to how specific alterations respond to our product candidates and the ability to identify such alterations. Furthermore, even if we are successful in identifying patients, we cannot be certain that the resulting patient populations for each mutation will be large enough to allow us to successfully obtain approval for each mutation type and commercialize our product candidates and achieve profitability. In addition, even if our approach is successful in showing clinical benefit for Class II or III BRAF mutation-driven cancers for our RAF program, or FGFR2 and FGFR3 alteration-driven cancers for our FGFR program, we may never successfully identify additional oncogenic alterations for other receptor tyrosine kinases. Therefore, we do not know if our approach of treating patients with genomically defined cancers will be successful, and if our approach is unsuccessful, our business will suffer.

***The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, EMA or other comparable foreign regulatory authorities.***

We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek marketing approvals for their commercial sale. Preclinical and 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 preclinical study and clinical trial processes, and, because our product candidates are in an early stage of development, there is a high risk of failure and we may never succeed in developing marketable products.

The results of preclinical studies may not be predictive of the results of clinical trials of our product candidates, and the results of early clinical trials may not be predictive of the results of later-stage clinical trials. Although product candidates may demonstrate promising results in preclinical studies and early clinical trials, they may not prove to be effective in subsequent clinical trials. For example, testing on animals occurs under different conditions than testing in humans and therefore, the results of animal studies may not accurately predict human experience. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through preclinical studies and clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. Likewise, early, smaller-scale clinical trials may not be predictive of eventual safety or effectiveness in large-scale pivotal clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy, insufficient durability of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence preclinical studies and clinical trials are never approved as products. The development of our product candidates and our stock price may also be impacted by inferences, whether correct or not, that are drawn between the success or failure of preclinical studies or clinical trials of our competitors or other companies in the biopharmaceutical industry, in addition to our own preclinical studies and clinical trials.



In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dose and dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Patients treated with our product candidates may also be undergoing surgical, radiation and chemotherapy treatments and may be using other approved products or investigational new drugs, which can cause side effects or adverse events that are unrelated to our product candidates. As a result, assessments of efficacy can vary widely for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes.

Any preclinical studies or clinical trials that we conduct may not demonstrate the safety and efficacy necessary to obtain regulatory approval to market our product candidates. If the results of our ongoing or future preclinical studies and clinical trials are inconclusive with respect to the safety and 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 prevented or delayed in obtaining marketing approval for such product candidates. In some instances, there can be significant variability in safety or efficacy results between different preclinical studies and 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.

We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain approval to market any of our product candidates.

***In addition to our RAF and FGFR programs, our prospects depend in part upon discovering, developing and commercializing product candidates from our CDK12 and other research programs, which may fail in development or suffer delays that adversely affect their commercial viability.***

Our future operating results are dependent on our ability to successfully discover, develop, obtain regulatory approval for and commercialize product candidates from our research programs, such as our CDK12 program, in addition to our lead RAF and FGFR programs. A research candidate can unexpectedly fail at any stage of development. The historical failure rate for research candidates is high due to risks relating to safety, efficacy, clinical execution, changing standards of medical care and other unpredictable variables. The results from preclinical testing or early clinical trials of a product candidate may not be predictive of the results that will be obtained in later stage clinical trials of the product candidate.

The success of other research candidates we may develop will depend on many factors, including the following:

- generating sufficient data to support the initiation or continuation of preclinical studies and clinical trials;
- addressing any delays resulting from factors related to the COVID-19 pandemic;
- obtaining regulatory permission to initiate clinical trials;
- contracting with the necessary parties to conduct clinical trials;
- successful enrollment of patients in, and the completion of, clinical trials on a timely basis;
- the timely manufacture of sufficient quantities of a product candidate for use in clinical trials; and
- adverse events in clinical trials.

Even if we successfully advance any research candidates into preclinical and clinical development, their success will be subject to all of the preclinical, clinical, regulatory and commercial risks described elsewhere in this “Risk Factors” section. Accordingly, there can be no assurance that we will ever be able to discover, develop, obtain regulatory approval of, commercialize or generate significant revenue from any product candidates.



***Our approach to the discovery and development of product candidates is unproven, and we may not be successful in our efforts to use and expand our Kinnate Discovery Engine to build a pipeline of product candidates with commercial value.***

A key element of our strategy is to use and expand our Kinnate Discovery Engine to build a pipeline of product candidates and progress these product candidates through clinical development. Although our research and development efforts to date have resulted in the discovery and preclinical development of product candidates in our RAF and FGFR programs, such product candidates, and any other product candidates we may develop may not be safe or effective as cancer therapeutics, and we may not be able to develop any other product candidates. Our Kinnate Discovery Engine is evolving and may not reach a state at which building a pipeline of product candidates is possible. For example, we may not be successful in identifying additional genomic alterations which are oncogenic and are targeted for patient populations or identifying acquired and intrinsic resistance mutations that present sufficient commercial opportunities. Even if we are successful in building a pipeline of product candidates, the potential product candidates that we identify may not be suitable for clinical development or generate acceptable clinical data, including as a result of being shown to have unacceptable toxicity or other characteristics that indicate that they are unlikely to be product candidates that will receive marketing approval from the FDA, EMA or other regulatory authorities or achieve market acceptance. If we do not successfully develop and commercialize product candidates, we will not be able to generate product revenue in the future, which likely would result in significant harm to our financial position and adversely affect our business.

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

Obtaining approval by the FDA, EMA and other comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. Even if we eventually complete clinical testing and receive approval for our product candidates, the FDA, EMA and other comparable foreign regulatory authorities may approve our product candidates for a more limited indication or a narrower patient population than we originally requested or may impose other prescribing limitations or warnings that limit the product candidate's commercial potential. We have not submitted for, or obtained, regulatory approval for any product candidate, and it is possible that none of our product candidates will ever obtain regulatory approval. Further, development of our product candidates and/or regulatory approval may be delayed for reasons beyond our control.

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

- the FDA, EMA or other comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- the FDA, EMA or other comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, are only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- the FDA, EMA or other comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;

- we may be unable to demonstrate to the FDA, EMA or other comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA, EMA or other comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the FDA, EMA or other comparable regulatory authorities may fail to approve companion diagnostic tests required for our product candidates; and
- the approval policies or regulations of the FDA, EMA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects.

***We have no experience as a company in conducting clinical trials.***

We have no experience as a company in conducting clinical trials. In part because of this lack of experience as a company and our limited infrastructure, we cannot be certain that our ongoing preclinical studies will be completed on time or that our planned preclinical studies and clinical trials will begin or be completed on time, if at all. Large-scale clinical trials would require significant additional financial and management resources and reliance on third-party clinical investigators, CROs, and consultants. Relying on third-party clinical investigators, CROs and consultants may force us to encounter delays that are outside of our control. We may be unable to identify and contract with sufficient investigators, CROs and consultants on a timely basis or at all. There can be no assurance that we will be able to negotiate and enter into any necessary services agreement with CROs on terms that are acceptable to us on a timely basis or at all.

***We may not be able to file Investigational New Drug applications (INDs) to commence clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed.***

We expect to submit an IND for our RAF program as soon as the first half of 2021 and for our FGFR program in the first half of 2022. However, we may not be able to file such INDs or INDs for future product candidates on the timelines we expect. For example, we may experience manufacturing delays or other delays with IND enabling studies. Moreover, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate clinical trials. Additionally, even if the FDA agrees with the design and implementation of the clinical trials set forth in an IND, we cannot guarantee that it will not change its requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or to a new IND. Any failure to file INDs on the timelines we expect or to obtain regulatory approvals for our planned clinical trials may prevent us from initiating or completing our clinical trials or commercializing our product candidates on a timely basis, if at all.

***Our product candidates may cause significant adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could prevent regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.***

If our product candidates are associated with undesirable side effects or have unexpected characteristics in preclinical studies or clinical trials when used alone or in combination with other approved products or investigational new drugs we may need to interrupt, delay or abandon their development or limit 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. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate and may harm our business, financial condition and prospects significantly. For example, while we have not

observed similar results in toxicology studies for our current next-generation RAF product candidate (KIN002787), during toxicology studies in cynomolgus monkeys for one of our prior generation RAF product candidates, moribund terminations of two monkeys in our high dose cohorts occurred. While we have not yet initiated clinical trials for any of our product candidates, it is likely that there will be side effects associated with their use as is typically the case with oncology drugs. Results of our studies or trials could reveal a high and unacceptable severity and prevalence of these or other side effects or adverse events. In such an event, our trials could be suspended or terminated and the FDA, EMA 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. Drug-related side effects could also 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 prospects significantly.

In addition, our product candidates may be used in populations for which safety concerns may be particularly scrutinized by regulatory agencies. In addition, our product candidates may be studied in combination with other therapies, which may exacerbate adverse events associated with the therapy. Patients treated with our product candidates may also be undergoing surgical, radiation and chemotherapy treatments, which can cause side effects or adverse events that are unrelated to our product candidate but may still impact the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses. For example, it is expected that some of the patients to be enrolled in our future clinical trials will die or experience major clinical events either during the course of our clinical trials or after participating in such trials for non-treatment related reasons.

If significant adverse events or other side effects are observed in any of our future clinical trials, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, EMA, other comparable foreign regulatory authorities or an institutional review board (IRB) may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition and prospects. Further, if any of our product candidates obtains marketing approval, toxicities associated with such product candidates previously not seen during clinical testing may also develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional contraindications, warnings and precautions being added to the drug label, significant restrictions on the use of the product or the withdrawal of the product from the market. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on preclinical studies or early stage clinical trials.

***Interim, topline and preliminary data from our preclinical studies and clinical trials that we announce or publish from time to time may change as more 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 publicly disclose preliminary, interim or topline data from our preclinical studies and clinical trials. These interim updates are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. For example, we may report responses in certain patients that are unconfirmed at the time and which do not ultimately result in confirmed responses to treatment after follow-up evaluations. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify

such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse changes between interim data and final data could significantly harm our business and prospects. Further, additional disclosure of interim data by us or by our competitors in the future could result in volatility in the price of our common stock.

In addition, the information we choose to publicly disclose regarding a particular study or trial is typically selected from a more extensive amount of available information. Investors 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 candidate or our business. If the preliminary or topline data that we report differ from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, any of our product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

***If we experience delays or difficulties in the enrollment or maintenance of patients in clinical trials, our regulatory submissions or receipt of necessary marketing approvals could be delayed or prevented.***

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to such trial's conclusion as required by the FDA, EMA or other comparable foreign regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials. Our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. In our RAF and FGFR programs, we will utilize genomic profiling of patients' tumors to identify suitable patients for recruitment into our clinical trials. We cannot be certain (i) how many patients will have the requisite alterations for inclusion in our clinical trials, (ii) that the number of patients enrolled in each program will suffice for regulatory approval or (iii) whether each specific BRAF mutation or FGFR alteration will be included in the approved drug label. If our strategies for patient identification and enrollment prove unsuccessful, we may have difficulty enrolling or maintaining patients appropriate for our product candidates.

Our ability to enroll patients may also be significantly delayed by the evolving COVID-19 pandemic and we do not know the extent and scope of such delays at this point. In addition, patients may not be able or willing to visit clinical trial sites for dosing or data collection purposes due to limitations on travel and physical distancing imposed or recommended by federal or state governments or patients' reluctance to visit the clinical trial sites during the pandemic. These factors resulting from the COVID-19 pandemic could delay our clinical trials and our regulatory submissions.

Patient enrollment may be affected if our competitors have ongoing clinical trials for programs that are under development for the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' programs. Patient enrollment for our current or any future clinical trials may be affected by other factors, including:

- size and nature of the patient population;
- severity of the disease under investigation;
- availability and efficacy of approved drugs for the disease under investigation;
- patient eligibility criteria for the trial in question as defined in the protocol, including biomarker-driven identification and/or certain highly-specific criteria related to stage of disease progression, which may limit the patient populations eligible for our clinical trials to a greater extent than competing clinical trials for the same indication that do not have biomarker-driven patient eligibility criteria;

- perceived risks and benefits of the product candidate under study;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved or other product candidates being investigated for the indications we are investigating;
- clinicians' willingness to screen their patients for biomarkers to indicate which patients may be eligible for enrollment in our clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion or, because they may be late-stage cancer patients, will not survive the full terms of the clinical trials.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain marketing approval for the sale of our product candidates. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining participation in our clinical trials through the treatment and any follow-up periods.

***The COVID-19 pandemic could adversely impact our business, including our planned clinical trials and ongoing and planned preclinical studies.***

In December 2019, COVID-19 was reported to have surfaced in Wuhan, China. Since then, the virus has spread to most countries across the world, including all 50 states within the United States, resulting in the World Health Organization characterizing COVID-19 as a pandemic. As a result of measures imposed by the governments in affected regions, many commercial activities, businesses and schools have been suspended as part of quarantines and other measures intended to contain this pandemic. As the COVID-19 pandemic continues to spread around the globe, we may experience disruptions that could severely impact our business and clinical trials, including:

- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays or difficulties in enrolling and retaining patients in any clinical trials, particularly elderly subjects, who are at a higher risk of severe illness or death from COVID-19;
- difficulties interpreting data from our clinical trials due to the possible effects of COVID-19 on patients;
- 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 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;
- interruption or delays in the operations of the FDA, EMA or other regulatory authorities, which may impact review and approval timelines;
- limitations in resources that would otherwise be focused on the conduct of our business, our preclinical studies or our clinical trials, including because of sickness or the desire to avoid contact with large groups of people or as a result of government-imposed "shelter in place" or similar working restrictions;
- interruptions, difficulties or delays arising in our existing operations and company culture as a result of all of our employees working remotely, including those hired during the COVID-19 pandemic;

- delays in receiving approval from regulatory authorities to initiate our clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials; interruptions in preclinical studies due to restricted or limited operations at the CROs conducting such studies;
- interruption in global freight and shipping that may affect the transport of clinical trial materials, such as investigational drug product to be used in our clinical trials;
- changes in regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are to be conducted, or to discontinue the clinical trials altogether, or which may result in unexpected costs;
- delays in necessary interactions with regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government or contractor personnel; and
- refusal of the FDA, EMA or other regulatory authorities to accept data from clinical trials in affected geographies outside of their respective jurisdictions.

We are still assessing the impact that the COVID-19 pandemic may have on our ability to effectively conduct our business operations as planned and there can be no assurance that we will be able to avoid a material impact on our business from the spread of COVID-19 or its consequences, including disruption to our business and downturns in business sentiment generally or in our industry or due to shutdowns that may be requested or mandated by federal, state and local governmental authorities. As a result of the COVID-19 pandemic, our employees are currently telecommuting, which may impact certain of our operations over the near term and long term.

Additionally, certain third parties with whom we engage or may engage, including collaborators, contract organizations, third-party manufacturers, suppliers, clinical trial sites, regulators and other third parties are similarly adjusting their operations and assessing their capacity in light of the COVID-19 pandemic. If these third parties experience shutdowns or continued business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted. For example, as a result of the COVID-19 pandemic, there could be delays in the procurement of materials or manufacturing supply chain for one or more of our product candidates, which could delay or otherwise impact our preclinical studies and our planned clinical trials. Additionally, all of our preclinical studies are conducted by CROs, which could be discontinued or delayed as a result of the pandemic. It is also likely that the disproportionate impact of COVID-19 on hospitals and clinical sites will have an impact on recruitment and retention for our planned clinical trials. In addition, certain clinical trial sites for product candidates similar to ours have experienced, and others may experience in the future, delays in collecting, receiving and analyzing data from patients enrolled in clinical trials due to limited staff at such sites, limitation or suspension of on-site visits by patients, or patients' reluctance to visit the clinical trial sites during the pandemic and we may experience similar delays if and when we begin clinical trials. CROs have also made certain adjustments to the operation of such trials in an effort to ensure the monitoring and safety of patients and minimize risks to trial integrity during the pandemic in accordance with the guidance issued by the FDA and may need to make further adjustments in the future that could impact the timing or enrollment of our clinical trials. Many of these adjustments are new and untested, may not be effective, may increase costs, and may have unforeseen effects on the enrollment, progress and completion of these trials and the findings from these trials. While we are currently continuing our preclinical activities and progressing in our plans for clinical trials, we may experience delays in the completion of our preclinical studies, the initiation of our planned clinical trials, patient selection or enrollment or in the progression of our activities related to our planned clinical trials, may need to suspend our clinical trials if and when commenced, and may encounter other negative impacts to such trials due to the effects of the COVID-19 pandemic.

We may be required to develop and implement additional clinical trial policies and procedures designed to help protect subjects from COVID-19. For example, in March 2020, the FDA issued a guidance, which the FDA subsequently updated, on conducting clinical trials during the pandemic, which describes a number of considerations for sponsors of clinical trials impacted by the pandemic, including



the requirement to include in the clinical trial report contingency measures implemented to manage the clinical trial, and any disruption of the clinical trial as a result of the COVID-19 pandemic; a list of all subjects affected by the COVID-19-pandemic related study disruption by unique subject identifier and by investigational site and a description of how the individual's participation was altered; and analyses and corresponding discussions that address the impact of implemented contingency measures (e.g., participant discontinuation from investigational product and/or study, alternative procedures used to collect critical safety and/or efficacy data) on the safety and efficacy results reported for the clinical trial. In June 2020, the FDA also issued a guidance on good manufacturing practice considerations for responding to COVID-19 infection in employees in drug products manufacturing, including recommendations for manufacturing controls to prevent contamination of drugs.

The global outbreak of COVID-19 continues to rapidly evolve. While the extent of the impact of the current COVID-19 pandemic on our business and financial results is uncertain, a continued and prolonged public health crisis such as the COVID-19 pandemic could have a material negative impact on our business, financial condition and operating results.

To the extent the COVID-19 pandemic adversely affects our business, financial condition and operating results, it may also have the effect of heightening many of the risks described in this "Risk Factors" section.

***We have limited resources and are currently focusing our efforts on our RAF and FGFR programs for development in particular indications and advancing our research programs. As a result, we may fail to capitalize on other indications or product candidates that may ultimately have proven to be more profitable.***

We are currently focusing our resources and efforts on our RAF and FGFR programs for particular indications and advancing our research programs, such as our CDK12 program. As a result, because we have limited resources, we may forgo or delay pursuit of opportunities for other indications or with other product candidates that may have greater commercial potential. In addition, while we currently have multiple product candidates in our RAF and FGFR programs, we are focusing our efforts on select product candidates from each of these programs to develop as lead product candidates in each program. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development activities for our RAF and FGFR programs and our research programs may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target markets for our RAF and FGFR programs and our research programs, or the product candidates we are currently developing in these programs, we may relinquish valuable rights to our product candidates or programs through collaboration, licensing or other strategic arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate or program.

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

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates. Our competitors have developed, are developing or may develop products, product candidates and processes competitive with our product candidates. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. We believe that a significant number of product candidates are currently under development, and may become commercially available in the future, for the treatment of conditions for which we may attempt to develop product candidates. In addition, our product candidates may need to compete with drugs physicians use off-label to treat the indications for which we seek approval. This may make it difficult for us to replace existing therapies with our product candidates.

In particular, there is intense competition in the field of oncology. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, emerging and start-up companies,



universities and other research institutions. We also compete with these organizations to recruit and retain qualified scientific and management personnel, which could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We expect to face competition from existing products and products in development for each of our programs. For our RAF program, there are currently three BRAF-targeted kinase inhibitor drugs approved for use in Class I BRAF mutations: Novartis AG's Tafenlar (dabrafenib), Zelboraf (vemurafenib) and Braftovi (encorafenib) are used in BRAF mutated melanomas, Tafenlar (dabrafenib) is also used in mutated non-small cell lung cancer (NSCLC) and anaplastic thyroid cancer, and Braftovi (encorafenib) is also used in mutated colorectal cancer (CRC). PLX8394, a BRAF homodimer disruptor, is currently in Phase II clinical trials with NovellusDx Ltd. Second-generation BRAF dimer signaling inhibitors, such as LXH254 and HM95573, designed to inhibit mitogen-activated protein kinase (MAPK) pathway signaling without causing pathway rebound, are in Phase I clinical trials with Novartis AG and Genentech, a member of the Roche Group, respectively. Mapkure, LLC's BGB3245 is also currently in clinical development and there are other RAF inhibitors currently in development. For our FGFR program, there are two currently approved selective FGFR2 and FGFR3 inhibitors: Incyte Corporation's Pemazyre (pemigatinib) and Janssen Biotech, Inc.'s Balversa (erdafitinib), and a number of programs that are in clinical development, including Taiho Oncology, Inc.'s TAS120 (futibatinib), QED Therapeutics, Inc.'s BGJ398 and Relay Therapeutics, Inc., which has an FGFR2-specific clinical candidate in development (RLY4008).

Many of our competitors, either alone or with their collaborators, have significantly greater financial resources, established presence in the market, and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. Large pharmaceutical and biotechnology companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing biotechnology product candidates. These companies also have significantly greater research and marketing capabilities than we do and may also have product candidates that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical and biotechnology companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result of all of these factors, our competitors may succeed in obtaining approval from the FDA, EMA or other comparable foreign regulatory authorities or in discovering, developing and commercializing product candidates in our field before we do.

Our potential commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, have a broader label, are marketed more effectively, are more widely reimbursed or are less expensive than any products that we may develop. Our competitors also may obtain marketing approval from the FDA, EMA or other comparable foreign regulatory authorities 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 or make our development more complicated. Even if the product candidates we develop achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our products we may develop, if approved, could be adversely affected. For additional information regarding our competition, see the section of this prospectus titled "Business—Competition."

***The manufacture of drugs is complex, and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented.***

Manufacturing drugs, especially in large quantities, is complex and may require the use of innovative technologies. Each lot of an approved drug product must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing drugs requires facilities specifically designed for and validated for this purpose, as well as sophisticated quality assurance and quality control procedures. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at the facilities of our manufacturer, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. The use of biologically derived ingredients can also lead to allegations of harm, including infections or allergic reactions, or closure of product facilities due to possible contamination.

If our third-party manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization as a result of these challenges, or otherwise, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

***Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.***

As product candidates progress through preclinical and clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. For example, we may introduce an alternative formulation of one or more of our product candidates during the course of our planned clinical trials. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates, if approved, and generate revenue.

***Our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.***

Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, third-party payors and others in the medical community. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the efficacy and safety profile as demonstrated in clinical trials compared to alternative treatments;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which a product candidate is approved;
- restrictions on the use of product candidates in the labeling approved by regulatory authorities, such as boxed warnings or contraindications in labeling, or a risk evaluation and mitigation strategy, if any, which may not be required of alternative treatments and competitor products;
- the potential and perceived advantages of our product candidates over alternative treatments;

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- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement by third-party payors, including government authorities;
- the availability of an approved product candidate for use as a combination therapy;
- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and undergo required diagnostic screening to determine treatment eligibility and of physicians to prescribe these therapies and diagnostic tests;
- the effectiveness of sales and marketing efforts;
- unfavorable publicity relating to our product candidates; and
- the approval of other new therapies for the same indications.

If any of our product candidates are approved but do not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate or derive sufficient revenue from that product candidate and our financial results could be negatively impacted.

***The market opportunities for any product candidates we develop, if approved, may be limited to certain smaller patient subsets and may be smaller than we estimate them to be.***

When cancer is detected early (referred to as localized disease), conventional treatments which include chemotherapy, hormone therapy, surgery and radiation therapy and/or selected targeted therapies may be adequate to cure the patient in many cases. However, once cancer has spread to other areas (advanced or metastatic disease), cancer treatments may not be sufficient to provide a cure but often can significantly prolong life without curing the cancer. First-line therapies designate treatments that are initially administered to patients with advanced or metastatic disease, while second- and third-line therapies are administered to patients when the prior therapies lose their effectiveness. The FDA, EMA and other regulatory bodies often approve cancer therapies for a particular line of treatment. Typically, drug approvals are initially granted for use in later lines of treatment, but with additional evidence of significant efficacy from clinical trials, biopharmaceutical companies can successfully seek and gain approval for use in earlier lines of treatment.

We plan to initially seek approval of our product candidates in most instances at least as a second- or third-line therapy, for use in patients with advanced or metastatic cancer where at least one prior therapy has limited clinical benefit or has lost its effectiveness. For those product candidates that prove to be sufficiently safe and effective, if any, we would expect to seek approval as a second-line therapy and potentially ultimately as a first line therapy. There is no guarantee that our product candidates, even if approved as a second, third or subsequent line of therapy would be approved for an earlier line of therapy, and prior to any such approvals we may have to conduct additional clinical trials that may be costly, time-consuming and subject to risk.

Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers in a position to receive a particular line of therapy and 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 scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of the cancers that we are targeting. The potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Consequently, even if our product candidates are approved, the number of patients that may be eligible for treatment with our product candidates may turn out to be much lower than expected. In addition, we have not yet conducted market research to determine how treating physicians would expect to prescribe a product that is approved for multiple tumor types if there are different lines of approved therapies for each such tumor type. Even if we obtain significant market share for our products, if approved, if the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications.

***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 such 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 Centers for Medicare & Medicaid Services (CMS), an agency within the U.S. Department of Health and Human Services (HHS). 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.

As federal and state governments implement additional health care cost containment measures, including measures to lower prescription drug pricing, we cannot be sure that our products, if approved, will be covered by private or public payors, and if covered, whether the reimbursement will be adequate or competitive with other marketed products. For example, President Trump recently signed executive orders aimed at lowering prescription drug prices. These and other actions by federal and state governments and health plans may put additional downward pressure on pharmaceutical pricing and health care costs, which could negatively impact coverage and reimbursement for our products if approved, our revenue, and our ability to compete with other marketed products and to recoup the costs of our research and development. For further discussion, see *"—We may face difficulties from changes to current regulations and future legislation. Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations."*

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.

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. Additionally, if any companion diagnostic provider is unable to obtain reimbursement or is inadequately reimbursed, that may limit the availability of such companion diagnostic, which would negatively impact prescriptions for our product candidates, if approved.

Outside the United States, the commercialization of therapeutics is 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 (EU), 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 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.

***Our business entails a significant risk of product liability and if we are unable to obtain sufficient insurance coverage such inability could have an adverse effect on our business and financial condition.***

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA, EMA or other regulatory authority investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs. FDA, EMA or other regulatory authority investigations could potentially lead to a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources and substantial monetary awards to trial participants or patients. We currently have product liability insurance that we believe is appropriate for our stage of development and may need to obtain higher levels prior to advancing our product candidates into clinical trials or marketing any of our product candidates, if approved. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have an adverse effect on our business and financial condition.

#### **Risks Related to Regulatory Approval and Other Legal Compliance Matters**

***We may be unable to obtain U.S. or foreign regulatory approval and, as a result, may be unable to commercialize our product candidates.***

Our product candidates are and will continue to be subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing and

distribution of drugs. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process must be successfully completed in the United States and in many foreign jurisdictions before a new drug can be approved for marketing. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. We cannot provide any assurance that any product candidate we may develop will progress through required clinical testing and obtain the regulatory approvals necessary for us to begin selling them.

We have not conducted, managed or completed large-scale or pivotal clinical trials nor managed the regulatory approval process with the FDA, EMA or any other regulatory authority. The time required to obtain approvals from the FDA, EMA and other regulatory authorities is unpredictable and requires successful completion of extensive clinical trials which typically takes many years, depending upon the type, complexity and novelty of the product candidate. The standards that the FDA and its foreign counterparts use when evaluating clinical trial data can, and often does, change during drug development, which makes it difficult to predict with any certainty how they will be applied. We may also encounter unexpected delays or increased costs due to new government regulations, including future legislation or administrative action, or changes in applicable FDA, EMA or other regulatory policy during the period of drug development, clinical trials and regulatory review.

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

- the FDA, EMA or other comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- the FDA, EMA or other comparable foreign regulatory authorities may determine that our product candidates are not safe and effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- the FDA, EMA or other comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials;
- we may be unable to demonstrate to the FDA, EMA or other comparable foreign regulatory authorities that our product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA, EMA or other comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, EMA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Any delay or failure in seeking or obtaining required approvals would have a material and adverse effect on our ability to generate revenue from any particular product candidates we are developing and for which we are seeking approval. Furthermore, any regulatory approval to market a drug may be subject to significant limitations on the approved uses or indications for which we may market, promote and advertise the drug or the labeling or other restrictions. In addition, the FDA has the authority to require a Risk Evaluation and Mitigation Strategy (REMS) plan as part of approving an NDA, or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. These requirements or restrictions might include limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may significantly limit the size of the market for the drug and affect reimbursement by third-party payors.



We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries, and generally includes all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval.

***We may develop our current or future product candidates in combination with other therapies, which would expose us to additional risks.***

We may develop our current or future product candidates in combination with one or more currently approved cancer therapies or therapies in development. Even if any of our current or future product candidates were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA, EMA or other comparable foreign regulatory authorities could revoke approval of the therapy used in combination with any of our product candidates, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our product candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for our product candidates or our own products being removed from the market or being less successful commercially.

We may also evaluate our current or future product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA, EMA or comparable foreign regulatory authorities. We will not be able to market and sell any product candidate in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval.

If the FDA, EMA or other comparable foreign regulatory authorities do not approve or withdraw their approval of these other therapies, or if safety, efficacy, commercial adoption, manufacturing or supply issues arise with the therapies we choose to evaluate in combination with any of our current or future product candidates, we may be unable to obtain approval of or successfully market any one or all of the current or future product candidates we develop. Additionally, if the third-party providers of therapies or therapies in development used in combination with our current or future product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our current or future product candidates, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

***We have never commercialized a product candidate as a company before and currently lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.***

We have never commercialized a product candidate as a company. We may license certain rights with respect to our product candidates to collaborators, and, if so, we will rely on the assistance and guidance of those collaborators. For product candidates for which we retain commercialization rights and marketing approval, we will have to develop our own sales, marketing and supply organization or outsource these activities to a third party.

Factors that may affect our ability to commercialize our product candidates, if approved, on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, developing adequate educational and marketing programs to increase public acceptance of our approved product candidates, ensuring regulatory compliance of our company, employees and third parties under applicable healthcare laws, and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization will be expensive and time-consuming and could delay the launch of our product candidates upon approval. We may not be able to build an effective sales and marketing organization. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may not generate revenues from them or be able to reach or sustain profitability.



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

We anticipate we will initially conduct clinical trials of our product candidates in the United States and we may choose to conduct our clinical trials internationally as well. The acceptance of study data by the FDA, EMA or other comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. In cases where data from United States clinical trials are intended to serve as the basis for marketing approval in the foreign countries outside the United States, the standards for clinical trials and approval may be different. There can be no assurance that any United States or foreign regulatory authority would accept data from trials conducted outside of its applicable jurisdiction. If the FDA, EMA 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 or clearance for commercialization in the applicable jurisdiction.

***Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.***

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA or EMA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product candidate in those countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our potential product candidates will be harmed.

***Even if our product candidates receive regulatory approval, they will be subject to significant post-marketing regulatory requirements and oversight.***

Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and on-going surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements and regulatory inspection. For example, the FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician training and 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, EMA or foreign regulatory authorities approve our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with current good manufacturing practices (cGMPs) and good clinical practices (GCPs) for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA, EMA and other regulatory authorities for compliance with cGMP

regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA, EMA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

- delays in or the rejection of product approvals;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers or manufacturing process;
- warning or untitled letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements;
- revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- imposition of a REMS, which may include distribution or use restrictions; and
- requirements to conduct additional post-market clinical trials to assess the safety of the product.

The FDA, EMA and other regulatory authorities' policies 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.

We may be required to develop and implement additional clinical trial policies and procedures designed to help protect subjects from the COVID-19 virus. For example, in March 2020, the FDA issued a guidance, which the FDA subsequently updated, on conducting clinical trials during the pandemic, which describes a number of considerations for sponsors of clinical trials impacted by the pandemic. In June 2020, FDA also issued a guidance on good manufacturing practice considerations for responding to COVID-19 infection in employees in drug products manufacturing, including recommendations for manufacturing controls to prevent contamination of drugs.

Moreover, the FDA strictly regulates the promotional claims that may be made about drug products. In particular, a product may not be promoted in the United States for uses that are not approved by the FDA as reflected in the product's approved labeling, or in other jurisdictions for uses that differ from the labeling or uses approved by the applicable regulatory agencies. While physicians may prescribe products for off-label uses, the FDA, EMA and other regulatory agencies actively enforce laws and regulations that prohibit the promotion of off-label uses by companies, including promotional communications made by companies' sales force with respect to off-label uses that are not consistent with the approved labeling, and a company that is found to have improperly promoted off-label uses may be subject to significant civil, criminal and administrative penalties. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates, if approved, and generate revenue.

***The FDA, EMA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.***

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA, EMA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. If we are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

***If we are required by the FDA, EMA or comparable regulatory authority to obtain approval of a companion diagnostic test in connection with approval of any of our product candidates or a group of therapeutic products, and we do not obtain or we face delays in obtaining approval of a diagnostic test, we will not be able to commercialize the product candidate and our ability to generate revenue will be materially impaired.***

If we are required by the FDA, EMA or comparable regulatory authority to obtain approval of a companion diagnostic test in connection with approval of any of our product candidates, such companion diagnostic test would be used during our more advanced phase clinical trials as well as in connection with the commercialization of our product candidates. To be successful in developing and commercializing product candidates in combination with these companion diagnostics, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared at the same time the product candidate is approved. To date, the FDA has required marketing approval of all companion diagnostic tests for cancer therapies. Various foreign regulatory authorities also regulate *in vitro* companion diagnostics as medical devices and, under those regulatory frameworks, will likely require the conduct of clinical trials to demonstrate the safety and effectiveness of our current diagnostics and any future diagnostics we may develop, which we expect will require separate regulatory clearance or approval prior to commercialization.

The approval of a companion diagnostic as part of the therapeutic product's labeling limits the use of the therapeutic product to only those patients who express certain biomarkers or the specific genomic alteration that the companion diagnostic was developed to detect. If the FDA, EMA or a comparable regulatory authority requires approval of a companion diagnostic for any of our product candidates, whether before or concurrently with approval of the product candidate, we, and/or future collaborators, may encounter difficulties in developing and obtaining approval for these companion diagnostics. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval of a companion diagnostic could delay or prevent approval or continued marketing of our related product candidates. Further, in April 2020, the FDA issued new guidance on developing and labeling companion diagnostics for a specific group of oncology therapeutic products, including recommendations to support a broader labeling claim rather than individual therapeutic products. We will continue to evaluate the impact of this guidance on our companion diagnostic development and strategy. This guidance and future issuances from the FDA, EMA and other regulatory authorities may impact our development of a companion diagnostic for our product candidates and result in delays in regulatory approval. We may be required to conduct additional studies to support a broader claim. Also, to the extent other approved diagnostics are able to broaden their labeling claims to include our approved drug products, we may be forced to abandon our companion diagnostic development plans or we may not be able to compete effectively upon approval, which could adversely impact our ability to generate revenue from the sale of our approved products and our business operations.

Additionally, we may rely on third parties for the design, development and manufacture of companion diagnostic tests for our product candidates that may require such tests. If we enter into such collaborative agreements, we will be dependent on the sustained cooperation and effort of our future collaborators in developing and obtaining approval for these companion diagnostics. It may be necessary to resolve issues such as selectivity/specificity, analytical validation, reproducibility, or clinical validation of companion diagnostics during the development and regulatory approval processes. Moreover, even if data from preclinical studies and early clinical trials appear to support development of a companion diagnostic for a product candidate, data generated in later clinical trials may fail to support the analytical and clinical validation of the companion diagnostic. We and our future collaborators may encounter difficulties in developing, obtaining regulatory approval for, manufacturing and commercializing companion diagnostics similar to those we face with respect to our product candidates themselves, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance. If we are unable to successfully develop companion diagnostics for our product candidates, or experience delays in doing so, the development of our product candidates may be adversely affected, our product candidates may not obtain marketing approval, and we may not realize the full commercial potential of any of our product candidates that obtain marketing approval. As a result, our business, results of operations and financial condition could be materially harmed. In addition, a diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic test that we anticipate using in connection with development and commercialization of product candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our product candidates.

***Where appropriate, we plan to secure approval from the FDA, EMA or comparable foreign regulatory authorities through the use of accelerated registration pathways. If we are unable to obtain such approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, EMA or comparable regulatory authorities, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA, EMA or such other regulatory authorities may seek to withdraw accelerated approval.***

Where possible, we plan to pursue accelerated development strategies in areas of high unmet need. We may seek an accelerated approval pathway for our one or more of our product candidates from the FDA, EMA or comparable foreign regulatory authorities. Under the accelerated approval provisions in the Federal Food, Drug, and Cosmetic Act, and the FDA's implementing regulations, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. If such post-approval studies fail to confirm the drug's clinical benefit, the FDA may withdraw its approval of the drug.

Prior to seeking accelerated approval, we will seek feedback from the FDA, EMA or comparable foreign regulatory authorities and will otherwise evaluate our ability to seek and receive such accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent feedback from the FDA, EMA or comparable foreign regulatory authorities, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or under another expedited regulatory designation (e.g., Fast Track designation, Breakthrough Therapy designation or orphan drug designation), there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA, EMA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidate would result in a longer time period to commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

***We may seek Fast Track designation from the FDA for one or more of our product candidates. Even if one or more of our product candidates receive Fast Track designation, we may be unable to obtain or maintain the benefits associated with the Fast Track designation.***

Fast Track designation is designed to facilitate the development and expedite the review of therapies for serious conditions and fill an unmet medical need. Programs with Fast Track designation may benefit from early and frequent communications with the FDA, potential priority review and the ability to submit a rolling application for regulatory review. Fast Track designation applies to both the product candidate and the specific indication for which it is being studied. If any of our product candidates receive Fast Track designation but do not continue to meet the criteria for Fast Track designation, or if our clinical trials are delayed, suspended or terminated, or put on clinical hold due to unexpected adverse events or issues with clinical supply, we will not receive the benefits associated with the Fast Track program. Furthermore, Fast Track designation does not change the standards for approval. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

***A Breakthrough Therapy designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.***

We may seek Breakthrough Therapy designation for one or more of our current or future product candidates. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for other expedited approval programs, including accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to candidate products considered for approval under non-expedited FDA review procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product no longer meets the conditions for qualification. Thus, even though we may seek Breakthrough Therapy designation for one or more of our current or future product candidates, there can be no assurance that we will receive Breakthrough Therapy designation.



***We may not be able to obtain orphan drug designation or obtain or maintain orphan drug exclusivity for our product candidates and, even if we do, that exclusivity may not prevent the FDA, EMA or other comparable foreign regulatory authorities, from approving competing products.***

Regulatory authorities in some jurisdictions, including the United States and the EU, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product candidate 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. Our target indications may include diseases with large patient populations or may include orphan indications. However, there can be no assurances that we will be able to obtain orphan designations for our product candidates.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product candidate that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product candidate is entitled to orphan drug exclusivity. Orphan drug exclusivity in the United States provides that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same indication for seven years, except in limited circumstances. The applicable exclusivity period is 10 years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified.

Even if we obtain orphan drug designation for a product candidate, we may not be able to obtain or maintain orphan drug exclusivity for that product candidate. We may not be the first to obtain marketing approval of any product candidate for which we have obtained orphan drug designation for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to ensure that we will be able to manufacture sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety 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 or the manufacturer of the product with orphan exclusivity is unable to maintain sufficient product quantity. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the product candidate any advantage in the regulatory review or approval process or entitles the product candidate to priority review.

***We may face difficulties from changes to current regulations and future legislation. Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.***

Existing regulatory policies 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.

For example, in March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ACA), was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and continues to significantly impact the U.S. pharmaceutical industry. There remain judicial and

Congressional challenges to certain aspects of the ACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. For example, various portions of the ACA are currently undergoing legal and constitutional challenges in the Fifth Circuit Court and the United States Supreme Court. It is 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. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2030 unless additional congressional action is taken. These Medicare sequester reductions are being suspended from May 1, 2020 through December 31, 2020 due to the COVID-19 pandemic. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations.

Moreover, there has been heightened governmental scrutiny recently over the manner in which drug 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. For example, 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. Additionally, 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 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 of using 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 to lower drug prices, including, among others, allowing importation of certain drugs, changing how drug rebates are negotiated by middlemen, like pharmacy benefit managers, and directing such rebates to be passed to patients as point-of-sale discounts, and requiring Medicare to pay certain Part B drugs at the lowest price available in economically comparable countries. President Trump stated that he has delayed the effective date of the international drug pricing order until August 24, 2020, in order to give the pharmaceutical industry an opportunity to discuss how they will reduce drug prices substantially. However, none of these executive orders make immediate policy changes. For policies contained within the executive orders to have any effect, agencies would need to take additional administrative action. How these executive orders will be implemented and their impact on the industry remain uncertain. Depending on the details of further administrative actions, some of these proposals could have significant impacts for drug manufacturers and providers. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We are unable to predict the future course of federal or state healthcare legislation in the United States directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. These and any further changes in the law or regulatory framework that reduce our revenue or



increase our costs could also have a material and adverse effect on our business, financial condition and results of operations. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates. It is also possible that additional governmental action is taken to address the COVID-19 pandemic.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for biotechnology products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Additionally, the collection and use of health data in the EU is governed by the General Data Protection Regulation (GDPR), which extends the geographical scope of EU data protection law to non-EU entities under certain conditions and imposes substantial obligations upon companies and new rights for individuals, as discussed below in “—Data collection is governed by restrictive regulations governing the use, processing and cross-border transfer of personal information.”

Finally, state and foreign laws may apply generally to the privacy and security of information we maintain, and may differ from each other in significant ways, thus complicating compliance efforts. For example, the California Consumer Privacy Act of 2018 (CCPA), which took effect on January 1, 2020, gives California residents expanded rights to access and require deletion of their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. In addition, the CCPA (a) allows enforcement by the California Attorney General, with fines set at \$2,500 per violation (i.e., per person) or \$7,500 per intentional violation and (b) authorizes private lawsuits to recover statutory damages for certain data breaches. While it exempts some data regulated by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and certain clinical trials data, 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 collect about California residents. Some observers note that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the U.S., which could increase our potential liability and adversely affect our business. Additionally, a new privacy law, the California Privacy Rights Act (CPRA), recently was certified by the California Secretary of State to appear on the ballot for the November 3, 2020 election. If this initiative is approved by California voters, the CPRA would significantly modify the CCPA, potentially resulting in further uncertainty and requiring us to incur additional costs and expenses.

***Inadequate funding for the FDA, the Securities and Exchange Commission (SEC) and other U.S. government agencies or the EMA or comparable foreign regulatory authorities could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner 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, EMA or comparable foreign regulatory authorities 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, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA, EMA 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. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

***Our relationships with healthcare professionals, clinical investigators, CROs and third-party payors in connection with our current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws, which could expose us to significant losses, including, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings.***

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, clinical investigators, CROs, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, as well as market, sell and distribute our product candidates for which we obtain marketing approval.

The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. 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. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act (FCA). There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection;

- federal civil and criminal false claims laws, including the FCA, which can be enforced through civil “qui tam” or “whistleblower” actions, and civil monetary penalty laws, impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other federal health care programs that are false or fraudulent; knowingly making or causing a false statement material to a false or fraudulent claim or an obligation to pay money to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing such an obligation. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the federal civil FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions;
- the federal Physician Payments Sunshine Act, created under the ACA and its implementing regulations, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to HHS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include payments and transfers of value made and ownership interests held during the previous year to certain non-physician providers such as physician assistants and nurse practitioners; and
- analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state

laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

We may also be subject to federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare and data privacy laws and regulations will involve on-going substantial costs. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, 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 federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private “qui tam” actions brought by individual whistleblowers in the name of the government, exclusion, debarment or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and 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. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

***Data collection is governed by restrictive regulations governing the use, processing and cross-border transfer of personal information.***

If we decide to conduct clinical trials or enroll patients in our future clinical trials, we may be subject to additional restrictions relating to privacy, data protection and data security. The collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the GDPR. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches (initially to supervisory authorities and, if the breach is serious enough, to individuals), and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater, for the most serious of violations. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers. Certain aspects of cross-border data transfers under the GDPR are uncertain as the result of legal proceedings in the EU, including a recent decision by the Court of Justice for the European Union that invalidated the EU-U.S. Privacy Shield and, to some extent, called into question the efficacy and legality of using standard contract clauses. This may increase the complexity of transferring personal data across borders. The

GDPR increased our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities.

Further, the vote in the United Kingdom (UK) in favor of exiting the EU, referred to as Brexit, has created uncertainty with regard to data protection regulation in the UK. Specifically, while the Data Protection Act of 2018, which “implements” and complements the GDPR achieved Royal Assent on May 23, 2018 and is now effective in the UK, aspects of data protection in the UK, such as the transfer of data from the EEA to the UK, remain uncertain. During the period of “transition” (i.e., until December 31, 2020), EU law will continue to apply in the UK, including the GDPR, after which the GDPR will be converted into UK law. Beginning in 2021, the UK will be a “third country” under the GDPR. We may, however, incur liabilities, expenses, costs, and other operational losses under GDPR and applicable EU Member States and UK privacy laws in connection with any measures we take to comply with them.

In addition, California recently enacted the CCPA, which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide new disclosure to consumers about such companies’ data collection, use and sharing practices, provide such consumers new ways to opt-out of certain sales or transfers of personal information, and provide consumers with additional causes of action in data breach situations. The CCPA went into effect on January 1, 2020, and the California Attorney General commenced enforcement actions for violations on July 1, 2020. Moreover, CPRA was recently certified by the California Secretary of State to appear on the ballot for the November 3, 2020 election. If this initiative is approved by California voters, the CPRA would significantly modify the CCPA, potentially resulting in further uncertainty and requiring us to incur additional costs and expenses in an effort to comply. The CCPA and, if it goes into effect, the CPRA, may impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Any actual or alleged failure to comply with U.S. or international laws and regulations relating to privacy, data protection, and data security could result in governmental investigations, proceedings and enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity, harm to our reputation, and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential 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 or impose other obligations or restrictions in connection with our use, retention and other processing of information, and we may otherwise face contractual restrictions applicable to our use, retention, and other processing of 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, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.***

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities. Misconduct by these parties could include failures to comply with FDA, EMA or comparable foreign regulatory authority regulations, provide accurate information to the FDA, EMA or comparable foreign regulatory authorities, comply with federal and state health care fraud and abuse laws and regulations, accurately report financial information or data or disclose unauthorized activities to us. In particular, research, sales, marketing and business arrangements in the health care 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. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of conduct, but it is not always possible to identify and deter misconduct by these 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. 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 penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations.

***Our business activities may be subject to the U.S. Foreign Corrupt Practices Act (FCPA) and similar anti-bribery and anti-corruption laws of other countries in which we operate, as well as U.S. and certain foreign export controls, trade sanctions, and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them.***

Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits companies and their employees and third-party intermediaries from offering, promising, giving or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, hospitals are owned and operated by the government, and doctors and other hospital employees would be considered foreign officials under the FCPA. Recently, the SEC and DOJ have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, disgorgement, and other sanctions and remedial measures, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international activities, our ability to attract and retain employees and our business, prospects, operating results and financial condition.

In addition, our products may be subject to U.S. and foreign export controls, trade sanctions and import 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 or domestic 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.

**Risks Related to Employee Matters, Managing Our Growth and Other Risks Related to Our Business**

***Our success is highly dependent on our ability to attract, hire and retain highly skilled executive officers and employees.***

We currently have a small team focused on research and development of small molecule kinase inhibitors. To succeed, we must recruit, hire, retain, manage and motivate qualified clinical, scientific, technical and management personnel, and we face significant competition for experienced personnel. We are highly dependent on the principal members of our management and scientific and medical staff. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. We could in the future have difficulty attracting and retaining experienced personnel and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide higher compensation, more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover, develop and commercialize our product candidates will be limited and the potential for successfully growing our business will be harmed.

Additionally, we rely on our scientific founders and other scientific and clinical advisors and consultants to assist us in formulating our research, development and clinical strategies. Most of these advisors and consultants are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, these advisors and consultants typically will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. Furthermore, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours. In particular, if we are unable to maintain consulting or employment relationships with our scientific founders and other scientific and clinical advisors and consultants, or if they provide services to our competitors, our development and commercialization efforts will be impaired and our business will be significantly harmed.

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

As of September 30, 2020, we had 27 full-time employees, including 21 employees engaged in research and development. In order to successfully implement our development and commercialization plans and strategies, and as we transition into operating as a public company, we expect to need significant additional managerial, operational, sales, marketing, financial and other personnel. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining, retaining and motivating our current and additional employees;
- managing our internal development efforts effectively, including the preclinical, clinical, FDA, EMA and other comparable foreign regulatory agencies' review process for our RAF and FGFR programs and our other product candidates, while complying with any contractual obligations to contractors and other third parties;
- managing increasing operational and managerial complexity; and
- improving our operational, financial and management controls, reporting systems and procedures.



Our future financial performance and our ability to successfully develop and, if approved, commercialize product candidates developed from our RAF and FGFR programs and other product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including key aspects of research, clinical development and manufacturing. There can be no assurance 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 third-party service providers is compromised for any reason, our preclinical studies and clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval for any of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing third-party service providers or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and/or engaging additional third-party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize our RAF and FGFR programs and any of our other product candidates and, accordingly, may not achieve our research, development and commercialization goals.

***Our internal computer systems, or those of any of our CROs, manufacturers, other contractors or consultants or potential future collaborators, may fail or suffer actual or suspected security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data, or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations, and potentially significant delays in our delivery to market.***

Despite the implementation of security measures in an effort to protect systems that store our information, given their size and complexity and the increasing amounts of information maintained on our internal information technology systems and external processing and storage systems (e.g., cloud), and those of our third-party CROs, other contractors (including sites performing our planned future clinical trials) and consultants, these systems are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure or lead to the loss, destruction, alteration or dissemination of, or damage to, our data. For example, companies have experienced an increase in phishing and social engineering attacks from third parties in connection with the COVID-19 pandemic. Also, due to the COVID-19 pandemic, all of our employees are working remotely. As a result, we may have increased cyber security and data security risks, due to increased use of home wi-fi networks and virtual private networks, as well as increased disbursement of physical machines. While we implement IT controls to reduce the risk of a cyber security or data security breach, there is no guarantee that these measures will be adequate to safeguard all systems, especially with an increased number of employees working remotely.

To the extent that any disruption or security breach were to result in a loss, destruction, unavailability, alteration or dissemination of, or damage to, our data (including confidential information) or applications, or for it to be believed or reported that any of these occurred, we could incur liability and reputational damage and the development and commercialization of our product candidates could be delayed. There can be no assurance that our data protection efforts and our investment in information technology, or the efforts or investments of CROs, consultants or other third parties, will prevent significant breakdowns or breaches in systems or other cyber incidents that cause loss, destruction, unavailability, alteration or dissemination of, or damage to, our data that could have a material adverse effect upon our reputation,

business, operations or financial condition. For example, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs and the development of our product candidates could be delayed. In addition, the loss of clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of our internal information technology systems or security breaches could result in the loss, misappropriation, and/or unauthorized access, use, or disclosure of, or the prevention of access to, data (including trade secrets or other confidential information, intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. For example, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to financial exposure related to investigation of the incident (including cost of forensic examinations), subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business. Our studies in China (discussed below) could increase our risk to such disruptions.

Notifications and follow-up actions related to a security incident could impact our reputation and cause us to incur significant costs, including legal expenses and remediation costs. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. We expect to incur significant costs in an effort to detect and prevent security incidents, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived security breach. We also rely on third parties to manufacture our product candidates, 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 incident were to result in a loss, destruction or alteration of, or damage to, our data, or inappropriate disclosure of confidential or proprietary information, we could be exposed to litigation and governmental investigations, the further development and commercialization of our product candidates could be delayed, and we could be subject to significant fines or penalties for any noncompliance with certain state, federal and/or international privacy and security laws.

Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption in or, failure or security breach of our systems or third-party systems where information important to our business operations or commercial development is stored. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention.

***Many of our research and preclinical activities are conducted by third parties outside of the United States, including in China. A significant disruption in the operations of those third parties, a trade war or political unrest could materially adversely affect our business, financial condition and results of operations.***

We contract many of our research and preclinical activities to third parties outside the United States, including in China. Any disruption in the operations of such third parties or in their ability to meet our needs, whether as a result of a natural disaster or other causes, could impair our ability to operate our business on a day-to-day basis and to continue development of our programs. Furthermore, since many of these third parties are located in China, we are exposed to the possibility of disruption and increased costs in the event of changes in the policies of the United States or China governments, political unrest or unstable economic conditions in China. For example, a trade war could lead to tariffs on the chemical intermediates used in our product candidates. Any of these matters could materially and adversely affect our development timelines, business and financial condition.

***Our operations are vulnerable to interruption by flood, fire, earthquakes, power loss, telecommunications failure, terrorist activity, pandemics and other events beyond our control, which could harm our business.***

Our office facilities are located in California. We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major flood, fire, earthquake, power loss, telecommunications failure, terrorist activity, pandemics or other disasters and do not have a recovery plan for such disasters. In addition, we do not carry sufficient insurance to compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could harm our business. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

***If we are unable to establish sales or marketing capabilities or enter into agreements with third parties to sell or market our product candidates, we may not be able to successfully sell or market our product candidates that obtain regulatory approval.***

We currently do not have and have never had a marketing or sales team. In order to commercialize any product candidates, if approved, we must build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services for each of the territories in which we may have approval to sell or market our product candidates. We may not be successful in accomplishing these required tasks.

Establishing an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates will be expensive and time-consuming and will require significant attention of our executive officers to manage. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could adversely impact the commercialization of any of our product candidates that we obtain approval to market if we do not have arrangements in place with third parties to provide such services on our behalf. Alternatively, if we choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration and such arrangements may prove to be less profitable than commercializing the product on our own. If we are unable to enter into such arrangements when needed, on acceptable terms or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval, or any such commercialization may experience delays or limitations. If we are unable to successfully commercialize our approved product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer, and we may incur significant additional losses.

***A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business.***

We may seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements and reimbursement regimes in foreign countries, such as the lack of pathways for accelerated drug approval, may result in foreign regulatory approvals taking longer and being more costly than obtaining approval in the United States;
- foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials or our interpretation of data from nonclinical studies or clinical trials;
- approval policies or regulations of foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval;
- impact of the COVID-19 pandemic on our ability to produce our product candidates and conduct clinical trials in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;

- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with legal requirements applicable to privacy, data protection, information security and other matters;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- 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;
- difficulties staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes and government payors in foreign countries;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, trade policies, treaties and tariffs.

These and other risks associated with international operations may materially adversely affect our ability to attain or maintain profitable operations.

***Our ability to utilize our net operating loss carryforwards and certain other tax attributes to offset future taxable income may be limited.***

Our federal net operating loss (NOL) carryforwards may be unavailable to offset future taxable income because of restrictions under U.S. tax law. Under tax legislation commonly referred to as the Tax Cuts and Jobs Act (Tax Act) as amended by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), our federal NOL carryforwards may be carried forward indefinitely, but for taxable years beginning after December 31, 2020, the deductibility of federal NOL carryforwards generated in tax years beginning after December 31, 2017 is limited to 80% of our current year taxable income. It is uncertain if and to what extent various states will conform to the Tax Act. As of December 31, 2019, we had available federal NOL carryforwards of \$19.3 million. We also have available California NOL carryforwards of approximately \$19.3 million as of December 31, 2019, which begin to expire in 2038.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (Code), if a corporation undergoes an “ownership change” (generally defined as a cumulative change in the corporation’s ownership by “5-percent shareholders” that exceeds 50 percentage points over a rolling three-year period), the corporation’s ability to use its pre-change NOL carryforwards and certain other pre-change tax attributes to offset its post-change taxable income may be limited. Similar rules may apply under state tax laws. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of this offering or subsequent shifts in our stock ownership, some of which are outside our control. We have not conducted any studies to determine annual limitations, if any, that could result from such changes in the ownership. There is also a risk that due to regulatory changes, such as suspensions on the use of NOL carryforwards, or other unforeseen reasons, our existing NOL carryforwards could expire or otherwise be unavailable to offset future income tax liabilities. For example, California recently enacted legislation limiting our ability to use our state NOL carryforwards for taxable years 2020, 2021 and 2022. Because our ability to utilize our NOL carryforwards

and certain other tax attributes could be limited as described above, we may not be able to utilize a material portion of our NOL carryforwards and certain other tax attributes, which could have a material adverse effect on our cash flows and results of operations.

## **Risks Related to Our Intellectual Property**

### ***Our success depends on our ability to protect our intellectual property and our proprietary technologies.***

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for our product candidates, proprietary technologies and their uses as well as our ability to operate without infringing upon the proprietary rights of others. We generally seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates, proprietary technologies and their uses that are important to our business. We also seek to protect our proprietary position by acquiring or in-licensing relevant issued patents or pending applications from third parties.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our patent applications or the patent applications of our future licensors will result in patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties.

Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our and our licensors' proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. These uncertainties and/or limitations in our ability to properly protect the intellectual property rights relating to our product candidates could have a material adverse effect on our financial condition and results of operations.

We cannot be certain that the claims in our U.S. pending patent applications, corresponding international patent applications and patent applications in certain foreign territories, or those of our future licensors, will be considered patentable by the United States Patent and Trademark Office (USPTO), courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our future issued patents will not be found invalid or unenforceable if challenged.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell our potential product candidates;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and

- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

The patent prosecution process is also expensive and time-consuming, and we and any future licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we or any future licensors will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

In addition, although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

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 intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

***If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.***

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications and those of our future licensors may not result in patents being issued which protect our product candidates or which effectively prevent others from commercializing competitive product candidates.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own or in-license in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own or in-license may be challenged or circumvented by third parties or may be narrowed or invalidated as a result of challenges by third parties. Consequently, we do not know whether our product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents or the patents of our future licensors by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents or the patents of our future licensors may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant review (PGR) and *inter partes* review (IPR), or other similar proceedings challenging our owned patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our product candidates 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. Moreover, our patents or the patents of our future licensors may become subject to post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our priority of invention or other features of patentability with respect to our patents and patent applications and those of our future licensors. Such challenges may result in loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and



management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our patents and patent applications or the patents and patent applications of our future licensors is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

***Intellectual property rights do not necessarily address all potential threats to our competitive advantage.***

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

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

Should any of these events occur, it could significantly harm our business, results of operations and prospects.

***Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.***

Our commercial success depends in part on avoiding infringement of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our product candidates and products that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry, including patent infringement lawsuits, oppositions, reexaminations, IPR proceedings and PGR proceedings before the USPTO and/or corresponding foreign patent offices. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing 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 the use or manufacture of our product candidates.



As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published, we may be unaware of third-party patents that may be infringed by commercialization of any of our product candidates, and we cannot be certain that we were the first to file a patent application related to a product candidate or technology. Moreover, because patent applications can take many years to issue, there may be currently-pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. There is also no assurance that there is not prior art of which we are aware, but which we do not believe is relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our products that may be approved in the future, or impair our competitive position. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Any claims of patent infringement asserted by third parties would be time consuming and could:

- result in costly litigation that may cause negative publicity;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing any of our product candidates until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- subject us to significant liability to third parties; or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non-exclusive, which could result in our competitors gaining access to the same technology.

Although no third party has asserted a claim of patent infringement against us as of the date of this prospectus, others may hold proprietary rights that could prevent our product candidates from being marketed. It is possible that a third party may assert a claim of patent infringement directed at any of our product candidates. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to our product candidates, treatment indications, or processes could subject us to significant liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or market 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. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Moreover, even if we or our future strategic partners were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign our product candidates, treatment indications, or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing our product candidates, which could harm our business, financial condition and operating results. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates and technology.

Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure.

In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

***We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.***

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

***We may be involved in lawsuits to protect or enforce our patents or our future licensors' patents, which could be expensive, time consuming and unsuccessful. Further, our issued patents or our future licensors' patents could be found invalid or unenforceable if challenged in court.***

Competitors may infringe our intellectual property rights. To prevent infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in a patent infringement proceeding, a court may decide that a patent we own or in-license is not valid, is unenforceable and/or is not infringed. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at one of our product candidates, the defendant could counterclaim that our patent or the patent of our future licensors is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of sufficient written description, non-enablement, or obviousness-type double patenting. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution.

Third parties may also raise similar invalidity claims before the USPTO or patent offices abroad, even outside the context of litigation. Such mechanisms include re-examination, PGR, IPR, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). The outcome following legal assertions of invalidity and/or 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 future licensors, and the patent examiners are unaware during prosecution. There is also no assurance that there is not prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our patents and patent applications or the patents and patent applications of our future licensors, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our technology or platform, or any product candidates that we may develop. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects.

In addition, if the breadth or strength of protection provided by our patents and patent applications or the patents and patent applications of our future licensors is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own patented product and practicing our own patented technology.

***Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common shares to decline.***

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings or developments in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing product candidates, approved products, programs or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

***Derivation proceedings may be necessary to determine priority of inventions, and an unfavorable outcome may require us to cease using the related technology or to attempt to license rights from the prevailing party.***

Derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our future licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with such proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our development programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our product candidates to market.

***Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications or those of our future licensors and the enforcement or defense of our issued patents or those of our future licensors.***

On September 16, 2011, the Leahy-Smith America Invents Act (the Leahy-Smith Act), was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first inventor to file" system in which, assuming that other requirements of patentability are met, the first inventor to file a patent application will be entitled to the patent regardless of whether a third party was first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013 but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and

enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we may not be certain that we or our future licensors are the first to either (1) file any patent application related to our product candidates or (2) invent any of the inventions claimed in the patents or patent applications.

The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including PGR, IPR, and derivation proceedings. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications or those of our future licensors and the enforcement or defense of our issued patents or those of our future licensors, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

***Changes in U.S. patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.***

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing pharmaceutical patents is costly, time consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us.

For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. 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 U.S. federal courts, the USPTO, or similar authorities in foreign jurisdictions, 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 patent and the patents we might obtain or license in the future.

***We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.***

We may also be subject to claims that former employees or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

***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 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. 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 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 for our product candidates, our business may be materially harmed.***

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one or more of our U.S. patents or those of our future licensors may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments). The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. A maximum of one patent may be extended per FDA approved product as compensation for the 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 and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of our product candidates. However, we may not be granted an extension because of, for example, 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 restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

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

Although we have pending patent applications in the United States and other countries, filing, prosecuting and defending patents 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 federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents, the patents of our future licensors, 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 many foreign countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or our future licensors' patents or marketing of competing products in violation of our proprietary rights. 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 or the patents of our future licensors at risk of being invalidated or interpreted narrowly

and our patent applications or the patent applications of our future licensors 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.

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 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.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents and/or applications and those of our future licensors. We have systems in place to remind us to pay these fees, and we rely on our outside patent annuity service to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, 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. If such an event were to occur, it could have a material adverse effect on our business.

***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.***

We intend to use registered or unregistered trademarks or trade names to brand and market ourselves and our products. 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, which we need to build name recognition among 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 trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

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

In addition, we rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, we cannot provide any assurances that all such agreements have been duly executed, and



any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced, and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

***We may be subject to claims that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets.***

We have entered into and may enter in the future into non-disclosure and confidentiality agreements to protect the proprietary positions of third parties, such as outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors, potential partners, and other third parties. We may become subject to litigation where a third party asserts that we or our employees inadvertently or otherwise breached the agreements and used or disclosed trade secrets or other information proprietary to the third parties. Defense of such matters, regardless of their merit, could involve substantial litigation expense and be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions. Moreover, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates and technology. Failure to defend against any such claim could subject us to significant liability for monetary damages or prevent or delay our developmental and commercialization efforts, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

Parties making claims against us may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. 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. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, operating results, financial condition and prospects.

***We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.***

As is common in the pharmaceutical industry, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other pharmaceutical companies including our competitors or potential competitors. We may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. 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, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

***Our rights to develop and commercialize our technology and product candidates may be subject, in part, to the terms and conditions of licenses granted to us by others.***

We may enter into license agreements in the future with others to advance our existing or future research or allow commercialization of our existing or future product candidates. These licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future.

In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the technology that we license from third parties. In such an event, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our future licensors fail to prosecute, maintain, enforce, and defend such patents or patent applications, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our future product candidates that are subject of such licensed rights could be adversely affected.

Our future licensors may rely on third-party consultants or collaborators or on funds from third parties such that our future licensors are not the sole and exclusive owners of the patents we in-license. If other third parties have ownership rights to our future in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

It is possible that we may be unable to obtain licenses at a reasonable cost or on reasonable terms, if at all. 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 redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, manufacturing methods, product candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

***If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our future licensors, we could lose license rights that are important to our business.***

Disputes may arise between us and our future 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 patents and other rights to third parties;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- our right to transfer or assign the license;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our future licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology from third parties 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. Moreover, if disputes over intellectual property that we license in the future prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

In spite of our best efforts, our future licensors might conclude that we materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If these licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

***The patent protection and patent prosecution for some of our product candidates may be dependent on third parties.***

While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our product candidates, there may be times when the filing and prosecution activities for patents and patent applications relating to our product candidates are controlled by our future licensors or collaboration partners. If any of our future licensors or collaboration partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our product candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our future licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

***Intellectual property discovered through government funded programs may be subject to federal regulations such as “march-in” rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.***

Although we do not currently own issued patents or pending patent applications that have been generated through the use of U.S. government funding, we may acquire or license in the future intellectual property rights that have been generated through the use of U.S. government funding or grants. Pursuant to the Bayh-Dole Act of 1980, the U.S. government has certain rights in inventions developed with government funding. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as “march-in rights”). If the U.S. government exercised its march-in rights in our future intellectual property rights that are generated through the use of U.S. government funding or grants, we could be forced to license or sublicense intellectual property developed by us or that we license on terms unfavorable to us, and there can be no assurance that we would receive compensation from the U.S. government for the exercise of such rights. The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government

or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property.

### **Risks Related to Our Dependence on Third Parties**

***We rely on third parties to conduct our preclinical studies, and plan to rely on third parties to conduct clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research and studies.***

We utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, contract manufacturing organizations (CMOs), and strategic partners to conduct and support our preclinical studies under agreements with us and plan to continue to do so for our future clinical trials. These third parties have had and will continue to have a significant role in the conduct of our preclinical studies and planned clinical trials and the subsequent collection and analysis of data. For example, our academic and industrial partners contribute highly enabling technologies and services that include: (i) over 60 medicinal chemists at leading CROs, (ii) bioinformatics support for our translational research efforts, (iii) crystallography and biophysical assay platforms to enable structure-based drug discovery, (iv) biochemical and cell-based assays to guide lead generation and optimization, and (v) patient-derived organoid and xenograft models to translate our findings to the clinical setting.

These third parties are not our employees, and except for remedies available to us under our agreements with such third parties, we have limited ability to control the amount or timing of resources that any such third party will devote to our preclinical studies or our planned clinical trials. The third parties we rely on for these services may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. Some of these third parties may terminate their engagements with us at any time. We also expect to have to negotiate budgets and contracts with CROs, clinical trial sites and CMOs and we may not be able to do so on favorable terms, which may result in delays to our development timelines and increased costs. If we need to enter into alternative arrangements with, or replace or add any third parties, it would involve substantial cost and require extensive management time and focus, or involve a transition period, and may delay our drug development activities, as well as materially impact our ability to meet our desired clinical development timelines.

Our heavy reliance on these third parties for such drug development activities will reduce our control over these activities. As a result, we will have less direct control over the conduct, timing and completion of preclinical studies and clinical trials and the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCP standards, regulations for conducting, recording and reporting the results of clinical trials to assure that data and reported results are reliable and accurate and that the rights, integrity and confidentiality of trial participants are protected. The EMA also requires us to comply with similar standards. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our

clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. There can be no assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials substantially comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under current cGMP regulations and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients, may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, or if these third parties need to be replaced, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

***We contract with third parties for the manufacture of our product candidates for preclinical studies and expect to continue to do so for additional preclinical studies, clinical trials and ultimately for commercialization. This reliance on third parties increases the risk that we will not have sufficient quality and quantities of our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.***

We do not currently have the infrastructure or internal capability to manufacture supplies of our product candidates for use in development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of our product candidates for preclinical studies and clinical trials under the guidance of members of our organization. We do not have long-term supply agreements, and we purchase our required drug product on a purchase order basis, which means that aside from any binding purchase orders we have from time to time, our supplier could cease supplying to us or change the terms on which it is willing to continue supplying to us at any time. If we were to experience an unexpected loss of supply of any of our product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing preclinical studies or clinical trials.

We expect to continue to rely on third-party manufacturers for the commercial supply of any of our product candidates for which we obtain marketing approval. We may be unable to maintain or establish required agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third party to manufacture our product candidates according to our schedule and specifications, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements, including cGMPs;

- the breach by the third-party contractors of our agreements with them;
- the failure of the third party to manufacture our product candidates according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the misappropriation of our proprietary information, including our trade secrets and know-how.

We do not have complete control over all aspects of the manufacturing process of our contract manufacturing partners and are dependent on these contract manufacturing partners for compliance with cGMP regulations for manufacturing both active pharmaceutical ingredients (API) and finished drug products. To date, we have obtained API and drug product for our product candidates from single-source third party contract manufacturers. We are in the process of developing our supply chain for each of our product candidates and intend to put in place framework agreements under which third-party contract manufacturers will generally provide us with necessary quantities of API and drug product on a project-by-project basis based on our development needs. As we advance our product candidates through development, we will consider our lack of redundant supply for the API and drug product for each of our product candidates to protect against any potential supply disruptions. However, we may be unsuccessful in putting in place such framework agreements or protecting against potential supply disruptions.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or comparable regulatory authorities, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, EMA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we will need to find alternative manufacturing facilities, and those new facilities would need to be inspected and approved by FDA, EMA or comparable regulatory authority prior to commencing manufacturing, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or drugs and harm our business and results of operations.

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

***Our manufacturing process needs to comply with FDA regulations relating to the quality and reliability of such processes. Any failure to comply with relevant regulations could result in delays in or termination of our clinical programs and suspension or withdrawal of any regulatory approvals.***

In order to commercially produce our products either at a third party's facility or in any facility of ours, we will need to comply with the FDA's cGMP regulations and guidelines. We may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. We are subject to inspections by the FDA and comparable foreign regulatory authorities to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our precision medicines as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could



significantly impair our ability to develop and commercialize our product candidates, including leading to significant delays in the availability of our precision medicines for our clinical trials or the termination of or suspension of a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant non-compliance could also result in the imposition of sanctions, including warning or untitled letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation and our business.

***If we engage in future acquisitions or strategic partnerships, 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 evaluate various acquisition opportunities and strategic partnerships, including licensing or acquiring complementary products, product candidates, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership 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, products and product candidates 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, 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 partnerships 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.

***If our third-party manufacturers use hazardous materials in a manner that causes injury or violates applicable law, we may be liable for damages.***

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical materials, by our third-party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

***If we decide to establish collaborations, but are not able to establish those collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans.***

Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We may seek to selectively form collaborations to expand our capabilities, potentially accelerate research and development activities and provide for commercialization activities by third parties. Any of these relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business.

We face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for a collaboration depends, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of preclinical studies or clinical trials, the likelihood of approval by the FDA, EMA or comparable foreign regulatory authorities, 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 drugs, the existence of uncertainty with respect to our ownership of intellectual property and industry and market conditions generally. The potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our product candidate. Further, we may not be successful in our efforts to establish a collaboration or other alternative arrangements for product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy.

In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Even if we are successful in entering into a collaboration, the terms and conditions of that collaboration may restrict us from entering into future agreements on certain terms with potential collaborators.

If and when we seek to enter into collaborations, 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 a product candidate, reduce or delay its development program or one or more of our other research programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

***We may enter into collaborations with third parties for the development and commercialization of product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.***

If we enter into any collaboration arrangements with any third parties for the development and commercialization of our product candidates, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations involving our product candidates would pose numerous risks to us, including the following:

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

programs based on clinical trial results, changes in the collaborators' strategic focus, including as a result of a business combination or sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates 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 product candidates if the collaborators believe that competitive products are more likely
- to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product relative to other products;
- we may grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all;
- collaborators may not provide us with timely and accurate information regarding development progress and activities under the collaboration or may limit our ability to share such information, which could adversely impact our ability to report progress to our investors and otherwise plan our own development of our product candidates;
- collaborators may own or co-own intellectual property covering our products or product candidates that result from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

#### **Risks Related to This Offering and Ownership of Our Common Stock**

***We do not know whether an active, liquid and orderly trading market will develop for our common stock or what the market price of our common stock will be and as a result it may be difficult for investors to sell their shares of our common stock.***

Prior to this offering, no market for shares of our common stock existed and an active trading market for our shares may never develop or be sustained following this offering. We will determine the initial public offering price for our common stock through negotiations with the underwriters, and the negotiated price may not be indicative of the market price of our common stock after this offering. The market value of our common stock may decrease from the initial public offering price. As a result of these and other factors, investors may be unable to resell their shares of our common stock at or above the initial public offering

price. The lack of an active market may impair investors' ability to sell their shares at the time they wish to sell them or at a price that they consider reasonable. The lack of an active market may also reduce the fair market value of investors' shares. Furthermore, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies, technologies or other assets by using our shares of common stock as consideration.

***The market price of our common stock may be volatile, and investors could lose all or part of their investment.***

The trading price of our common stock following this offering is likely to be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. The stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this prospectus, these factors include:

- the timing and results of INDs, preclinical studies and clinical trials of our product candidates or those of our competitors;
- the success of competitive products or announcements by potential competitors of their product development efforts;
- regulatory actions with respect to our products or product candidates or our competitors' products or product candidates;
- actual or anticipated changes in our growth rate relative to 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;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- market conditions in the pharmaceutical and biotechnology sector;
- changes in the structure of healthcare payment systems;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- expiration of market stand-off or lock-up agreements;
- the impact of any natural disasters or public health emergencies, such as the COVID-19 pandemic; and
- general economic, political, industry and market conditions, including the impending presidential election in the United States in 2020.

The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk factors" section, could have a dramatic and adverse impact on the market price of our common stock.

***If securities or industry analysts do not publish research or reports, or if they publish adverse or misleading research or reports, regarding us, our business or our market, our stock price and trading volume could decline.***

The trading market for our common stock will be influenced by the research and reports that securities or industry analysts publish about us, our business or our market. We do not currently have and may never obtain research coverage by securities or industry analysts. If no or few securities or industry analysts commence coverage of us, our stock price would be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue adverse or misleading research or reports regarding us, our business model, our intellectual property, our stock performance or our market, or if our operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

***Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.***

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into license or collaboration agreements or strategic partnerships with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next.

In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including, after the closing of this offering, our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly.

Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and cost of, and level of investment in, research and development activities relating to our programs, which will change from time to time;
- our ability to enroll patients in clinical trials and the timing of enrollment;
- the cost of manufacturing our current product candidates and any future product candidates, which may vary depending on FDA, EMA or other comparable foreign regulatory authority guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies or other assets;
- the timing and outcomes of preclinical studies and clinical trials for product candidates from our RAF and FGFR programs, and any product candidates from our research programs, or competing product candidates;
- the need to conduct unanticipated clinical trials or trials that are larger or more complex than anticipated;
- competition from existing and potential future products that compete with our RAF or FGFR programs or any of our research programs, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review or approval of product candidates from our RAF or FGFR programs, or any of our research programs;
- the level of demand for any of our product candidates, if approved, which may fluctuate significantly and be difficult to predict;

- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future products that compete with our RAF or FGFR programs, or any of our research programs;
- our ability to commercialize product candidates from our RAF or FGFR programs, or any of our research programs, if approved, inside and outside of the United States, either independently or working with third parties;
- our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic and political environment.

The cumulative effect of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

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

Prior to this offering, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 81.59% of our outstanding voting stock and, upon the closing of this offering, that same group will beneficially own approximately % of our outstanding voting stock (based on the number of shares of common stock outstanding as of September 30, 2020, assuming no exercise of the underwriters' option to purchase additional shares, no exercise of outstanding options and no purchases of shares in this offering by any of this group), in each case assuming the conversion of all outstanding shares of our convertible preferred stock into shares of our common stock immediately prior to the closing of this offering. These stockholders, acting together, may be able to impact matters requiring stockholder approval. For example, they may be able to impact elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that investors may feel are in their best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with each investor's interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

***Investors will incur immediate and substantial dilution as a result of this offering.***

Investors that purchase common stock in this offering will incur immediate and substantial dilution of approximately \$ per share, representing the difference between the assumed initial public offering price of \$ per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, and our pro forma net tangible book value per share after giving effect to this offering and the automatic conversion of all outstanding shares of our convertible preferred stock immediately prior to the closing of this offering. As of September 30, 2020, there were 7,037,046 shares subject to outstanding options with a weighted-average exercise price of \$2.49 per share. To the extent that these outstanding options are ultimately exercised or the underwriters exercise their option to purchase additional shares, investors will incur further dilution. See the section titled "Dilution" for a further description of the dilution investors will experience immediately after this offering.



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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. After this offering, we will have outstanding shares of common stock, based on the number of shares outstanding as of September 30, 2020, assuming: (1) no exercise of the underwriters' option to purchase additional shares and (2) the conversion of all outstanding shares of our convertible preferred stock into shares of common stock immediately prior to the completion of this offering. This includes the shares that we sell in this offering, which may be resold in the public market immediately without restriction, unless purchased by our affiliates. Of the remaining shares, shares of our common stock are currently restricted as a result of securities laws or market stand-off or lock-up agreements but will be able to be sold after this offering as described in the section titled "Shares Eligible for Future Sale." Moreover, after this offering, holders of an aggregate of 31,824,284 shares of our common stock will have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also intend to register all shares of common stock that we may issue under our equity incentive plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described in the section titled "Underwriting."

Our executive officers, directors and the holders of substantially all of our capital stock and securities convertible into or exchangeable for our capital stock have entered into market stand-off agreements with us and lock-up agreements with the underwriters under which they have agreed, subject to specific exceptions described in the section titled "Underwriting," not to, among other things, sell, directly or indirectly, any shares of common stock without the permission of Goldman Sachs & Co. LLC, SVB Leerink LLC and Piper Sandler & Co. for a period of 180 days following the date of this prospectus. We refer to such period as the lock-up period. When the lock-up period expires, we and our securityholders subject to a lock-up agreement or market stand-off agreement will be able to sell our shares in the public market. In addition, Goldman Sachs & Co. LLC, SVB Leerink LLC and Piper Sandler & Co. may, in their sole discretion, release all or some portion of the shares subject to lock-up agreements at any time and for any reason. See the description of the market stand-off agreement with us and the lock-up agreement with the underwriters in the section titled "Shares Eligible for Future Sale" for more information. Sales of a substantial number of such shares upon expiration of the lock-up and market stand-off 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 investors to sell their common stock at a time and price that they deem appropriate.

***We are an "emerging growth company" and a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies will make our common stock less attractive to investors.***

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (JOBS Act). For as long as we continue to be an emerging growth company, we intend to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended (Sarbanes-Oxley Act);
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements; and

- exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

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 avail ourselves of this exemption from new or revised accounting standards and, therefore, will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

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

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 continue 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 our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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

***We will incur increased costs as a result of operating as a public company, and our management will devote substantial time to related compliance initiatives.***

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company, and these expenses may increase even more after we are no longer an “emerging growth company.” We will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (Exchange Act), the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Protection Act, as well as rules adopted, and to be adopted, by the SEC and . 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, which will increase our operating expenses. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage, particularly in light of recent cost increases related to coverage. We cannot accurately predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

In addition, as a public company we will be required to incur additional costs and obligations in order to comply with SEC rules that implement Section 404 of the Sarbanes-Oxley Act. Under these rules, beginning with our second annual report on Form 10-K after we become a public company, we will be required to make a formal assessment of the effectiveness of our internal control over financial reporting, and once we cease to be an emerging growth company, we will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaging in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of our internal

control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are designed and operating effectively, and implement a continuous reporting and improvement process for internal control over financial reporting.

***We have identified a material weakness in our internal control over financial reporting. If our remediation of the material weakness is not effective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.***

In connection with the audit of our financial statements as of December 31, 2018 and 2019, and for the period from January 4, 2018 (inception) to December 31, 2018 and the year ended December 31, 2019, we identified a material weakness in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness related to a lack of appropriately designed and implemented controls over the review and approval of manual journal entries, which led to our inability to maintain segregation of duties between the creation and posting of journal entries. The material weakness did not result in a misstatement to our financial statements.

We have taken and are taking steps to remediate this material weakness through the implementation of appropriate segregation of duties and related systems and procedures. However, we are still in the process of implementing these steps and cannot assure investors that these measures will significantly improve or remediate the material weakness described above. We have identified other deficiencies in our internal control over financial reporting that have not risen to the level of a material weakness, which we are in the process of remediating.

We may in the future discover additional weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

We, and our independent registered public accounting firm, were not required to perform an evaluation of our internal control over financial reporting as of December 31, 2019 in accordance with the provisions of the Sarbanes-Oxley Act. Accordingly, we cannot assure you that we have identified all, or that we will not in the future have additional, material weaknesses. Material weaknesses may still exist when we become required to report on the effectiveness of our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act after the completion of this offering.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our stock could decline, and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities.

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

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

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

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

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

***We may be subject to securities litigation, which is expensive and could divert management attention.***

The market price of our common stock may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

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

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to any appreciation in the value of their stock.

***Anti-takeover provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as they will be in effect upon closing of this offering, and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our common stock.***

Our amended and restated certificate of incorporation and amended and restated bylaws, as they will be in effect upon closing of this offering, will contain provisions that could depress the market price of our common stock by acting to discourage, delay or prevent a change in control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions, among other things:

- establish a classified board of directors so that not all members of our board are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board;
- provide that directors may only be removed "for cause" and only with the approval of two-thirds of our stockholders;
- authorize the issuance of "blank check" preferred stock that our board could use to implement a stockholder rights plan (also known as a "poison pill");
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting;

- authorize our board of directors to amend the bylaws;
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings; and
- require a super-majority vote of stockholders to amend some provisions described above.

In addition, Section 203 of the General Corporation Law of the State of Delaware (DGCL), prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

Any provision of our amended and restated certificate of incorporation, amended and restated bylaws or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock.

***Our amended and restated bylaws that will become effective upon the closing of this offering provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums 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 bylaws that will become effective upon the closing of this offering provide that the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another State court in Delaware or the federal district court for the District of Delaware) is the exclusive forum for the following (except for any claim as to which such court determines that there is an indispensable party not subject to the jurisdiction of such court (and the indispensable party does not consent to the personal jurisdiction of such court within 10 days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than such court or for which such court does not have subject matter jurisdiction):

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of fiduciary duty;
- any action asserting a claim against us arising under the DGCL, our amended- and restated certificate of incorporation or our amended and restated bylaws; and
- any action asserting a claim against us that is 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.

Such amended and restated bylaws further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

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 lawsuits against us and our directors, officers and other employees. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings. We also note that stockholders cannot waive compliance (or consent to noncompliance) with the federal securities laws and the rules and regulations thereunder. It is possible that a court could find these types of provisions to be inapplicable or unenforceable, and if a court were to find either exclusive-forum provision in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.

**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus contains forward-looking statements. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy, development plans, planned preclinical studies and clinical trials, future results of clinical trials, expected research and development costs, regulatory strategy, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. In some cases, investors can identify forward-looking statements by terms such as “may,” “will,” “should,” “would,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions. Forward-looking statements contained in this prospectus include, but are not limited to, statements about:

- the ability of our preclinical studies and planned clinical trials to demonstrate safety and efficacy of our product candidates, and other positive results;
- the timing, progress and results of preclinical studies and planned clinical trials for our current product candidates and other product candidates we may develop, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the studies or trials will become available, and our research and development programs;
- the timing, scope and likelihood of regulatory filings and approvals, including timing of INDs and final FDA approval of our current product candidates and any other future product candidates;
- the timing, scope or likelihood of foreign regulatory filings and approvals;
- our ability to develop and advance our current product candidates and programs into, and successfully complete, clinical studies;
- our manufacturing, commercialization, and marketing capabilities and strategy;
- our plans relating to commercializing our product candidates, if approved, including the geographic areas of focus and sales strategy;
- the need to hire additional personnel and our ability to attract and retain such personnel;
- the size of the market opportunity for our product candidates, including our estimates of the number of patients who suffer from the diseases we are targeting;
- our expectations regarding the approval and use of our product candidates in combination with other drugs;
- our competitive position and the success of competing therapies that are or may become available;
- our estimates of the number of patients that we will enroll in our clinical trials;
- the beneficial characteristics, and the potential safety, efficacy and therapeutic effects of our product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our plans relating to the further development of our product candidates, including additional indications we may pursue;
- existing regulations and regulatory developments in the United States, Europe and other jurisdictions;
- our expectations regarding the impact of the COVID-19 pandemic on our business;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering our current product candidates and other product candidates we may develop, including the extensions of existing patent terms where available, the validity of intellectual property rights held by third parties, and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights;



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- our continued reliance on third parties to conduct additional preclinical studies and planned clinical trials of our product candidates, and for the manufacture of our product candidates for preclinical studies and clinical trials;
- our ability to obtain, and negotiate favorable terms of, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- the pricing and reimbursement of our current product candidates and other product candidates we may develop, if approved;
- the rate and degree of market acceptance and clinical utility of our current product candidates and other product candidates we may develop;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our financial performance;
- the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements;
- the impact of laws and regulations;
- our expectations regarding the period during which we will remain an emerging growth company under the JOBS Act; and
- our anticipated use of our existing resources and the net proceeds from this offering.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties and assumptions described in the section titled “Risk Factors” and elsewhere in this prospectus. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, investors should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein until after we distribute this prospectus, whether as a result of any new information, future events or otherwise.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

**MARKET, INDUSTRY AND OTHER DATA**

This prospectus contains estimates, projections and other information concerning our industry, our business and the markets for our product candidates, including data regarding the estimated size of such markets and the incidence of certain medical conditions. We obtained the industry, market and similar data set forth in this prospectus from our internal estimates and research and from academic and industry research, publications, surveys and studies conducted by third parties, including governmental agencies. In some cases, we do not expressly refer to the sources from which this data is derived. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. While we believe that the data we use from third parties are reliable, we have not separately verified this data. Further, while we believe our internal research is reliable, such research has not been verified by any third party. Investors are cautioned not to give undue weight to any such information, projections and estimates.

## USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of the shares of our common stock in this offering will be approximately \$            million, or approximately \$            million if the underwriters exercise their option to purchase additional shares in full, based upon the assumed initial public offering price of \$            per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each \$1.00 increase or decrease in the assumed initial public offering price of \$            per share would increase or decrease, as applicable, the net proceeds to us from this offering by approximately \$            million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1.0 million shares in the number of shares offered by us would increase or decrease, as applicable, the net proceeds to us from this offering by approximately \$            million, assuming the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to obtain additional capital to support our operations, establish a public market for our common stock and facilitate our future access to the public capital markets.

We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, as follows:

- approximately \$            million to fund the continued development of our most advanced product candidate, KIN002787;
- approximately \$            million to fund the continued development of product candidates in our FGFR program; and
- the remaining amounts, if any, to fund the continued development of our other research programs, as well as for working capital and other general corporate purposes.

Our expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above. We believe opportunities may exist from time to time to expand our current business through licenses with or acquisitions of, or investments in, complementary businesses, products or technologies. While we have no current agreements, commitments or understandings for any specific licenses, acquisitions or investments at this time, we may use a portion of the net proceeds for these purposes. As a result, our management will have broad discretion over the use of the net proceeds from this offering.

Based on our current operating plan, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents as of the date of this prospectus, will be sufficient to fund our operating expenses and capital expenditures for at least the next            months. In particular, we expect such funds to enable us to            . The net proceeds from this offering, together with our existing cash and cash equivalents, will not be sufficient to fund any of our product candidates through regulatory approval, and we anticipate needing to raise additional capital to complete the development of and commercialize our product candidates. It is difficult to predict the cost and timing required to complete development and obtain regulatory approval of, and commercialize, our product candidates due to, among other factors, our lack of experience as a company with initiating, conducting and completing preclinical studies and clinical trials, and uncertainty regarding the scope and design of clinical trials required to obtain regulatory approval for our product candidates, the rate of subject enrollment in our planned clinical trials, filing requirements with various regulatory agencies, clinical trial results, and the actual costs of manufacturing, supplying and commercializing our product candidates. The amounts and timing of our expenditures will depend upon numerous factors including the cost and results of our research and

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development efforts, the timing, cost and success of preclinical studies and any clinical trials we may commence in the future, the timing of regulatory submissions, our ability to obtain additional financing, the amount of cash obtained through our existing collaborations and future collaborations, if any, and any unforeseen cash needs.

Pending their use, we intend to invest the net proceeds of this offering in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

## **DIVIDEND POLICY**

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain any future earnings and do not expect to pay any dividends in the foreseeable future. Any future determination to declare cash dividends will be made at the discretion of our board of directors, subject to applicable laws, and will depend on a number of factors, including our financial condition, results of operations, capital requirements, contractual restrictions, general business conditions and other factors that our board of directors may deem relevant.

## CAPITALIZATION

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

- on an actual basis;
- on a pro forma basis to reflect (i) the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 31,824,284 shares of common stock immediately prior to the completion of this offering and (ii) the filing and effectiveness of our amended and restated certificate of incorporation, which will occur immediately prior to the completion of this offering; and
- on a pro forma as adjusted basis to reflect (i) the pro forma adjustments set forth above and (ii) our issuance and sale of        shares of common stock in this offering at the assumed initial public offering price of \$        per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma as adjusted information set forth below is illustrative only and will depend on the actual initial public offering price and other terms of this offering determined at pricing. Investors should read this information in conjunction with our financial statements and the related notes appearing elsewhere in this prospectus, as well as the sections titled “Selected Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

As of September 30, 2020			
	Actual	Pro Forma	Pro Forma As Adjusted <sup>(1)</sup>
	(unaudited)		
	(in thousands, except per share amounts)		
Cash and cash equivalents	<u>\$156,859</u>	<u>\$156,859</u>	<u>\$</u>
Convertible preferred stock, \$0.0001 par value per share; 31,790,040 shares authorized, 31,790,040 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	\$190,835	\$ —	\$
Stockholders’ equity (deficit):			
Preferred stock, \$0.0001 par value per share; no shares authorized, issued and outstanding, actual;        shares authorized, no shares issued and outstanding, pro forma and pro forma as adjusted	—	—	
Common stock, \$0.0001 par value per share; 47,000,000 shares authorized, 4,664,042 shares issued and 4,627,992 outstanding, actual;        shares authorized, 36,452,278 shares issued and outstanding, pro forma; shares authorized,        shares issued and outstanding, pro forma as adjusted	—	4	
Additional paid-in capital	1,360	192,191	
Treasury stock at cost, 36,068 shares of common stock	(75)	(75)	
Accumulated deficit	<u>(39,622)</u>	<u>(39,622)</u>	
Total stockholders’ equity (deficit)	<u>(38,337)</u>	<u>152,498</u>	
Total capitalization	<u>\$152,498</u>	<u>\$152,498</u>	<u>\$</u>

- (1) Each \$1.00 increase or decrease in the assumed initial public offering price of \$        per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, each of our pro forma as adjusted cash and cash equivalents, additional paid-in capital, total stockholders’ equity (deficit) and total capitalization by approximately \$        million, assuming that the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1.0 million shares in the number of shares of common stock offered by us would increase or decrease, as applicable, each of our pro forma as adjusted cash and cash



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equivalents, additional paid-in capital, total stockholders' equity (deficit) and total capitalization by approximately \$ million, assuming the assumed initial public offering price of \$ per share, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters' option to purchase additional shares is exercised in full, our pro forma as adjusted cash and cash equivalents, additional paid-in capital, total stockholders' equity (deficit) and total capitalization as of September 30, 2020, would be \$ million, \$ million, \$ million, and \$ million, respectively.

The number of shares of our common stock issued and outstanding, pro forma and pro forma as adjusted in the table above, is based on 36,452,278 shares of our common stock outstanding as of September 30, 2020 (including our convertible preferred stock on an as-converted basis), and excludes:

- 7,037,046 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2020, with a weighted-average exercise price of \$2.49 per share;
- shares of common stock issuable upon the exercise of options granted after September 30, 2020, with a weighted-average exercise price of \$ per share;
- 1,379,209 shares of common stock for future issuance under our 2018 Equity Incentive Plan, as amended (2018 Plan), as of September 30, 2020, which shares will be added to the shares to be reserved for future issuance under our 2020 Equity Incentive Plan (2020 Plan);
- shares of common stock reserved for future issuance under our 2020 Plan, which will become effective on the business day immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan; and
- shares of common stock reserved for future issuance under our 2020 Employee Stock Purchase Plan (2020 ESPP), which will become effective on the business day immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan.

## DILUTION

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

Our historical net tangible book value (deficit) as of September 30, 2020, was \$(38.3) million, or \$(8.28) per share of our common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets less our total liabilities and convertible preferred stock, which is not included within our stockholders' equity (deficit). Historical net tangible book value (deficit) per share represents historical net tangible book value (deficit) divided by the number of shares of our common stock outstanding as of September 30, 2020.

Our pro forma net tangible book value as of September 30, 2020, was \$152.5 million, or \$4.18 per share of our common stock. Pro forma net tangible book value represents the amount of our total tangible assets less our total liabilities. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares outstanding as of September 30, 2020, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock as of September 30, 2020, into an aggregate of 31,824,284 shares of our common stock immediately prior to the completion of this offering as if such conversion had occurred on September 30, 2020.

After giving further effect to our sale of \_\_\_\_\_ shares of common stock in this offering at the assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of September 30, 2020, would have been approximately \$ \_\_\_\_\_ million, or approximately \$ \_\_\_\_\_ per share. This represents an immediate increase in pro forma net tangible book value per share of approximately \$ \_\_\_\_\_ to our existing stockholders and an immediate dilution in pro forma net tangible book value per share of approximately \$ \_\_\_\_\_ to investors purchasing shares of common stock in this offering.

Dilution per share to investors purchasing shares of common stock in this offering is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the assumed initial public offering price per share paid by investors purchasing shares of common stock in this offering.

The following table illustrates this dilution on a per share basis to new investors (without giving effect to any exercise by the underwriters of their option to purchase additional shares):

Assumed initial public offering price per share	\$
Historical net tangible book value (deficit) per share as of September 30, 2020	\$(8.28)
Pro forma increase in net tangible book value per share as of September 30, 2020	<u>12.46</u>
Pro forma net tangible book value per share as of September 30, 2020	4.18
Increase in pro forma net tangible book value per share attributable to investors purchasing shares of common stock in this offering	<u>          </u>
Pro forma as adjusted net tangible book value per share	<u>          </u>
Dilution per share to investors participating in this offering	<u>\$</u>

Each \$1.00 increase or decrease in the assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, the pro forma as adjusted net tangible book value per share after this offering by approximately \$ \_\_\_\_\_ per share and the dilution to investors purchasing shares of common stock in this offering by approximately \$ \_\_\_\_\_ per share, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase of 1.0 million shares in the number of shares offered by us would increase the pro forma as adjusted net

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tangible book value per share after this offering by approximately \$ and decrease the dilution per share to investors purchasing shares of common stock in this offering by approximately \$, assuming no change in the assumed initial public offering price and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each decrease of 1.0 million shares in the number of shares offered by us would decrease the pro forma as adjusted net tangible book value per share after this offering by approximately \$ and increase the dilution per share to investors purchasing shares of common stock in this offering by approximately \$, assuming no change in the assumed initial public offering price and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise their option to purchase additional shares of common stock in this offering in full at the assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus and assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, the pro forma as adjusted net tangible book value per share after this offering would be approximately \$ per share, and the dilution per share to investors purchasing shares of common stock in this offering would be approximately \$ per share.

The following table summarizes, on the pro forma as adjusted basis described above, as of September 30, 2020, the number of shares of common stock purchased from us, the total consideration paid, or to be paid, and the weighted-average price per share paid, or to be paid, by existing stockholders and by investors purchasing shares in this offering at the assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		Weighted-Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders before this offering		%	\$	%	\$
Investors purchasing shares in this offering					\$
Total		100.0%	\$	100.0%	

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

Each \$1.00 increase or decrease in the assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, the total consideration paid by investors purchasing shares in 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. Similarly, each increase or decrease of 1.0 million shares in the number of shares offered by us would increase or decrease, as applicable, the total consideration paid by investors purchasing shares in this offering by approximately \$ million, assuming no change in the assumed initial public offering price.

The foregoing tables and calculations (other than the historical net tangible book value calculation) are based on the shares of our common stock outstanding as of September 30, 2020 (including our convertible preferred stock on an as-converted basis), and excludes:

- 7,037,046 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2020, with a weighted-average exercise price of \$2.49 per share;

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- shares of common stock issuable upon the exercise of options granted after September 30, 2020, with a weighted-average exercise price of \$            per share;
- 1,379,209 shares of common stock for future issuance under our 2018 Plan as of September 30, 2020, which shares will be added to the shares to be reserved for future issuance under our 2020 Plan;
- shares of common stock reserved for future issuance under our 2020 Plan, which will become effective on the business day immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan; and
- shares of common stock reserved for future issuance under our 2020 ESPP, which will become effective on the business day immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan.

To the extent that any outstanding options are exercised or new options are issued under our equity benefit plans, or we issue additional shares of common stock or other securities convertible into or exercisable or exchangeable for shares of our capital stock in the future, there will be further dilution to investors purchasing shares of common stock in this offering.

## SELECTED FINANCIAL DATA

The following tables set forth our selected financial data for the periods and as of the dates indicated. We have derived the selected statements of operations data for the period from January 4, 2018 (inception) to December 31, 2018 and for the year ended December 31, 2019, and the selected balance sheet data as of December 31, 2018 and 2019, from our audited financial statements appearing elsewhere in this prospectus. We have derived the selected statements of operations data for the nine months ended September 30, 2019 and 2020, and the selected balance sheet data as of September 30, 2020, from our unaudited interim financial statements appearing elsewhere in this prospectus. Our unaudited interim financial statements have been prepared on a basis consistent with our audited financial statements and, in the opinion of management, reflect all adjustments, consisting solely of normal recurring adjustments, necessary for the fair presentation of the financial information in those statements. Investors should read the following selected financial data together with our financial statements and the related notes appearing elsewhere in this prospectus and the information in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our historical results are not necessarily indicative of our future results, and the results for any interim period are not necessarily indicative of the results to be expected for the full year or any other period. The summary financial data in this section are not intended to replace the financial statements and the related notes appearing elsewhere in this prospectus.

	Period from January 4, 2018 (inception) through December 31, 2018	Year Ended December 31, 2019	Nine Months Ended September 30,	
			2019	2020
	(unaudited)			
	(in thousands, except share and per share amounts)			
Statements of Operations Data:				
Operating expenses:				
Research and development (includes related party amounts of \$1,454, \$2,301, \$1,551 and \$0, respectively)	\$ 5,675	\$ 8,955	\$ 5,896	\$ 17,261
General and administrative (includes related party amounts of \$1,600, \$2,609, \$1,827 and \$92, respectively)	1,955	3,057	2,131	\$ 5,021
Total operating expenses	7,630	12,012	8,027	22,282
Loss from operations	(7,630)	(12,012)	(8,027)	(22,282)
Other income:				
Interest income	—	43		228
Total other income	—	43		228
Net loss and comprehensive loss	\$ (7,630)	\$ (11,969)	\$ (8,027)	\$ (22,054)
Gain on extinguishment of Series A convertible preferred stock	—	2,031	2,031	—
Net loss attributable to common stockholders	\$ (7,630)	\$ (9,938)	\$ (5,996)	\$ (22,054)
Weighted-average shares outstanding, basic and diluted	4,504,024	4,517,713	4,517,500	4,578,904
Net loss attributable to common stockholders per share, basic and diluted	\$ (1.69)	\$ (2.20)	\$ (1.33)	\$ (4.82)
Pro forma weighted-average shares outstanding, basic and diluted (unaudited)		13,333,894		28,743,251
Pro forma net loss attributable to common stockholders per share, basic and diluted (unaudited)		\$ (0.75)		\$ (0.77)

	As of December 31,		As of
	2018	2019	September 30,
			2020
			(unaudited)
	(in thousands)		
Balance Sheet Data:			
Cash and cash equivalents	\$ 6,999	\$ 76,453	\$156,859
Working capital <sup>(1)</sup>	7,610	75,506	150,780
Total assets	8,077	77,605	159,197
Current liabilities	467	1,945	6,699
Total liabilities	467	1,945	6,699
Convertible preferred stock	—	93,146	190,835
Accumulated deficit	(7,630)	(17,568)	(39,622)
Total stockholders' equity (deficit)	7,610	(17,486)	(38,337)

(1) We define working capital as current assets less current liabilities. See our financial statements appearing elsewhere in this prospectus for further details regarding our current assets and current liabilities.



## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*Investors should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes appearing elsewhere in this prospectus and in the section titled "Selected Financial Data." Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus includes forward-looking statements that involve risks, uncertainties and assumptions. As a result of many factors, including those factors set forth in the section titled "Risk Factors," our actual results could differ materially from the results described in or implied by these forward-looking statements. Investors should carefully read the section titled "Risk Factors" to gain an understanding of the factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section titled "Special Note Regarding Forward-Looking Statements."*

### Overview

We are a biopharmaceutical company focused on the discovery and development of small molecule kinase inhibitors for difficult-to-treat, genomically defined cancers. Our mission is to expand the reach of targeted therapeutics by developing products for underserved populations. We utilize our deep expertise in structure-based drug discovery, translational research and patient-driven precision medicine, which we collectively refer to as our Kinnate Discovery Engine, to develop our targeted therapies. We focus our discovery and development efforts on three patient populations: (1) those with cancers that harbor known oncogenic drivers (gene mutations that cause cancers) with no currently available targeted therapies, (2) those with genomically well-characterized tumors that have intrinsic resistance to currently available treatments (non-responders), and (3) those whose tumors have acquired resistance over the course of therapy to currently available treatments. We believe our unique approach may enable us to develop drugs with an increased probability of clinical success while reducing the cost and risk of drug development. Our most advanced product candidate is KIN002787, which is a RAF inhibitor we are developing for the treatment of patients with lung cancer, melanoma and other solid tumors. Unlike currently available treatments that target only Class I BRAF kinase mutations, we have designed KIN002787 to target Class II and Class III BRAF mutations, where it would be a first-line targeted therapy, in addition to covering Class I BRAF mutations. We anticipate filing an IND for our RAF candidate with the FDA in the first half of 2021. Additionally, in our KIN003 program we are evaluating FGFR inhibitor candidates for the treatment of patients with ICC and UC. Our FGFR candidates are designed to address clinically observed genomic alterations in FGFR2 and FGFR3 that drive resistance to current therapies. We anticipate filing an IND for one of our FGFR candidates with the FDA in the first half of 2022. Our RAF and FGFR candidates have demonstrated proof of concept in preclinical models and, subject to our planned IND submissions taking effect, we anticipate initiating a Phase 1 clinical trial for KIN002787 in 2021 and an additional Phase 1 clinical trial for our KIN003 program in the first half of 2022. We are also advancing a number of other small molecule research programs, including a CDK12 inhibitor in our KIN004 program to target the treatment of OC, TNBC and mCRPC.

Since our inception in 2018, we have devoted substantially all of our resources to research and development activities, including with respect to our RAF and FGFR programs and other research programs, business planning, establishing and maintaining our intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these operations.

We do not have any products approved for commercial sale, and we have not generated any revenue from product sales or other sources since inception. Our ability to generate product revenue sufficient to achieve profitability, if ever, will depend on the successful development and eventual commercialization of one or more of our product candidates which we expect, if it ever occurs, will take a number of years. We also do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical and clinical testing, as well as for commercial manufacturing if any of our product candidates obtain marketing approval. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment and personnel while also enabling us to focus our expertise and resources on the development of our product candidates.

To date, we have financed our operations primarily through private placements of our convertible preferred stock. As of September 30, 2020, we had raised aggregate gross proceeds of \$191.6 million from these private placements and we had cash and cash equivalents of \$156.9 million. Based on our current operating plan, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents as of the date of this prospectus, will be sufficient to fund our planned operating expenses and capital expenditure requirements for at least the next months.

We have incurred significant losses since the commencement of our operations. Our net losses for the period from January 4, 2018 (inception) to December 31, 2018 were \$7.6 million and for the year ended December 31, 2019 were \$12.0 million and \$8.0 million and \$22.1 million for the nine months ended September 30, 2019 and 2020, respectively, and we expect to continue to incur significant and increasing losses for the foreseeable future as we continue to advance our product candidates, and as we transition to operating as a public company. Our net losses may fluctuate significantly from period to period, depending on the timing of expenditures on our research and development activities. As of September 30, 2020, we had an accumulated deficit of \$39.6 million.

We expect our expenses and capital requirements will increase substantially in connection with our ongoing activities as we:

- advance our RAF and FGFR programs from discovery and preclinical development into and through clinical development;
- advance the development of our other small molecule research programs, including our CDK12 inhibitor;
- expand our pipeline of product candidates through our own product discovery and development efforts;
- seek to discover and develop additional product candidates;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any approved product candidates and related additional commercial manufacturing costs;
- implement operational, financial and management systems;
- attract, hire and retain additional clinical, scientific, management and administrative personnel;
- maintain, expand, protect and enforce our intellectual property portfolio, including patents, trade secrets and know how; and
- operate as a public company.

We will require substantial additional funding to develop our product candidates and support our continuing operations. Until such time that we can generate significant revenue from product sales or other sources, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, which could include income from collaborations, strategic partnerships or marketing, distribution, licensing or other strategic arrangements with third parties, or from grants. We may be unable to raise additional funds or to enter into such agreements or arrangements on favorable terms, or at all. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic and otherwise. Our failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations or financial condition, including requiring us to have to delay, reduce or eliminate our product development or future commercialization efforts. Insufficient liquidity may also require us to relinquish rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our development efforts. We cannot provide assurance that we will ever be profitable or generate positive cash flow from operating activities.

The global COVID-19 pandemic continues to rapidly evolve. The extent of the impact of the COVID-19 on our business, operations and development timelines and plans remains uncertain, and will depend on certain developments, including the duration and spread of the outbreak and its impact on our development activities, planned clinical trial enrollment, future trial sites, CROs, third-party manufacturers, and other third parties with whom we do business, as well as its impact on regulatory authorities and our key scientific and management personnel. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. To the extent possible, we are conducting business as usual, with necessary or advisable modifications to employee travel and with our employees working remotely. We will continue to actively monitor the rapidly evolving situation related to COVID-19 and may take further actions that alter our operations, including those that may be required by federal, state or local authorities, or that we determine are in the best interests of our employees and other third parties with whom we do business. At this point, the extent to which the COVID-19 pandemic may affect our business, operations and development timelines and plans, including the resulting impact on our expenditures and capital needs, remains uncertain.

We were incorporated in the State of Delaware in January 2018, and are headquartered in San Diego, California. In April 2019, we merged with Immanate Therapeutics Inc. (Immanate) with Kinnate Biopharma Inc. being the surviving entity. Both companies were previously under the common control of Fount Therapeutics, LLC (FTL). As the merged entities were under common control, the financial statements report the financial position, results of operations and cash flows of the companies as though the transfer of net assets and equity interests had occurred at inception on January 4, 2018. Fount Service Corp. (FSC), a subsidiary of FTL, historically provided management services and other services to us, either directly or via arrangements with third parties. These services included research and development and general and administrative functions, such as finance, audit, accounting, human resources, technology, facilities, and other management services necessary for our operations. Employees of FSC were subsequently hired by us, and the material agreements of FSC with third parties relating to the continuing services to be provided to us have been assigned to us or we have entered into new, direct agreements with such third parties and we no longer rely on FTL or FSC for such services. Our research and development team is primarily based in San Diego, California, with a portion of our management team based in the San Francisco Bay Area.

## **Components of Our Results of Operations**

### ***Revenue***

To date, we have not generated any revenue and we do not expect to generate any revenue from the sale of products or from other sources in the foreseeable future.

### ***Operating Expenses***

#### ***Research and Development***

Research and development expenses account for a significant portion of our operating expenses and consist primarily of external and internal expenses incurred in connection with the discovery and development of our product candidates.

External expenses include:

- expenses incurred in connection with the discovery and preclinical development of our product candidates, including under agreements with third parties, such as consultants and CROs;
- the cost of manufacturing compounds for use in our preclinical studies, including under agreements with third parties, such as consultants and CMOs; and
- costs associated with consultants for chemistry, manufacturing and controls (CMC) development, regulatory, statistics and other services.

Internal expenses include:

- for 2020, employee-related expenses, including salaries and benefits, travel and stock-based compensation expense for employees engaged in research and development functions; and
- for 2019, research and development services provided by FSC and stock-based compensation expense.

We expense research and development expenses in the periods in which they are incurred. External expenses are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers or our estimate of the level of service that has been performed at each reporting date. We track external expenses on a lead program and other program basis. However, we do not track internal costs on a program specific basis because these costs are deployed across multiple programs and, as such, are not separately classified. We utilize third party contractors for our research and development activities and CMOs for our manufacturing activities and we do not have our own laboratory or manufacturing facilities. Therefore, we have no material facilities expenses attributed to research and development.

Product candidates in later stages of development generally have higher development costs than those in earlier stages. As a result, we expect that our research and development expenses will increase substantially over the next several years as we advance our product candidates through preclinical studies into and through clinical trials, continue to discover and develop additional product candidates and expand our pipeline, maintain, expand, protect and enforce our intellectual property portfolio, and hire additional personnel.

The successful development of our product candidates is highly uncertain, and we do not believe it is possible at this time to accurately project the nature, timing and estimated costs of the efforts necessary to complete the development of, and obtain regulatory approval for, any of our product candidates. To the extent our product candidates continue to advance into clinical trials, as well as advance into larger and later-stage clinical trials, our expenses will increase substantially and may become more variable. We are also unable to predict when, if ever, we will generate revenue from our product candidates to offset these expenses. Our expenditures on current and future preclinical and clinical programs are subject to numerous uncertainties in timing and cost to completion. The duration, costs and timing of preclinical studies and clinical trials and development of our product candidates will depend on a variety of factors, including:

- the timing and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- our ability to maintain our current research and development programs and to establish new ones;
- establishing an appropriate safety profile with IND-enabling toxicology studies;
- successful patient enrollment in, and the initiation and completion of, clinical trials;
- per subject trial costs;
- the number of trials required for regulatory approval;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible subjects and initial clinical trials;
- the number of subjects that participate in the trials;
- the drop-out and discontinuation rate of subjects;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of subject participation in the trials and follow-up;
- the successful completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to applicable regulatory authorities;
- the receipt of regulatory approvals from applicable regulatory authorities;
- the timing, receipt and terms of any marketing approvals and post-marketing approval commitments from applicable regulatory authorities;
- the extent to which we establish collaborations, strategic partnerships or other strategic arrangements with third parties, if any, and the performance of any such third party;

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- obtaining and retaining research and development personnel;
- establishing commercial manufacturing capabilities or making arrangements with CMOs;
- development and timely delivery of commercial-grade drug formulations that can be used in our planned clinical trials and for commercial launch; and
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights.

Any changes in the outcome of any of these factors could significantly impact the costs, timing and viability associated with the development of our product candidates.

### *General and Administrative*

General and administrative expenses in 2019 consisted of fees paid to FTL and FSC for various services such as finance, audit, accounting, human resources, technology, facilities, and other management services necessary for our operations, as well as for legal expenses. General and administrative expenses in 2020 consisted of salaries and benefits, travel and stock-based compensation expense for personnel in executive, human resources, finance and administrative functions; professional fees for legal, patent, consulting, accounting and audit services; and expenses for technology and facilities. We expense general and administrative expenses in the periods in which they are incurred.

We expect that our general and administrative expenses will increase substantially over the next several years as we hire additional personnel to support the continued research and development of our programs and growth of our business. Following the completion of this offering, we also anticipate that we will incur substantially higher expenses as a result of operating as a public company, including expenses related to accounting, audit, legal, regulatory, compliance with the rules and regulations of the SEC, Sarbanes-Oxley Act and those of any national securities exchange on which our securities are traded, director and officer insurance, investor and public relations, and other administrative and professional services.

### **Other Income**

#### *Interest Income*

Interest income primarily consists of interest income generated from our cash equivalents in interest-bearing money market accounts.

## **Results of Operations**

### **Comparison of the Nine Months Ended September 30, 2019 and 2020**

The following table summarizes our results of operations for the periods indicated:

	Nine Months Ended September 30,	
	2019	2020
	(in thousands)	
Operating expenses:		
Research and development (includes related party amounts of \$1,551 and \$0, respectively)	\$ 5,896	\$ 17,261
General and administrative (includes related party amounts of \$1,827 and \$92, respectively)	2,131	5,021
Total operating expenses	8,027	22,282
Loss from operations	(8,027)	(22,282)
Other Income:		
Interest income	—	228
Total other income	—	228
Net loss and comprehensive loss	<u><u>\$(8,027)</u></u>	<u><u>\$(22,054)</u></u>

**Research and Development Expenses**

The following table summarizes our research and development expenses incurred during the periods indicated:

	Nine Months Ended September 30,	
	2019	2020
	(in thousands)	
External expenses:		
Lead programs <sup>(1)</sup>	\$2,777	\$11,785
Other programs and other unallocated costs	<u>1,568</u>	<u>2,082</u>
Total external expenses	4,345	13,867
Internal expenses	<u>1,551</u>	<u>3,394</u>
Total research and development expenses	<u>\$5,896</u>	<u>\$17,261</u>

(1) For the periods presented, consists of our RAF and FGFR programs.

Research and development expenses were \$5.9 million for the nine months ended September 30, 2019, compared to \$17.3 million for the nine months ended September 30, 2020, an increase of \$11.4 million. The increase was primarily driven by an increase of \$9.0 million in external expenses for our RAF and FGFR programs. In addition, internal research and development expenses increased \$1.8 million as a result of us hiring additional research and development personnel beyond those who were engaged through FTL and FSC in 2019, allowing us to increase our capabilities. External expenses for other non-lead programs increased by \$0.5 million reflecting increased spend in early-stage pipeline research.

**General and Administrative Expenses**

General and administrative expenses were \$2.1 million for the nine months ended September 30, 2019, compared to \$5.0 million for the nine months ended September 30, 2020, an increase of \$2.9 million. This increase was primarily driven by the hiring of senior management in 2020, an increase in accounting fees and an expansion of our activity.

**Interest Income**

There was no interest income for the nine months ended September 30, 2019, compared to \$0.2 million for the nine months ended September 30, 2020. The increase reflected the interest earned on the proceeds of the Series B and Series C convertible preferred stock financing in 2019 and 2020, respectively.



**Comparison of the Period from January 4, 2018 (Inception) to December 31, 2018, and Year Ended December 31, 2019**

The following table summarizes our results of operations for the periods indicated:

	For the Period January 4, 2018 (Inception) through December 31, 2018	Year Ended December 31, 2019
	(in thousands)	
Operating expenses:		
Research and development (includes related party amounts of \$1,454 and \$2,301, respectively)	\$ 5,675	\$ 8,955
General and administrative (includes related party amounts of \$1,600 and \$2,609, respectively)	1,955	3,057
Total operating expenses	7,630	12,012
Loss from operations	(7,630)	(12,012)
Other Income:		
Interest income	—	43
Total other income	—	43
Net loss and comprehensive loss	<u><u>\$(7,630)</u></u>	<u><u>\$(11,969)</u></u>

*Research and Development Expenses*

The following table summarizes our research and development expenses incurred during the periods indicated:

	For the Period January 4, 2018 (Inception) through December 31, 2018	Year Ended December 31, 2019
	(in thousands)	
External expenses:		
Lead programs <sup>(1)</sup>	\$ 378	\$4,500
Other programs and other unallocated costs	3,806	2,120
Total external expenses	4,184	6,620
Internal expenses	1,491	2,335
Total research and development expenses	<u><u>\$5,675</u></u>	<u><u>\$8,955</u></u>

(1) For the periods presented, consists of our RAF and FGFR programs.

Research and development expenses were \$5.7 million for the period from January 4, 2018 (inception) through December 31, 2018, compared to \$9.0 million for the year ended December 31, 2019, an increase of \$3.3 million. The increase was primarily driven by an increase of \$4.1 million in external expenses for our RAF and FGFR programs, and to a lesser extent by an increase of \$0.8 million in internal expenses resulting from hiring and expansion of activity at FTL and FSC. This was partially offset by a decrease of \$1.7 million in external expenses for other non-lead programs, as these other programs were deferred or revised.

### *General and Administrative Expenses*

General and administrative expenses were \$2.0 million for the period from January 4, 2018 (inception) through December 31, 2018, compared to \$3.1 million for the year ended December 31, 2019, an increase of \$1.1 million. This increase was primarily driven by an increase in fees to FTL and FSC for their services.

### *Interest Income*

There was no interest income for the period from January 4, 2018 (inception) through December 31, 2018, compared to \$43,000 for the year ended December 31, 2019. The increase reflected the interest earned on the proceeds of the Series B convertible preferred stock financing in 2019.

## **Liquidity and Capital Resources**

### ***Sources of Liquidity***

Since our inception, we have not generated any revenue from product sales or other sources and have incurred significant operating losses and negative cash flows from our operations. As of September 30, 2020, we had an accumulated deficit of \$39.6 million. To date, we have funded our operations primarily through private placements of our convertible preferred stock. As of September 30, 2020, we had raised aggregate gross proceeds of \$191.6 million from these private placements and had cash and cash equivalents of \$156.9 million.

Our primary uses of cash to date have been to fund our research and development activities, including with respect to our RAF and FGFR programs and other research programs, business planning, establishing and maintaining our intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these operations.

### ***Future Funding Requirements***

To date, we have not generated any revenue. We do not expect to generate any meaningful revenue unless and until we obtain regulatory approval of and commercialize any of our product candidates, and we do not know when, or if, that will occur. Until such time as we can generate significant revenue from product sales, if ever, we will continue to require substantial additional capital to develop our product candidates and fund operations for the foreseeable future. We expect our expenses to increase significantly in connection with our ongoing activities as described in greater detail below. We are subject to all the risks incident in the development of new biopharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may harm our business. We expect our expenses to increase significantly, as we:

- advance our RAF and FGFR programs from discovery and preclinical development into and through clinical development;
- advance the development of our other small molecule research programs, including our CDK12 inhibitor;
- expand our pipeline of product candidates through our own product discovery and development efforts;
- seek to discover and develop additional product candidates;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any approved product candidates and related additional commercial manufacturing costs;
- implement operational, financial and management systems;
- attract, hire and retain additional clinical, scientific, management and administrative personnel;
- maintain, expand, protect and enforce our intellectual property portfolio, including patents, trade secrets and know how; and
- operate as a public company.

In order to complete the development of our product candidates and to build the sales, marketing and distribution infrastructure that we believe will be necessary to commercialize our product candidates, if approved, we will require substantial additional funding. Until we can generate a sufficient amount of revenue from the commercialization of our product candidates, we may seek to raise any necessary additional capital through the sale of equity, debt financings or other capital sources, which could include income from collaborations, strategic partnerships or marketing, distribution, licensing or other strategic arrangements with third parties, or from grants. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, including restricting our operations and limiting our ability to incur liens, issue additional debt, pay dividends, repurchase our common stock, make certain investments or engage in merger, consolidation, licensing or asset sale transactions. If we raise funds through collaborations, strategic partnerships and other similar arrangements with third parties, we may be required to grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. We may be unable to raise additional funds or to enter into such agreements or arrangements on favorable terms, or at all. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic and otherwise. If we are unable to raise additional funds when needed, we may be required to delay, reduce or eliminate our product development or future commercialization efforts.

Based on our current operating plan, we believe that our existing cash and cash equivalents as of the date of this prospectus, without giving effect to the net proceeds from this offering, will be sufficient to fund our planned operating expenses and capital expenditure requirements for at least the next 12 months. We also believe that our existing cash and cash equivalents as of the date of this prospectus, after giving effect to the net proceeds from this offering, will be sufficient to fund our planned operating expenses and capital expenditure requirements for at least the next \_\_\_\_\_ months. We have based our projections of operating capital requirements on our current operating plan, which includes several assumptions that may prove to be incorrect, and we may use all of our available capital resources sooner than we expect.

Because of the numerous risks and uncertainties associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount and timing of our working capital requirements. Our future funding requirements will depend on many factors, including:

- the scope, timing, progress, results and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials;
- the scope, timing, progress, results and costs of researching and developing other product candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the costs of manufacturing commercial-grade products and sufficient inventory to support commercial launch;
- the revenue, if any, received from commercial sale of our products, should any of our product candidates receive marketing approval;
- the cost and timing of attracting, hiring and retaining skilled personnel to support our operations and continued growth;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations, strategic partnerships or marketing, distribution, licensing or other strategic arrangements with third parties on favorable terms, if at all;

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- the extent to which we acquire or in-license other product candidates and technologies, if any;
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future product candidates, if any; and
- the costs associated with operating as a public company.

A change in the outcome of any of these or other factors with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plans.

### Cash Flows

The following tables summarizes our cash flow for the periods indicated:

	Nine Months Ended September 30,	
	2019	2020
	(in thousands)	
Net cash used in operating activities	\$(7,180)	\$(16,405)
Net cash used in investing activities	—	(359)
Net cash provided by financing activities	5,930	97,170
Net (decrease) increase in cash and cash equivalents	<u>\$(1,250)</u>	<u>\$ 80,406</u>

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

	Period from January 4, 2018 (Inception) through December 31, 2018	Year Ended December 31, 2019
	(in thousands)	
Net cash used in operating activities	\$(8,202)	\$(10,526)
Net cash provided by financing activities	15,201	79,980
Net increase in cash and cash equivalents	<u>\$ 6,999</u>	<u>\$ 69,454</u>

#### Operating Activities

Net cash used in operating activities during the nine months ended September 30, 2019 was \$7.2 million. This consisted of our net loss of \$8.0 million and a net increase in working capital of \$0.8 million, primarily due to increases in accounts payable and accrued expenses for research and development activities and a decrease in related party receivables, net.

Net cash used in operating activities during the nine months ended September 30, 2020 was \$16.4 million. This consisted of our net loss of \$22.1 million and a net increase in working capital of \$4.3 million, primarily due to increases in accounts payable and accrued expenses for research and development activities and a decrease in intercompany receivables, net and stock compensation expense of \$1.3 million.

Net cash used in operating activities during the period from January 4, 2018 (inception) to December 31, 2018 was \$8.2 million. This consisted of our net loss of \$7.6 million and a net decrease in working capital of \$0.6 million, primarily due to an outstanding related-party net receivable from FTL and FSC.

Net cash used in operating activities during the year ended December 31, 2019 was \$10.5 million. This consisted of our net loss of \$12.0 million and a net increase in working capital of \$1.4 million, primarily due to increases in accounts payable and accrued expenses for research and development activities.

### *Investing Activities*

Net cash used in investing activities during the nine months ended September 30, 2020 was \$0.4 million and related to the purchase of property and equipment.

There was no investing activities for the other periods presented above.

### *Financing Activities*

Net cash provided by financing activities during the nine months ended September 30, 2019 was \$5.9 million. This consisted of proceeds of \$5.9 million resulting from the sale of shares of Series A convertible preferred stock, net of issuance costs.

Net cash provided by financing activities during the nine months ended September 30, 2020 was \$97.2 million. This consisted of proceeds of \$97.7 million resulting from the sale of shares of Series C convertible preferred stock, net of issuance costs, and the payment of deferred offering costs of \$0.5 million.

Net cash provided by financing activities during the period from January 4, 2018 (inception) to December 31, 2018 was \$15.2 million. This consisted of proceeds of \$15.2 million resulting from the sale of shares of Series A convertible preferred stock, net of issuance costs.

Net cash provided by financing activities during the year ended December 31, 2019 was \$80.0 million. This primarily consisted of proceeds of \$5.8 million resulting from the sale of shares of Series A convertible preferred stock, net of issuance costs, and proceeds of \$74.2 million resulting from the sale of shares of Series B convertible preferred stock, net of issuance costs.

### **Contractual Obligations and Commitments**

We lease certain office space in San Diego, California under a short-term lease with base monthly rent payments of \$13,000 that expires December 31, 2020. We have not yet determined whether we will seek to renew this lease, enter into a lease for other office space, or take an alternative approach to our office space needs in the future. In addition, we have entered into agreements in the normal course of business with certain vendors for the provision of goods and services, which includes manufacturing services with CMOs and development services with CROs. These agreements may include certain provisions for purchase obligations and termination obligations that could require payments for the cancellation of committed purchase obligations or for early termination of the agreements. The amount of the cancellation or termination payments vary and are based on the timing of the cancellation or termination and the specific terms of the agreement. These obligations and commitments are not separately presented.

### **Internal Control Over Financial Reporting**

In connection with the audit of our financial statements as of December 31, 2018 and 2019, and for the period from January 4, 2018 (inception) to December 31, 2018 and the year ended December 31, 2019, we identified a material weakness in our internal control over financial reporting related to a lack of appropriately designed and implemented controls over the review and approval of manual journal entries, which led to our inability to maintain segregation of duties between the creation and posting of journal entries. This material weakness did not result in a misstatement in our financial statements. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. We have taken and are taking steps to remediate this material weakness through implementation of appropriate segregation of duties and related systems and procedures. However, we are still in the process of implementing these steps and we cannot assure investors that these measures will significantly improve or remediate the material weakness. If remediation of this material weakness is not effective, or if we fail to develop and maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate consolidated financial statements or comply with applicable laws and regulations could be impaired. See the section titled "Risk Factors—Risks Related to This Offering and Ownership of Our Common Stock—We have identified a material weakness in our internal control over financial

reporting. If our remediation of the material weakness is not effective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock."

#### **Off-Balance Sheet Arrangements**

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

#### **Critical Accounting Policies and Significant Judgments and Estimates**

Our financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our 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 a periodic basis. Our actual results may differ from these estimates.

While our significant accounting policies are described in more detail in the notes to our financial statements appearing elsewhere in this prospectus, we believe that the following accounting policies are critical to understanding our historical and future performance, as the policies relate to the more significant areas involving management's judgments and estimates used in the preparation of our financial statements.

#### ***Research and Development Expenses***

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, based on a pre-determined schedule or when contractual milestones are met, but some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in the financial statements based on facts and circumstances known to us at that time. If timelines or contracts are modified based upon changes in the protocol or scope of work to be performed, we modify our estimates and accruals accordingly on a prospective basis.

We base our expenses related to external research and development services on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expenses accordingly.

Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.



**Stock-Based Compensation**

Stock-based compensation expense represents the cost of the grant date fair value of employee, officer, director and non-employee stock option grants, estimated in accordance with the applicable accounting guidance, recognized on a straight-line basis over the vesting period. The vesting period generally approximates the expected service period of the awards. We recognize forfeitures as they occur.

The fair value of stock options is estimated using a Black-Scholes valuation model on the date of grant. The Black-Scholes option-pricing model requires inputs based on certain subjective assumptions. Changes to these assumptions can materially affect the fair value of stock options and ultimately the amount of stock-based compensation expense recognized in our financial statements. These assumptions include:

- *Fair Value of Common Stock*—See the subsection titled “—Determination of the Fair Value of Common Stock” below.
- *Expected Term*—We have opted to use the “simplified method” for estimating the expected term of options, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option, which is generally 10 years.
- *Expected Volatility*—Due to our limited operating history and a lack of company-specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The historical volatility data was computed using the daily closing prices for the selected companies’ shares during the equivalent period of the calculated expected term of the stock-based awards. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available.
- *Risk-Free Interest Rate*—The risk-free interest rates used are based on the U.S. Treasury yield in effect at the time of grant for zero-coupon U.S. treasury notes with maturities approximately equal to the expected term of the stock options.
- *Expected Dividend*—To date, we have not issued any dividends and do not expect to issue dividends over the life of the options and therefore have estimated the dividend yield to be zero.

See Note 7 to both our audited financial statements and unaudited interim condensed financial statements appearing elsewhere in this prospectus for more information concerning certain of the specific assumptions we used in applying the Black-Scholes valuation model to determine the estimated fair value of our stock options.

Stock-based compensation expense was \$39,000 for each of the period from January 4, 2018 (inception) to December 31, 2018 and the year ended December 31, 2019 and \$0 and \$1.3 million for the nine months ended September 30, 2019 and 2020, respectively. As of September 30, 2020, there was \$12.0 million of total unrecognized stock-based compensation expense related to unvested stock-based compensation awards, which is expected to be recognized over a weighted-average period of approximately 3.5 years. The intrinsic value of all outstanding options as of \_\_\_\_\_, 2020 was \$ \_\_\_\_\_, based on the assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, of which \$ \_\_\_\_\_ is related to vested options and \$ \_\_\_\_\_ is related to unvested options.

**Determination of the Fair Value of Common Stock**

As there has been no public market for our common stock to date, the estimated fair value of our common stock has been determined by our board of directors as of the date of each option grant, with input from management, considering our most recently available third-party valuation of our common stock as well as our board of directors’ assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent third-party valuation to the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants’ Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, second edition (Practice Aid). The

Practice Aid identifies various available methods for allocating enterprise value across classes and series of capital stock to determine the estimated fair value of common stock at each valuation date. In accordance with the Practice Aid, our board of directors considered the following methods:

- *Probability-Weighted Expected Return Method.* The probability-weighted expected return method (PWERM) is a scenario-based analysis that estimates the fair value of common stock based upon an analysis of future values for the business, assuming various outcomes. The common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible forecasted outcomes as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at a non-marketable indication of value for the common stock.
- *Option Pricing Method.* Under the option pricing method (OPM), shares are valued by creating a series of call options, representing the present value of the expected future returns to the stockholders, with exercise prices based on the liquidation preferences and conversion terms of each equity class. The estimated fair values of the preferred and common stock are inferred by analyzing these options.
- *Hybrid Return Method.* The Hybrid Return Method is a blended approach using aspects of both the PWERM and OPM, in which the equity value in one of the scenarios is calculated using an OPM.

Based on our early stage of development and other relevant factors, our board of directors determined that the Hybrid Return Method, reflecting a hybrid of our valuation under the OPM and a liquidation/partial recovery scenario, was the most appropriate method for allocating our enterprise value to determine the estimated fair value of our common stock for valuations through May 2020. For our valuation as of July 20, 2020, our board of directors determined that OPM was the most appropriate method for allocating our enterprise value to determine the estimated fair value of our common stock. For our valuation as of September 4, 2020, our board of directors determined that PWERM was the most appropriate method of allocating our enterprise value to determine the estimated fair value of our common stock. In determining the estimated fair value of our common stock, our board of directors also considered the fact that our stockholders could not freely trade our common stock in the public markets. Accordingly, we applied discounts to reflect the lack of marketability of our common stock based on the weighted-average expected time to liquidity.

In addition to considering the third-party valuations of our common stock, our board of directors 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 our convertible preferred stock to outside investors in arms-length transactions, and the superior rights, preferences and privileges of the preferred stock relative to our common stock at the time of each grant;
- the progress of our research and development programs, including their stage of development, and our business strategy;
- external market and other conditions affecting the biotechnology industry, and trends within the biotechnology 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;
- the likelihood of achieving a liquidity event for our securityholders, such as an initial public offering or a sale of our company, taking into consideration prevailing market conditions;
- the hiring of key personnel and the experience of management; and
- the analysis of initial public offerings and the market performance of peer companies in the biopharmaceutical industry, as well as completed mergers and acquisitions of peer companies.

The assumptions underlying these valuations represent our board's and management's best estimates, which involve inherent uncertainties and the application of significant judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation expense could be materially different.

Following the closing of this offering, the fair value of our common stock will be determined based on the closing price of our common stock as reported on the date of grant on the primary exchange on which our common stock is traded.

### **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 financial statements appearing elsewhere in this prospectus.

### **Quantitative and Qualitative Disclosures About Market Risks**

#### ***Interest Rate Risk***

As of December 31, 2019 and September 30, 2020, our cash equivalents consisted of interest-bearing money market accounts. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term maturities of our investments, a hypothetical 100 basis point increase or decrease in interest rates during any of the periods presented would not have had a material impact on our financial results.

As of December 31, 2019 and September 30, 2020, we had no debt outstanding and are therefore not exposed to interest rate risk with respect to debt.

#### ***Effects of Inflation***

Inflation generally affects us by increasing our cost of labor and research and development contracts. We do not believe that inflation has had a material effect on our financial results during the periods presented.

#### ***Foreign Currency Risk***

Our expenses are generally denominated in U.S. dollars. However, we have entered into a limited number of contracts with vendors for research and development services that are denominated in foreign currencies, including the Canadian dollar. We are subject to foreign currency transaction gains or losses on our contracts denominated in foreign currencies. To date, foreign currency transaction gains and losses have not been material to our financial statements, and we have not had a formal hedging program with respect to foreign currency. A hypothetical 10% increase or decrease in exchange rates during any of the periods presented would not have had a material impact on our financial results.

### **Emerging Growth Company and Smaller Reporting Company Status**

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended (JOBS Act). We will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have more than \$1.07 billion in annual revenue; (ii) the date we qualify as a "large accelerated filer," with at least \$700 million of equity securities held by non-affiliates; (iii) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period; and (iv) the last day of the fiscal year ending after the fifth anniversary of our initial public offering. As a result of this status, we have taken advantage of reduced reporting requirements in this prospectus and may elect to take advantage of other reduced reporting requirements in our future filings with the SEC. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies. We have elected to use the extended transition period to enable us to comply with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date on which we (i) are no longer an emerging growth company and (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We are also a “smaller reporting company” meaning that the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than \$700 million and our annual revenue was less than \$100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after this offering if either (i) the market value of our stock held by non-affiliates is less than \$250 million or (ii) our annual revenue was less than \$100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than \$700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation and other matters.

## Overview

We are a biopharmaceutical company focused on the discovery and development of small molecule kinase inhibitors for difficult-to-treat, genomically defined cancers. Our mission is to expand the reach of targeted therapeutics by developing products for underserved populations. We utilize our deep expertise in structure-based drug discovery, translational research and patient-driven precision medicine, which we collectively refer to as our Kinnate Discovery Engine, to develop our targeted therapies. We focus our discovery and development efforts on three patient populations: (1) those with cancers that harbor known oncogenic drivers (gene mutations that cause cancers) with no currently available targeted therapies, (2) those with genomically well-characterized tumors that have intrinsic resistance to currently available treatments (non-responders), and (3) those whose tumors have acquired resistance over the course of therapy to currently available treatments. We believe our unique approach may enable us to develop drugs with an increased probability of clinical success while reducing the cost and risk of drug development. Our most advanced product candidate is KIN002787, which is a Rapidly Accelerated Fibrosarcoma (RAF) inhibitor we are developing for the treatment of patients with lung cancer, melanoma and other solid tumors. Unlike currently available treatments that target only Class I B-Rapidly Accelerated Fibrosarcoma (BRAF) kinase mutations, we have designed KIN002787 to target Class II and Class III BRAF mutations, where it would be a first-line targeted therapy, in addition to covering Class I BRAF mutations. We anticipate filing an Investigational New Drug application (IND) for our RAF candidate with the U.S. Food and Drug Administration (FDA) in the first half of 2021. Additionally, in our KIN003 program we are evaluating Fibroblast Growth Factor Receptors (FGFR) inhibitor candidates for the treatment of patients with intrahepatic cholangiocarcinoma (ICC), a cancer of the bile ducts in the liver, and urothelial carcinoma (UC), a cancer of the bladder lining. Our FGFR candidates are designed to address clinically observed genomic alterations in FGFR2 and FGFR3 that drive resistance to current therapies. We anticipate filing an IND for one of our FGFR candidates with the FDA in the first half of 2022. Our RAF and FGFR candidates have demonstrated proof of concept in preclinical models and, subject to our planned IND submissions taking effect, we anticipate initiating a Phase 1 clinical trial for KIN002787 in 2021 and an additional Phase 1 clinical trial for our KIN003 program in the first half of 2022.

In our *in vitro* and *in vivo* preclinical studies evaluating our RAF product candidate, KIN002787, we observed kinase inhibition selectivity and a reduction in the size of tumors from KIN002787 treated models of human cancer. In internal *in vitro* and *in vivo* head-to-head comparisons, we have seen improved kinase inhibition selectivity and pharmaceutical properties compared to a number of currently approved and in-development drugs. Importantly, KIN002787 demonstrated inhibition of RAF dimer signaling while minimizing mitogen-activated protein kinase (MAPK) pathway rebound, potentially resulting in a broad therapeutic index. We anticipate filing an IND for KIN002787 with the FDA in the first half of 2021 and, subject to such submission taking effect, initiating a Phase 1 clinical trial in 2021. We are designing our first in human (FIH) clinical trial primarily to assess the safety and tolerability of KIN002787 in patients with advanced or metastatic solid tumors driven by specific classes of BRAF mutations, which are known oncogenic drivers, while also characterizing pharmacological and anti-cancer properties of KIN002787.

We are evaluating our FGFR inhibitor candidates for the treatment of patients with ICC and UC. In preclinical studies, we have observed inhibitory activity across a broad range of clinically-relevant genomic alterations in FGFR2 and FGFR3 that drive resistance to current therapies. Because our preclinical studies demonstrated our candidates' ability to cover the initial alterations and preemptively address these resistance mutations, we believe we may be able to meaningfully increase the duration of response (DoR) for certain patients by addressing these alterations. We plan to develop our candidates initially for patients whose tumors have acquired resistance to therapies targeting FGFR2 or FGFR3 alterations, which limits the durability of response. As with other precision oncology approaches, addressing resistance mutations may also ultimately enable us to develop a first-line therapy. In this program, we plan to adopt many of the same principles as our RAF program but will primarily focus on cancers that are driven by alterations in FGFR2 and FGFR3. We plan to nominate a lead product candidate in our KIN003 program in 2021, file an IND with the FDA in the first half of 2022 and, subject to such submission taking effect, initiate a Phase 1 clinical trial in the first half of 2022.

Through the broad applicability of our Kinnate Discovery Engine, we are also advancing a number of other small molecule research programs, including a Cyclin-Dependent Kinase 12 (CDK12) inhibitor in our KIN004 program. CDK12 is an essential regulator of DNA damage response (DDR) genes for which no targeted therapies are currently approved or, to our knowledge, in clinical development. We expect to develop a CDK12 inhibitor candidate to target the treatment of ovarian carcinoma (OC), triple-negative breast cancer (TNBC) and metastatic castration-resistant prostate cancer (mCRPC). CDK12 and our other small molecule research programs are aimed at addressing cancer cases not covered by existing targeted therapies.

Precision medicine is predicated on the relationship between genomic alterations, protein dysfunctions and diseases, and aims to specifically and potentially drug genomically validated target proteins (i.e., genomic variants potentially implicated in the biology of disease) while minimizing side effects. As genomic profiling of cancer patients becomes more commonplace, it is becoming increasingly clear that cancers developing in various sites throughout the body may share the same type of genomic alterations. As such, tumors may be identified and treated according to their distinctive genomic alterations, rather than focusing on simply the tissue of origin. Both research and clinical data suggest that some tumors, while having multiple identifiable genomic alterations, are primarily dependent on an aberrantly activated kinase for their proliferation and survival. Kinases, which are cellular enzymes that regulate the biological activity of proteins through a ubiquitous process known as phosphorylation, play a central role in the formation and metastatic spread of many cancers and therefore are the focus of our drug development efforts.

Kinase inhibition is a proven approach to fighting cancer, and for nearly two decades, has addressed an increasing number of oncology indications. Kinases are enzymes that regulate the biological activity of proteins. Mutated kinases can result in deregulated activity that results in cancerous cell proliferation. Currently approved drugs that inhibit the activity of mutated oncogenic kinases (kinase inhibitors) have demonstrated significant clinical benefit to hundreds of thousands of cancer patients globally. The worldwide sales of small molecule kinase inhibitors in oncology were reported to be \$23 billion in 2019 and are estimated to grow to more than \$50 billion in 2024. However, because of the limitations of currently approved drugs, it is estimated that only 10% of all patients with advanced or metastatic cancer today are eligible for these treatments. This low penetration of targeted therapies demonstrates a substantial unmet patient need and market opportunity.

In the current RAF inhibitor landscape, no targeted therapies have been approved for Class II or Class III BRAF mutation-driven cancers. In the current FGFR inhibitor landscape, approved and clinical-phase FGFR inhibitors provide benefit, but the DoR of such inhibitors is limited due to acquired mutational resistance. Taken together, this represents a substantial opportunity for developing novel and potentially transformative drugs for underserved patient populations with difficult-to-treat, genomically defined cancers.

We believe our expertise and the foundational principles driving our Kinnate Discovery Engine offer an opportunity to identify and develop precision medicine solutions for populations that are currently underserved. Our Kinnate Discovery Engine encompasses:

- **Structure-based drug discovery.** Through our integrated biology and chemistry approach led by experts in small molecule kinase inhibitors, we identify compounds with a high probability of success in inhibiting selective kinase targets.
- **Translational research.** We employ a biomarker-driven approach to predict and increase the likelihood of therapeutic response to our product candidates in patients.
- **Patient-driven precision medicine.** Capitalizing on next-generation sequencing (NGS) technologies and guidance from leaders at experienced precision medicine cancer centers, we define emerging patient populations for our product candidates.

Leveraging our Kinnate Discovery Engine, to date we have generated more than 3,300 new chemical entities (NCEs), conducted more than 4,000 Drug Metabolism and Pharmacokinetics (DMPK) studies, developed more than 170 unique *in vitro* assays and completed more than 80 *in vivo* pharmacology studies, while profiling 30 compounds for kinome selectivity. We have nominated KIN002787 as the lead candidate in our RAF program and plan to nominate a candidate in our FGFR program in 2021. We plan to file an IND for



KIN002787 in the first half of 2021 and, subject to such submission taking effect, initiate a Phase 1 clinical trial in 2021. We also anticipate filing an IND for KIN003 in the first half of 2022 and, subject to such submission taking effect, initiating a Phase 1 clinical trial in the first half of 2022.




This productivity is a result of the accomplished team we have assembled. Our team has extensive experience in the discovery, development and commercialization of novel therapeutics, including small molecule kinase inhibitors. Our team includes one of the inventors of Inlyta (axitinib), Lorbrena (lorlatinib) and Xalkori (crizotinib), the research co-lead for LXH254 and the translational co-lead for PLX8394. Our team members have also been involved with the development of Mektovi (binimetinib), Cabometyx (cabozantinib), Tabrecta (capmatinib), Zykadia (ceritinib), Braftovi (encorafenib), Rozlytrek (entrectinib) and EGF816. Nima Farzan, our Chief Executive Officer, has 20 years of experience leading biopharmaceutical companies from preclinical to commercial stage, and was the CEO of PaxVax, Inc. where he led the sale of the company to Emergent BioSolutions Inc. Eric Murphy, Ph.D., our Chief Scientific Officer and co-founder, has 20 years of experience in small molecule oncology research across academia, contract research organizations (CROs), and biotech and large pharmaceutical companies, and was the Global Head of Oncology R&D Strategy and External Innovations at Crown Bioscience Inc. Richard Williams, MBBS, Ph.D., our Chief Medical Officer, has more than 10 years of global clinical strategy and drug development experience in the biopharmaceutical industry and was most recently Chief Medical Officer and Global Head of Oncology Programs at WuXi NextCODE Genomics USA, Inc. (now known as Genuity Science, Inc.). Mark Meltz, our Chief Operating Officer and General Counsel, has 20 years of experience leading corporate legal teams and was Senior Vice President and General Counsel at Audentes Therapeutics, Inc., where he helped lead the company's sale to Astellas Pharma Inc.

We are also supported by a distinguished group of scientific advisors and investors. Our scientific advisors include researchers who publish widely-cited research on topics relevant to the study and treatment of cancer, lead clinical units at experienced precision medicine cancer centers in the United States and are actively involved in our drug development process and programs. Our current investors include Foresite Capital, OrbiMed, RA Capital Management, Nextech Invest, Vida Ventures, Viking Global Investors, Venrock Healthcare Capital Partners, Fidelity Management & Research Company, LLC, Boxer Capital of Tavistock Group, Janus Henderson Investors, Surveyor Capital (a Citadel company) and Logos Capital.

## **Our Programs**

We are currently focused on the development of small molecule kinase inhibitors for difficult-to-treat, genomically defined cancers. By leveraging our deep expertise in structure-based drug discovery, translational research and patient-driven precision medicine, which we collectively refer to as our Kinnate Discovery Engine, we aim to bring new treatment options to three patient populations: (1) those with cancers that harbor known oncogenic drivers with no currently available targeted therapies, (2) those with genomically well-characterized tumors that have intrinsic resistance to currently available treatments (non-responders), and (3) those whose tumors have acquired resistance over the course of therapy to currently available treatments.

Our lead programs include candidates in preclinical development for cancers that are driven by specific oncogenic alterations in either the BRAF kinase gene, or in the FGFR2 and FGFR3 kinase genes. We are also advancing a number of other small molecule research programs, including a CDK12 inhibitor in lead optimization and several other undisclosed targets with compounds at the lead identification stage.

Target, Program	Discovery	Lead Optimization	IND-Enabling	Phase 1	Phase 2	Phase 3	Next Anticipated Milestones
RAF KIN002787							IND H1 2021 Initiate Phase 1 in 2021
FGFR2/3 KIN003							IND H1 2022 Initiate Phase 1 in H1 2022
CDK12 KIN004							

### RAF Program: KIN002787

In our most advanced program, we are developing KIN002787, a small molecule kinase inhibitor targeting specific classes of BRAF kinase mutations (Class II and Class III BRAF mutations) that characterize subsets of lung cancer, melanoma and other solid tumors. No targeted therapies have currently been approved for Class II or Class III BRAF mutation-driven cancers, unlike the Class I BRAF mutations where three BRAF-targeted kinase inhibitor drugs have been approved by the FDA. Patients with cancers driven by Class II or Class III BRAF mutations have not responded to existing targeted therapies and have few treatment options currently available to them. Initially, we plan to develop KIN002787 for the treatment of patients with non-small cell lung cancer (NSCLC) and melanoma subpopulations with Class II or Class III BRAF mutations that include specific BRAF point mutations (other than BRAF <sup>V600E</sup>), BRAF insertions/deletions (indels) and BRAF gene fusion events. We believe KIN002787 may provide substantial clinical benefit to these cancer patients who are inadequately served by current therapies.

In our *in vitro* and *in vivo* preclinical studies evaluating KIN002787, we observed kinase inhibition selectivity and a reduction in the size of tumors from drug treated models of human cancer. In internal *in vitro* and *in vivo* head-to-head comparisons, we have seen improved kinase inhibition selectivity and pharmaceutical properties compared to a number of currently approved and in-development drugs. Importantly, KIN002787 demonstrated inhibition of RAF dimer signaling while minimizing MAPK pathway rebound, potentially resulting in a broad therapeutic index. We anticipate filing an IND for KIN002787 with the FDA in the first half of 2021 and, subject to such submission taking effect, initiating a Phase 1 clinical trial in 2021. We are designing our FIH clinical trial primarily to assess safety and tolerability of KIN002787 in patients with advanced or metastatic solid tumors driven by specific classes of BRAF mutations, while also characterizing pharmacological and anti-cancer properties of KIN002787.

### FGFR Program: KIN003

We are developing small-molecule kinase inhibitors that target cancer-associated alterations in FGFR2 and FGFR3 genes, which (together with BRAF mutations) are among the most commonly identified oncogenic drivers detected in solid tumor cancers. Our KIN003 program aims to address the initial alteration and clinically-observed and predicted mutations in FGFR2 fusion gene-positive ICC and FGFR3-altered UC that drive resistance to current FGFR2- and FGFR3-targeted therapies. We believe this will translate to deeper, more sustained and more clinically impactful cancer responses than those observed with either of the two currently FDA-approved FGFR inhibitors, or other targeted drugs that, to our knowledge, are currently in development.

We are evaluating our FGFR inhibitor candidates for the treatment of patients with ICC and UC. In preclinical studies, we have observed inhibitory activity across a broad range of clinically-relevant genomic alterations in FGFR2 and FGFR3 that drive resistance to current therapies. Because our preclinical studies demonstrated our candidates' ability to cover the initial alterations and preemptively address these resistance mutations, we believe we may be able to meaningfully increase the DoR for certain patients by addressing these alterations. We plan to develop our candidates initially for patients whose tumors have acquired resistance to therapies targeting FGFR2 or FGFR3 alterations, which limits the durability of response. As with other precision oncology approaches, addressing resistance mutations

may also ultimately enable us to develop a first-line therapy. In this program, we plan to adopt many of the same principles as our RAF program but to primarily focus on cancers that are driven by alterations in FGFR2 and FGFR3. We plan to nominate a lead product candidate in our KIN003 program in 2021, file an IND with the FDA in the first half of 2022 and, subject to such submission taking effect, initiate a Phase 1 clinical trial in the first half of 2022.

#### **CDK12 Inhibitor Program (KIN004) and Other Research programs**

Through the broad applicability of our Kinnate Discovery Engine, we are also advancing a number of other small molecule research programs, including a CDK12 inhibitor in our KIN004 program. CDK12 is an essential regulator of DDR genes for which no targeted therapies are currently approved or, to our knowledge, in clinical development. We expect to develop a CDK12 inhibitor candidate to target the treatment of OC, mCRPC and TNBC. CDK12 and our other small molecule research programs are aimed at addressing cancer cases not covered by existing targeted therapies.

#### **Our Strategy**

Our mission is to expand the reach of targeted therapeutics by developing products for underserved populations. The key elements of our strategy are to:

- ***Rapidly advance the development of our lead targeted therapy RAF and FGFR candidates.*** Our lead product candidates are designed to address clinically validated cancer targets in patient populations with limited treatment options. Our candidates are designed to address either Class II and Class III BRAF mutations or FGFR2 and FGFR3 genomic alterations. We believe that these small molecule candidates offer the potential for substantial clinical benefit when administered as monotherapy. Additionally, because of their enhanced pharmacological properties, we believe there may be future opportunities for combination therapy development. We anticipate filing an IND for KIN002787 with the FDA in the first half of 2021 and, subject to such submission taking effect, initiating a Phase 1 clinical trial in 2021. We plan to nominate a lead product candidate in our KIN003 program in 2021, file an IND with the FDA in the first half of 2022 and, subject to such submission taking effect, initiate a Phase 1 clinical trial in the first half of 2022.

If we are successful in achieving clinically meaningful anti-cancer activity in specific solid tumor types, we expect to engage with regulatory authorities to discuss whether we may qualify for any of the FDA's existing expedited regulatory approval pathways. Ultimately, the procedures and length of time that will be required to satisfy the FDA's review and approval are outside of our control.
- ***Develop a pipeline of product candidates focused on overcoming the limitations of current targeted oncology therapeutics.*** Currently, it is estimated that only 10% of all patients with advanced or metastatic cancer today are eligible for commercially available small molecule kinase inhibitors. Additionally, up to half of these patients may not respond to these treatments and up to half of those who do initially respond may develop resistance. Ultimately, it is estimated that only 2% to 3% of patients with advanced or metastatic cancer will have durable responses to currently available targeted therapeutics. We are therefore focused on developing drugs that can:
  - *Target known oncogenic drivers* (e.g., Class II or Class III BRAF mutations) in selected cancer types that are not currently addressed by approved therapies. Our BRAF-targeting small molecule kinase inhibitors exemplify this strategy. The successful development and FDA approval of three BRAF-targeted kinase inhibitor drugs for use in Class I BRAF mutations establishes BRAF as a validated cancer drug target.
  - *Overcome acquired resistance mutations* to existing targeted therapies, potentially improving the durability of response. For example, in our FGFR program we seek to develop targeted therapies that cover initial genomic alterations and preemptively address acquired resistance mutations that arise with current targeted therapies.

- *Treat non-responders* to currently approved therapies where advancements in next generation sequencing have identified, and will continue to reveal, genomic drivers of intrinsic resistance. We expect to develop our CDK12 inhibitor and future programs that will target mechanisms of intrinsic resistance.
- ***Increase our probability of clinical success by prioritizing known oncogenic drivers for development and incorporating biomarkers into preclinical and clinical development.*** Typically, drug development carries high attrition rates from the preclinical stage through FDA approval, with some studies showing that only approximately 10% of the candidates entering Phase 1 trials are ultimately approved. We aim to improve the probability of clinical success through several approaches:
  - *Targeting known oncogenic drivers.* We attempt to select targets for drug development that behave as oncogenic drivers, which increases the likelihood of seeing objective measures of tumor responses early in clinical development. If we are successful in inhibiting these targets with our product candidates, we may increase the likelihood of achieving tumor responses. This approach has been successful for kinase inhibitors designed to treat patients with oncogenic alterations in lung cancer, melanoma, leukemia and other types of cancer.
  - *Developing small molecule kinase inhibitors.* Small molecule kinase inhibitors are a proven modality that has demonstrated success in the past with multiple currently approved drugs across many solid tumor and hematologic malignancy indications. By testing our molecules against *in vitro* and *in vivo* models utilized by prior approved drugs, we believe we can efficiently benchmark and optimize our compounds.
  - *Incorporating biomarkers into our preclinical and clinical development.* By evaluating a wide range of biomarkers in our preclinical studies and our human clinical trials, we can more rapidly determine patient populations that may or may not respond to our candidates. Continuing to use biomarkers in clinical trials allows us to potentially select defined patient populations that may demonstrate a stronger benefit and thereby ultimately increase our probability of success.

While we are aiming to improve our probability of clinical success by utilizing these strategies, any drug development program carries potential safety liabilities and uncertainty and there is no guarantee that any of our candidates will obtain regulatory approval.

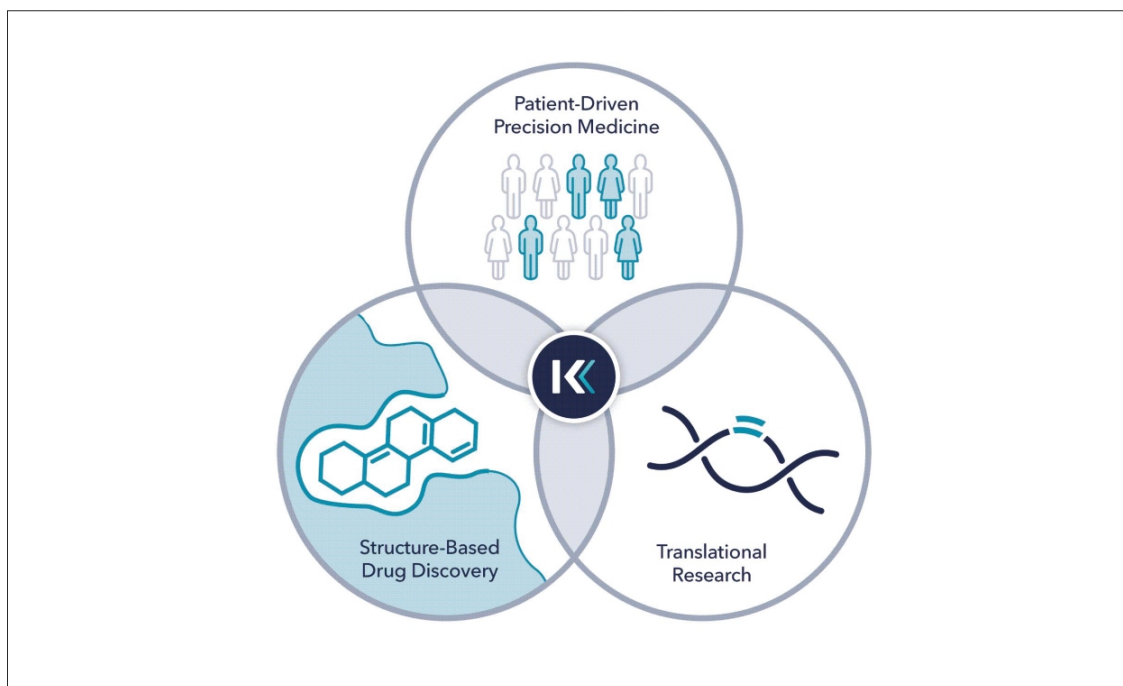
- ***Leverage our existing relationships, collaborations and experience to efficiently develop and expand our product portfolio.*** Our team has extensive experience in identifying, discovering, developing and commercializing innovative cancer therapeutics. We are combining this broad oncology expertise with a network of collaborators to further develop our existing pipeline as well as to identify new research and development opportunities. We have established deep collaborations with leaders, with whom we have advisory agreements, at experienced precision medicine cancer centers and research institutions, including Massachusetts General Hospital Cancer Center, with whom we have a sponsored research agreement, Memorial Sloan Kettering Cancer Center and Moores Cancer Center at UCSD. These collaborations allow us to explore the mechanistic understanding of the biology of our targets and sensitivity and resistance to our molecules. We have also leveraged our relationships to build a network of global external partners to advance our pipeline. For example, we have service agreements with academic and industrial partners who contribute highly enabling technologies and services that include: (1) over 60 medicinal chemists at leading CROs, (2) bioinformatics support for our translational research efforts, (3) crystallography and biophysical assay platforms to enable structure-based drug discovery, (4) biochemical and cell-based assays to guide lead generation and optimization, and (5) patient-derived organoid and xenograft models to translate our findings to the clinical setting. We utilize these collaborations and partnerships in many aspects of preclinical development for our pipeline of candidates and anticipate further utilizing them in our clinical development efforts. Additionally, these collaborations and partnerships may allow us to accelerate identification of new opportunities, including new patient populations we may target to understand emerging mechanisms of resistance.

- **Maximize the clinical impact and value of our portfolio.** We retain full global development and commercialization rights to our pipeline of candidates. We intend to build an integrated biopharmaceutical company that will manage all aspects of product development and commercialization globally. We may seek to develop rational combination therapy strategies among products within our own portfolio, while also maximizing portfolio value through selective co-development and/or commercialization collaborations.

### Our Kinnate Discovery Engine

The key elements of our strategy come together to form our Kinnate Discovery Engine, which seeks to leverage our team's significant industry expertise to drive towards accelerated clinical development, regulatory review, and ultimately, potential new drug approval. We are led by a management team of precision oncology experts with decades of collective experience in the discovery, development and commercialization of novel therapeutics who have held leadership positions at four of the top global oncology companies: Amgen Inc., AstraZeneca plc, Novartis AG, and Pfizer Inc. This expertise extends to our established collaborations with leaders at experienced precision medicine cancer centers and research institutions.

### The Kinnate Discovery Engine



We believe our expertise and the foundational principles driving our highly productive Kinnate Discovery Engine offer an opportunity to identify and develop precision oncology solutions for populations that are currently underserved. Our Kinnate Discovery Engine encompasses:

- **Structure-based drug discovery.** Through our integrated biology and chemistry approach led by experts in small molecule kinase inhibitors, we identify compounds with a high probability of success in inhibiting selective kinase targets.
- **Translational research.** We employ a biomarker-driven approach to predict and increase the likelihood of therapeutic response to our product candidates in patients.

- **Patient-driven precision medicine.** Capitalizing on NGS technologies and guidance from leaders at experienced precision medicine cancer centers, we define emerging patient populations for our product candidates.

### **Structure-based Drug Discovery**

Through our integrated biology and chemistry approach led by experts in small molecule kinase inhibitors, we leverage structure-based drug discovery to identify compounds with a high probability of success in inhibiting selective kinase targets. Our team, which includes over 60 contract-based medicinal chemists, utilizes molecular design to overcome clinically relevant resistance mutations, while maintaining improved pharmaceutical properties. For example, the proprietary co-crystal structure of KIN002787 in the BRAF protein developed by our team has demonstrated what we believe is a unique and highly selective BRAF inhibitor.

### **Translational Research**

A biomarker-driven approach drives our translational research programs and supports our unique capabilities to predict and increase the potential likelihood of clinical impact. Our collaborations with leaders at experienced precision medicine cancer centers enable us to perform extensive cellular testing in Class II and Class III BRAF mutations, including BRAF fusions and indels, and in profile compounds in FGFR2 fusion-driven cancer cells that mimic secondary resistance mutations found in specific populations of patients. Together, these translational research programs have allowed us to develop a deep understanding of specific pathways and accelerate the progression of our programs into seminal cellular screening and *in vivo* efficacy studies.

### **Patient-driven Precision Medicine**

By capitalizing on NGS technologies and guidance from leaders at experienced precision medicine cancer centers, we define emerging patient populations for development programs leveraging our patient-driven approach to precision medicine. We plan to utilize available NGS technologies to detect genomic alterations within DNA and RNA from patients' tumors to enable patient enrolment in our clinical trials. In collaboration with leaders at experienced precision medicine cancer centers we are developing biomarker-based development programs that we anticipate will accelerate patient enrollment for our candidates that may reach clinical trials.

Leveraging our Kinnate Discovery Engine, to date we have generated more than 3,300 NCE's, conducted more than 4,000 DMPK studies, developed more than 170 unique *in vitro* assays and completed more than 80 *in vivo* pharmacology studies, while profiling 30 compounds for kinase selectivity.

### **Our History, Team and Investors**

We were founded in 2018 by Steve Kaldor, Ph.D., and Eric Murphy, Ph.D. Dr. Kaldor has a successful track record as a drug inventor and founder of life science companies, including Quantice Pharmaceuticals, Inc., which was sold to Celgene Corporation in 2015. Throughout his career, Dr. Murphy has focused on kinase biology and drug discovery research with a particular emphasis on oncogenic receptor tyrosine kinase and complex MAPK pathway signaling in both academic and industry research organizations, including The Scripps Research Institute, Moores Cancer Center at UCSD, and Novartis AG.

Our management team includes:

- **Precision oncology and kinase inhibitor experts** who have held leadership positions at four of the top global oncology companies: Amgen Inc., AstraZeneca plc, Novartis AG, and Pfizer Inc. Our team includes one of the inventors of Inlyta (axitinib), Lorbrena (lorlatinib) and Xalkori (crizotinib), the research co-lead for LXH254 and the translational co-lead for PLX8394. Our team members have also been involved with the development of Mektovi (binimetinib), Cabometyx (cabozantinib), Taltrex (capmatinib), Zykadia (ceritinib), Braftovi (encorafenib), Rozlytrek (entrectinib) and EGF816.



- **Functional experts across domains such as biomarkers and toxicology** who have developed their expertise at companies including AstraZeneca plc, Exelixis, Inc., GRAIL, Inc., Puma Biotechnology, Inc. and WuXi NextCODE Genomics USA, Inc. (now known as Genuity Science, Inc.).
- **Senior leaders with a track record of success** who have built and operated drug development businesses from research and development to commercial-stage operations at companies including Audentes Therapeutics, Inc., Biogen Inc., Novartis AG, PaxVax, Inc. (now part of Emergent BioSolutions Inc.), and Quantice Pharmaceuticals, Inc.

We intend to leverage the experience of our leadership team to efficiently advance our pipeline. In addition to our strong leadership team, our scientific advisors include researchers who publish widely-cited research on topics relevant to the study and treatment of cancer, lead clinical units at experienced precision medicine cancer centers in the United States and are actively involved in our drug development process and programs. Our scientific advisory board includes:

- **Keith Flaherty, M.D.**, Director of Clinical Research at the Massachusetts General Hospital Cancer Center, and Professor of Medicine at Harvard Medical School. Dr. Flaherty was a co-founder of Loxo Oncology, Inc. and is on our board of directors.
- **Ryan Corcoran, M.D., Ph.D.**, Director of the Gastrointestinal Cancer Center Program, Scientific Director of the Termeer Center for Targeted Therapy at the Massachusetts General Hospital Cancer Center and Associate Professor of Medicine at Harvard Medical School.
- **Ezra Cohen, M.D.**, Co-Director of the San Diego Center for Precision Immunotherapy, Assistant Director for Translational Science, and head of the Solid Tumor Therapeutics research program at Moores Cancer Center at UCSD.
- **Luis Alberto Diaz, Jr., M.D.**, Head of the Division of Solid Tumor Oncology, Grayer Family Chair, at Memorial Sloan Kettering Cancer Center.
- **Andrew Lowy, M.D.**, Professor of Surgery, Chief of the Division of Surgical Oncology and Clinical Director for Cancer Surgery at Moores Cancer Center at UCSD.
- **John Iafrate, M.D.**, Professor of Pathology at Harvard Medical School and Director of the Center for Integrated Diagnostics at the Massachusetts General Hospital Cancer Center.

Since our inception, we have raised over \$190 million from a syndicate of leading life sciences investors that includes Foresite Capital, OrbiMed, RA Capital Management, Nextech Invest, Vida Ventures, Viking Global Investors, Venrock Healthcare Capital Partners, Fidelity Management & Research Company, LLC, Boxer Capital of Tavistock Group, Janus Henderson Investors, Surveyor Capital (a Citadel company) and Logos Capital.

## **Background and Limitation of Current Targeted Therapies**

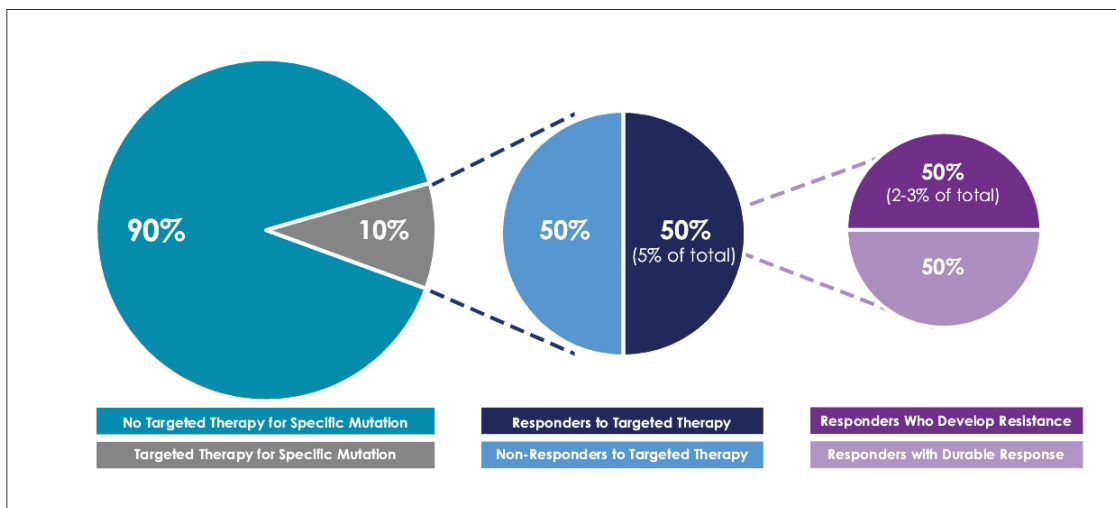
### **Background**

Cancer is a heterogeneous group of diseases that share the commonality of abnormal cell growth and proliferation and enhanced cellular survival. This unregulated cell replication is driven by the progressive accumulation of mutations in, and dysregulated gene expression of, critical genes that ordinarily tightly regulate processes of cellular growth and metabolism, survival, proliferation and cellular lifespan.

Over the last several years, as genomic profiling of cancer patients has become more commonplace and genomic sequencing technology has undergone key advancements, it has become increasingly clear that cancers developing in various sites throughout the body may share the same genomic alterations. Further, when evaluated in controlled experimental systems, these cancer-associated genomic alterations (oncogenes) represent critical genomic drivers for which these cancers are dependent for their growth and survival, a concept referred to as oncogene addiction. The ultimate validation of an oncogene as a true driver gene to which the cancer is addicted is achieved when selected cancer patients whose tumors carry the mutated oncogene gain substantial clinical benefit from treatment with specific and potent drugs that target the oncogene in question.

Both research and clinical data suggest that some tumors, while having multiple identifiable genomic alterations, are primarily dependent on an aberrantly activated kinase for their proliferation and survival. Kinases, which are cellular enzymes that regulate the biological activity of proteins through a ubiquitous process known as phosphorylation, represent one of the largest classes of oncogenic drivers when aberrantly mutated or expressed in the cell. Kinase inhibition is a proven approach to fighting cancer and for nearly two decades has addressed an increasing number of oncology indications. Kinases represent the largest class of oncogenic drivers for which many targeted therapy cancer drugs have been successfully developed. Currently approved kinase inhibitors have demonstrated significant clinical benefit to hundreds of thousands of cancer patients globally. It has been shown that patients with tumors driven by oncogenic kinases can demonstrate rapid and measurable tumor shrinkage when treated with the corresponding kinase inhibitor. Furthermore, while therapeutic benefit can often be significant and durable, tolerability is also frequently improved compared to conventional cancer treatments like chemotherapies. An example of this benefit has been seen when an epidermal growth factor receptor (EGFR) kinase inhibitor is administered to a lung cancer patient with a tumor-bearing activating EGFR kinase mutation EGFR. In many cases, such clinical responses and increases in patient tolerability can be dramatic enough to support expedited regulatory approval and commercialization of these targeted therapies. The worldwide sales of small molecule kinase inhibitors in oncology were reported to be \$23 billion in 2019 and are estimated to grow to more than \$50 billion in 2024.

However, despite the advancement of precision medicine in oncology, a significant unmet need remains for the majority of cancer patients for whom no genomically targeted therapies exist or for which a resistance to targeted treatments has evolved. As depicted in the figure below, we estimate that currently only 10% of all patients with advanced or metastatic cancer are eligible for targeted therapeutics, where a defined genomic driver is matched with a currently approved targeted therapy. Of those patients, up to 50% (5% of all patients) will respond to the therapy (the responders), while the remainder gain no clinical benefit due to intrinsic resistance (the non-responders). Furthermore, among the responders, the majority (conservatively estimated at 50% to 80%) will eventually develop acquired resistance, lose their beneficial response to the therapy and experience disease progression despite continued treatment with the targeted therapy. Therefore, it is estimated that only 2% to 3% of current patients with advanced or metastatic cancer will have durable responses to currently available targeted therapeutics.



### Limitations of Current Targeted Therapies

#### RAF Inhibitors

RAF kinases are a family of proteins that are involved in growth signaling, and include ARAF, BRAF and CRAF. BRAF mutations, which increase signaling, are divided into three classes: mutations where BRAF signals as a monomer (Class I), as a dimer of BRAF molecules (Class II) and as a dimer of BRAF and CRAF molecules (Class III). BRAF mutations occur in approximately 6% of all human cancers but there are only three BRAF targeted kinase inhibitor drugs currently approved by the FDA for use in Class I

BRAF mutation-driven cancers: Tafenlar (dabrafenib), Zelboraf (vemurafenib) and Braftovi (encorafenib) are used in mutated melanomas, Tafenlar (dabrafenib) is also used in mutated NSCLC and anaplastic thyroid cancer, and Braftovi (encorafenib) is also used in mutated colorectal cancer (CRC). Class I BRAF mutations activate the BRAF kinase as a monomer, an individual protein molecule, not depending on dimerization, which is the binding of two protein molecules, for increased kinase activity. These inhibitors produce objective responses in approximately 50% of melanoma patients, meaning approximately 50% of patients are non-responders. An even higher percentage of CRC, NSCLC and thyroid cancer patients are non-responders.

Class II and Class III BRAF mutations drive many cancers, but have been historically more challenging to target. For example, approximately 62% of BRAF mutations in NSCLC and approximately 21% of BRAF mutations in melanoma are identified as Class II and Class III BRAF mutations where the currently approved Class I inhibitors are not effective. Therefore, a significant unmet medical need remains to develop new drugs that can effectively treat cancers driven by Class II and Class III BRAF mutations.

#### *FGFR Inhibitors*

Genomic alterations in the FGFR gene family occur in approximately 7% of human cancers. Approximately 30% to 35% of patients with UC and ICC whose tumors are driven by FGFR-dependent driver genes will respond to the two currently approved FGFR-targeting drugs, Balversa (erdafitinib) and Pemazyre (pemigatinib). Of the responding patients, the majority only demonstrate partial responses (i.e., partial tumor shrinkage) and the median DoR is only five months for Balversa (erdafitinib) and nine months for Pemazyre (pemigatinib), presenting a substantial need to develop potent and selective next-generation FGFR-targeting agents that can drive deeper responses and longer lasting clinical benefit among responding patients.

Most recently, the emergence of mutational resistance in FGFR driver genes (at or even prior to the emergence of clinical progression or relapse in drug-treated patients) has highlighted the limitation of both currently approved FGFR-targeting drugs and other clinical stage compounds. While this acquired mutational resistance in FGFR serves to further validate FGFR driver genes as drug targets, it also highlights both the need and the opportunity to develop potent, selective and specific FGFR-targeting agents which target existing mutational resistance and prevent emergence of new resistance mutations.

### **Our Approach and Development Programs**

#### ***Our Approach***

We employ a consistent, systematic approach to identify kinases that drive difficult-to-treat, genomically defined cancers. Through this approach, we aim to develop kinase inhibitor product candidates with therapeutic windows that provide durable and meaningful clinical responses to benefit patients in three patient populations:

- those with cancers that harbor known oncogenic drivers with no currently available targeted therapies;
- those with genomically well-characterized tumors that have intrinsic resistance to currently available treatments (non-responders); and
- those whose tumors have acquired resistance over the course of therapy to currently available treatments.

By focusing on these three well-characterized patient populations, we believe that we will have a more efficient development path with potentially improved response rates in such populations. Due to advancements in genomic profiling and collaborations with leaders at experienced precision medicine cancer centers and research institutions, we have established and continue to develop a deep expertise and understanding of specific oncogenic drivers. Our collaborations allow us to:

- define emerging patient populations;

- demonstrate selective *in vitro* and *in vivo* activity and define dose-exposure pharmacodynamic (PD) relationships in clinically relevant models;
- test prioritized compounds against specific mutations and fusions;
- investigate mechanism of action—the specific biochemical interaction through which a drug substance produces its pharmacological effect—to support the refinement of strategies for patient selection and patient stratification for both monotherapy and rationale combinations; and
- develop biomarker-based development strategies that will drive patient selection in our clinical programs.

The combination of these defined patient populations, our deep understanding of oncogenic drivers and our Kinnate Discovery Engine allows us to target known kinases that have previously been difficult to inhibit selectively and also to identify, characterize and develop product candidates for novel kinase targets with clearly validated paths to early clinical signals.

Our lead preclinical programs include small molecule inhibitors targeting specific classes of BRAF kinase mutations (Class II and Class III BRAF mutations) and specific alterations of FGFR2 and FGFR3 that aim to overcome the genomic resistance commonly limiting the efficacy of existing therapies. We are also advancing a number of other small molecule research programs, including a CDK12 inhibitor.

### **Our RAF Program: KIN002787**

#### *Overview*

Our most advanced product candidate is KIN002787, which is a RAF inhibitor we are developing for the treatment of patients with lung cancer, melanoma and other solid tumors. Unlike currently available treatments that target only Class I BRAF kinase mutations, we have designed KIN002787 to target Class II and Class III BRAF mutations, where it would be a first-line targeted therapy, in addition to covering Class I BRAF mutations. In our *in vivo* and *in vitro* preclinical studies evaluating KIN002787, we observed anti-tumor activity and kinase selectivity. Importantly, KIN002787 demonstrated inhibition of RAF dimer signaling while minimizing MAPK pathway rebound, potentially resulting in a broad therapeutic index. We anticipate filing an IND for KIN002787 with the FDA in the first half of 2021 and, subject to such submission taking effect, initiating a Phase 1 clinical trial in 2021.

#### *Background*

BRAF mutations are found in multiple solid tumor cancer indications including NSCLC, melanoma, CRC, ovarian cancer and thyroid cancer. BRAF mutations drive tumor growth by activating the MAPK pathway.

BRAF mutations can be divided into three classes:

- Class I: BRAF mutations where BRAF monomers activate the MAPK signaling pathway.
- Class II: BRAF mutations that generate BRAF homodimers, where two BRAF molecules combine, which are RAS-independent and activate the MAPK pathway. These are frequently the result of point mutations, indels or gene fusions, in which the kinase domain of BRAF is aberrantly joined to a partner gene.
- Class III: BRAF mutations with minimal kinase activity that induce BRAF's dimerization to other RAF kinase family members (e.g., ARAF or CRAF), creating a RAF heterodimer with enhanced affinity to activated RAS and increased enzymatic activity and downstream signaling.

All of the currently approved RAF inhibitors and many of those in clinical development target Class I mutations. Our RAF program targets Class II and Class III BRAF mutations, which represent cancer patient populations not currently treated by existing targeted therapeutics, in addition to covering Class I BRAF mutations.

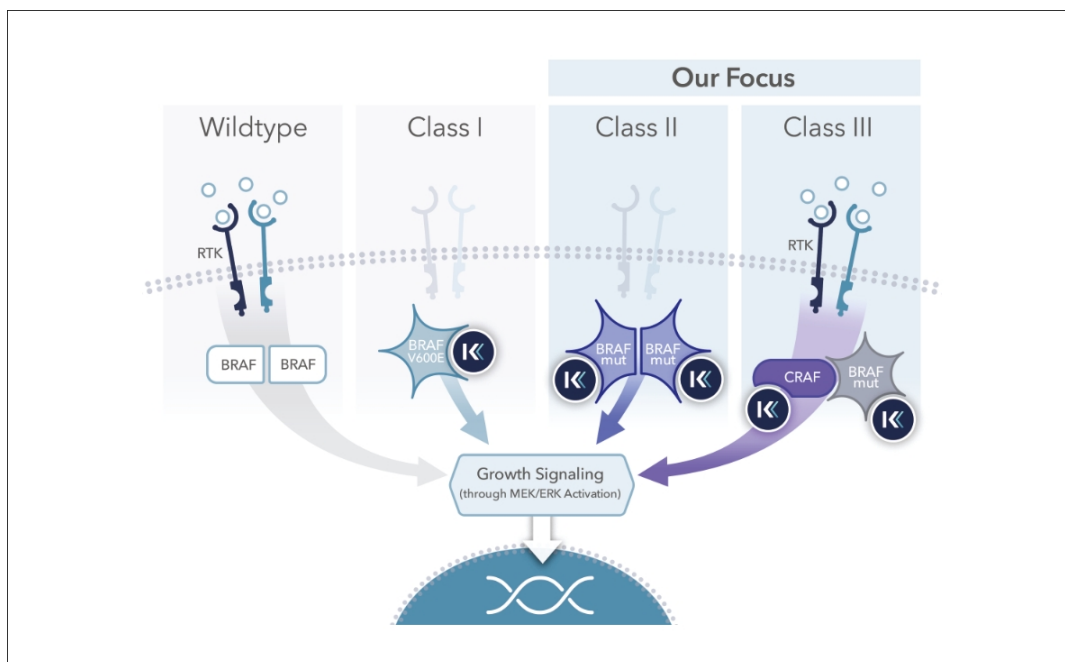
The distinguishing features of the three classes of BRAF mutations are summarized in the table below.

**Distinguishing features of BRAF Class I, Class II and Class III mutations.**

Feature	Class I	Class II	Class III
<b>Examples of BRAF Mutations</b>	V600E	BRAF indels or BRAF gene fusions	D594G
<b>Ras dependency</b>	RAS-independent	RAS-independent	RAS-dependent
<b>Monomer or Dimer function</b>	BRAF monomer	BRAF homodimers	BRAF + CRAF heterodimers
<b>Co-occurring mutations in the pathway</b>	Rare	Rare	Frequent (e.g., RAS mutations or NF1 loss)
<b>Number of currently approved drugs (cancer indications)</b>	1 (Melanoma only) 1 (Melanoma & NSCLC & thyroid cancer) 1 (Melanoma & CRC)	None	None

As shown in the figure below, the three currently approved BRAF-inhibiting drugs target Class I BRAF mutations, whereas we are focused on developing potent and selective BRAF kinase inhibitors that can address additional BRAF dimer-dependent Class II and Class III mutations.

**Cellular signaling of the three classes of BRAF mutations in human cancers.**



BRAF mutations occur in approximately 6% of all human cancers, including solid tumors and hematologic malignancies. Currently, all approved RAF inhibitors target Class I mutations. We believe that a significant opportunity remains to develop novel kinase inhibitors that address patients with Class II and Class III BRAF mutations. The BRAF market opportunity has grown due to recent advances in genomic profiling, allowing for the identification of Class II and Class III BRAF mutations that had not previously been possible. We believe there are patients with Class II and Class III BRAF mutations in a number of different cancers, including NSCLC, melanoma and CRC, as well as ovarian cancer and thyroid cancer, among other tumors. As commercially available diagnostic panels covering Class II and Class III BRAF mutations are more widely accessible and adopted, we believe the BRAF market will continue to grow.

#### *Our Opportunity and Solution*

This lack of currently available therapies for Class II and Class III BRAF kinase mutations presents a substantial need to develop potent inhibitors which can demonstrate inhibition of RAF dimer signaling while minimizing MAPK activation (pathway rebound) for patients with lung cancer, melanoma and other solid tumors that exhibit Class II and Class III BRAF kinase mutations.

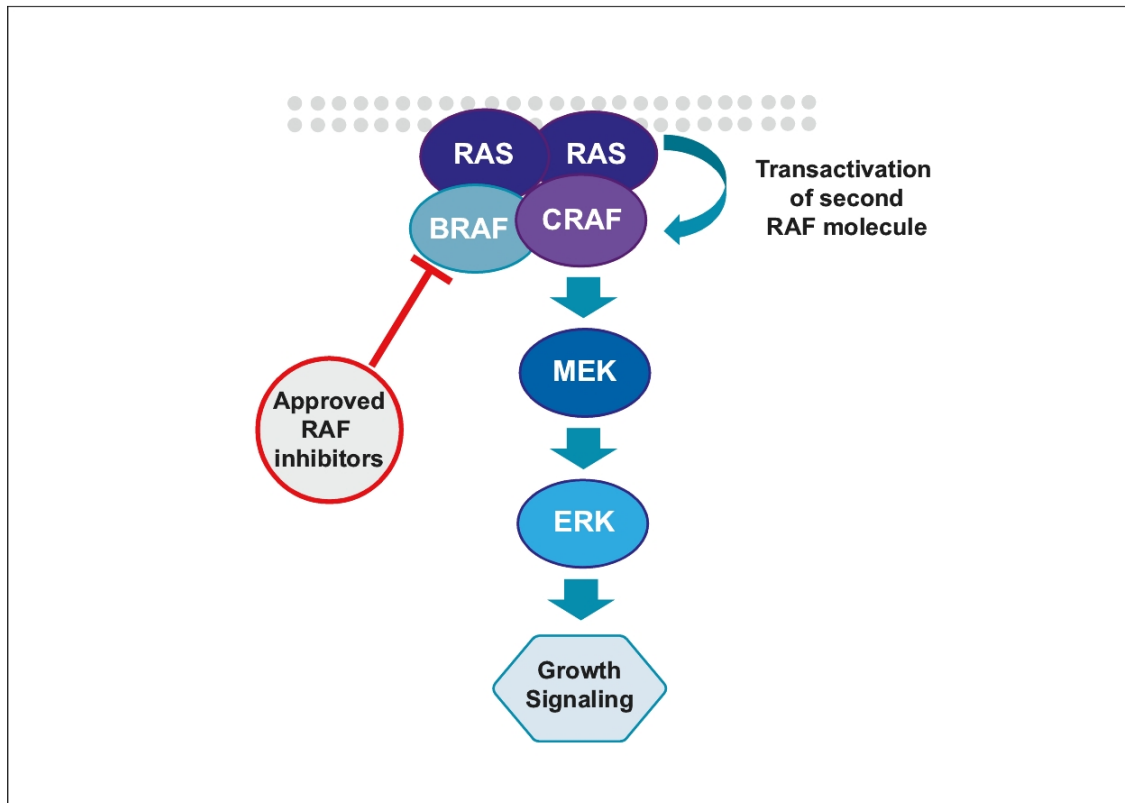
#### Pathway Rebound

##### *The pathway rebound challenge*

Currently approved RAF inhibitor therapies do not inhibit both molecules in the dimer. Consequently, the non-inhibited molecule in the dimer is activated as depicted in the figure below. Therefore, instead of inhibiting the MAPK signaling pathway, the drug activates signaling, which is referred to as paradoxical activation or pathway rebound. This pathway rebound, which sometimes reaches levels that are significantly higher than the original signal, limits the RAF inhibitor's efficacy against cancer growth and also often causes other unwanted effects such as spurring additional cancer growth in non-cancerous tissues. For example, patients with Class I mutations treated by Zelboraf (vemurafenib) have been shown to develop squamous cell carcinomas (SCCs) and skin hyperplasias (e.g., hyperkeratosis) because this pathway rebound activates the MAPK signaling pathway in previously normal skin tissue.



Pathway rebound is a limitation of approved RAF kinase inhibitors.



In Class II BRAF mutations, the dimer is asymmetric and the active site of the second BRAF molecule is structurally distinct, making it difficult for current therapies to effectively inhibit RAF dimer dependent signaling. Furthermore, in Class III BRAF mutations, the second molecule of the dimer is often CRAF (see figure above), which emphasizes the requirement to bind and inhibit both BRAF and CRAF for effective signaling inhibition. To effectively block both molecules in these dimers, while avoiding pathway rebound and maintaining anti-tumor efficacy in patients with Class II and Class III BRAF mutations, a compound needs to have activity across RAF isoforms while maintaining selectivity against other kinases.

#### *Our solution to pathway rebound*

To address pathway rebound, KIN002787 is specifically designed to inhibit both molecules of the dimer simultaneously, regardless of RAF isoform type. By inhibiting both molecules simultaneously, we aim to overcome the challenges created by asymmetric molecules and the subsequent potential for pathway rebound. We develop candidates using structure-based design and a screen with disease-relevant human cancer cell lines sensitive to pathway rebound. Enzymatic (biochemical) assays, as opposed to cellular screens, cannot identify compounds that may be effective against both molecules of a dimer because dimer formation does not occur outside of a cellular context. Our approach allows us to develop small molecules that may bind to both sides of the RAF dimer.

## Maintaining Target Coverage

### *The target coverage challenge*

An additional factor to address when developing drugs for Class II or Class III BRAF mutations is the requirement to maintain high levels of target coverage between doses. Low drug concentration may trigger pathway rebound as there may be insufficient coverage to inhibit both molecules of the RAF dimer. Maintaining adequate target coverage at all times is critical to avoid rebound signaling.

Other drug candidates in development for Class II or Class III BRAF mutations, such as NovellusDX's PLX8394 and Novartis' LXH254 in particular, we believe possess certain pharmaceutical properties which may have limited their target coverage. As a result, these drug candidates have been dosed to high levels and/or combined with other drugs in clinical trials, which has the potential to lead to increased toxicity and treatment complexity, in an attempt to maintain inhibition of the pathway.

### *Our solution to maintain broad target coverage*

Once we identify compounds that can bind to both molecules of the dimer, we focus on optimization of pharmaceutical properties to ensure sufficient coverage to inhibit both molecules of the RAF dimer, ultimately aiming to achieve optimal target coverage. KIN002787 is designed to have enhanced solubility, which has led to improved pharmacokinetic (PK) properties across animal models that result in improved anti-cancer activity.

We believe that the pharmaceutical property enhancements of our candidate will afford better patient tolerability and more complete and effective coverage of the intended target. We anticipate this will translate to deeper and more sustained disease control and greater flexibility for rational combination therapy strategies in the future.

### *Our RAF Product Candidate: KIN002787*

We plan on focusing our clinical development efforts in Class II or Class III BRAF mutation-driven cancers where patients do not respond to existing therapies or have few treatment options currently available to them. We initially plan to develop KIN002787 for the treatment of patients with NSCLC and melanoma subpopulations with Class II or Class III BRAF mutations. These tumor types are especially dependent upon these BRAF mutations, creating promising opportunities to therapeutically target these genomic drivers. In addition, we plan to explore treatment of other tumor types as we move forward with our development program.

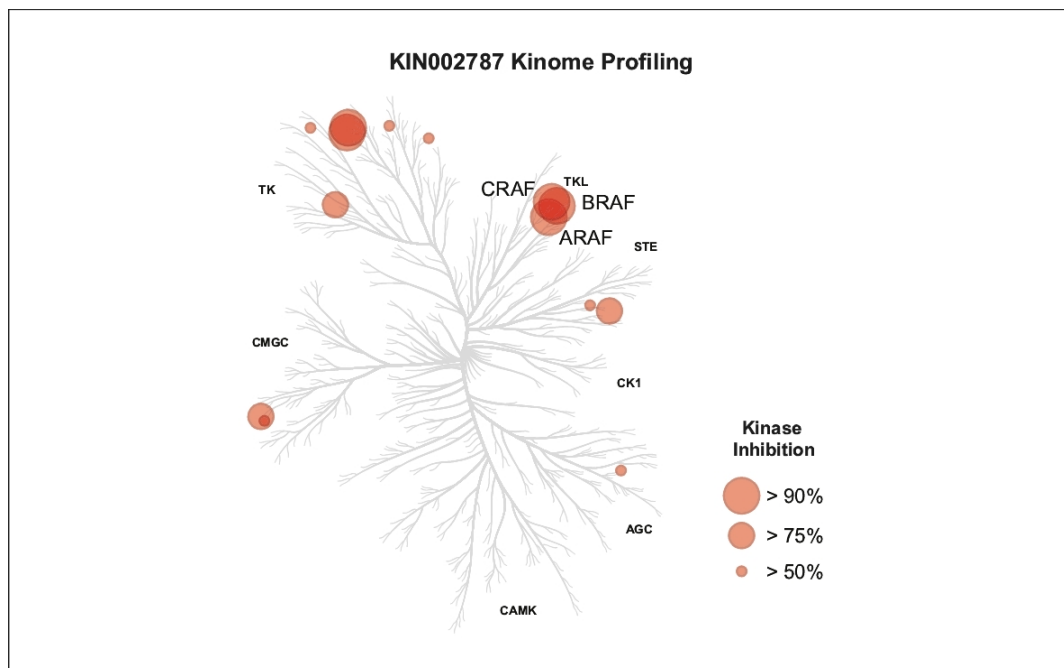
KIN002787 is an orally available, reversible small molecule RAF inhibitor. KIN002787 selectively targets RAF kinases and has demonstrated anti-cancer activity in sensitized cancer models driven by Class II BRAF fusions and BRAF homodimer-dependent indels and Class III BRAF mutations.

Our preclinical studies of KIN002787 have demonstrated tumor regressions in specific cancer models representing our target patient populations that harbor tumors driven by BRAF Class II and Class III mutations where no approved targeted therapy currently exists. KIN002787 has also demonstrated improved pharmaceutical properties and human equivalent dose (HED) predictions compared to certain ongoing clinical development programs. These results support our belief that KIN002787 has the potential to demonstrate therapeutic response by addressing challenges related to MAPK pathway rebound and target coverage.

We are conducting 28-day oral toxicology assessments of KIN002787 using industry-standard rat and cynomolgus monkey as relevant species for human risk assessment. Based on final review of these data, we plan to file an IND with the FDA in 2021. We are also developing related backup molecules that we would plan to advance into the clinic only if, following the initiation of clinical trials for KIN002787, we determine such molecules may have a superior safety or efficacy profile.

*Preclinical Results*

Based on evaluating more than 300 kinase assays, KIN002787 displayed a highly selective kinome profile. These results were determined by radiometric kinase inhibition assays, the preferred standard for evaluating small molecule inhibitors. As depicted in the figure below, in this kinome profiling study, KIN002787 substantially inhibited all three RAF kinases (ARAF, BRAF, CRAF) and partially inhibited few other (off-target) kinases. It therefore demonstrated a selective kinase profile.

**Selective RAF kinase enzymatic inhibition as demonstrated by kinome profiling of KIN002787.**

*Kinome tree depicting kinase selectivity for KIN002787 across 372 kinases in single dose (1000 nM), duplicate measurements in radiometric kinase assay format at Reaction Biology Corp. Percent (%) inhibition is relative to DMSO control. Kinases with >50% inhibition are shown with circle size indicating the relative potency. Kinome tree graphic was generated using CORAL (<http://phanstiel-lab.med.unc.edu/CORAL/>).*

We performed additional studies to characterize the kinase inhibitory activity of KIN002787 on kinases that were inhibited in the kinome profiling studies. As depicted in the table below, we measured the inhibitory activity of KIN002787 on selected kinases typically inhibited by the RAF inhibitor class by utilizing an enzymatic (biochemical) assay. The drug concentrations that inhibited 50% of kinase activity are presented in nanomolar (nM) concentrations. We observed a highly selective kinome profile for KIN002787 with greater than 867X inhibitory activity against RAF family kinases compared to the other notable off-target kinases, an exception is DDR1 (more than 15X higher IC<sub>50</sub> than BRAF), which has a highly similar active site.

**Inhibitory concentrations 50% (IC<sub>50</sub>s) determined from dose-response inhibition curves of kinases inhibited in the kinome profiling.**

Kinase	KIN002787 IC <sub>50</sub> (nM)
<b>CRAF</b>	<b>0.573</b>
<b>BRAF<sup>V600E</sup></b>	<b>1.53</b>
<b>ARAF</b>	<b>2.41</b>
<b>BRAF</b>	<b>3.46</b>
DDR1	108
PDGFRB	445
p38alpha	1230
EPHA2	>3000
KDR	>3000
LCK	>3000
SRC	>3000

*The selectivity of KIN002787 was evaluated by comparing the inhibitory activity against ARAF, BRAF, and CRAF to off-target kinases discovered in the kinome profiling that was performed at a compound concentration of 1000 nM. Radiometric kinase assays were run at Km ATP concentration with compounds starting at 3000 nM. The half-maximal inhibitory concentrations (IC<sub>50</sub>) were determined using a four-parameter fit model from a 10-point dose response curve performed with 3 replicates at each drug concentration and are presented in nM concentrations. Common BRAF inhibitor off-targets (EPHA2, KDR, LCK, and SRC) are represented as greater than the top drug concentration tested (> 3000 nM).*

As shown in the table below, KIN002787 exhibited activity against Class II and Class III BRAF mutations in cellular settings as measured by inhibition of pathway signaling. In these studies, we utilized phosphorylation of extra-cellular signal-regulated kinase (ERK) as a sensitive measure of MAPK signaling inhibition. With KIN002787 we observed much lower MAPK pathway inhibition in cells expressing WT BRAF as exemplified by the MIA-PaCa-2 and CHL-1 cells. In contrast, a representative MEK inhibitor, Cotellic (cobimetinib), demonstrated inhibition across all evaluated cellular settings including BRAF WT. We believe this selectivity of BRAF mutant versus BRAF WT is a differentiator and advantage of KIN002787 by avoiding pathway inhibition in normal cells.

Half maximal effective concentrations 50% (EC<sub>50</sub>s) of MAPK signaling as determined from dose-response inhibition of phosphorylation of ERK (pERK) in the indicated human cancer cell lines.

Mutant BRAF Class	Cell Line	BRAF / MAPK Pathway Alteration(s)	Roche cobimetinib EC <sub>50</sub> (nM)	Novartis LXH254 EC <sub>50</sub> (nM)	Kinnate KIN002787 EC <sub>50</sub> (nM)
I	A375	<i>BRAF</i> <sup>V600E</sup>	4	157	62
II	BxPC3	<i>BRAF</i> indel	6	25	31
II	OV90	<i>BRAF</i> indel	2	16	25
II	H2405	<i>BRAF</i> indel	2	6	4
III	WM3629	<i>BRAF</i> <sup>D594G</sup> / <i>NRAS</i> <sup>G12D</sup>	3	4	8
III	CAL12T	<i>BRAF</i> <sup>G466V</sup>	4	22	12
WT	MiaPaCa-2	<i>BRAF</i> WT / <i>KRAS</i> <sup>G12C</sup>	9	357	517
WT	CHL-1	<i>BRAF</i> WT / <i>NRAS</i> WT	5	368	579

Cellular inhibitory activity for KIN002787 compared to cobimetinib and LXH254 in internal head-to-head comparisons. More potent inhibition is reflected by a lower EC<sub>50</sub> number presented in nM concentration. Cells were treated with the indicated compounds for 1 hour and pERK was measured in cell lysates using a homogenous time-resolved fluorescence assay. The compounds were run in 10-point, 3-fold serial dilution response starting at 10,000 nM to determine EC<sub>50</sub> using a 4-parameter fit model. All samples were run in triplicate and represent an average of 2 or more independent experiments.

Enhancement of pharmaceutical properties was a major priority for our RAF inhibitor designs as traditional RAF inhibitors, both currently approved and in clinical development, have suffered from poor pharmaceutical properties including aqueous solubility. High aqueous solubility improves drug absorption, which leads to greater potency. By modifying chemical scaffolds with chemical groups that improve aqueous solubility while maintaining potency of RAF inhibition, we identified KIN002787 which demonstrated an aqueous solubility greater than 100 micromolar (uM) at pH 4.5 and greater than 300 uM at pH 2.0. These are substantially improved aqueous solubilities as compared to LXH254, as shown in the table below. These improved pharmaceutical properties of KIN002787 increased drug exposure (greater than 3,000 area under the curve per dose (AUC/dose)) while achieving clearance rates more than 10-fold below liver blood flow (90 mL/min/kg) in mouse PK experiments. Low clearance rates improve target coverage. Improved aqueous solubility, lower clearance *in vivo*, and increased drug exposure all enhance the likelihood that KIN002787 may achieve greater target coverage in the clinical setting that we anticipate will lead to enhanced anti-tumor activity.

Improved AUC and increased exposure seen in mouse studies as a result of increased aqueous solubility and low clearance rates.

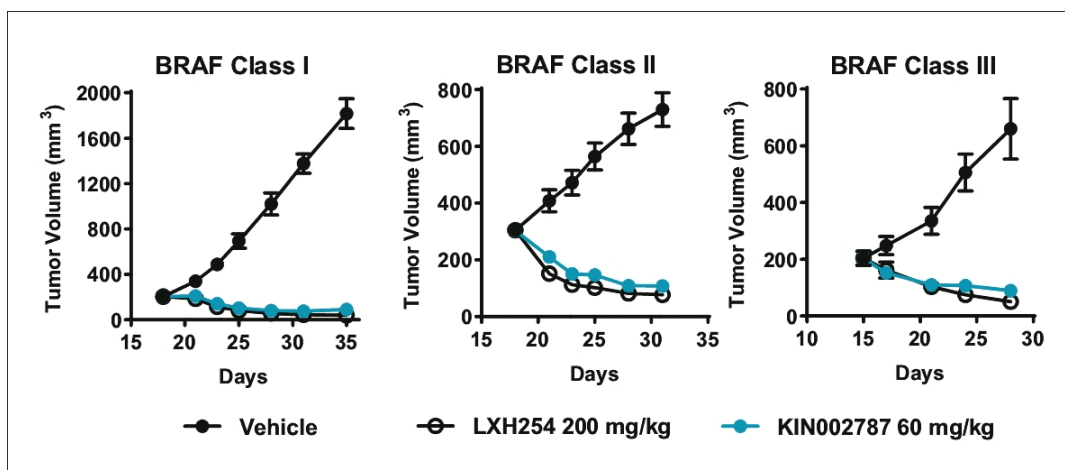
Feature	Parameter	Novartis LXH254	Kinnacle KIN002787
<i>In vitro</i> drug solubility	<b>Aqueous Solubility (μM)</b>		
	pH = 7.4	8	29
	pH = 4.5	7	196
	pH = 2.0	50	312
<i>In vivo</i> mouse pharmacology	<b>100 mg/kg per oral dose</b>		
	Clearance (mL/min/kg)	10	8
	AUC / dose (ng*h/mL)	1123	3335

KIN002787 displayed improved pH-dependent solubility as compared to LXH254 in internal head-to-head comparisons. Increased solubility is demonstrated by higher amount (μM) of drug soluble at the indicated pH. This increased solubility improved exposure in mice resulting in >3000 area under the curve (AUC) / dose following a single oral dose at 100 mg/kg.

*Tumor regressions in internal head-to-head preclinical studies for KIN002787*

Daily dosing of KIN002787 was well tolerated in athymic nude mice bearing A375 (BRAF Class I mutation), BxPC-3 (BRAF Class II mutation) or WM3629 (BRAF Class III mutation) human tumor cell xenografts in doses up to 60 mg/kg/day. As shown in the figure below, all three tumor models demonstrated tumor growth inhibition, as measured by mean tumor volume, at a dose of 60 mg/kg/day. For comparison, we treated cohorts of tumor-bearing animals with 200 mg/kg/day of LXH254 leading to similar inhibitory activity to 60 mg/kg of KIN002787. This 200 mg/kg/day dose of LXH254 represents more than a four-fold increased free drug exposure relative to the highest clinical dose (600 mg BID).

**Anti-tumor activity in BRAF Class I (left), Class II (middle), and Class III (right) driven cancer models in response to KIN002787.**



Tumor growth inhibition of A375 BRAF<sup>V600E</sup> melanoma (BRAF Class I), BxPC-3 *indel*  $\Delta$ NTAP pancreatic cancer (Class II), and WM3629 BRAF<sup>D594G</sup>/NRAS<sup>G12D</sup> melanoma (Class III) xenografts in athymic nude mice. KIN002787 or LXH254 or vehicle control dosing was initiated when tumors reached >200 mm³ after tumor inoculation and was performed by oral administration once a day. Groups consisted of n=9 mice and represent the average of tumor measurements +/- standard error of the mean (SEM).

#### PD Studies and Pathway Rebound

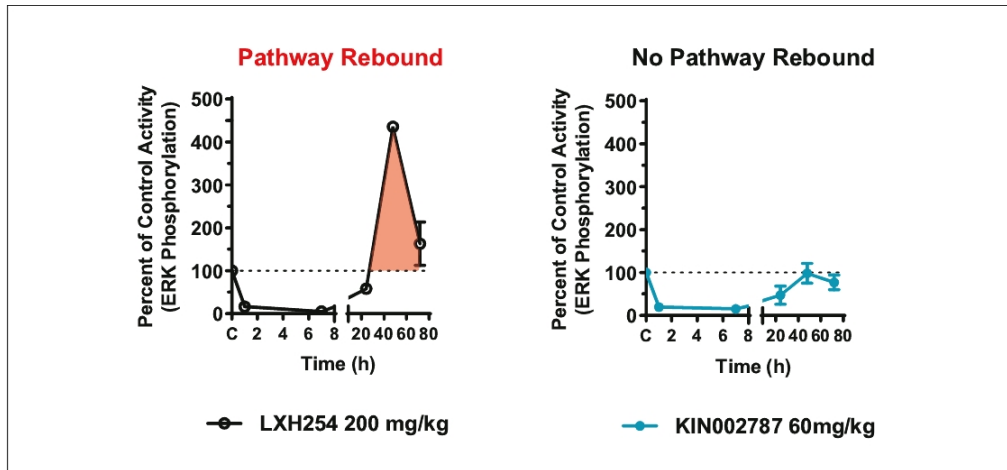
In these studies, we measured phosphorylated ERK (pERK) as a sensitive marker of MAPK signaling in human WM3629 cancer cell line xenografts (BRAF Class III mutation) that were recovered from tumor-bearing mice after they had received a single dose of KIN002787. As depicted in the figure below, a



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single 60 mg/kg dose demonstrated inhibition of ERK phosphorylation within 1 hour of treatment which was maintained through 7 hours post-treatment, while ERK phosphorylation partially recovered by 24 hours and returned to pre-treatment levels (100% of the control or baseline value) by 48 hours after treatment. Treatment with a single dose of LXH254 at 200 mg/kg led to pathway rebound of ERK phosphorylation to levels above 400% at 48 hours post-treatment, as depicted by the area shaded in red above 100% in the figure on the left below. In contrast, as depicted in the figure on the right below, KIN002787 did not demonstrate significant pathway rebound in these studies in BRAF Class III mutant tumors.

### Inhibition of RAF kinase activity in WM3629 BRAF Class III mutant tumors *in vivo*.



Inhibition of MAPK pathway signaling after treatment with LXH254 at 200 mg/kg (left) or KIN002787 at 60 mg/kg (right) in WM3629 BRAF<sup>D594G</sup>/NRAS<sup>G12D</sup> melanoma xenografts (BRAF Class III model) in athymic nude mice. All dosing performed by oral administration with n=3 tumors / time point. Tumors were measured for phosphorylated ERK (pERK) and represented as the average  $\pm$  SEM. C = control pERK levels from untreated tumors that serve as the reference for drug-treated tumor samples.

KIN002787 is designed to and has demonstrated the ability in preclinical studies to:

- inhibit RAF across both sides of the RAF dimer, which enables populations beyond Class I mutations to be targeted;
- enable large drug exposures *in vivo* for BRAF mutant target coverage while avoiding pathway rebound; and
- target Class II and Class III BRAF mutations, which has been enabled by technological advances and increased access to genomic profiling.

To support translation of KIN002787 into biomarker-defined clinical trials, we have established research programs with Massachusetts General Hospital Cancer Center. These programs evaluate KIN002787 in Class II BRAF mutations and in patient-derived xenograft models of Class II and Class III BRAF mutations. Outcomes are focused on supporting PK and PD relationships in clinically relevant models of Class II and Class III BRAF mutations.

#### Clinical Development Plan

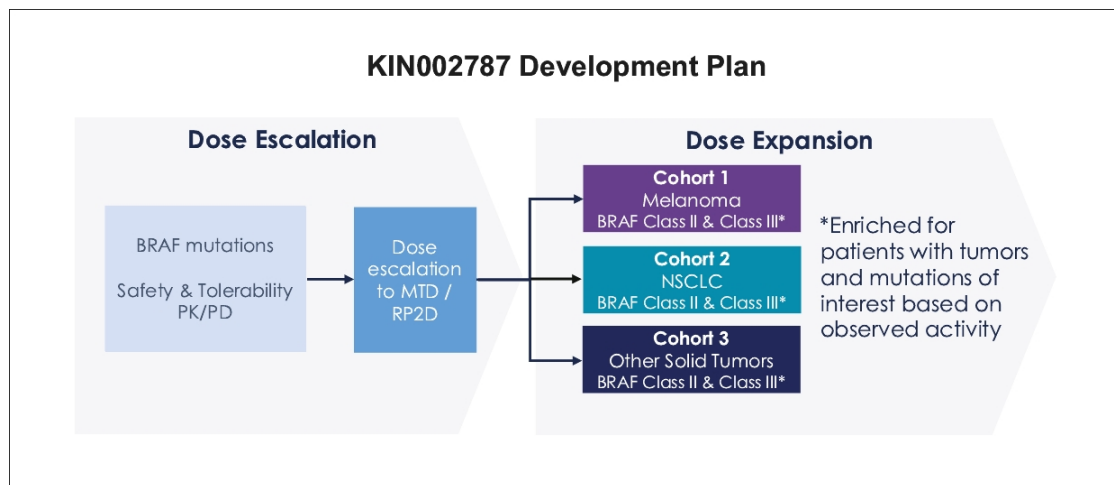
We anticipate filing an IND for KIN002787 with the FDA in the first half of 2021 and, subject to such submission taking effect, initiating a Phase 1 clinical trial in 2021. We are designing our FIH clinical trial primarily to assess safety and tolerability of KIN002787 in patients with advanced or metastatic solid tumors driven by specific classes of BRAF mutations, while also characterizing pharmacological and anti-cancer properties of KIN002787.

Our planned FIH trial is designed to occur in two stages:

- **Part A: Dose Escalation:** Patients with advanced or metastatic solid tumors bearing any BRAF Class I, Class II or Class III mutation (including NSCLC, melanoma and other solid tumors) will be sequentially enrolled in cohorts of 1 to 3 patients each to receive oral KIN002787 monotherapy.
- **Part B: Dose Expansion:** Patients with advanced or metastatic solid tumors bearing either a Class II or Class III BRAF mutation (including NSCLC, melanoma and other solid tumors, but excluding Class I mutation-driven cancers) will be sequentially enrolled in one of a number of cohorts defined by disease or biomarker of up to 20 to 30 patients per cohort to receive oral KIN002787 as a single anti-cancer agent.

The objectives of the trial is to (1) assess the safety and tolerability of KIN002787 when administered to cancer patients, (2) understand the relationship between dose and schedule of drug with PK, PD and changes in tumor-associated biomarkers, (3) determine a recommended Phase 2 dose and schedule, and (4) gain an initial understanding of single agent anti-cancer efficacy in defined cancer patient cohorts. Our primary efficacy measures will include objective measures of tumor response, including number of responding patients, response rate, depth of response and DoR, utilizing standardized tumor imaging assessments at pre-specified intervals. The figure below illustrates our current clinical development plan.

**Clinical development plan for KIN002787 in patients with BRAF-driven advanced solid tumors.**



In both Parts A and B, we plan to leverage CLIA-compliant local tumor tissue genomic profiling, such as MSK-IMPACT profiling, at Memorial Sloan Kettering Cancer Center, or tumor genomic analysis performed at a central commercial laboratory, such as Foundation Medicine, Inc., for detection and inclusion of specific BRAF mutation-driven cancer patients in our FIH trial. We also plan to biobank tumor tissue specimens for central retrospective analysis which we believe will enable the assessment of primary genomic alterations and other exploratory analyses.

We are actively engaged with leading clinical and translational investigators in targeted therapy oncology drug development at experienced precision medicine cancer centers and Phase 1 drug development centers in the United States in preparation for the launch of our clinical program in 2021. As we move into Part B (Dose Expansion), we plan to expand our network of qualified investigators in North America, and selectively initiate clinical sites in other geographies such as Europe and the Asia-Pacific region.

Based on the totality of clinical data from our FIH trial, and predicated upon an acceptable safety and tolerability profile and a strong positive efficacy signal, we then expect to engage with the FDA and other regulatory agencies to plan one or more Phase 2 potentially registration-enabling trials in the United

States and potentially other geographies. Where possible, we will explore applicable regulatory strategies pursued by other targeted therapy companies, for example Orphan drug designation, Breakthrough Therapy and Fast Track designation, Priority Review and/or Accelerated Approval.

#### *Growing Our RAF Franchise*

Beyond development of KIN002787, we continue activities on alternative molecules based on chemotypes that are differentiated from KIN002787. Additionally, we are investigating potential next-generation candidates selectively targeting RAF isoforms (BRAF- or CRAF-selective) with the possibility of expanding the therapeutic index and enabling further precision medicine strategies. For example, we may target *RAF 1* (CRAF protein) gene fusions that are known drivers in primary central nervous system (CNS) tumors, which remains a substantial unmet need. These programs are currently in preclinical research and we intend to develop them for future precision oncology clinical trials.

#### **Our FGFR Program: KIN003**

##### *Overview*

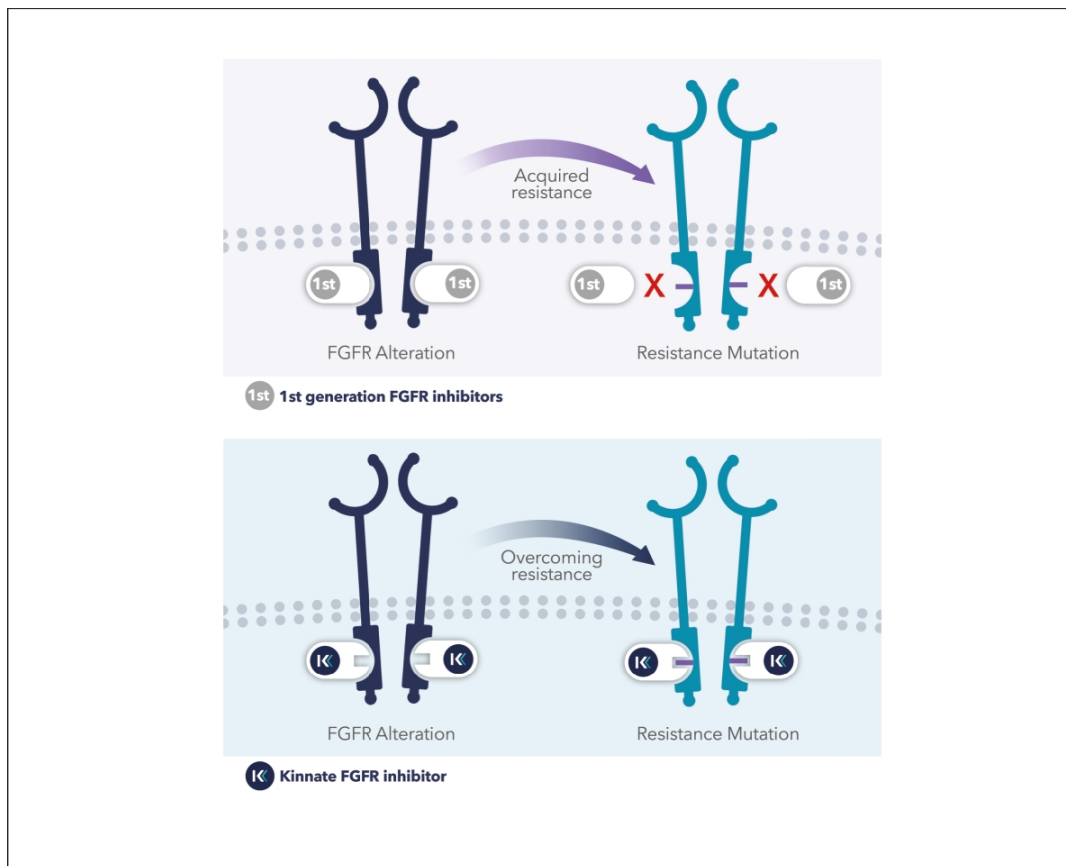
We are evaluating our FGFR inhibitor candidates for the treatment of patients with ICC and UC. In preclinical studies, we have observed inhibitory activity across a broad range of clinically-relevant genomic alterations in FGFR2 and FGFR3 that drive resistance to current therapies. Because our preclinical studies demonstrated our candidates' ability to cover the initial alterations and preemptively address these resistance mutations, we believe we may be able to meaningfully increase the DoR for certain patients by addressing these alterations. We plan to develop our candidates initially for patients whose tumors have acquired resistance to therapies targeting FGFR2 or FGFR3 alterations, which limits the durability of response. As with other precision oncology approaches, addressing resistance mutations may also ultimately enable us to develop a first-line therapy. We anticipate filing an IND with the FDA in the first half of 2022 and, subject to such submission taking effect, initiating a Phase 1 clinical trial in the first half of 2022.

##### *Background*

Aberrations in FGFR signaling are an emerging opportunity for targeted therapy across multiple types of cancer, particularly UC and ICC and also gastric and breast cancers. Currently approved FGFR inhibitors have demonstrated clinical benefit, but response rates and DoR are limited. For FDA approved FGFR targeted drugs Balversa (erdafitinib) and Pemazyre (pemigatinib), as well as TAS120 (futibatinib), which is in development, the response rate is approximately 30% to 35% among UC and ICC patients whose tumors are driven by FGFR-dependent driver genes. Further, the vast majority of those responding patients only demonstrate partial responses (i.e., partial tumor shrinkage) and the median DoR is only five months for Balversa (erdafitinib) and nine months for Pemazyre (pemigatinib). These resistance profiles are often caused by gatekeeper and molecular brake variants that emerge within the FGFR driver gene. The figure below shows the sensitivity and resistance of various oncogenic FGFR2 and FGFR3 indels and fusion genes. This lack of a response for most patients and short DoR for others presents a substantial need to develop potent and selective next-generation FGFR-targeting agents that can drive deeper and longer-lasting clinical benefit among responding patients.

First-generation inhibitors including Balversa (erdafitinib), Pemazyre (pemigatinib) and futibatinib and our next-generation FGFR-targeting small molecules in development effectively target non drug-resistant FGFR2 and FGFR3 driver genes. Among these, we believe only our FGFR-targeting small molecules have been shown in preclinical studies to effectively inhibit the full spectrum of clinically-described and predicted resistance mutations in FGFR cancer driver genes.

**Kinnate's FGFR inhibitors retain activity against common FGFR2 and FGFR3 resistance mutations.**



Hyperphosphatemia, an elevated level of phosphate in the blood, is a common, and typically manageable, adverse effect of FGFR-targeting drugs. This adverse event is driven by FGFR1-dependent inhibition of phosphate reabsorption in the kidney. Typically, hyperphosphatemia is managed by dietary modification and phosphate-binding medication. Many oncology drug developers have tried to select against FGFR1 instead of targeting 1, 2 or 3 specific FGFR isoforms, but given very high sequence similarity in the kinase domains of FGFR family members, it remains exceptionally challenging to retain potent FGFR2 and FGFR3 inhibition and avoid FGFR1 kinase inhibition. Based on our conversations with clinicians and key opinion leaders, we believe that broad coverage of FGFR2 and FGFR3 and resistance mutations is more important clinically than reducing hyperphosphatemia. Additionally, inhibition of FGFR1 may have clinical benefits.

FGFR2 fusions have been observed in 10% to 16% of patients with ICC, while FGFR3 mutations are estimated to be found in approximately 15% to 20% of patients with UC. Given these populations and the significant percentage of patients who develop resistance to currently approved FGFR inhibitors, we believe there is a significant commercial opportunity to develop a next-generation FGFR inhibitor that will effectively cover the initial fusions or alterations and the common resistance alleles that may eventually develop.

*The Opportunity*

The lack of a response for most patients and short DoR for others with respect to existing therapies presents a substantial need to develop potent and selective next-generation FGFR-targeting agents that can drive deeper and longer-lasting clinical benefit among responding patients.

## Resistance Mutations

### *The challenge of resistance mutations*

Most recently, the emergence of resistance mutations in FGFR driver genes (at or even prior to the emergence of clinical progression or relapse in drug-treated patients) has highlighted the limitation of both currently approved FGFR-targeting drugs and other clinical stage compounds. While this acquired mutational resistance in FGFR serves to further validate FGFR driver genes as drug targets, it also highlights both the need and the opportunity to develop potent, selective and specific FGFR-targeting agents that target existing mutational resistance and prevent emergence of new resistance mutations.

Common mechanisms driving this acquired resistance are referred to as gatekeeper mutations (V565F/I in FGFR2 and V555M in FGFR3) and molecular brake mutations (N550K/H in FGFR2 or N540S or K650M/E in FGFR3). The mutated gatekeeper amino acid influences binding site properties which can prevent binding of FGFR inhibitors to the target site (FGFR2 and FGFR3). Molecular brake mutations increase kinase activation, overcoming drug efficacy. Both gatekeeper and molecular brake mutations drive acquired resistance to current therapies.

### *Our solution to resistance mutations*

We believe that selectively targeting the initial oncogenic alteration in addition to acquired gatekeeper and/or molecular brake alterations has the potential to overcome the challenges presented by resistance mutations. To improve DoR, our next-generation FGFR inhibitors in development target acquired resistance mutations identified in patients treated with FGFR targeted therapies. We are seeking to develop product candidates to inhibit the initial alteration or fusion in addition to the gatekeeper and molecular brake resistance mutations. Specifically, we have designed our candidates to address mutations, such as gatekeeper and molecular brake mutations, which we believe to be the most common acquired resistance mutations.

While we are initially pursuing this as a second-line treatment, we ultimately plan to explore first-line therapy as well, where coverage across both initial and acquired mutations may translate to longer DoR, displacing existing FGFR2 and FGFR3 targeting drugs. This is analogous to the path taken in the successful development of Tagrisso (osimertinib), an EGFR-targeting small molecule drug that potently inhibits both WT and specific, critical gatekeeper EGFR mutations that confer resistance to first-generation EGFR-targeting drugs such as Tarceva (erlotinib).

## Limited Coverage

### *The challenge with limited coverage*

Isoform-selective FGFR inhibition may lead to activation of other FGFR kinases. This reactivation of FGFR1, FGFR2, or FGFR3 signaling represents a potential compensation mechanism that drives resistance to selective therapies. Evidence of this has already been seen with FGFR2-specific inhibitors that have resulted in the appearance of FGFR1 or FGFR3 oncogenic driver alterations. Without broad inhibition of the FGFR kinase family, DoR and response rates may be limited.

### *Our solution to overcoming limited coverage*

Our next-generation FGFR inhibitor candidates are structurally designed to inhibit molecular brake and gatekeeper mutations while maintaining broad coverage across FGFR isoforms (i.e., FGFR1, FGFR2 and FGFR3). This broad-based approach may prevent compensatory mechanisms that would otherwise limit response rates or DoR.

FGFR1, FGFR2, and FGFR3 alterations are predominantly found in different tumor types. FGFR2 alterations are known oncogenic drivers in ICC and FGFR3 alterations are known oncogenic drivers in urothelial tumors. In addition, evidence suggests that FGFR1 alterations exist in breast cancer and may be oncogenic drivers. Therefore, a drug that broadly inhibits FGFR isoforms may be effective across multiple tumor types.

In addition to covering broad FGFR isoforms, there is an opportunity to cover other potential escape routes by providing coverage of FGFR indels and single nucleotide variants (SNVs) beyond the fusions targeted by currently approved therapies. Coverage across both the intrinsic and acquired resistance mechanisms may translate into more durable DoR, displacing existing FGFR2 and FGFR3 targeting drugs.

#### *Our FGFR Candidates*

Our FGFR candidates are designed to address clinically observed genomic alterations in FGFR2 and FGFR3 that drive resistance to current therapies. We are evaluating potential FGFR candidates for the treatment of patients with ICC and UC and may eventually expand into other FGFR-driven solid tumors, such as breast cancer.

In preclinical studies we have observed inhibitory activity across a broad range of clinically relevant mutations that drive acquired resistance. We believe that by addressing these mutations and broadly covering FGFR isoforms, we may be able to meaningfully increase the DoR.

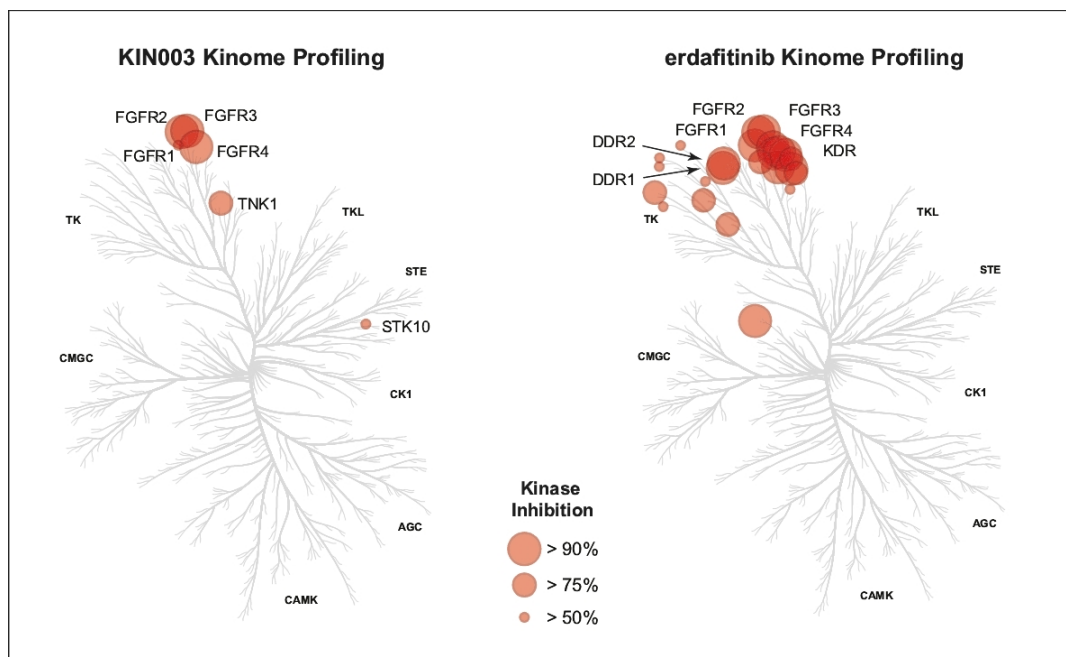
We have completed *in vitro* and *in vivo* profiling of our FGFR candidates and plan to conduct dose range finding and good laboratory practice (GLP) toxicological studies. Based on final review of these data, we anticipate nominating a lead product candidate in 2021, filing an IND with the FDA in the first half of 2022 and, subject to such submission taking effect, initiating a Phase 1 clinical trial in the first half of 2022.

#### *Preclinical Results*

Based on evaluating more than 300 kinase assays, KIN003 displayed a highly selective kinome profile. As depicted in the figure below, in this kinome profiling study, KIN003 substantially inhibited (> 90% kinase inhibition) three FGFR kinases (FGFR2, FGFR3, and FGFR4) and partially inhibited a few other (off-target) kinases including TNK1 and STK10. By comparison, the FDA approved FGFR2/3 inhibitor erdafitinib (Balversa) inhibited the FGFR family of kinases, but demonstrated off-target inhibition of the tyrosine kinase family including several receptor tyrosine kinases (e.g. KDR, PDGFRalpha, KIT, CSF1R, DDR1, DDR2) that are known to be common off-targets for FGFR inhibitors. Therefore, KIN003 demonstrated an improved kinase selectivity profile relative to erdafitinib.



**Selective FGFR family kinase enzymatic inhibition as demonstrated by kinome profiling of KIN003 compared to erdafitinib.**



Kinome tree depicting kinase selectivity for KIN003 and erdafitinib across 322 kinases in single dose (1000 nM), duplicate measurements at Carina Biosciences Inc. Biochemical assays were measured by a shift in electrophoretic mobility of a peptide substrate upon phosphorylation with the designated kinase. Percent (%) inhibition is relative to DMSO control. Kinases with >50% inhibition are shown with circle size indicating the relative potency as depicted in the legend. Kinome tree graphic was generated using CORAL (<http://phanstiel-lab.med.unc.edu/CORAL/>).

As shown in the table below, initial preclinical study results for our FGFR program, KIN003, in enzymatic inhibition assays showed inhibition of the gatekeeper mutations (FGFR2 V565F and FGFR3 V555M) when compared to the FDA approved FGFR inhibitors, Balversa (erdafitinib) and Pemazyre (pemigatinib), and the FGFR inhibitor clinical candidate TAS120 (futibatinib).

**Biochemical inhibition assays of indicated FGFR-targeting reference compounds and KIN003 against WT FGFR1, FGFR2, and FGFR3 and selected FGFR2 and FGFR3 resistance mutations.**

Kinase Domain	Alteration	Janssen erdafitinib IC <sub>50</sub> (nM)	Incyte pemigatinib IC <sub>50</sub> (nM)	Taiho futibatinib IC <sub>50</sub> (nM)	Kinnate KIN003 IC <sub>50</sub> (nM)
FGFR1 WT	N/A	0.22	0.4	2.1	4.2
FGFR2 WT	N/A	0.15	0.4	1.4	3.8
FGFR2 V565F	Gatekeeper	330	>500	>500	22.5
FGFR2 N550H	Mol. Brake	4.1	19.8	36.4	22.5
FGFR3 WT	N/A	0.73	1.5	5.3	6.0
FGFR3 V555M	Gatekeeper	137	>500	324	23.5
FGFR3 K650M	Mol. Brake	3.5	20	8.3	4.2
<b>Ratios of Resistance Mutations Compared to Unmutated (WT) (Fold Difference in IC<sub>50</sub>)</b>					
R2 V565F / R2 WT	Gatekeeper	2200X	>1250X	>385X	6X
R2 N550H / R2 WT	Mol. Brake	27X	50X	31X	6X
R3 V555M / R3 WT	Gatekeeper	188X	>333X	61X	4X
R3 K650M / R3 WT	Mol. Brake	5X	13X	1.6X	0.7X

Enzymatic inhibition of KIN003 compared to erdafitinib, pemigatinib and futibatinib in internal head-to-head comparisons measuring FGFR family kinases and common resistance mutations. Biochemical activity is measured by a shift in electrophoretic mobility of a peptide substrate upon phosphorylation with the designated FGFR kinase. The potency of kinase inhibition is presented as the concentration of specified compound that inhibited 50% of the maximum kinase activity (IC<sub>50</sub>). Kinase inhibition assays were performed at 100 uM ATP concentration with no pre-incubation of the compounds with the kinase. In the lower section of the table, the relative inhibitory activity of the specified compound toward mutant versus respective WT kinase was displayed as fold differences in IC<sub>50</sub>. Ratios <10X (as highlighted by green text for KIN003) represented equivalent kinase inhibition of either the resistance mutation or corresponding WT kinase. Ratios >10X (as highlighted by red text) represented a substantial loss of activity against the indicated resistance mutation compared to the corresponding WT kinase.

In preclinical studies, our FGFR-targeting molecules demonstrated equivalent inhibition of cell viability in human CCLP-1 cholangiocarcinoma cells engineered to express either unmutated FGFR2 gene fusions (WT) or comparable gene fusions that harbor secondary resistance mutations (e.g., V565F and N550K). As depicted in the table below, in preclinical studies, KIN003 demonstrated substantial and similar inhibition of cell viability in WT and specific mutant FGFR2 gene fusion positive CCLP-1 human cells. Other FGFR-targeting compounds were assayed in the same studies and displayed significantly less inhibition of specific mutant FGFR2 alleles. For example, pemigatinib and futibatinib had EC<sub>50</sub> values for the FGFR2 V565F mutation that were more than 10,000 nM and 170 nM, respectively. Fold-differences in sensitivity between WT and specific mutant FGFR2 alleles are presented in the lower part of the table.

In addition to the V565F and N550K acquired resistance mutations described above, there are other clinically relevant mutations, including additional gatekeeper mutations, V565L and V565I, and other activating mutations such as M538I in FGFR2. These mutations may limit the potency of both approved FGFR inhibitors (erdafitinib and pemigatinib) and FGFR therapies in clinical development, such as RLY-4008. KIN003 demonstrates a ratio less than 6-fold for these resistance mutations compared to the unmutated FGFR fusion in cellular settings. This suggests that KIN003 has a unique ability to retain activity across V565L, V565I, and M538I, and therefore demonstrates a potential advantage in limiting the appearance of these resistance mutations in FGFR2-driven cancers.

**KIN003 cellular inhibition of FGFR2 fusion gene-driven CCLP-1 cells bearing clinically relevant resistance mutations that limit the potency of FGFR targeted therapies.**

Kinase Domain	Alteration	Janssen erdafitinib EC <sub>50</sub> (nM)	Incyte pemigatinib EC <sub>50</sub> (nM)	Taiho futibatinib EC <sub>50</sub> (nM)	Kinnate KIN003 EC <sub>50</sub> (nM)
FGFR2 WT	Fusion	1.3	10.2	0.42	3.7
M538I	Fusion + Activating Mut.	2.8	27.3	0.98	7.3
N550H	Fusion + Mol. Brake	6.5	68.9	2.1	6.7
N550K	Fusion + Mol. Brake	19.6	1579	5.9	7.6
V565F	Fusion + Gatekeeper	2423	>10000	170	5.9
V565L	Fusion + Gatekeeper	23.9	--	--	6.7
V565I	Fusion + Gatekeeper	6.5	--	--	7.0
<b>Ratios of Resistance Mutations to Unmutated WT FGFR2 Alleles (Fold Difference in EC<sub>50</sub>)</b>					
M538I / WT	Activating Mutation	2.1x	2.7x	2.1x	2.0x
N550H / WT	Molecular Brake	4.9x	6.8x	5x	1.8x
N550K / WT	Molecular Brake	14.7x	155x	14x	2.1x
V565F / WT	Gatekeeper	1823x	>1000x	405x	1.6x
V565L / WT	Gatekeeper	18x	--	--	1.8x
V565I / WT	Gatekeeper	4.9x	--	--	1.9x

Sensitivity of engineered CCLP-1 cells to specified compounds is indicated by the concentration of compound required to effect a 50% reduction in cell viability (EC<sub>50</sub>) in the upper section of the table. The corresponding fold-difference between resistance mutations and unmutated WT FGFR2 fusion alleles is indicated in the lower section of the table. Ratios <10X (as highlighted by green text for KIN003) represented equivalent inhibition of CCLP-1 cells expressing either the indicated resistance mutation or the WT FGFR2 fusion. Ratios >10X represented a significant loss of inhibition against the indicated resistance mutation compared to the WT FGFR2 fusion, while ratios >100X (as highlighted by red text) represented a substantial loss of activity against the indicated resistance mutation compared to the WT FGFR2 fusion in these cellular viability assays.

The currently approved FGFR inhibitors bind to the kinase active site in a reversible binding mode. By modifying small molecules with a reactive chemical warhead that irreversibly (covalently) reacts with a specific cysteine amino acid found in the active site of the kinase, we believe that FGFR inhibitors can achieve enhanced selectivity and potency across clinically-relevant secondary resistance mutations, including those that have been observed among futibatinib-treated patients.

Examples of approved kinase inhibitors that employ this irreversible binding mode include Imbruvica (ibrutinib) and Tagrisso (osimertinib), each of which covalently reacts with a specific cysteine found in the active sites of BTK and EGFR kinases, respectively. Similar to osimertinib's irreversible binding to EGFR while maintaining activity against T790M gatekeeper mutations, our designs enable an irreversible interaction with the cysteine in the FGFR1, FGFR2, and FGFR3 kinase active site, while avoiding the hindrance of binding by gatekeeper mutations that was observed with futibatinib.

#### Clinical Development Plan

We plan to nominate a lead product candidate in our KIN003 program in 2021, file an IND with the FDA in the first half of 2022 and, subject to such submission taking effect, initiate a Phase 1 clinical trial in the first half of 2022. In this program, we plan to adopt many of the same principles as our RAF program but to primarily focus on cancers that are driven by alterations in FGFR2 and FGFR3.

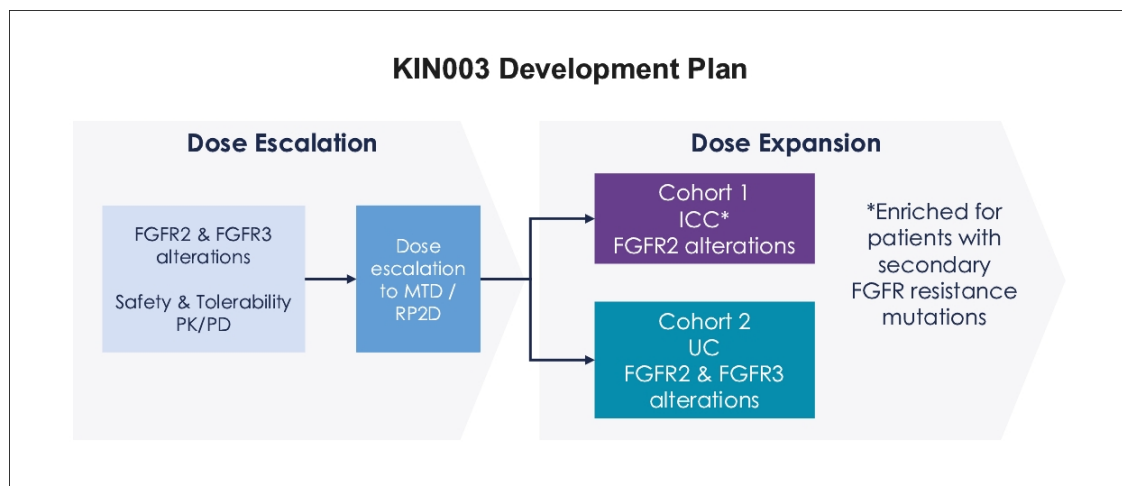
Specifically, we are planning for the following:

- a Phase 1 trial design that incorporates both sequential dose escalation and dose expansion phases;
- enrollment of patient populations with molecularly-defined FGFR2- or FGFR3-alteration driven cancers; and

- expansion into a number of cohorts defined by disease or biomarker.

The figure below illustrates our current clinical development plan for our FGFR program.

**Clinical development plan for KIN003 in patients with FGFR2- and FGFR3-driven advanced solid tumors.**



**CDK12 (KIN004) and Other Research Programs**

*CDK12 (KIN004)*

We are also advancing a number of other small molecule research programs, including a CDK12 inhibitor in our KIN004 program. CDK12 is an essential regulator of DDR genes and no approved CDK12-targeting therapies are currently available or, to our knowledge, in clinical development. We are developing a candidate to target the unmet clinical need in the treatment of OC, mCRPC and TNBC.

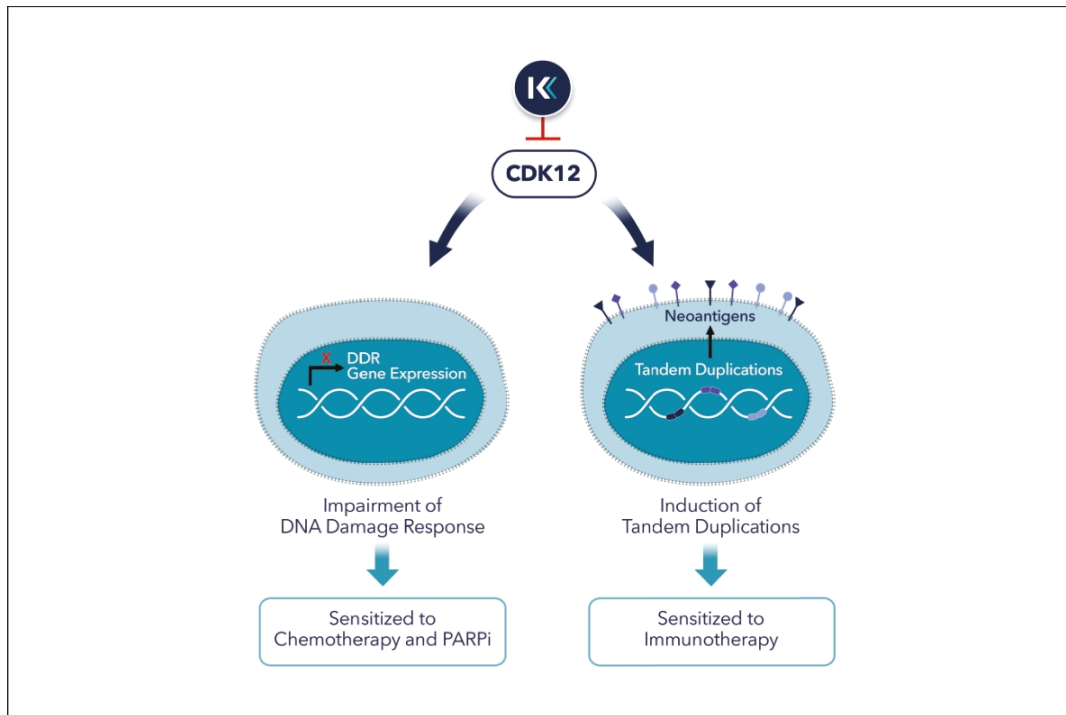
Despite the significant clinical benefits of approved poly ADP-Ribose polymerase (PARP) inhibitors in the treatment of eligible patients with advanced or metastatic OC and mCRPC, and immune checkpoint inhibitors (ICIs) (including PD-1 and PD-L1 targeting agents) for those with TNBC, acquired drug resistance remains a significant challenge in the majority of cases.

We believe that targeted CDK12 inhibition with a selective small molecule therapeutic offers the potential to:

- significantly augment the clinical benefits of PARP inhibitors, chemotherapeutic agents and ICIs in the subset of these cancer patients who are currently eligible to be treated with these drugs; and
- therapeutically sensitize cancers from expanded populations of OC, mCRPC and TNBC patients who are not currently eligible to receive PARP inhibitors or ICIs, and who yet may gain substantial benefit from combination therapy with either PARP inhibitors, conventional chemotherapies, or an ICI agent.

CDK12 is a critical regulator of both the DDR pathway and neoantigen formation in tumors. The figure below illustrates the CDK12 pathway regulating DDR gene transcription. We are developing selective CDK12 irreversible kinase inhibitors that are designed to induce DDR deficiencies in patients with DDR-proficient tumors.

**Therapeutic CDK12 inhibition sensitizes cancer cells to existing cancer therapies through two distinct mechanisms which operate in parallel.**



*(Left) CDK12 inhibition significantly reduces expression of DNA damage response (DDR) genes through its selective impact on transcription of long genes, many of which encode regulators of the DNA damage pathway. This inhibition leads to dramatic sensitization of cancer cells to DNA damaging chemotherapy and PARP inhibitors (PARPi). (Right) CDK12 inhibition is expected to produce large tandem duplications in cellular DNA that express neoantigens that are subsequently presented on the cell surface. We expect that expression of these neoantigens provides a unique opportunity to synergize with immune checkpoint inhibitors (ICIs) to produce an enhanced anti-tumor immune response.*

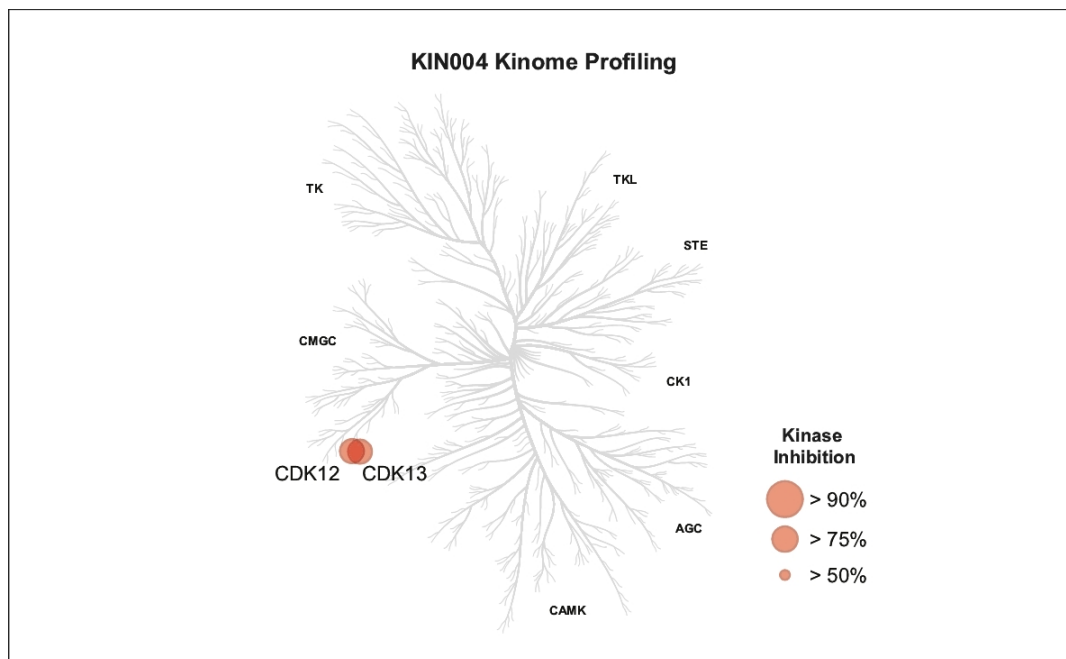
CDK12 inhibition sensitizes tumors to DNA damaging agents and induces synthetic lethality in both DDR-deficient and, more importantly, DDR-proficient tumors. Synthetic lethality is an approach in oncology drug development that is focused on identifying and selecting patient subgroups with specific genomic alterations in tumors that are most likely to benefit from these therapies and improving tolerability and reducing toxicity by not affecting normal, non-cancerous cells.

Our goal is to limit the expression of DDR genes including BRCA1 and BRCA2, among other DDR genes, to shift DDR-proficient tumors into a sensitized DDR-deficient state. This would enable a synthetic lethality approach in DDR-proficient tumors via combination therapy with currently approved PARP inhibitors.

Additionally, in published third party preclinical studies, CDK12 inactivation induced formation of large tandem duplications that expressed as fusion-induced neoantigens and synergized with ICIs to augment an enhanced anti-tumor immune response, which we anticipate will translate to a deeper and more durable clinical benefit.

CDK12 has a novel cysteine in the active site of the enzyme, enabling specificity via an irreversible (covalent) binding mode as described for our FGFR program. We have employed structure-based drug discovery efforts from an early co-crystal structure that led to highly specific small molecules to CDK12, as shown by the kinome profile in the figure below.

**Selective CDK12 kinase enzymatic inhibition as demonstrated by kinome profiling of KIN004.**



Kinome tree depicting kinase selectivity for KIN004 at 1000 nM across 275 kinases in single dose, duplicate measurements (272 kinases at Thermo Fisher Scientific and 3 kinases at Reaction Biology Europe GmbH). Percent (%) inhibition is relative to DMSO control. Kinases with >50% inhibition are shown with circle size indicating the relative potency as depicted in the legend. Kinome tree graphic was generated using CORAL (<http://phanstiel-lab.med.unc.edu/CORAL/>).

Following kinome profiling, related CDK family members were tested in radiometric enzymatic assays and demonstrated a >40X selectivity of CDK12 compared to CDK7 and CDK9 and >50X selectivity of CDK12 compared to CDK2. These active sites are highly related among the CDK family members and these selectivity ratios enable specific targeting of CDK12 *in vivo*.

**Inhibitory concentrations 50% (IC<sub>50</sub>s) determined from dose-response inhibition curves of kinases inhibited in the kinome profiling.**

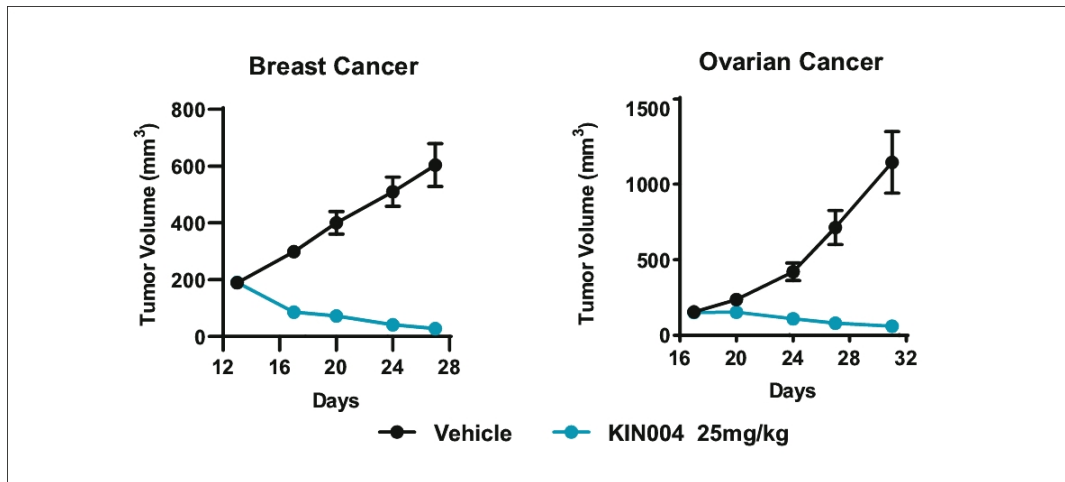
Kinase	KIN004 IC <sub>50</sub> (nM)
CDK12	97
CDK2	5104
CDK7	3913
CDK9	3952
Ratios (Fold Difference in IC <sub>50</sub> )	
CDK12/CDK2	>50X
CDK12/CDK7	>40X
CDK12/CDK9	>40X

KIN004 follow-up 10 point dose response kinase assays demonstrated selective CDK12 inhibition compared to highly homologous CDK2, CDK7, and CDK9 family members. Results in the table represent IC<sub>50</sub> averages (from curves fitted with a 4-parameter analysis) of greater than 3 independent experiments for CDK7, CDK9, and CDK12, and 2 independent experiments for CDK2 performed at Reaction Biology Europe GmbH. All radiometric assays were performed for 30 minutes with an optimal ATP concentration for the respective kinase.



In our preclinical studies, selective CDK12 pharmacological inhibition via biweekly, intravenous administration of a compound in the KIN004 program demonstrated tumor regressions at 25 mg/kg in two independent BRCA1/2 WT breast (HCC70 tumors) and ovarian (OVCAR-3) tumors implanted in athymic nude mice shown in the figure below. This is important as DDR-deficient tumors (e.g. BRCA1 mutant) are hypersensitive to both CDK12 and PARP inhibition. This proof of concept suggests that CDK12 inhibition impacted DDR pathways and has the potential to expand into patient populations beyond those settings that are currently approved for treatment with PARP inhibitors.

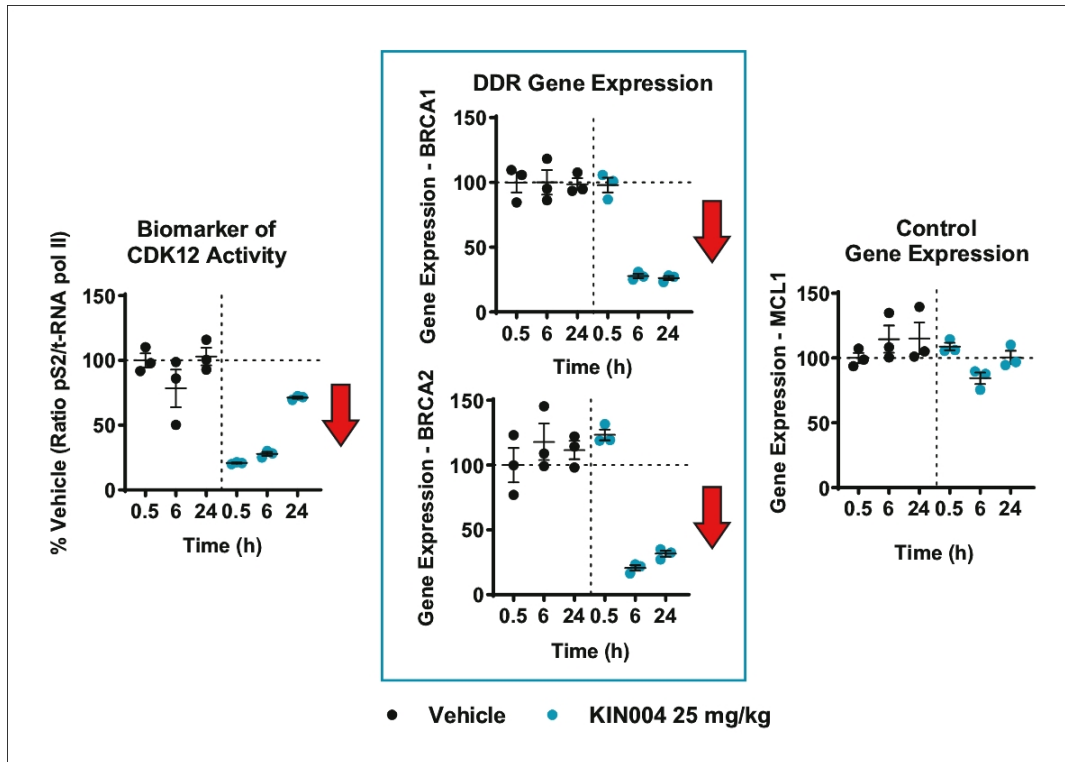
**Anti-tumor activity of KIN004 in DDR-proficient breast and ovarian tumors *in vivo*.**



HCC70 breast tumors (left) and OVCAR-3 ovarian tumors (right) represent BRCA1/2 WT cancers that were DDR-proficient and were not sensitized to PARP inhibitor treatment. KIN004 was dosed at 25 mg/kg twice per week by intravenous administration and tumor volumes represent averages of n=8 tumors / group +/-SEM.

Treatment of HCC70 tumor xenografts with 25 mg/kg KIN004 demonstrated a time-dependent inhibition of biomarkers known to be the target of CDK12 activity in the cell. The same HCC70 tumors demonstrated time-dependent inhibition of gene expression of known DDR genes including BRCA1 and BRCA2 shown in the central panel of the outlined figure below. As a control, MCL1 expression was measured as this gene is regulated by CDK7, and no change in expression was observed. The absence of any effect of KIN004 on gene expression of MCL1 confirmed the selective inhibition of CDK12 over CDK7 that was demonstrated in biochemical assays. This *in vivo* modulation of CDK12-regulated DDR genes in BRCA1/2 WT tumors further supports the mechanism by which DDR-proficient tumors are converted to a DDR-deficient state by selective pharmacological CDK12 irreversible inhibition.

**CDK12 inhibition downregulated DDR gene expression *in vivo* in breast tumors.**



(Left) HCC70 tumors treated with 25 mg/kg KIN004 demonstrated time-dependent inhibition of phosphorylation of RNA Polymerase II on serine 2. Middle (teal outlined cluster of 2 graphs): Treatment of HCC70 tumors with 25 mg/kg KIN004 decreased expression of BRCA1 and BRCA2 as expected since CDK12 activity is well-documented as regulating transcription of these and additional DNA damage response genes. (Right) KIN004 did not modulate MCL1 gene expression *in vivo* and signals selective CDK12 inhibition relative to CDK7 inhibition. CDK7 is known to regulate MCL1 gene expression, a proapoptotic gene, and lack of CDK7 inhibition is expected to leave MCL1 gene expression unaffected as depicted in the graph. All time points represent analysis of n=3 HCC70 tumors for each readout presented. In all figures above, black circles represent untreated tumors (Vehicle) for reference and teal circles represent tumors treated by intravenous administration with 25 mg/kg of KIN004.

We are currently optimizing an orally bioavailable compound series in the KIN004 program. Additionally, we are evaluating fusion-induced neoantigen generation with selective pharmacological CDK12 inhibition in mouse cancer models with intact immune systems. These “proof of mechanism” studies will enable combination efficacy experiments with immune checkpoint inhibitors (ICIs - e.g. anti-PD-1 monoclonal antibody) to understand the synthetic lethality potential of this combination approach. There is an evolving biological understanding of CDK12 inactivating mutations in prostate and ovarian cancers that produce fusion-induced neoantigens, sensitizing these tumors for combinations with ICIs. Currently ICIs are being tested clinically in patients with tumors with naturally occurring inactive CDK12.

#### **Additional Research Programs**

Our Kinnate Discovery Engine is continuing to execute on target and lead identification to develop therapeutics that address oncogenic drivers in high unmet need populations. Additionally, we are exploring intrinsic and acquired resistance mechanisms to drugs that are currently approved or in development to improve clinical benefit and response rates. To enable efficiency, we are leveraging our global collaborations with leaders at a variety of academic centers, respected industry partners, and key opinion leader networks, to identify additional development opportunities that complement our internal research and development efforts.

## Market Opportunity

### **Precision Medicine Opportunity**

We are developing a pipeline of targeted therapeutics for the treatment of genomically defined cancer patient populations. Targeted therapies have transformed the treatment of some cancers by providing substantial clinical benefit and have emerged as an important part of the standard of care for cancer patients. Kinase inhibition is a proven approach to fighting cancer, and for nearly two decades, has addressed an increasing number of oncology indications. Currently approved kinase inhibitors have demonstrated significant clinical benefit to hundreds of thousands of cancer patients globally. The worldwide sales of small molecule kinase inhibitors in oncology were reported to be \$23 billion in 2019 sales and are estimated to grow to more than \$50 billion in 2024. However, because of the limitations of currently approved therapeutics, it is estimated that only 10% of all patients with advanced or metastatic cancer today are eligible for these treatments. Additionally, up to half of these patients may not respond to these treatments and up to half of those who do initially respond may develop resistance. Ultimately, it is estimated that only 2% to 3% of current cancer patients with advanced or metastatic cancer will have durable responses to currently available targeted therapeutics. This low penetration of precision medicine demonstrates a substantial unmet patient need and market opportunity.

### **RAF Program Opportunity**

BRAF mutations occur in approximately 6% of all human cancers, including solid tumors and hematologic malignancies.

In the current RAF inhibitor landscape, no targeted therapies have been approved for Class II or Class III BRAF mutation-driven cancers. We believe this offers a significant opportunity. Class II and Class III BRAF mutations are found broadly in advanced or metastatic cancer patients, including:

- approximately 62% of all BRAF-mutated lung cancers;
- approximately 21% of all BRAF-mutated melanomas; and
- approximately 18% of all BRAF-mutated CRCs.

We believe there are an aggregate of approximately 2.5 million cancer patients in the United States, in France, Germany, Italy, Spain and the United Kingdom (the EU5 countries), and in Japan with active disease across NSCLC, melanoma and CRC. These patients are either (i) newly diagnosed or (ii) have disease that has progressed or recurred, at the same or different stage or site, or (iii) have been diagnosed as having Stage IV cancer in the past. Of these NSCLC, melanoma and CRC patients, approximately 97,000 have advanced or metastatic disease with a Class I, Class II or Class III BRAF mutation, including approximately 29,000 patients who have either a Class II or Class III BRAF mutation.

While these patients with Class II and Class III BRAF mutations represent our initial target patient populations, we believe KIN002787 may also be able to address Class I BRAF mutations, such as the approximate 27,000 patients who have advanced NSCLC and melanoma with Class I BRAF mutations. There are currently three BRAF-targeted kinase inhibitor drugs approved for use in Class I BRAF mutations: Novartis AG's Tafenlar (dabrafenib), Zelboraf (vemurafenib) and Braftovi (encorafenib) are used in BRAF mutated melanomas, Tafenlar (dabrafenib) is also used in BRAF mutated NSCLC and anaplastic thyroid cancer, and Braftovi (encorafenib) is also used in mutated CRC. These three drugs generated over \$1.4 billion in aggregate worldwide sales in 2019.

In addition to NSCLC, melanoma and CRC populations, there are patients with Class II or Class III BRAF mutations in ovarian cancer and thyroid cancer, among other solid tumors. In addition, we believe KIN002787 may be able to treat patients with earlier stage disease, such as the approximate 2,000 patients who have Stage IIIa NSCLC with Class II or Class III BRAF mutations and the approximate 3,500 patients who have Stage III melanoma with Class II or Class III BRAF mutations. Furthermore, we believe that KIN002787 may also be able to treat patients in other geographies with high disease burden like China, where there are approximately 650,000 patients newly diagnosed with NSCLC annually, of which approximately 9,800 patients have advanced NSCLC with a Class II or Class III BRAF mutation.

Due to recent advances in genomic profiling and commercially available diagnostics, many more patients with Class II and Class III BRAF mutations are being identified. As the use of genomic profiling and diagnostics becomes more prevalent, we believe the identified patient population will continue to grow.

### ***FGFR Program Opportunity***

FGFR signaling plays a crucial role in tumor cell proliferation, angiogenesis, migration and survival. While currently approved FGFR inhibitors provide benefit, DoR is limited by various factors, including acquired mutational resistance.

The benefit of FGFR-selective inhibitors is ultimately impeded by the emergence of acquired resistance. These resistance profiles are often caused by gatekeeper and molecular brake variants. We believe there is a significant commercial opportunity to develop a next-generation FGFR inhibitor that will effectively cover the initial fusions or alterations and the common resistance alleles that may eventually develop.

We believe that there are approximately 137,000 UC patients with a tumor-containing FGFR3 alteration in the United States, the EU5 countries and Japan. Of these UC patients, more than 19,000 have metastatic disease which represents our initial target patient population.

It is estimated that in the United States, Europe and Japan, there are approximately 2,500 patients newly diagnosed each year with ICC with advanced or metastatic disease whose disease is driven by an FGFR2 alteration.

Additionally, all patient populations with FGFR2 indels, which are not currently indicated by existing therapies or patients with FGFR alterations in other tumor types are not included in these estimates. Our FGFR program, which we have designed to address a broad set of genomic alterations, may be able to target these patient populations as well. As comprehensive genomic profiling reveals new patient populations with FGFR alterations, we are positioned to explore development of our next-generation FGFR inhibitor in these populations.

### ***CDK12 Program Opportunity***

Therapeutic inhibition of CDK12 presents unique opportunities to sensitize several cancer types to a broad array of proven therapeutic approaches including currently approved PARP inhibitors, conventional chemotherapeutic drugs, and ICIs.

Multiple PARP inhibitors, including Zejula (niraparib), Lynparza (olaparib), Rubraca (rucaparib) and Talzenna (talazoparib) have currently been approved for the treatment of tumors with BRCA and other DNA damage repair alterations, including ovarian, breast and pancreatic cancers. These four drugs generated over \$1.6 billion in aggregate worldwide sales in 2019.

Our CDK12 inhibition-based sensitization strategy may permit enhanced PARP therapeutic targeting with greater clinical benefit in patients who are currently eligible to receive PARP inhibitors and may expand the patient population eligible to receive PARP inhibitors in the future.

Further, CDK12 inhibition-induced sensitization to DNA damage can be evaluated through the combination of a CDK12 inhibitor with either a single agent chemotherapeutic drug or with selected combination chemotherapy regimens which often confer their clinical benefit through induction of DNA damage in tumors. Conventional chemotherapies, despite their limitations of use and toxicity, still represent the cornerstone of systemic treatment for the vast majority of advanced or metastatic cancer patients who are not currently served by targeted therapies.

ICIs have proven clinical benefit in specific solid tumor cancer patient populations. As a drug class, ICIs are reported to have generated over \$28 billion in sales in 2019. In addition, through induction of neoantigens in solid tumors, we anticipate that CDK12 inhibition will sensitize solid tumors to the therapeutic benefit of ICIs.

## Competition

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, the expertise of our team, and our development experience and scientific knowledge provide us with competitive advantages, we face increasing competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Product candidates that we successfully develop and commercialize may compete with existing therapies and new therapies that may become available in the future.

Many of our competitors, either alone or with their collaborators, have significantly greater financial resources, established presence in the market, and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Additional mergers and acquisitions may result in even more resources being concentrated in our competitors.

Our commercial potential could be reduced or eliminated if our competitors develop and commercialize products that are safer or more effective, have fewer or less severe side effects, and are more convenient or less expensive than products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we can, which could result in our competitors establishing a strong market position before we are able to enter the market or could otherwise make our development more complicated. We believe the key competitive factors affecting the success of all of our programs are likely to be efficacy, including DoR and breadth of coverage, safety and patient convenience.

There are currently three BRAF-targeted kinase inhibitor drugs approved for use in Class I BRAF mutations: Novartis AG's Tafenlar (dabrafenib), Zelboraf (vemurafenib) and Braftovi (encorafenib) are used in BRAF mutated melanomas, Tafenlar (dabrafenib) is also used in BRAF mutated NSCLC and anaplastic thyroid cancer, and Braftovi (encorafenib) is also used in mutated CRC. PLX8394, a BRAF homodimer disruptor, is currently in Phase II clinical trials with NovellusDx Ltd., but is limited to a subset of BRAF Class II alterations that are driven by BRAF homodimers. Second-generation BRAF dimer signaling inhibitors, such as LXH254 and HM95573, designed to inhibit MAPK pathway signaling without causing pathway rebound, are in Phase I clinical trials with Novartis AG and Genentech, a member of the Roche Group, respectively. Mapkure, LLC's BGB3245 is also currently in clinical development and there are other RAF inhibitors currently in development.

There are two currently approved selective FGFR2 and FGFR3 inhibitors: Incyte Corporation's Pemazyre (pemigatinib) and Janssen Biotech, Inc.'s Balversa (erdafitinib). There are a number of programs in clinical development, including Taiho Oncology, Inc.'s TAS120 (futibatinib) and QED Therapeutics, Inc.'s BGJ398. Relay Therapeutics, Inc. has an FGFR2-specific candidate in clinical development (RLY4008) that has been shown to be FGFR1-sparing, which may indicate less measurable hyperphosphatemia, a challenge associated with this class of medications that can be managed clinically, but it has shown limited potency against FGFR3. FGFR1-sparing approaches, such as Relay's FGFR2 candidate, are believed to be typically less effective at inhibiting the N550 molecular brake mutation, a highly fit mutation that can drive resistance.

## Our Scientific Collaborations and Our Scientific Advisory Board

To help advance our programs, we are working with Massachusetts General Hospital Cancer Center, a leading clinical research institution, and plan to enter into additional collaborations. Each of these collaborations is (or will be) focused on translational strategies to support the clinical study of our new therapy candidates. For example, we will work with these research organizations to:

- define emerging patient populations;

- demonstrate selective *in vitro* and *in vivo* activity and define dose-exposure pharmacodynamic relationships in clinically relevant models;
- test prioritized compounds against specific mutations and fusions;
- investigate mechanism of action—the specific biochemical interaction through which a drug substance produces its pharmacological effect—to support the refinement of strategies for patient selection and patient stratification for both monotherapy and rationale combinations; and
- develop biomarker-based development strategies that will drive patient selection in our clinical programs.

Further, we have built a scientific advisory board with experts in the field of oncology. Our scientific advisors include researchers who publish widely-cited research on topics relevant to the study and treatment of cancer, lead clinical units at experienced precision medicine cancer centers in the United States and are actively involved in our drug development process and programs. Our scientific advisory board currently includes:

- **Keith Flaherty, M.D.**, Director of Clinical Research at the Massachusetts General Hospital Cancer Center, and Professor of Medicine at Harvard Medical School. Dr. Flaherty was a co-founder of Loxo Oncology, Inc. and is on our board of directors.
- **Ryan Corcoran, M.D., Ph.D.**, Director of the Gastrointestinal Cancer Center Program, Scientific Director of the Termeer Center for Targeted Therapy at the Massachusetts General Hospital Cancer Center and Associate Professor of Medicine at Harvard Medical School.
- **Ezra Cohen, M.D.**, Co-Director of the San Diego Center for Precision Immunotherapy, Assistant Director for Translational Science, and head of the Solid Tumor Therapeutics research program at Moores Cancer Center at UCSD.
- **Luis Alberto Diaz, Jr., M.D.**, Head of the Division of Solid Tumor Oncology, Grayer Family Chair, at Memorial Sloan Kettering Cancer Center.
- **Andrew Lowy, M.D.**, Professor of Surgery, Chief of the Division of Surgical Oncology and Clinical Director for Cancer Surgery at Moores Cancer Center at UCSD.
- **John Iafrate, M.D.**, Professor of Pathology at Harvard Medical School and Director of the Center for Integrated Diagnostics at the Massachusetts General Hospital Cancer Center.

We have also established collaborations through service agreements with global CROs, under which we utilize over 150 full-time equivalent personnel to provide scale and expertise in areas including, among others, research chemistry, chemical manufacturing, biology, pharmacology and toxicology, and clinical studies.

### Intellectual Property

We strive to protect and enhance the proprietary technology, inventions and improvements that are commercially important to our business, including seeking, maintaining and defending our patent rights. We own the patent applications relating to our lead and planned product candidates. Our policy is to seek to protect our proprietary position by, among other methods, filing patent applications in the United States and in jurisdictions outside of the United States directed to our proprietary technology, inventions, improvements and product candidates that are important to the development and implementation of our business. We also rely on trade secrets and know-how relating to our proprietary technology and product candidates and continuing innovation to develop, strengthen and maintain our proprietary position in the field of oncology. We also plan to rely on data exclusivity, market exclusivity and patent term extensions when available. Our commercial success will depend in part on our ability to obtain and maintain patent and other proprietary 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 may own or license in the future; and to operate without infringing on the valid and enforceable patents and other proprietary rights of third parties.



As of October 15, 2020, our patent portfolio consisted of pending patent applications that we own related to our RAF, FGFR and CDK12 programs. In total, as of that date, we owned two pending U.S. non-provisional patent applications, thirteen pending U.S. provisional patent applications and ten pending foreign patent applications, including six international patent applications filed under the Paris Cooperation Treaty (PCT application) and two filings each in Argentina and Taiwan.

More specifically, with respect to our RAF program, we own one pending U.S. non-provisional patent application and three pending foreign patent applications, including a PCT application and a patent application each in Argentina and Taiwan, with claims directed to our first-generation RAF inhibitory compounds, as composition of matter, as well as claims directed to pharmaceutical compositions comprising such compounds and uses of such compounds. Any patents that may issue from our pending patent applications are expected to expire in April 2040, absent any patent term adjustments or patent term extensions for regulatory delay. Additionally, we own one PCT application and five pending U.S. provisional patent applications directed to other RAF inhibitory compounds as composition of matter including KIN002787, pharmaceutical compositions comprising such compounds, and related methods of using such compounds. Any patents that may issue from these pending patent applications are expected to expire in 2040 or 2041 absent any patent term adjustments or extensions.

With respect to our FGFR program, we own three pending U.S. provisional applications and one pending PCT application with claims directed to KIN003 and other FGFR inhibitory compounds, as composition of matter, as well as claims directed to pharmaceutical compositions comprising such compounds and uses of such compounds. Any patents that may issue from our pending patent applications are expected to expire in 2040 or 2041, absent any patent term adjustments or patent term extensions for regulatory delay.

With respect to our CDK12 program, we own one pending U.S. non-provisional patent application, four pending U.S. provisional applications, and three pending foreign patent applications, including a PCT application and a patent application each in Argentina and Taiwan, with claims directed to KIN004 and other related compounds, as composition of matter, as well as claims directed to pharmaceutical compositions comprising such compounds and uses of such compounds. Any patents that may issue from our pending patent applications are expected to expire between June 2039 and December 2040, absent any patent term adjustments or patent term extensions for regulatory delay. We also own one pending U.S. provisional application and two pending PCT applications directed to other CDK12 inhibitory compounds as composition of matter, pharmaceutical compositions comprising such compounds, and related methods of using such compounds. Any patents that may issue from these pending patent applications are expected to expire between 2040 and 2041 absent any patent term adjustments or extensions.

We also possess substantial know-how and trade secrets relating to the development and commercialization of our product candidates, including related manufacturing processes and technology.

With respect to our product candidates and processes that we intend to develop and commercialize in the normal course of business, we intend to pursue patent protection covering, when possible, compositions, methods of use, dosing and formulations. We may also pursue patent protection with respect to manufacturing and drug development processes and technologies.

Issued patents can provide protection for varying periods of time, depending upon the date of filing of the patent application, the date of patent issuance and the legal term of patents in the countries in which they are obtained. In general, patents issued for applications filed in the United States can provide exclusionary rights for 20 years from the earliest effective filing date. In addition, in certain instances, the term of an issued U.S. patent that covers or claims an FDA approved product can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period, which is called patent term extension. 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 term of patents outside of the United States varies in accordance with the laws of the foreign jurisdiction, 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.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the scope of claims allowable in patents in the field of oncology has emerged in the United States. The relevant patent laws and their interpretation outside of the United States are also uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our technology or product candidates and could affect the value of such intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell or importing products that infringe our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our technology, inventions and improvements. We cannot guarantee that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may file in the future, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our products, the methods of use or manufacture of those products. Moreover, even our issued patents may not guarantee us the right to practice our technology in relation to the commercialization of our products. Patent and other intellectual property rights in the pharmaceutical and biotechnology space are evolving and involve many risks and uncertainties. For example, third parties may have blocking patents that could be used to prevent us from commercializing our product candidates and practicing our proprietary technology, and our issued patents may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or could limit the term of patent protection that otherwise may exist for our product candidates. In addition, the scope of the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies that are outside the scope of the rights granted under any issued patents. For these reasons, we may face competition with respect to our product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any patent protection for such product may expire or remain in force for only a short period following commercialization, thereby reducing the commercial advantage the patent provides.

### **Commercialization**

We intend to retain significant development and commercial rights to our product candidates and, if marketing approval is obtained, to commercialize our product candidates on our own, or potentially with a partner, in the United States and other regions. We currently have no sales, marketing or commercial product distribution capabilities. We intend to build the necessary infrastructure and capabilities over time for the United States, and potentially other regions, following further advancement of our product candidates. Clinical data, the size of the addressable patient population, the size of the commercial infrastructure and manufacturing needs may all influence or alter our commercialization plans.

### **Manufacturing**

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical and clinical testing, as well as for commercial manufacturing if any of our product candidates obtain marketing approval. We also rely, and expect to continue to rely, on third parties to package, label, store and distribute our investigational product candidates, as well as our commercial products if marketing approval is obtained. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment and personnel while also enabling us to focus our expertise and resources on the development of our product candidates.

To date, we have obtained active pharmaceutical ingredients (API) and drug product for our product candidates from Regis Technologies, Inc. and Serán BioScience, Inc., respectively, upon whom we

currently rely as single-source CMOs. We are in the process of developing our supply chain for each of our product candidates and intend to put in place framework agreements under which third-party CMOs will generally provide us with necessary quantities of API and drug product on a project-by-project basis based on our development needs.

As we advance our product candidates through development, we will explore adding backup suppliers for the API and drug product for each of our product candidates to protect against any potential supply disruptions.

We generally expect to rely on third parties for the manufacture of any companion diagnostics we may develop.

### **Government Regulation**

Government authorities in the United States at the federal, state and local level and in other countries regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and biological products. Generally, before a new drug can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

### ***U.S. Drug Development***

In the United States, the FDA regulates drugs under the Food, Drug, and Cosmetic Act (FDCA). Drugs also are subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or post-market may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Our product candidates are considered small molecule drugs and must be approved by the FDA through the NDA process before they may be legally marketed in the United States. The process generally involves the following:

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with GLP;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent IRB, or ethics committee at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, good clinical practice (GCP) requirements and other clinical trial-related regulations to establish substantial evidence of the safety and efficacy of the investigational product for each proposed indication;
- submission to the FDA of an NDA after completion of all pivotal trials;
- determination by the FDA within 60 days of its receipt of an NDA to accept the filing for substantive review;

- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the drug will be produced to assess compliance with cGMP requirements assuring that the facilities, methods and controls are adequate to preserve the drug's 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 filing;
- FDA review and approval of the NDA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug in the United States; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy (REMS), and the potential requirement to conduct post-approval studies.

The data required to support an NDA are generated in two distinct developmental stages: preclinical and clinical. The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for any current and future product candidates will be granted on a timely basis, or at all.

### **Preclinical Studies and IND**

The preclinical developmental stage generally involves laboratory evaluations of drug chemistry, formulation and stability, as well as studies to evaluate toxicity in animals, which support subsequent clinical testing. The sponsor 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 the IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin.

Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as *in vitro* and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, to the FDA as part of an IND. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises 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 before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

### **Clinical Trials**

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an institutional review board (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 must also approve the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial 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 generally accept a well-designed and well-conducted foreign clinical trial not conducted under an IND if the trial was conducted in accordance with the ethical principles contained in the Declaration of Helsinki pursuant to 21 CFR 312.120(c)(4), incorporating the 1989 version of the Declaration, or with the laws and regulations of the foreign regulatory authority where the trial was conducted, such as the European Medicines Agency (EMA), whichever provides greater protection of the human subjects, and with GCP and GMP 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.

Clinical trials in the United States generally are conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3, and may overlap.

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, tolerability and safety of the drug.
- Phase 2 clinical trials involve studies in disease-affected patients to determine the dose and dosing schedule required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, possible adverse effects and safety risks are identified, and a preliminary evaluation of efficacy is conducted.
- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use and its safety in use, and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, are conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA. The sponsor is also responsible for submitting written IND safety reports, including reports of serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the drug, findings from animal or *in vitro* testing that suggest a significant risk for human subjects, and any clinically significant increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure.

Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated check-points based on access to certain data from the trial.

Concurrent with clinical trials, companies usually complete additional animal safety studies and also must develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process, as performed by the manufacturing facility, must be capable of

consistently producing quality batches of our product candidates. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that our product candidates do not undergo unacceptable deterioration over their labeled shelf life.

We may be required to develop and implement additional clinical trial policies and procedures designed to help protect subjects from the COVID-19 virus. For example, in March 2020, the FDA issued a guidance, which the FDA subsequently updated, on conducting clinical trials during the pandemic, which describes a number of considerations for sponsors of clinical trials impacted by the pandemic, including the requirement to include in the clinical trial report contingency measures implemented to manage the clinical trial, and any disruption of the clinical trial as a result of the COVID-19 pandemic; a list of all subjects affected by the COVID-19-pandemic related study disruption by unique subject identifier and by investigational site and a description of how the individual's participation was altered; and analyses and corresponding discussions that address the impact of implemented contingency measures (e.g., participant discontinuation from investigational product and/or study, alternative procedures used to collect critical safety and/or efficacy data) on the safety and efficacy results reported for the clinical trial. In June 2020, FDA also issued a guidance on good manufacturing practice considerations for responding to COVID-19 infection in employees in drug products manufacturing, including recommendations for manufacturing controls to prevent contamination of drugs.

### ***NDA Review Process***

Following completion of the clinical trials, data is analyzed to assess whether the investigational product is safe and effective for the proposed indicated use or uses. The results of preclinical studies and clinical trials are then submitted to the FDA as part of an NDA, along with proposed labeling, chemistry and manufacturing information to ensure product quality and other relevant data. In short, the NDA is a request for approval to market the drug in the United States for one or more specified indications and must contain proof of safety and efficacy for a drug.

The application must include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. 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 the FDA. FDA approval of an NDA must be obtained before a drug may be legally marketed in the United States.

Under the Prescription Drug User Fee Act (PDUFA), as amended, each NDA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for each marketed human drug. 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 for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews all submitted NDAs before it accepts them for filing and may request additional information rather than accepting the NDA for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has 10 months, from the filing date, in which to complete its initial review of a new molecular-entity NDA and respond to the applicant, and six months from the filing date of a new molecular-entity NDA designated for priority review. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs, and the review process is often extended by FDA requests for additional information or clarification.

Before approving an NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel drug products or drug 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 an advisory committee, but it considers such recommendations when making decisions on approval. The FDA likely will reanalyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. After the FDA evaluates an NDA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug 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 in the NDA identified by the FDA. The Complete Response Letter may require additional clinical data, additional pivotal Phase 3 clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, preclinical studies and/or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA's interpretation of data may differ from our interpretation.

### ***Orphan Drugs***

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally 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 and for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product.

Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition 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 to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety or providing a major contribution to patient care or in instances of drug supply issues. However, competitors may receive approval of either a different product for the same indication or the same product for a different indication but that could be used off-label in the orphan indication. Orphan drug exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval before we do for the same product, as defined by the FDA, for the same indication for which we are seeking approval, or if a product candidate is determined to be contained within the scope of the competitor's product for the same indication. If one of our products designated as an orphan drug receives marketing approval for an indication broader than that which is designated, it may not be entitled to orphan drug exclusivity. Orphan drug status in the European Union has similar, but not identical, requirements and benefits.

### ***Expedited Development and Review Programs***

The FDA has a fast track program that is intended to expedite or facilitate the process for reviewing new drugs that meet certain criteria. Specifically, new drugs are eligible for fast track designation if they are intended to treat a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to both the product and the specific indication for which it is being studied. The sponsor can request the FDA to designate the product for fast track status any time before receiving NDA approval, but ideally no later than the pre-NDA meeting with the FDA.

Any product submitted to the FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it treats a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies.

A product may also be eligible for accelerated approval, if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (IMM), which is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. FDA may withdraw drug approval or require changes to the labeled indication of the drug if confirmatory post-market trials fail to verify clinical benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with the drug. If the FDA concludes that a drug shown to be effective can be safely used only if distribution or use is restricted, it may require such post-marketing restrictions as it deems necessary to assure safe use of the product.

Additionally, a drug may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. The benefits of breakthrough therapy designation include the same benefits as fast track designation, plus intensive guidance from the FDA to ensure an efficient drug development program. Fast track designation, priority review, accelerated approval and breakthrough therapy designation do not change the standards for approval, but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or may decide that the time period for FDA review or approval will not be shortened.

### ***Post-approval Requirements***

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping requirements, requirements to report adverse events and comply with promotion and advertising requirements, which include restrictions on promoting drugs for unapproved uses or patient populations, known as “off-label promotion,” and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such uses. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Further, if there are any modifications to the drug, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or NDA 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 REMS, to assure the safe use of the product. A REMS 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. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. 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 letters, or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications;
- suspension or revocation of product approvals;
- product seizure or detention;
- refusal to permit the import or export of products; 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. Drugs 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.

#### ***Other U.S. Regulatory Matters***

Pharmaceutical manufacturers are subject to various healthcare laws, regulation, and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such healthcare regulatory matters include, without limitation:

- Our conduct, including those of our employees, as well as our business operations and relationships with third parties, including current and future arrangements with healthcare providers, third-party payors, customers, and others may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which we research, as well as, sell, market, and distribute any products for which we obtain marketing approval. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include, but are not limited to: the federal Anti-Kickback Statute, which makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Moreover, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act.
- The federal false claims, including the civil False Claims Act that can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalties prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government, and/or impose exclusions from federal health care programs and/or penalties for parties who engage in such prohibited conduct.
- The Federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations also impose obligations on covered entities such as health

insurance plans, healthcare clearinghouses, and certain health care providers and their respective business associates, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.

- The federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to Centers for Medicare & Medicaid Services (CMS) information regarding certain payments and other transfers of value to physicians, as defined by such law, and teaching hospitals as well as information regarding ownership and investment interests held by physicians and their immediate family members; additionally, President Trump signed into law in 2018 the "Substance Use-Disorder Prevention that Promoted Opioid Recovery and Treatment for Patients and Communities Act" which, under the provision entitled "Fighting the Opioid Epidemic with Sunshine," in part, extends the reporting and transparency requirements for physicians under the Physician Payments Sunshine Act to physician assistants, nurse practitioners, and other mid-level practitioners, with reporting requirements going into effect in 2022 for payments made in 2021.
- Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, state laws that require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and require the registration of their sales representatives, state laws that require biotechnology companies to report information on the pricing of certain drug products, and state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Pricing and rebate programs must also comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the ACA. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws. In addition, the distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act as well as other applicable consumer safety requirements.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in significant civil, criminal and administrative penalties, including damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, injunctions, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals or refusal to allow a firm to enter into supply contracts, including government contracts.

#### ***U.S. Patent-term Restoration and Marketing Exclusivity***

Depending upon the timing, duration and specifics of FDA approval of any future product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits restoration of the patent term of up to five years as compensation for patent term lost during product development and FDA regulatory review process. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's

approval date. The patent-term restoration period is generally one-half the time between the effective date of an IND or the issue date of the patent, whichever is later, and the submission date of an NDA plus the time between the submission date of an NDA or the issue date of the patent, whichever is later, and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

Market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application (ANDA), or a 505(b)(2) NDA submitted by another company for a generic version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness or generate such data themselves.

### ***European Union Drug Development***

Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the EU, the EU Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the member state regimes. Under the current regime, before a clinical trial can be initiated, it must be approved in each of the EU countries where the trial is to be conducted by two distinct bodies: the National Competent Authority (NCA), and one or more Ethics Committees (ECs). Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the Member State where they occurred.

The EU clinical trials legislation currently is undergoing a transition process mainly aimed at harmonizing and streamlining clinical-trial authorization, simplifying adverse-event reporting procedures, improving the supervision of clinical trials and increasing their transparency. Recently enacted Clinical Trials Regulation EU No 536/2014 ensures that the rules for conducting clinical trials in the EU will be identical. In the meantime, Clinical Trials Directive 2001/20/EC continues to govern all clinical trials performed in the EU.

### ***European Union Drug Review and Approval***

In the European Economic Area (EEA), which is comprised of the 28 Member States of the European Union and three European Free Trade Association States (Norway, Iceland and Liechtenstein), medicinal products can only be commercialized after obtaining a Marketing Authorization (MA). There are two types of marketing authorizations.

- The Community MA is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use (CHMP), of the EMA, and is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicines such as gene-therapy, somatic cell-therapy or tissue-engineered medicines and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.
- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member States through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State (RMS). The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics (SOPC), and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Member States Concerned) for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SOPC, labeling or packaging proposed by the RMS, the product is subsequently granted a national MA in all the Member States (i.e., in the RMS and the Member States Concerned).

Under the above described procedures, before granting the MA, EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. Similar to the U.S. patent term-restoration, Supplementary Protection Certificates (SPCs) serve as an extension to a patent right in Europe for up to five years. SPCs apply to specific pharmaceutical products to offset the loss of patent protection due to the lengthy testing and clinical trials these products require prior to obtaining regulatory marketing approval.

### ***Coverage and Reimbursement***

Sales of our products will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. 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 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, no uniform policy of coverage and reimbursement for drug products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products will be made on a payor-by-payor basis.

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. 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 products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

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, in most foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

### ***Healthcare Reform***

The United States government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. For example, the ACA substantially changed the way healthcare is financed by both the government and private insurers, and continues to significantly impact the U.S. pharmaceutical industry. The ACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the HHS Secretary as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price (AMP), to 23.1% of AMP and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits. Additionally, for a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer.

There remain judicial and Congressional challenges to certain aspects of the ACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed several Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, 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, several bills affecting the implementation of certain taxes under the ACA have passed. On December 22, 2017, President Trump signed into law new federal tax legislation commonly referred to as the Tax Cuts and Jobs Act (the Tax Act) which includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual

mandate.” 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. The Bipartisan Budget Act of 2018 (the BBA), among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare Part D drug plans. In December 2018, CMS published a new final rule permitting further collections and payments to and from certain ACA-qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On April 27, 2020, the United States Supreme Court reversed a federal circuit decision that previously upheld Congress’ denial of \$12 billion in “risk corridor” funding. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit upheld the District Court ruling 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. It is unclear how such litigation and other efforts to repeal and replace the ACA will impact the ACA and our business. We will continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business. Complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2030 unless additional congressional action is taken. The CARES Act, which was signed into law on March 27, 2020, and designed to provide financial support and resources to individuals and businesses affected by COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020, through December 31, 2020, and extended the sequester by one year, through 2030, in order to offset the added expense of the 2020 cancellation. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations.

Additionally, there has been heightened governmental scrutiny recently over the manner in which drug 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. For example, at the federal level, the Trump administration’s budget proposals 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. Additionally, 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 has solicited feedback on some of these measures and has implemented others under its authority. 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. For example, on July 24, 2020, the Trump administration announced four executive orders to lower drug prices, including allowing importation of certain drugs, changing how drug rebates are negotiated by middlemen, like pharmacy benefit managers, and directing such rebates to be passed to patients as point-of-sale discounts, and requiring Medicare to pay certain Part B drugs at the lowest price available in economically comparable countries. President Trump has delayed the effective

date of the international drug pricing order, pending discussion with major drug companies. How these executive orders will be implemented and their impact on the industry remain uncertain. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We are unable to predict the future course of federal or state healthcare legislation in the United States directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. 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. These and any further changes in the law or regulatory framework that reduce our revenue or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations.

### **Facilities**

Our corporate headquarters are located in San Diego, California, where we lease 3,676 square feet of office space, under a lease that expires on December 31, 2020. We have not yet determined whether we will seek to renew this lease, enter into a lease for other office space, or take an alternative approach to our office space needs in the future. We believe that this existing facility is adequate for our current needs and that suitable additional or alternative space will be available in the future on commercially reasonable terms, if required.

### **Employees**

As of September 30, 2020, we had 27 full-time employees. Of these employees, 21 were engaged in research and development activities. Substantially all of our employees are based in San Diego, California and San Francisco, California. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

### **Legal Proceedings**

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not currently a party to any material legal proceedings. Regardless of outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

## MANAGEMENT

### Executive Officers and Directors

The following table sets forth the names and positions of our executive officers and directors and their ages as of September 30, 2020:

Name	Age	Position
<b>Executive Officers:</b>		
Nima Farzan	44	President, Chief Executive Officer and Director
Mark Meltz	47	Chief Operating Officer, General Counsel, Treasurer and Secretary
Eric Murphy, Ph.D.	45	Chief Scientific Officer
Richard Williams, MBBS, Ph.D.	52	Chief Medical Officer
<b>Non-Employee Directors:</b>		
Dean Mitchell	64	Chair and Director
Melissa Epperly*	47	Director
Keith Flaherty, M.D.	50	Director
Carl Gordon, Ph.D.	55	Director
Stephen Kaldor, Ph.D.	58	Director
Michael Rome, Ph.D.	36	Director
Laurie Smaldone Alsup, M.D.	66	Director
Jim Tananbaum, M.D.	57	Director

(1) Member of the audit committee

(2) Member of the compensation committee

(3) Member of the corporate governance and nominating committee

\* Ms. Epperly was appointed to the board of directors in October 2020

### Executive Officers

*Nima Farzan* has served as our President and Chief Executive Officer and as a member of our board of directors since March 2020. Mr. Farzan has also served as an Executive in Residence at Foresite Capital, a venture capital fund, from February 2020 to March 2020. From October 2018 to March 2020, Mr. Farzan worked as an advisor to various life sciences companies, including Emergent BioSolutions Inc. and MODA Pharmaceuticals. Prior to joining us, Mr. Farzan was with PaxVax, Inc. (now part of Emergent BioSolutions Inc.), a biopharmaceutical company, where he served initially as Chief Operating Officer and then Chief Executive Officer and President from September 2011 to October 2018. From August 2004 to September 2011, he served in a number of roles at Novartis AG a pharmaceutical company, including VP, Global Program Head for Metabolic Disease and VP, US Marketing at Novartis Vaccines and Diagnostics, a division of Novartis. Mr. Farzan currently serves on the board of directors of Keros Therapeutics, Inc. (Nasdaq: KROS). Mr. Farzan holds a B.A. in Human Biology from Stanford University and an M.B.A. from Harvard Business School.

We believe Mr. Farzan is qualified to serve on our board of directors because of the perspective and experience he brings as our Chief Executive Officer, his experience in leadership positions in the biotechnology industry, his educational background and his strong scientific knowledge.

*Mark Meltz* has served as our Chief Operating Officer and General Counsel since April 2020 and our Treasurer and Secretary since May 2020. Prior to joining us, from March 2019 to February 2020 he served as Senior Vice President and General Counsel at Audentes Therapeutics, Inc., a biotechnology company. From June 2014 to March 2019, Mr. Meltz served as Executive Vice President and Chief Business Development and Legal Officer at PaxVax, Inc. (now part of Emergent BioSolutions Inc.), a biotechnology company. From April 2012 to June 2014, Mr. Meltz served as Associate General Counsel at

Biogen Inc., a biotechnology company. From May 2007 to March 2012, Mr. Meltz was with Novartis Vaccines and Diagnostics, a division of Novartis, a biotechnology company, where he served most recently as Head, Legal, North America. He holds a B.A. in Psychology from Yale University and a J.D. from Boston College Law School.

*Eric Murphy, Ph.D.* co-founded Kinnate Biopharma Inc. and has served as our Chief Scientific Officer since January 2018. Dr. Murphy also served on our board of directors from January 2018 until March 2020. Prior to joining us, he was with Crown Bioscience, a translational research and pharmacology company, from January 2016 to October 2017, where he served as Global Head, Oncology R&D Strategy and External Innovations and Global Scientific Director, Translational Oncology. From March 2014 to June 2015, Dr. Murphy served as Director, Discovery Biology at Samumed LLC, a biopharmaceutical company. From July 2011 to March 2014, Dr. Murphy served as a Research Investigator at the Genomics Institute of the Novartis Research Foundation. From May 2005 to June 2011, Dr. Murphy served in multiple positions at the Moores UCSD Cancer Center, initially as a Research Associate from 2005 to 2007 and then as an Assistant Project Scientist from 2008 to 2011. From March 2003 to May 2005, Dr. Murphy was a postdoctoral fellow at the Scripps Research Institution. Dr. Murphy holds a B.S. in Biochemistry from the University of California, Davis and a Ph.D. in Biology/Biological Sciences from the University of California, Irvine.

*Richard Williams, MBBS, Ph.D.* has served as our Chief Medical Officer since June 2020. Prior to joining us, he was with WuXi NextCODE Genomics USA, Inc. (now known as Genuity Science, Inc.) from March 2018 to June 2020, where he served most recently as Chief Medical Officer from June 2019 to June 2020. From January 2017 to February 2018, Dr. Williams served as the Medical Director and Group Medical Director at GRAIL, Inc. a biotechnology company. From September 2015 to January 2017, Dr. Williams was with Amgen, where he most recently served as Head, Early Development Oncology Group from June 2016 to January 2017. From November 2012 to September 2015, Dr. Williams was with Puma Biotechnology, Inc. where he most recently served as the Senior Medical Director, Clinical Research & Development from November 2013 to September 2015. From September 2010 to November 2012, Dr. Williams was with Amgen as Clinical Research Medical Director in their Global Development (late phase) group. Dr. Williams holds an MBBS, in Medicine and Surgery and a Ph.D. in Cancer Biology from the University of Queensland.

#### **Non-Employee Directors**

*Dean Mitchell* has served as a member of our board of directors since August 2020 and has served as the Chair of our board of directors since August 2020. Mr. Mitchell also served as Executive Chair of the board of directors of Covis Pharma Holdings, a specialty pharmaceutical company, from July 2013 until its sale in March 2020. He previously served as Chair of PaxVax, a biopharmaceutical company, from October 2016 to October 2018. Prior to that, he served as President and Chief Executive Officer of Lux Biosciences, Inc., a biotechnology company focusing on the treatment of ophthalmic diseases, from July 2010 to July 2013. Mr. Mitchell served as President and Chief Executive Officer of Lux Biosciences, Inc., a biotechnology company focusing on the treatment of ophthalmic diseases, from July 2010 to August 2013. Prior to Lux Biosciences, he served as President and Chief Executive Officer of both Alkermes, Inc., a publicly traded specialty pharmaceutical company, from 2006 until its acquisition by King Pharmaceuticals, Inc. in 2008, and Guilford Pharmaceuticals, Inc., a publicly traded pharmaceutical company focused in oncology and acute care, from 2004 until its acquisition by MGI Pharma Inc. in 2005. From 2001 to 2004 he served in various senior executive capacities in the worldwide medicines group of Bristol-Myers Squibb Company, a pharmaceutical company. Prior to the Bristol-Myers Squibb Company, he spent 14 years at GlaxoSmithKline plc, in assignments of increasing responsibility spanning sales, marketing, general management, commercial strategy and clinical development and product strategy. Mr. Mitchell also serves on the boards of directors of ImmunoGen, Inc. (Nasdaq: IMGN), Precigen, Inc. (Nasdaq: PGEN) and Theravance BioPharma, Inc. (Nasdaq: TBPH). Mr. Mitchell holds a B.S. in Applied Biology from Coventry University and an M.B.A. from Cass Business School, London.

We believe that Mr. Mitchell's qualifications to serve on our board of directors include his management experience in the pharmaceutical and biotherapeutics industries and his experience as an executive officer and board member of several biotechnology companies.

*Melissa Epperly* has served on our board of directors since October 2020. Ms. Epperly has served as Chief Financial Officer at Zentalis Pharmaceuticals, Inc. since September 2019. Prior to her current position, she served as Chief Financial Officer of PsiOxus Therapeutics Ltd., a clinical-stage gene therapy cancer company, from June 2018 to August 2019. Prior to that, Ms. Epperly also served as Chief Financial Officer and Head of Business Development at R-Pharm US, a commercial-stage oncology company, from October 2015 to June 2018. Ms. Epperly also served as a Director at Anchorage Capital Group, a credit-focused hedge fund from August 2012 to September 2015. Ms. Epperly holds a B.A. in Biochemistry and Economics from the University of Virginia and an M.B.A. from Harvard Business School.

We believe Ms. Epperly is qualified to serve on our board of directors because she brings extensive experience as a senior financial executive in the life sciences industry.

*Keith Flaherty, M.D.* has served as a member of our board of directors since December 2019. Dr. Flaherty is the Director of Clinical Research at Massachusetts General Hospital Cancer Center, where he has worked since July 2009. Since July 2009, Dr. Flaherty has served as an Associate Professor of Medicine at Harvard Medical School and since October 2015 as Professor of Medicine. He has also served as the Chair of the Developmental Therapeutics Committee at the Eastern Cooperative Oncology Group and American College of Radiology Imaging Network (ECOG-ACRIN) Cancer Research Group, and in April 2013 he was appointed as the ECOG Deputy Chair for Biomarker Science. Dr. In September 2018, Dr. Flaherty joined the National Cancer Institute (NCI) Board of Scientific Advisors. Dr. Flaherty trained in internal medicine at Brigham and Women's Hospital, and in medical oncology at the University of Pennsylvania, earning board certifications in these specialties. Dr. Flaherty currently serves on the boards of directors of Clovis Oncology, Inc. (Nasdaq: CLVS) and Checkmate Pharmaceuticals, Inc. (Nasdaq: CMPI), and formerly served on the board of Loxo Oncology, Inc. (Nasdaq: LOXO) (acquired by Eli Lilly and Company). Dr. Flaherty holds an M.D. from The Johns Hopkins School of Medicine and a B.S. in Neurobiology from Yale University.

We believe Dr. Flaherty is qualified to serve on our board of directors because of his scientific and educational background and his extensive expertise in the oncology field.

*Carl Gordon, CFA, Ph.D.* has served on our board of directors since December 2019. Dr. Gordon is a founding partner, Managing Partner, and Co-Head of Global Private Equity at OrbiMed Advisors LLC, an investment firm, since January 1998. Dr. Gordon currently serves on the boards of directors of Keros Therapeutics, Inc. (Nasdaq: KROS), Turning Point Therapeutics, Inc. (Nasdaq: TPTX) and Prevail Therapeutics, Inc. (Nasdaq: PRVL), as well as several private companies. Dr. Gordon previously served on the boards of directors of Alector Inc. (Nasdaq: ALEC), X4 Pharmaceuticals, Inc. (formerly Arsanis, Inc.) (Nasdaq: XFOR), Acceleron Pharma Inc., (Nasdaq: XLRN), ARMO BioSciences, Inc. (Nasdaq: ARMO), Intellia Therapeutics, Inc. (Nasdaq: NTLA), Selecta Biosciences, Inc. (Nasdaq: SELB), SpringWorks Therapeutics, Inc. (Nasdaq: SWTX) and Passage Bio Inc. (Nasdaq: PASG). Dr. Gordon holds 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.

We believe Dr. Gordon is qualified to serve on our board of directors because of his extensive expertise and experience investing in the life science industry.

*Stephen Kaldor, Ph.D.* has served on our board of directors since January 2018. Dr. Kaldor co-founded Kinnate Biopharma, Inc. in January 2018 and served as our President and Chief Executive Officer until March 2020. He has served as a consultant to the Company since March 2020, and also currently serves as a Strategic Advisor at Frontera Pharmaceuticals, a biopharmaceutical company, a position he has held since March 2016. Prior to joining us, Dr. Kaldor served as Chief Executive Officer of Quantice Pharmaceuticals, Inc., a cancer drug biotechnology company, from February 2011 until its acquisition by Celgene Corporation in April 2015. Prior to that, Dr. Kaldor served as President and Chief Executive Officer of Ambrx Inc., a biotechnology company, from July 2007 to June 2010. He was also President and Chief Scientific Officer of Syrrx Inc., a biopharmaceutical company, from March 2003 until its acquisition by Takeda Pharmaceutical Company Limited in 2005, and continued on as President and



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Chief Scientific Officer until July 2007. Dr. Kaldor serves on the board of directors of Crinetics Pharmaceuticals, Inc. (Nasdaq: CRNX). Dr. Kaldor began his career at Eli Lilly and Company in 1990. Dr. Kaldor holds a B.A. in Chemistry from Columbia University and a Ph.D. in Organic Chemistry from Harvard University.

We believe Dr. Kaldor is qualified to serve on our board of directors due to his experience as a drug inventor and founder of life science companies and his educational background, as well as his perspective having previously served as our President and Chief Executive Officer.

*Michael Rome, Ph.D.* has served on our board of directors since December 2019. He has served in various roles with Foresite Capital Management, an investment firm, since August 2016, including serving as Managing Director since May 2020. Prior to that, he served as an Analyst at DAFNA Capital Management LLC, a healthcare hedge fund, from September 2015 to July 2016. Dr. Rome also worked in early-stage drug development as a Senior Scientist for Vault Pharma, an academic start-up out of the California NanoSystems Institute at UCLA from April 2014 to September 2015. Dr. Rome holds a B.S. in Molecular, Cellular and Developmental Biology from University of California, Los Angeles and a Ph.D. in Biochemistry, Biophysics and Molecular Biology from California Institute of Technology.

We believe Dr. Rome is qualified to serve on our board of directors because of his extensive experience in investing in diverse biotechnology companies and his depth of knowledge and substantial experience as a research scientist.

*Laurie Smaldone Alsup, M.D.* has served on our board of directors since August 2020. Since March 2016, Dr. Smaldone Alsup has served as the Chief Scientific Officer and Chief Medical Officer of NDA Group AB, a drug regulatory and drug consulting company. Prior to her current position, she served as the President and Chief Scientific Officer of PharmApprove LLC, a drug development consulting company, from August 2011 until its acquisition by NDA Group AB in March 2016. Prior to that, from 2008 to 2011, Dr. Smaldone Alsup served as the President and Chief Executive Officer of Phytomedics, Inc., a biopharmaceutical company, and in senior positions at Bristol-Myers Squibb, a pharmaceutical company, including as Vice President, Corporate Strategy and Business Risk Management and as Senior Vice President, Global Regulatory Science. Dr. Smaldone Alsup serves on the boards of directors of Blackberry, Ltd. (NYSE: BB), Arvinas, Inc. (Nasdaq: ARVN), and Theravance Biopharma, Inc. (Nasdaq: TBPH). Dr. Smaldone Alsup holds a B.A. in Biology and Philosophy from Fordham College and a M.D. from Yale School of Medicine.

We believe Dr. Smaldone Alsup is qualified to serve on our board of directors due to her medical expertise, her expertise as an executive in the biotechnology industry and her experience as a public company board member, including within the biotechnology industry.

*Jim Tananbaum, M.D.* is a founding board member of Kinnate, first appointed to our board of directors in March 2018, and has served on our board of directors from March 2018 to December 2019 and since June 2020. He has also served as Founder and CEO of Foresite Capital Management, an investment firm, since 2010. Prior to that, he co-founded, and served as Managing Director of, Prospect Venture Partners, an investment firm. Dr. Tananbaum also co-founded Theravance, Inc., now Innoviva, Inc., in 1997. Dr. Tananbaum currently serves on the board of directors of FS Development Corp. (Nasdaq:FSDC). He holds a B.S. and BSEE in Applied Math, Electrical Engineering/Computer Science from Yale University, an M.D. from Harvard Medical School, an M.B.A. from Harvard Business School, and an M.S. from the Harvard-MIT Health Sciences and Technology Program.

We believe Dr. Tananbaum is qualified to serve on our board of directors because of his educational background and extensive experience in investing in biotechnology companies.

### **Family Relationships**

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

## Legal Proceedings and Bankruptcy

There are no material legal proceedings to which any of our directors is a party adverse to us or in which any such person has a material interest adverse to us. Phytomedics, Inc., where Dr. Smaldone Alsop served as Chief Executive Officer, filed a voluntary petition for relief under Chapter 7 of the U.S. Bankruptcy Code in May 2011.

## Board Composition

Our board of directors currently consists of nine members. After the completion of this offering, the number of directors will be fixed from time to time by our board of directors, subject to the terms of our amended and restated certificate of incorporation and amended and restated bylaws. Each of our current directors will continue to serve as a director until the election and qualification of his or her successor, or until his or her earlier death, resignation or removal.

Our amended and restated certificate of incorporation will provide that our board of directors will be divided into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of stockholders, with the other classes continuing for the remainder of their respective three-year terms. Our current directors will be divided among the three classes as follows:

- the Class I directors will be \_\_\_\_\_, and their terms will expire at the annual meeting of stockholders to be held in 2021;
- the Class II directors will be \_\_\_\_\_, and their terms will expire at the annual meeting of stockholders to be held in 2022; and
- the Class III directors will be \_\_\_\_\_, and their terms will expire at the annual meeting of stockholders to be held in 2023.

At each annual meeting of stockholders, upon the expiration of the term of a class of directors, the successor to each such director in the class will be elected to serve from the time of election and qualification until the third annual meeting following his or her election and until his or her successor is duly elected and qualified, in accordance with our amended and restated certificate of incorporation. 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 our directors.

This classification of our board of directors may have the effect of delaying or preventing changes in control of our company.

## Director Independence

Upon the completion of this offering, we anticipate that our common stock will be listed on the \_\_\_\_\_. Under the rules of \_\_\_\_\_, independent directors must comprise a majority of a listed company's board of directors within one year of the completion of this offering. In addition, the rules of \_\_\_\_\_ require that, subject to specified exceptions, each member of a listed company's audit, compensation and corporate governance and nominating committees be independent. Audit committee members and compensation committee members must also satisfy the independence criteria set forth in Rule 10A-3 and Rule 10C-1, respectively, under the Securities Exchange Act of 1934, as amended (the Exchange Act). Under the rules of \_\_\_\_\_, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

To be considered to be independent for purposes of Rule 10A-3 and under the rules of \_\_\_\_\_, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (i) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries or (ii) be an affiliated person of the listed company or any of its subsidiaries.

To be considered independent for purposes of Rule 10C-1 and under the rules of \_\_\_\_\_, the board of directors must affirmatively determine that each member of the compensation committee is

independent, including a consideration of all factors specifically relevant to determining whether the director has a relationship to the company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including: (i) the source of compensation of such director, including any consulting, advisory or other compensatory fee paid by the company to such director and (ii) whether such director is affiliated with the company, a subsidiary of the company or an affiliate of a subsidiary of the company.

Our board of directors undertook a review of its composition, the composition of its committees and the independence of our directors and considered whether any director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that \_\_\_\_\_, representing \_\_\_\_\_ of our eight directors, do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the rules of \_\_\_\_\_.

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 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 titled "Certain Relationships and Related Party Transactions."

### **Board Leadership Structure**

Our board of directors is currently chaired by Mr. Mitchell. As a general policy, our board of directors believes that separation of the positions of Chair of our board of directors and Chief Executive Officer reinforces the independence of our board of directors from management, creates an environment that encourages objective oversight of management's performance and enhances the effectiveness of our board of directors as a whole. As such, Mr. Farzan serves as our President and Chief Executive Officer while Mr. Mitchell serves as the Chair of our board of directors but is not an officer. We currently expect and intend the positions of Chair of our board of directors and Chief Executive Officer to continue to be held by two individuals in the future.

### **Role of the Board in Risk Oversight**

Our board of directors has an active role, as a whole and also at the committee level, in overseeing the management of our risks. Our board of directors is responsible for general oversight of risks and regular review of information regarding our risks, including credit risks, liquidity risks and operational risks. The compensation committee is responsible for overseeing the management of risks relating to our executive compensation plans and arrangements. The audit committee is responsible for overseeing the management of risks relating to accounting matters and financial reporting. The corporate governance and nominating committee is responsible for overseeing the management of risks associated with the independence of our board of directors and potential conflicts of interest. Although each committee is responsible for evaluating certain risks and overseeing the management of such risks, our entire board of directors is regularly informed through discussions from committee members about such risks.

### **Board Committees**

Prior to the completion of this offering, our board of directors will have an audit committee, a compensation committee and a corporate governance and nominating committee, each of which will have the composition and the responsibilities described below.

### **Audit Committee**

Upon the effectiveness of the registration statement of which this prospectus forms a part, the members of our audit committee will be . will be the chair of our audit committee and is an audit committee financial expert, as that term is defined under the SEC rules implementing Section 407 of the Sarbanes-Oxley Act of 2002, and possesses financial sophistication, as defined under the rules of . Our audit committee will oversee our corporate accounting and financial reporting process and assist our board of directors in monitoring our financial systems. Our audit committee will also:

- select and hire the independent registered public accounting firm to audit our financial statements;
- help to ensure the independence and performance of the independent registered public accounting firm;
- approve audit and non-audit services and fees;
- review financial statements and discuss with management and the independent registered public accounting firm our annual audited and quarterly financial statements, the results of the independent audit and the quarterly reviews and the reports and certifications regarding internal controls over financial reporting and disclosure controls;
- prepare the audit committee report that the SEC requires to be included in our annual proxy statement;
- review reports and communications from the independent registered public accounting firm;
- review the adequacy and effectiveness of our internal controls and disclosure controls and procedure;
- review our policies on risk assessment and risk management;
- review and monitor conflicts of interest situations, and approve or prohibit any involvement in matters that may involve a conflict of interest or taking of a corporate opportunity;
- review related party transactions; and
- establish and oversee procedures for the receipt, retention and treatment of accounting related complaints and the confidential submission by our employees of concerns regarding questionable accounting or auditing matters.

Our audit committee will operate under a written charter, to be effective upon the effectiveness of the registration statement of which this prospectus forms a part, which will satisfy the applicable rules of the SEC and the listing standards of .

### **Compensation Committee**

Upon the effectiveness of the registration statement of which this prospectus forms a part, the members of our compensation committee will be . will be the chair of our compensation committee. Our compensation committee will oversee our compensation policies, plans and benefits programs. The compensation committee will also:

- oversee our overall compensation philosophy and compensation policies, plans and benefit programs;
- review and approve compensation for our executive officers and directors;
- prepare the compensation committee report that the SEC will require to be included in our annual proxy statement; and
- administer our equity compensation plans.

Our compensation committee will operate under a written charter, to be effective upon the effectiveness of the registration statement of which this prospectus forms a part, which will satisfy the applicable rules of the SEC and the listing standards of .

**Corporate Governance and Nominating Committee**

Upon the effectiveness of the registration statement of which this prospectus forms a part, the members of our corporate governance and nominating committee will be . will be the chair of our corporate governance and nominating committee. Our corporate governance and nominating committee will oversee and assist our board of directors in reviewing and recommending nominees for election as directors. Specifically, the corporate governance and nominating committee will:

- identify, evaluate and make recommendations to our board of directors regarding nominees for election to our board of directors and its committees;
- consider and make recommendations to our board of directors regarding the composition of our board of directors and its committees;
- review developments in corporate governance practices;
- evaluate the adequacy of our corporate governance practices and reporting; and
- evaluate the performance of our board of directors and of individual directors.

Our corporate governance and nominating committee will operate under a written charter, to be effective upon the effectiveness of the registration statement of which this prospectus forms a part, which will satisfy the applicable rules of the SEC and the listing standards of .

**Scientific Advisory Board Compensation**

We provide cash compensation annually to certain members of our scientific advisory board for service as a member of our scientific advisory board. We also reimburse each member of our scientific advisory board for all reasonable and necessary travel expenses in connection with the performance of his or her services. From time to time, we have also granted certain members of our scientific advisory board options to purchase shares of our common stock.

**Director Compensation**

Prior to this offering, we have not implemented a formal policy with respect to compensation payable to our non-employee directors. Other than cash compensation that we paid to Dr. Flaherty in 2019 for consulting services provided by Dr. Flaherty, we did not pay any compensation, including equity awards, to any of our non-employee directors in 2019. See the "Director Compensation" table below for information about the consulting fees paid to Dr. Flaherty. We reimburse our directors for expenses associated with attending meetings of our board of directors and its committees. Following the completion of this offering, we expect to implement an annual cash and equity compensation program for our non-employee directors.

Dr. Kaldor is our only current director who was an employee director during 2019. See the section titled "Executive Compensation" for information about Dr. Kaldor's compensation that he received for serving as our President and Chief Executive Officer during 2019.

The following table presents the total compensation each of our non-employee directors received during the year ended December 31, 2019.

Name	Fees Earned or Paid in Cash (\$)	Option Awards (\$)	Total (\$)
Melissa Epperly	—	—	—
Keith Flaherty, M.D.	41,250	—	41,250
Carl Gordon, Ph.D.	—	—	—
Dean Mitchell	—	—	—
Michael Rome, Ph.D.	—	—	—
Laurie Smaldone Alsup, M.D.	—	—	—
Jim Tananbaum, M.D.	—	—	—

### **Compensation Committee Interlocks and Inside Participation**

None of the members of our board of directors who will serve on our compensation committee upon the effectiveness of the registration statement of which this prospectus forms a part is or has been an officer or employee of our company. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board of directors or compensation committee (or other board committee performing equivalent functions or, in the absence of any such committee, the entire board of directors) of any entity that has one or more executive officers serving on our board of directors or compensation committee.

### **Code of Business Conduct and Ethics**

Prior to the effectiveness of the registration statement of which this prospectus forms a part, we intend to adopt a written code of business conduct and ethics that will apply to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions. Following this offering, the code of business conduct and ethics will be available on our website at [www.kinnate.com](http://www.kinnate.com). We intend to disclose future amendments to such code, or any waivers of its requirements, applicable to any principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions or our directors on our website identified above or in a current report on Form 8-K. Information contained on the website is not incorporated by reference into this prospectus and should not be considered to be part of this prospectus. The inclusion of our website address in this prospectus is an inactive textual reference only.



## EXECUTIVE COMPENSATION

Our named executive officers for 2019, which consist of each person who served as our principal executive officer during 2019 and our next most highly compensated executive officer during 2019, are:

- Stephen Kaldor, Ph.D., a current member of our board of directors and former President and Chief Executive Officer; and
- Eric Murphy, Ph.D., our Chief Scientific Officer.

Because only two individuals served as our executive officers at any time during the year ended December 31, 2019, we have only two named executive officers for 2019. We appointed Nima Farzan as our current president and chief executive officer in March 2020. In addition to the disclosures below for our named executive officers, we are providing supplemental disclosure of compensation arrangements we are entering into in connection with this offering with our other executive officers listed in the section titled “Management – Executive Officers”.

### Summary Compensation Table

The following table sets forth information regarding the compensation of our named executive officers for the year ended December 31, 2019.

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Option Awards (\$)	All Other Compensation (\$)	Total (\$)
Stephen Kaldor, Ph.D. <i>Director and former President and Chief Executive Officer</i>	2019	336,156	67,275	—	1,481	404,912
Eric Murphy, Ph.D. <i>Chief Scientific Officer</i>	2019	336,156	67,275	—	344	403,776

### Outstanding Equity Awards at Fiscal Year End

The following table sets forth information concerning outstanding equity awards held by each of our named executive officers as of December 31, 2019:

Name	Grant Date <sup>(1)</sup>	Option Awards				Stock Awards	
		Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price (\$) <sup>(2)</sup>	Option Expiration Date	Number of Shares of Stock that Have Not Vested (#)	Market Value of Shares of Stock that Have Not Vested (\$) <sup>(3)</sup>
Stephen Kaldor, Ph.D.	—	—	—	—	—	—	—
Eric Murphy, Ph.D.	—	—	—	—	—	—	—

### Executive Employment Arrangements

Each of our current executive officers has executed our standard form of confidential information, invention assignment and arbitration agreement.

Prior to the completion of this offering, we intend to enter into a confirmatory employment letter with each of our current executive officers, including Mr. Farzan and Dr. Murphy. Each confirmatory employment letter will provide for continued employment with us on an at-will basis and include terms for base salary, benefits and target cash incentive payments.

## Potential Payments Upon Termination or Change in Control

Prior to the completion of this offering, we expect to adopt arrangements for our executive officers that provide for certain severance and change in control benefits.

## Employee Benefit and Stock Plans

### 2020 Equity Incentive Plan

Prior to the effectiveness of this offering, we expect that our board of directors will adopt, and our stockholders will approve, our 2020 Equity Incentive Plan (the 2020 Plan). The 2020 Plan will be effective on the business day immediately prior to the effective date of the registration statement of which this prospectus forms a part. Our 2020 Plan will provide for the grant of incentive stock options, within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended (the Code), to our employees and any of our parent and subsidiary corporations' employees, and for the grant of nonstatutory stock options, restricted stock, restricted stock units, stock appreciation rights and performance awards to our employees, directors, and consultants and our subsidiary corporations' employees and consultants.

*Authorized Shares.* A total of \_\_\_\_\_ shares of our common stock are reserved for issuance pursuant to our 2020 Plan. In addition, the shares reserved for issuance under our 2020 Plan will also include (i) those shares reserved but unissued under our 2018 Plan as of the date of stockholder approval of the 2020 Plan and (ii) shares of our common stock subject to or issued pursuant to awards granted under our 2018 Plan that, after the date of stockholder approval of the 2020 Plan, expire or otherwise terminate without having been exercised in full or are forfeited to or repurchased by us due to failure to vest (provided that the maximum number of shares that may be added to the 2020 Plan pursuant to (i) and (ii) is \_\_\_\_\_ shares). The number of shares available for issuance under our 2020 Plan will also include an annual increase on the first day of each fiscal year for a period of ten years, beginning with our 2021 fiscal year, equal to the least of:

- \_\_\_\_\_ shares;
- \_\_\_\_\_ percent ( \_\_\_\_\_ %) of the outstanding shares of our common stock as of the last day of the immediately preceding fiscal year; or
- such other amount as our board of directors may determine.

Shares issuable under our 2020 Plan will be authorized, but unissued, or reacquired shares of our common stock. If an award expires or becomes unexercisable without having been exercised in full, is surrendered pursuant to an exchange program, or, with respect to restricted stock, restricted stock units or performance awards, is forfeited to or repurchased by us due to failure to vest, the unpurchased shares (or for awards other than stock options or stock appreciation rights, the forfeited or repurchased shares) will become available for future grant or sale under the 2020 Plan (unless the 2020 Plan has terminated). With respect to stock appreciation rights, only the net shares actually issued will cease to be available under the 2020 Plan and all remaining shares under stock appreciation rights will remain available for future grant or sale under the 2020 Plan (unless the 2020 Plan has terminated). Shares that have actually been issued under the 2020 Plan will not be returned to the 2020 Plan except if shares issued pursuant to awards of restricted stock, restricted stock units, or performance awards are repurchased by or forfeited to us due to failure to vest, such shares will become available for future grant under the 2020 Plan. Shares used to pay the exercise price of an award or satisfy the tax withholding obligations related to an award will become available for future grant or sale under the 2020 Plan. To the extent an award is paid out in cash rather than shares, such cash payment will not result in a reduction in the number of shares available for issuance under the 2020 Plan.

*Plan Administration.* Our board of directors or one or more committees appointed by our board of directors will administer our 2020 Plan. We expect that the compensation committee of our board of directors will initially administer our 2020 Plan. In addition, if we determine it is desirable to qualify transactions under our 2020 Plan as exempt under Rule 16b-3 of the Exchange Act, such transactions will be structured to satisfy the requirements for exemption under Rule 16b-3. Subject to the provisions of our 2020 Plan, the administrator has the power to administer our 2020 Plan and make all determinations deemed necessary or advisable for administering the 2020 Plan, including but not limited to, the power to

determine the fair market value of our common stock, select the service providers to whom awards may be granted, determine the number of shares covered by each award, approve forms of award agreements for use under the 2020 Plan, determine the terms and conditions of awards (including, but not limited to, the exercise price, the time or times at which awards may be exercised, any vesting acceleration or waiver or forfeiture restrictions and any restriction or limitation regarding any award or the shares relating thereto), construe and interpret the terms of our 2020 Plan and awards granted under it, prescribe, amend and rescind rules relating to our 2020 Plan, including creating sub-plans, modify or amend each award, including but not limited to the discretionary authority to extend the post-termination exercisability period of awards (except no option or stock appreciation right will be extended past its original maximum term), and allow a participant to defer the receipt of payment of cash or the delivery of shares that would otherwise be due to such participant under an award. The administrator also has the authority to allow participants the opportunity to transfer outstanding awards to a financial institution or other person or entity selected by the administrator and to institute an exchange program by which outstanding awards may be surrendered or cancelled in exchange for awards of the same type, which may have a higher or lower exercise price and/or different terms, awards of a different type, and/or cash or by which the exercise price of an outstanding award is increased or reduced. The administrator's decisions, interpretations, and other actions are final and binding on all participants and given the maximum deference permitted by applicable law.

*Stock Options.* Both incentive stock options and non-statutory stock options may be granted under our 2020 Plan. The exercise price of options granted under our 2020 Plan must at least be equal to the fair market value of our common stock on the date of grant. The term of an option may not exceed ten years. With respect to any participant who owns more than 10% of the voting power of all classes of our (or any parent or subsidiary of ours) outstanding stock, the term of an incentive stock option granted to such participant must not exceed five years and the exercise price must equal at least 110% of the fair market value on the grant date. The administrator will determine the methods of payment of the exercise price of an option, which may include cash, shares or other property acceptable to the administrator, as well as other types of consideration permitted by applicable law. After the termination of service of an employee, director, or consultant, he or she may exercise his or her option for the period of time stated in his or her option agreement. In the absence of a specified time in an award agreement, if termination is due to death or disability, the option will remain exercisable for 12 months following the termination of service. In all other cases, in the absence of a specified time in an award agreement, the option will remain exercisable for three months following the termination of service. An option, however, may not be exercised later than the expiration of its term. Subject to the provisions of our 2020 Plan, the administrator will determine the other terms of options.

*Stock Appreciation Rights.* Stock appreciation rights may be granted under our 2020 Plan. Stock appreciation rights allow the recipient to receive the appreciation in the fair market value of our common stock between the exercise date and the date of grant. Stock appreciation rights may not have a term exceeding ten years. After the termination of service of an employee, director, or consultant, he or she may exercise his or her stock appreciation right for the period of time stated in his or her stock appreciation rights agreement. In the absence of a specified time in an award agreement, if termination is due to death or disability, the stock appreciation rights will remain exercisable for 12 months following the termination of service. In all other cases, in the absence of a specified time in an award agreement, the stock appreciation rights will remain exercisable for three months following the termination of service. However, in no event may a stock appreciation right be exercised later than the expiration of its term. Subject to the provisions of our 2020 Plan, the administrator will determine the other terms of stock appreciation rights, including when such rights become exercisable and whether to pay any increased appreciation in cash or with shares of our common stock, or a combination thereof, except that the per share exercise price for the shares to be issued pursuant to the exercise of a stock appreciation right will be no less than 100% of the fair market value per share on the date of grant.

*Restricted Stock.* Restricted stock may be granted under our 2020 Plan. Restricted stock awards are grants of shares of our common stock that vest in accordance with terms and conditions established by the administrator. The administrator will determine the number of shares of restricted stock granted to any employee, director, or consultant and, subject to the provisions of our 2020 Plan, will determine the terms and conditions of such awards. The administrator may impose whatever vesting conditions it determines

to be appropriate (for example, the administrator may set restrictions based on the achievement of specific performance goals or continued service to us), except the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed. Recipients of restricted stock awards generally will have voting and dividend rights with respect to such shares upon grant without regard to vesting, unless the administrator provides otherwise. Shares of restricted stock that do not vest are subject to our right of repurchase or forfeiture.

*Restricted Stock Units.* Restricted stock units may be granted under our 2020 Plan. Restricted stock units are bookkeeping entries representing an amount equal to the fair market value of one share of our common stock. Subject to the provisions of our 2020 Plan, the administrator will determine the terms and conditions of RSUs, including the vesting criteria and the form and timing of payment. The administrator may set vesting criteria based upon the achievement of company-wide, divisional, business unit or individual goals (including, but not limited to, continued employment or service), applicable federal or state securities laws or any other basis determined by the administrator in its discretion. The administrator, in its sole discretion, may pay earned restricted stock units in the form of cash, in shares or in some combination thereof. In addition, the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed.

*Performance Awards.* Performance awards may be granted under the 2020 Plan. Performance awards are awards that may be earned in whole or in part upon the attainment of performance goals or other vesting criteria that the administrator may determine, and that may be denominated in cash or stock. Subject to the terms and conditions of the 2020 Plan, the administrator will determine the terms and conditions of performance awards, including any vesting criteria and form and timing of payment. The administrator may set vesting criteria based upon the achievement of company-wide, divisional, business unit, or individual goals (including, but not limited to, continued employment or service), applicable federal or state securities laws or any other basis determined by the administrator in its discretion. The administrator, in its sole discretion, may pay earned performance awards in the form of cash, shares, or a combination of both. Notwithstanding the foregoing, the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed.

*Outside Directors.* All outside (non-employee) directors will be eligible to receive all types of awards (except for incentive stock options) under our 2020 Plan. To provide a maximum limit on the cash compensation and equity awards that can be made to our outside directors, our 2020 Plan provides that in any given fiscal year, an outside director will not be granted cash compensation and equity awards with an aggregate value greater than \$ , with the value of each equity award based on its grant date fair value as determined according to U.S. Generally Accepted Accounting Principles for purposes of this limit. Any cash compensation paid or awards granted to an individual for his or her services as an employee or consultant (other than as an outside director) will not count toward this limit. This maximum limit provision does not reflect the intended size of any potential grants or a commitment to make grants to our outside directors under our 2020 Plan in the future.

*Non-Transferability of Awards.* Unless the administrator provides otherwise, our 2020 Plan generally does not allow for the transfer of awards and only the recipient of an award may exercise an award during his or her lifetime. If the administrator makes an award transferrable, such award will contain such additional terms and conditions as the administrator deems appropriate.

*Certain Adjustments.* In the event of certain changes in our capitalization, such as a dividend or other distribution, recapitalization, stock split reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, reclassification, repurchase or exchange of our shares or other change in our corporate structure affecting our shares (other than ordinary dividends or other ordinary distributions), in order to prevent diminution or enlargement of the benefits or potential benefits available under our 2020 Plan, the administrator will adjust the number and class of shares that may be delivered under our 2020 Plan and/or the number, class, and price of shares covered by each outstanding award and any numerical share limits set forth in our 2020 Plan.

*Dissolution or Liquidation.* In the event of our proposed liquidation or dissolution, the administrator will notify participants as soon as practicable and, to the extent not exercised, all awards will terminate immediately prior to the consummation of such proposed transaction.

*Merger or Change in Control.* Our 2020 Plan provides that in the event of a merger or change in control, as defined under our 2020 Plan, each outstanding award will be treated as the administrator determines, without a participant's consent. The administrator is not required to treat all awards, all awards held by a participant or all awards of the same type similarly.

If a successor corporation or its parent or subsidiary does not assume or substitute for any outstanding award, then the participant will fully vest in and have the right to exercise all of his or her outstanding options and stock appreciation rights, all restrictions on restricted stock and restricted stock units will lapse, and for awards with performance-based vesting, unless specifically provided for otherwise under the applicable award agreement or other agreement or policy applicable to the participant, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels and all other terms and conditions met. If an option or stock appreciation right is not assumed or substituted in the event of a merger or change in control, the administrator will notify the participant in writing or electronically that such option or stock appreciation right will be exercisable for a period of time determined by the administrator in its sole discretion and the option or stock appreciation right will terminate upon the expiration of such period.

For awards granted to an outside director, in the event of a change in control, the outside director will fully vest in and have the right to exercise all of his or her outstanding options and stock appreciation rights, all restrictions on restricted stock and restricted stock units will lapse and, for awards with performance-based vesting, unless specifically provided for otherwise under the applicable award agreement or other agreement or policy applicable to the participant, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels and all other terms and conditions met.

*Clawback.* Awards will be subject to any clawback policy of ours, and the administrator also may specify in an award agreement that the participant's rights, payments, and/or benefits with respect to an award will be subject to reduction, cancellation, forfeiture, and/or recoupment upon the occurrence of certain specified events. Our board of directors may require a participant to forfeit, return, or reimburse us all or a portion of the award and/or shares issued under the award, any amounts paid under the award, and any payments or proceeds paid or provided upon disposition of the shares issued under the award in order to comply with such clawback policy or applicable laws.

*Amendment; Termination.* The administrator has the authority to amend, alter, suspend or terminate our 2020 Plan, provided such action does not materially impair the rights of any participant. Our 2020 Plan will remain in effect until terminated in accordance with its terms.

#### **2020 Employee Stock Purchase Plan**

Prior to the effectiveness of this offering, we expect that our board of directors will adopt, and our stockholders will approve, our 2020 Employee Stock Purchase Plan (ESPP). Our ESPP will be effective upon the later of its adoption by our board of directors or on the business day immediately prior to the effective date of the registration statement of which this prospectus forms a part. However, no offering period or purchase period under the ESPP will begin unless and until otherwise determined by our board of directors.

*Authorized Shares.* A total of \_\_\_\_\_ shares of our common stock will be available for sale under our ESPP. The number of shares of our common stock that will be available for sale under our ESPP also includes an annual increase on the first day of each fiscal year beginning with our fiscal 2021, equal to the least of:

- \_\_\_\_\_ shares;
- \_\_\_\_\_ percent ( \_\_\_\_\_ %) of the outstanding shares of our common stock as of the last day of the immediately preceding fiscal year; or
- such other amount as the administrator may determine.

*ESPP Administration.* We expect that the compensation committee of our board of directors will administer our ESPP and will have full and exclusive discretionary authority to construe, interpret, and apply the terms of the ESPP, delegate ministerial duties to any of our employees, designate separate offerings under the ESPP, designate our subsidiaries and affiliates as participating in the ESPP, determine

eligibility, adjudicate all disputed claims filed under the ESPP, and establish procedures that it deems necessary for the administration of the ESPP, including, but not limited to, adopting such procedures and sub-plans as are necessary or appropriate to permit participation in the ESPP by employees who are foreign nationals or employed outside the United States. The administrator's findings, decisions and determinations are final and binding on all participants to the full extent permitted by law.

*Eligibility.* Generally, all of our employees will be eligible to participate in the ESPP if they are customarily employed by us, or any participating subsidiary or affiliate, for at least 20 hours per week and more than five months in any calendar year. The administrator, in its discretion, may, prior to an enrollment date, for all options to be granted on such enrollment date in an offering, determine that an employee who (i) has not completed at least two years of service (or a lesser period of time determined by the administrator) since his or her last hire date; (ii) customarily works not more than 20 hours per week (or a lesser period of time determined by the administrator); (iii) customarily works not more than five months per calendar year (or a lesser period of time determined by the administrator); (iv) is a highly compensated employee within the meaning of Section 414(q) of the Code; or (v) is a highly compensated employee within the meaning of Section 414(q) of the Code with compensation above a certain level or is an officer or subject to disclosure requirements under Section 16(a) of the Exchange Act, is or is not eligible to participate in such offering period.

However, an employee may not be granted rights to purchase shares of our common stock under our ESPP if such employee:

- immediately after the grant would own capital stock and/or hold outstanding options to purchase such stock possessing 5% or more of the total combined voting power or value of all classes of capital stock of ours or of any parent or subsidiary of ours; or
- holds rights to purchase shares of our common stock under all employee stock purchase plans of ours or any parent or subsidiary of ours that accrue at a rate that exceeds \$25,000 worth of shares of our common stock for each calendar year in which such rights are outstanding at any time.

*Offering Periods and Purchase Periods.* Our ESPP includes a component (the 423 Component) that is intended to qualify as an "employee stock purchase plan" under Code Section 423, and a component that does not comply with Code Section 423 (the Non-423 Component). For purposes of this summary, a reference to our ESPP generally will mean the terms and operations of the 423 Component. Our ESPP will provide for six-month offering periods. Each offering period will have one purchase period with the same duration as the offering period. The offering periods will be scheduled to begin on the first trading day on or after \_\_\_\_\_ and \_\_\_\_\_ of each year, except for the first offering period, which will begin on the first trading day on or after the effective date of the registration statement of which this prospectus forms a part and end on the first trading day on or after \_\_\_\_\_, 2021. The administrator is authorized to change the duration of future offering periods and purchase periods under our ESPP, including the starting and ending dates of offering periods and purchase periods and the number of purchase periods in any offering periods, provided that no offering period will have a duration exceeding 27 months. If the fair market value of a share of our common stock on a purchase date is less than the fair market value on the first trading day of the offering period, participants in that offering period will be withdrawn from that offering period following their purchase of shares on that purchase date and automatically will be enrolled in a new offering period.

*Contributions.* Our ESPP will permit participants to purchase shares of our common stock through contributions (in the form of payroll deductions or otherwise to the extent permitted by the administrator) of up to \_\_\_\_\_ % of their eligible compensation. A participant may purchase a maximum of \_\_\_\_\_ shares of our common stock during a purchase period.

*Exercise of Purchase Right.* If our board of directors authorizes an offering and purchase period under the ESPP, amounts contributed and accumulated by the participant during any offering period will be used to purchase shares of our common stock at the end of each purchase period. The purchase price of the shares will be \_\_\_\_\_ % of the lower of the fair market value of our common stock on the first trading



day of the offering period or on the exercise date. Participants may end their participation at any time during an offering period and will be paid their accrued contributions that have not yet been used to purchase shares of our common stock. Participation ends automatically upon termination of employment with us.

*Non-Transferability.* A participant may not transfer rights granted under our ESPP (other than by will, the laws of descent and distribution or as otherwise provided under our ESPP).

*Merger or Change in Control.* Our ESPP will provide that in the event of a merger or change in control, as defined under our ESPP, a successor corporation may assume or substitute each outstanding purchase right. If the successor corporation refuses to assume or substitute for the outstanding purchase right, the offering period then in progress will be shortened, and a new exercise date will be set that will be before the date of the proposed merger or change in control. The administrator will notify each participant that the exercise date has been changed and that the participant's option will be exercised automatically on the new exercise date unless prior to such date the participant has withdrawn from the offering period.

*Amendment; Termination.* The board will have the authority suspend or terminate our ESPP and the administrator will have the authority to amend the ESPP, except that, subject to certain exceptions described in our ESPP, no such action may adversely affect any outstanding rights to purchase shares of our common stock under our ESPP. Our ESPP automatically will terminate in 2040, unless we terminate it sooner.

### **2018 Equity Incentive Plan, as Amended**

Our 2018 Equity Incentive Plan (the 2018 Plan) allows us to provide incentive stock options, within the meaning of Section 422 of the Code, nonstatutory stock options, stock appreciation rights, restricted stock awards and restricted stock units (each, an "award" and the recipient of such award, a participant) to eligible employees, directors and consultants, including employees and consultants of any of our parent or subsidiary companies. It is expected that as of one business day prior to the effectiveness of the registration statement of which this prospectus forms a part, our 2018 Plan will terminate and we will not grant any additional awards under our 2018 Plan thereafter. However, our 2018 Plan will continue to govern the terms and conditions of the outstanding awards previously granted under our 2018 Plan.

As of September 30, 2020, stock options covering 7,037,046 shares of our common stock were outstanding under our 2018 Plan and there were no stock appreciation rights, restricted stock awards or restricted stock units outstanding under our 2018 Plan.

*Plan Administration.* Our compensation committee has the authority, concurrent with our board of directors to administer our 2018 Plan. Different committees may administer our 2018 Plan with respect to different service providers. The administrator has all authority and discretion necessary or appropriate to administer our 2018 Plan and to control its operation, including the authority to construe and interpret the terms of our 2018 Plan and the awards granted under our 2018 Plan. The administrator's decisions are final and binding on all participants and any other persons holding awards.

The administrator's powers include the power to institute an exchange program (without stockholder approval) under which (i) outstanding awards are surrendered or cancelled in exchange for awards of the same type (which may have higher or lower exercise prices and different terms), awards of a different type and/or cash; (ii) participants would have the opportunity to transfer any outstanding awards to a financial institution or other person or entity selected by the administrator; and/or (iii) the exercise price of an outstanding award is increased or reduced. The administrator's powers also include the power to prescribe, amend and rescind rules and regulations relating to our 2018 Plan, to modify or amend each award and to make all other determinations deemed necessary or advisable for administering our 2018 Plan.

*Eligibility.* Employees, directors and consultants, including employees and consultants of any of our parent or subsidiary companies, are eligible to receive awards, provided such consultants render bona fide services not in connection with the offer or sale of securities in a capital-raising transaction and do not directly promote or maintain a market for our securities. Only our employees or employees of our parent or subsidiary companies are eligible to receive incentive stock options.

*Stock Options.* Stock options have been granted under our 2018 Plan. Subject to the provisions of our 2018 Plan, the administrator determines the term of an option, the number of shares subject to an option, and the time period in which an option may be exercised.

The term of an option is stated in the applicable award agreement, but the term of an option may not exceed 10 years from the grant date. The administrator determines the exercise price of options, which generally may not be less than 100% of the fair market value of our common stock on the grant date, except as provided for in the 2018 Plan. However, an incentive stock option granted to an individual who directly or by attribution owns more than 10% of the total combined voting power of all of our classes of stock or of any our parent or subsidiary companies will have a term of no longer than five years from the grant date and will have an exercise price of at least 110% of the fair market value of our common stock on the grant date. In addition, to the extent that the aggregate fair market value of the shares with respect to which incentive stock options are exercisable for the first time by an employee during any calendar year (under all plans of ours and any of our parent or subsidiary companies) exceeds \$100,000, such options will be treated as nonstatutory stock options.

The administrator determines how a participant may pay the exercise price of an option, and the permissible methods are generally set forth in the applicable award agreement. If a participant's status as a "service provider" (as defined in our 2018 Plan) terminates, that participant may exercise the vested portion of his or her option for the period of time stated in the applicable award agreement. Vested options generally will remain exercisable for 30 days or such longer period of time as set forth in the applicable award agreement if a participant's status as a service provider terminates for a reason other than death or disability. If a participant's status as a service provider terminates due to death or disability, vested options generally will remain exercisable for six months from the date of termination (or such other longer period as set forth in the applicable award agreement). In no event will an option remain exercisable beyond its original term. If a participant does not exercise his or her option within the time specified in the award agreement, the option will terminate. Except as described above, the administrator has the discretion to determine the post-termination exercisability periods for an option.

*Non-Transferability of Awards.* Unless determined otherwise by the administrator, awards may not be sold, transferred, pledged, assigned or otherwise alienated or hypothecated in any manner other than by will or by the laws of descent and distribution. In addition, during an applicable participant's lifetime, only that participant may exercise their award. If the administrator makes an award transferable, such award may only be transferred (i) by will, (ii) by the laws of descent and distribution or (iii) as permitted by Rule 701 of the Securities Act of 1933, as amended (the Securities Act).

*Certain Adjustments.* If there is a dividend or other distribution (whether in the form of cash, shares, other securities or other property), recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase, exchange of shares or our other securities or other change in our corporate structure affecting the shares, the administrator will make proportionate adjustments to the number and class of shares that may be delivered under our 2018 Plan or the number, class and price of shares covered by each outstanding award. The administrator's determination regarding such adjustments will be final, binding and conclusive.

*Dissolution or Liquidation.* In the event of our proposed dissolution or liquidation, the administrator will notify each participant as soon as practicable prior to the effective date of such proposed transaction. To the extent it has not been previously exercised, an award will terminate immediately prior to the consummation of such proposed action.

*Merger and Change in Control.* In the event of our merger with or into another corporation or entity or a "change in control" (as defined in our 2018 Plan), each outstanding award will be treated as the administrator determines, including, without limitation, that (i) awards will be assumed, or substantially equivalent awards will be substituted, by the acquiring or succeeding corporation (or an affiliate thereof) with appropriate adjustments as to the number and kind of shares and prices; (ii) upon written notice to a participant, the participant's awards will terminate upon or immediately prior to the consummation of such merger or change in control; (iii) outstanding awards will vest and become exercisable, realizable or payable, or restrictions applicable to an award will lapse, in whole or in part, prior to or upon consummation of such merger or change in control, and, to the extent the administrator determines,

terminate upon or immediately prior to the effectiveness of such merger or change in control; (iv) (1) the termination of an award in exchange for an amount of cash or property, if any, equal to the amount that would have been attained upon the exercise of such award or realization of the participant's rights as of the date of the occurrence of the transaction (and, for the avoidance of doubt, if as of the date of the occurrence of the transaction the administrator determines in good faith that no amount would have been attained upon the exercise of such award or realization of the participant's rights, then such award may be terminated by us without payment) or (2) the replacement of such award with other rights or property selected by the administrator in its sole discretion; or (v) any combination of the foregoing. The administrator will not be obligated to treat all awards, all awards a participant holds or all awards of the same type, similarly.

In the event that the successor corporation does not assume or substitute for an award (or portion thereof), the participant will fully vest in and have the right to exercise all of his or her outstanding options and stock appreciation rights, including shares as to which such awards would not otherwise be vested or exercisable, all restrictions on restricted stock and restricted stock units will lapse, and, with respect to awards with performance-based vesting, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels and all other terms and conditions met. In addition, if an option or stock appreciation right is not assumed or substituted in the event of a merger or change in control, the administrator will notify the participant in writing or electronically that the option or stock appreciation right will be exercisable for a period of time determined by the administrator in its sole discretion, and the option or stock appreciation right will terminate upon the expiration of such period.

*Amendment and Termination.* Our board of directors may, at any time, amend, alter, suspend or terminate our 2018 Plan in any respect, including, without limitation, amendment of any form of award agreement or instrument to be executed pursuant to our 2018 Plan. To the extent necessary and desirable to comply with applicable laws (including any applicable stock exchange rules), we will obtain stockholder approval of any amendment to our 2018 Plan. No amendment, alteration, suspension or termination of our 2018 Plan will impair the rights of a participant, unless mutually agreed otherwise between the participant and the administrator in writing. As noted above, it is expected that as of one business day prior to the effectiveness of the registration statement of which this prospectus forms a part, our 2018 Plan will be terminated, and we will not grant any additional awards under our 2018 Plan thereafter.

#### **Executive Incentive Compensation Plan**

Prior to the effectiveness of this offering, we expect that our board of directors will adopt an Executive Incentive Compensation Plan (Incentive Compensation Plan). We expect that our Incentive Compensation Plan will be effective on the business day immediately prior to the effective date of the registration statement of which this prospectus forms a part. Our Incentive Compensation Plan will allow our compensation committee to grant incentive awards, generally payable in cash, to employees selected by our compensation committee, including our named executive officers, based upon performance goals established by our compensation committee.

Under our Incentive Compensation Plan, our compensation committee will determine the performance goals applicable to any award, which goals may include, without limitation, goals related to research and development, regulatory milestones or regulatory-related goals, gross margin, financial milestones, new product or business development, operating margin, product release timelines or other product release milestones, publications, cash flow, procurement, savings, internal structure, leadership development, project, function or portfolio-specific milestones, license or research collaboration agreements, capital raising, initial public offering preparations, patentability and individual objectives such as peer reviews or other subjective or objective criteria. The performance goals may differ from participant to participant and from award to award.

We expect that the compensation committee of our board of directors will administer our Incentive Compensation Plan and will, in its sole discretion and at any time, increase, reduce or eliminate a participant's actual award, and/or increase, reduce or eliminate the amount allocated to the bonus pool for a particular performance period. The actual award may be below, at or above a participant's target award,

in the discretion of the administrator. The administrator may determine the amount of any increase, reduction or elimination on the basis of such factors as it deems relevant, and it will not be required to establish any allocation or weighting with respect to the factors it considers.

Actual awards generally will be paid in cash (or its equivalent) only after they are earned, and, unless otherwise determined by the administrator, to earn an actual award a participant must be employed by us through the date the actual award is paid. The administrator of the Incentive Compensation Plan may reserve the right to settle an actual award with a grant of an equity award under our then-current equity compensation plan, which equity award may have such terms and conditions, including vesting, as the administrator determines. Payment of awards will occur as soon as practicable after they are earned, but no later than the dates set forth in our Incentive Compensation Plan.

Awards under our Incentive Compensation Plan are subject to any clawback policy of ours, which we may be required to adopt from time to time to comply with applicable laws. The administrator also may impose such other clawback, recovery or recoupment provisions with respect to an award under our Incentive Compensation Plan as the administrator determines necessary or appropriate, including for example, reduction, cancellation, forfeiture or recoupment upon a termination of a participant's employment for cause. Certain participants may be required to reimburse us for certain amounts paid under an award under our Incentive Compensation Plan in connection with certain accounting restatements we may be required to prepare due to our material noncompliance with any financial reporting requirements under applicable securities laws, as a result of misconduct.

Our board of directors and our compensation committee will have the authority to amend, suspend or terminate our Incentive Compensation Plan, provided such action does not impair the existing rights of any participant with respect to any earned awards.

#### **401(k) Plan**

We maintain a 401(k) retirement savings plan (401(k) plan) for the benefit of our employees, including our named executive officers who remain employed with us, and who satisfy certain eligibility requirements. Under the 401(k) plan, eligible employees may elect to defer a portion of their compensation, within the limits prescribed by the Code and the applicable limits of the 401(k) plan, on a pre-tax or after-tax (Roth) basis, through contributions to the 401(k) plan. The 401(k) plan permits us to make matching and other contributions to eligible participants. The 401(k) plan is intended to qualify under Sections 401(a) and 501(a) of the Code. As a tax-qualified retirement plan, pre-tax contributions to the 401(k) plan and earnings on those pre-tax contributions are not taxable to the employees until distributed from the 401(k) plan, and earnings on Roth contributions are not taxable when distributed from the 401(k) plan.

#### **Limitation of Liability and Indemnification**

Our amended and restated certificate of incorporation and amended and restated bylaws, each to be effective upon the completion of this offering, will provide that we will indemnify our directors and officers, and may indemnify our employees and other agents, to the fullest extent permitted by Delaware law. Delaware law prohibits our amended and restated certificate of incorporation from limiting the liability of our directors for the following:

- any breach of the director's duty of loyalty to us or to our stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or unlawful stock repurchases or redemptions; and
- any transaction from which the director derived an improper personal benefit.

If Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law, as so amended. Our amended and restated certificate of incorporation does not eliminate a director's duty of care and, in appropriate circumstances, equitable remedies, such as

injunctive or other forms of non-monetary relief, remain available under Delaware law. This provision also does not affect a director's responsibilities under any other laws, such as the federal securities laws or other state or federal laws. Under our amended and restated bylaws, we will also be empowered to purchase insurance on behalf of any person whom we are required or permitted to indemnify.

In addition to the indemnification required in our amended and restated certificate of incorporation and amended and restated bylaws, we intend to enter into an indemnification agreement with each member of our board of directors and each of our officers prior to the completion of the offering. These agreements provide for the indemnification of our directors and officers for certain expenses and liabilities incurred in connection with any action, suit, proceeding or alternative dispute resolution mechanism or hearing, inquiry or investigation that may lead to the foregoing, to which they are a party, or are threatened to be made a party, by reason of the fact that they are or were a director, officer, employee, agent or fiduciary of our company, or any of our subsidiaries, by reason of any action or inaction by them while serving as an officer, director, agent or fiduciary, or by reason of the fact that they were serving at our request as a director, officer, employee, agent or fiduciary of another entity. In the case of an action or proceeding by or in the right of our company or any of our subsidiaries, no indemnification will be provided for any claim where a court determines that the indemnified party is prohibited from receiving indemnification. We believe that these charter and bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

The limitation of liability and indemnification provisions 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. Moreover, 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, including employment, termination of employment and change in control arrangements, with our directors and executive officers, including those discussed in the sections titled “Management” and “Executive Compensation” and the registration rights described in the section titled “Description of Capital Stock—Registration Rights,” the following is a description of each transaction since January 1, 2017 and each currently proposed transaction in which:

- we have been or are to be a participant;
- the amount involved exceeded or exceeds \$120,000; and
- any of our directors, executive officers or holders of more than 5% of our outstanding capital stock, or any immediate family member of, or person sharing the household with, any of these individuals or entities, had or will have a direct or indirect material interest.

### Convertible Preferred Stock Issuances

In March 2018, June 2018 and October 2018, we issued and sold an aggregate of 3,489,982 shares of our Series A convertible preferred stock at a purchase price of \$3.3429 per share for an aggregate purchase price of \$11.7 million.

In April 2019, we entered into an amended and restated Series A Preferred Stock Purchase Agreement pursuant to which (i) the number of shares issued in such 2018 financings was amended and restated to a new total of 5,833,328 and (ii) we issued and sold an additional 3,000,000 shares of our Series A convertible preferred stock at an updated purchase price of \$2.00 per share for an aggregate purchase price of \$6.0 million.

Also in April 2019, we entered into an Agreement and Plan of Merger with Immanate Therapeutics Inc. (Immanate), pursuant to which we acquired Immanate in exchange for the issuance of 750,000 shares of our Series A convertible preferred stock. At the effective time of the merger, the outstanding shares of Immanate preferred stock were exchanged for the shares of our Series A convertible preferred stock and the outstanding shares of Immanate common stock and options to purchase Immanate common stock were canceled.

In December 2019, we issued and sold 11,981,343 shares of our Series B convertible preferred stock at a purchase price of \$6.218 per share for an aggregate purchase price of \$74.5 million.

In July 2020 and August 2020, we issued and sold an aggregate of 10,225,369 shares of our Series C convertible preferred stock at a purchase price of \$9.584 per share for an aggregate purchase price of \$98.0 million. These shares are convertible into an aggregate of 10,259,613 shares of common stock.

Purchasers of our Series A, Series B and Series C convertible preferred stock and recipients of the shares issued in the merger with Immanate include venture capital funds that beneficially owned more than 5% of our outstanding capital stock at the time of such transactions and/or are represented on our board of directors. The following tables present the number of shares and the total purchase price paid by these entities.

### Series A Convertible Preferred Stock Issued in Series A Convertible Preferred Stock Financings

Investor	Shares of Series A Convertible Preferred Stock	Total Series A Convertible Preferred Stock Purchase Price
Eshelman Ventures, LLC	1,958,331	\$ 3,916,664
Foresite Capital Fund IV, L.P. <sup>(1)</sup>	6,874,997	\$13,749,997

- (1) Michael Rome, Ph.D., is a member of our board of directors and a Managing Director of Foresite Capital. Jim Tananbaum, M.D., is a member of our board of directors and CEO and Managing Director of Foresite Capital. Additional details regarding this stockholder and its equity holdings, including the identities of the natural persons who exercise voting and dispositive power with respect to its shares, are provided in this prospectus under the section titled “Principal Stockholders.”



**Series A Convertible Preferred Stock Issued in Merger with Immanate**

Investor	Shares of Series A Convertible Preferred Stock
Eshelman Ventures, LLC	187,500
Foresite Capital Fund IV, L.P. <sup>(1)</sup>	562,500

- (1) Michael Rome, Ph.D., is a member of our board of directors and a Managing Director of Foresite Capital. Jim Tananbaum, M.D., is a member of our board of directors and CEO and Managing Director of Foresite Capital. Additional details regarding this stockholder and its equity holdings, including the identities of the natural persons who exercise voting and dispositive power with respect to its shares, are provided in this prospectus under the section titled "Principal Stockholders."

**Series B Convertible Preferred Stock**

Investor	Shares of Series B Convertible Preferred Stock	Total Series B Convertible Preferred Stock Purchase Price
Eshelman Ventures, LLC	402,058	\$ 2,499,997
Foresite Capital Fund IV, L.P. <sup>(1)(2)</sup>	3,216,468	\$19,999,998
Nextech V Oncology S.C.S., SICAV-SIF <sup>(2)</sup>	2,733,998	\$17,000,000
OrbiMed Private Investments VII, LP <sup>(2)(3)</sup>	3,216,468	\$19,999,998
Vida Ventures, LLC <sup>(2)</sup>	2,412,351	\$14,999,999

- (1) Michael Rome, Ph.D., is a member of our board of directors and a Managing Director of Foresite Capital. Jim Tananbaum, M.D., is a member of our board of directors and CEO and Managing Director of Foresite Capital.
- (2) Additional details regarding this stockholder and its equity holdings, including the identities of the natural persons who exercise voting and dispositive power with respect to its shares, are provided in this prospectus under the section titled "Principal Stockholders."
- (3) Carl Gordon, Ph.D., a member of our board of directors, is a Founding Partner and Co-Head of Global Private Equity at OrbiMed Advisors, LLC.

**Series C Convertible Preferred Stock**

Investor	Shares of Series C Convertible Preferred Stock	Total Series C Convertible Preferred Stock Purchase Price
Entities affiliated with Fidelity Management & Research Company, LLC	1,043,405	\$ 9,999,994
Entities affiliated with Foresite Capital <sup>(1)(2)</sup>	432,984	\$ 4,149,719
Nextech V Oncology S.C.S., SICAV-SIF <sup>(2)</sup>	150,010	\$ 1,437,696
Entities affiliated with OrbiMed Advisors <sup>(2)(3)</sup>	176,481	\$ 1,691,394
Entities affiliated with RA Capital Management, L.P. <sup>(2)</sup>	3,651,919	\$34,999,992
Vida Ventures, LLC <sup>(2)</sup>	132,356	\$ 1,268,500

- (1) Michael Rome, Ph.D., is a member of our board of directors and a Managing Director of Foresite Capital. Jim Tananbaum, M.D., is a member of our board of directors and CEO and Managing Director of Foresite Capital.
- (2) Additional details regarding this stockholder and its equity holdings, including the identities of the natural persons who exercise voting and dispositive power with respect to its shares, are provided in this prospectus under the section titled "Principal Stockholders."
- (3) Carl Gordon, Ph.D., a member of our board of directors, is a Founding Partner and Co-Head of Global Private Equity at OrbiMed Advisors, LLC.

## **Investors' Rights Agreement**

We are party to an investors' rights agreement, as amended, with certain holders of our capital stock, including entities affiliated with Fidelity Management & Research Company, LLC, entities affiliated with Foresite Capital, Nextech V Oncology S.C.S., SICAV-SIF, entities affiliated with OrbiMed Advisors, entities affiliated with RA Capital Management, L.P., and Vida Ventures, LLC. Under our investors' rights agreement, certain holders of our capital stock have the right to demand that we file a registration statement or request that their shares of our capital stock be covered by a registration statement that we are otherwise filing. See the section titled "Description of Capital Stock—Registration Rights" for additional information regarding these registration rights.

## **Voting Agreement**

We are party to a voting agreement, as amended, with certain holders of our capital stock, including entities affiliated with Fidelity Management & Research Company, LLC, entities affiliated with Foresite Capital, Nextech V Oncology S.C.S., SICAV-SIF, entities affiliated with OrbiMed Advisors, entities affiliated with RA Capital Management, L.P., Vida Ventures, LLC, Nima Farzan, our President, Chief Executive Officer and a member of our board of directors, Stephen Kaldor, Ph.D., a member of our board of directors, Eric Murphy, Ph.D., our Chief Scientific Officer, Mark Meltz, our Chief Operating Officer and General Counsel, Richard Williams, Ph.D., our Chief Medical Officer, and Fount Therapeutics, LLC (FTL), an affiliate of Dr. Kaldor and Dr. Murphy. The parties to the voting agreement have agreed, subject to certain conditions, to vote the shares of our capital stock held by them so as to elect the following individuals as directors: (i) two individuals designated by Foresite Capital Fund IV, L.P., currently Michael Rome, Ph.D., and Jim Tananbaum, M.D.; (ii) one individual designated by OrbiMed Private Investments VII, LP, currently Carl Gordon, Ph.D.; (iii) our chief executive officer, currently Nima Farzan; (iv) one individual designated by the holders a majority of the outstanding shares of common stock held by the parties to the voting agreement, currently Stephen Kaldor, Ph.D.; and (v) four individuals not employed by or consultants to the us or affiliated with any of the holders of the our convertible preferred stock and designated by a majority of the other members of our board of directors, currently Keith Flaherty, M.D., Dean Mitchell, Lauri Smaldone Alsup, M.D., and Melissa Epperly.

Upon the consummation of this offering, the obligations of the parties to the voting agreement to vote their shares so as to elect these nominees, as well as the other rights and obligations under this agreement, will terminate and none of our stockholders will have any special rights regarding the nomination, election or designation of members of our board of directors. Our existing certificate of incorporation contains provisions regarding election of members of the board of directors that correspond to the voting agreement; however, such provisions will be removed in the amended and restated certificate of incorporation that will be effective at the closing of this offering.

## **Indemnification Agreements**

We have entered into separate indemnification agreements with each of our directors and executive officers, in addition to the indemnification provided for in our amended and restated certificate of incorporation and bylaws. The indemnification agreements and our amended restated certificate of incorporation and bylaws that will be in effect upon the closing of this offering require us to indemnify our directors, executive officers and certain controlling persons to the fullest extent permitted by Delaware law. See the section titled "Executive Compensation—Limitation of Liability and Indemnification" for additional information.

## **Master Services Agreement**

In June 2018 we entered into a Master Services Agreement with FTL and Fount Service Corp., a wholly owned subsidiary of FTL (FSC). Dr. Kaldor, one of our directors and our former Chief Executive Officer, and Dr. Murphy, our current Chief Scientific Officer and formerly one of our directors, are officers and directors of FTL and FSC and are the majority owners of FTL. Pursuant to the terms of this agreement, FTL and FSC agreed to provide management services and other services to us, either directly or via arrangements with third parties. These services included research and development and

general and administrative functions, such as finance, audit, accounting, human resources, technology, facilities, and other management services necessary for our operations. Under the agreement, we were also entitled to use hardware and computer systems and office space and other facilities provided by FTL and FSC. Services provided under the agreement were invoiced to us at cost plus five percent. We incurred expenses under the agreement of approximately \$3.1 million in 2018, \$4.9 million in 2019 and \$53,000 in 2020 for services provided under the agreement. FTL and FSC ceased providing any material services under this agreement in January 2020.

#### **Related Party Transaction Policy**

Our audit committee will have the primary responsibility for reviewing and approving or disapproving “related party transactions,” which are transactions between us and related persons in which the aggregate amount involved exceeds or may be expected to exceed \$120,000 and in which a related person has or will have a direct or indirect material interest. The charter of our audit committee will provide that our audit committee shall review and approve in advance any related party transaction.

Prior to the effectiveness of the registration statement of which this prospectus forms a part, we intend to adopt a formal written policy providing that we are not permitted to enter into any transaction that exceeds \$120,000 and in which any related person has a direct or indirect material interest without the consent of our audit committee. In approving or rejecting any such transaction, our audit committee is to consider the relevant facts and circumstances available and deemed relevant to our audit committee, including whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person’s interest in the transaction.

## PRINCIPAL STOCKHOLDERS

The following table sets forth the beneficial ownership of our common stock as of September 30, 2020, by:

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

We have determined beneficial ownership in accordance with the rules of the SEC, and thus it represents sole or shared voting or investment power with respect to our securities. Unless otherwise indicated below, to our knowledge, the persons and entities named in the table have sole voting and sole investment power with respect to all shares that they beneficially owned, subject to community property laws where applicable. The information does not necessarily indicate beneficial ownership for any other purpose, including for purposes of Sections 13(d) and 13(g) of the Exchange Act.

We have based our calculation of the percentage of beneficial ownership prior to this offering on 36,452,278 shares of our common stock outstanding as of September 30, 2020, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into 31,824,284 shares of our common stock immediately prior to the completion of this offering. We have based our calculation of the percentage of beneficial ownership after this offering on \_\_\_\_\_ shares of our common stock outstanding immediately after the completion of this offering, assuming no exercise by the underwriters of their option to purchase additional shares. We have deemed shares of our common stock subject to stock options that are currently exercisable or exercisable within 60 days of September 30, 2020, to be outstanding and to be beneficially owned by the person holding the stock option for the purpose of computing the percentage ownership of that person. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person.

Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o Kinnate Biopharma Inc., 11975 El Camino Real, Suite 101, San Diego, CA 92130.

Name of Beneficial Owner	Shares Beneficially Owned Prior to this Offering		Shares Beneficially Owned After this Offering	
	Shares	Percentage	Shares	Percentage
<b>5% and Greater Stockholders:</b>				
Entities affiliated with Foresite Capital <sup>(1)</sup>	12,145,700	33.32%		
Entities affiliated with OrbiMed <sup>(2)</sup>	3,824,489	10.49%		
Entities affiliated with RA Capital Management <sup>(3)</sup>	3,664,152	10.05%		
Nextech V Oncology S.C.S., SICAV-SIF <sup>(4)</sup>	3,250,820	8.92%		
Vida Ventures, LLC <sup>(5)</sup>	2,868,350	7.87%		
Stephen Kaldor, Ph.D. <sup>(6)</sup>	2,232,196	6.08%		
Eric Murphy, Ph.D. <sup>(7)</sup>	1,994,786	5.47%		
<b>Named Executive Officers and Directors:</b>				
Nima Farzan <sup>(8)</sup>	1,582,226	4.16%		
Eric Murphy, Ph.D. <sup>(7)</sup>	1,994,786	5.47%		
Dean Mitchell <sup>(9)</sup>	18,750	*		
Melissa Epperly <sup>**</sup>	—	—		
Keith Flaherty, M.D. <sup>(10)</sup>	81,947	*		
Carl Gordon, Ph.D. <sup>(11)</sup>	3,824,489	10.49%		
Stephen Kaldor, Ph.D. <sup>(6)</sup>	2,232,196	6.08%		
Michael Rome, Ph.D. <sup>(12)</sup>	—	—		
Laurie Smaldone Alsup, M.D. <sup>(13)</sup>	9,375	*		
Jim Tananbaum, M.D. <sup>(14)</sup>	12,145,700	33.32%		
All current executive officers and directors as a group (11 persons) <sup>(15)</sup>	22,364,156	57.56%		

\* Represents beneficial ownership of less than 1% of the outstanding shares of our common stock.

\*\* Ms. Epperly was appointed to the board of directors in October 2020.

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- (1) Consists of (i) 11,322,674 shares of capital stock held by Foresite Capital Fund IV, LP (Fund IV), (ii) 617,269 shares of capital stock held by Foresite Capital Fund V, LP (Fund V), and (iii) 205,757 shares of capital stock held by Foresite Capital Opportunity Fund V, L.P. (Opportunity Fund V), each on an as-converted to common stock basis. Jim Tananbaum, M.D., is a member of our board of directors and CEO and Managing Director of Foresite Capital. Foresite Capital Management IV, LLC (FCM IV) is the general partner of Fund IV and may be deemed to have sole voting and dispositive power over the shares held by Fund IV; Foresite Capital Management V, LLC (FCM V) is the general partner of Fund V and may be deemed to have sole voting and dispositive power over the shares held by Fund V; and Foresite Capital Opportunity Management V, LLC (FCOM V) is the general partner of Opportunity Fund V and may be deemed to have sole voting and dispositive power over the shares held by Opportunity Fund V. Dr. Tananbaum, in his capacity as managing member of FCM IV, FCM V, and FCOM V, may be deemed to have sole voting and dispositive power over all of such shares. Dr. Tananbaum disclaims beneficial ownership of the shares held by Fund IV, Fund V, and Opportunity Fund V except to the extent of his pecuniary interest therein, if any. The address of Dr. Tananbaum and each of the entities listed above is 600 Montgomery Street, Suite 4500, San Francisco, CA 94111.
- (2) Consists of (i) 3,720,047 shares of capital stock held by OrbiMed Private Investments VII, LP (OPI VII) and (ii) 104,442 shares of capital stock held by OrbiMed Genesis Master Fund, L.P. (Genesis), each on an as-converted to common stock basis. OrbiMed Capital GP VII LLC (OrbiMed GP VII) is the general partner of OPI VII and OrbiMed Advisors LLC (OrbiMed 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 power and investment power over the securities held by OPI VII and as a result, may be deemed to have beneficial ownership over such securities. OrbiMed Genesis GP LLC (Genesis GP) is the general partner of Genesis. OrbiMed 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 Advisors exercises voting and investment power through a management committee comprised of Carl L. Gordon, Ph.D., Sven H. Borho, and Jonathan T. Silverstein, each of whom disclaims beneficial ownership of the shares held by OPI VII and Genesis. The address of each of the individuals and entities listed above is 601 Lexington Avenue, 54th Floor, New York, NY 10022.
- (3) Consists of (i) 2,476,714 shares of capital stock held by RA Capital Healthcare Fund, L.P. (RA Capital Healthcare Fund), (ii) 916,038 shares of capital stock held by RA Capital Nexus Fund, L.P. (RA Capital Nexus Fund and, together with RA Capital Healthcare Fund, the Funds) and (iii) 271,400 shares of capital stock held by a separately managed account (the Account), each on an as-converted to common stock basis. RA Capital Management, L.P. (Adviser) is the investment manager for the Funds and the Account. The general partner of the Adviser is RA Capital Management GP, LLC (GP Adviser), of which Dr. Peter Kolchinsky and Mr. Rajeev Shah are the managing members. The Adviser, the Adviser GP, Dr. Kolchinsky, and Mr. Shah may be deemed indirect beneficial owners of the shares held by the Funds and the Account. The Advisor, the Advisor GP, Dr. Kolchinsky, and Mr. Shah disclaim beneficial ownership of all applicable shares except to the extent of their actual pecuniary interest therein. The address of each of the individuals and entities listed above is 200 Berkeley Street, 18th Floor, Boston, MA 02116.
- (4) Consists of 3,520,820 shares of capital stock held by Nextech V Oncology S.C.S. SICAV-SIF (Nextech V), on an as-converted to common stock basis. Nextech Invest Ltd. is a managing member of Nextech V. Nextech V GP S.A.R.L (Nextech V GP) is the general partner of Nextech V. Philippe Detournay, Dalia Bleyer and Thomas Lips are managers of Nextech V GP. Each of Mr. Detournay, Ms. Bleyer, and Mr. Lips exercise investment and voting control over the shares held by Nextech V. Each of Mr. Detournay, Ms. Bleyer, and Mr. Lips disclaim beneficial ownership over the shares held by Nextech V, except to the extent of their respective pecuniary interest therein, if any. The address of each of the individuals and entities listed above is 8, Rue Lou Hemmer, L-1748 Senningerberg, Grand Duchy of Luxembourg.
- (5) Consists of 3,250,820 shares of capital stock held by Vida Ventures, LLC (Vida), on an as-converted to common stock basis. VV Manager, LLC (VV Manager) is a managing member of Vida. Arjun Goyal, Fred Cohen, Arie Beldegrun, Leonard Potter and Stefan Vitorovic are also managing members of VV Manager. Arjun Goyal, Fred Cohen, Arie Beldegrun, Leonard Potter and Stefan Vitorovic exercise investment and voting control over the shares held by Vida. Each of Arjun Goyal, Fred Cohen, Arie Beldegrun, Leonard Potter and Stefan Vitorovic disclaim beneficial ownership of the shares held by Vida, except to the extent of their pecuniary interest therein, if any. The address of each of the individuals and entities listed above is 40 Broad Street, Suite 201, Boston, MA 02109.
- (6) Consists of (i) 1,994,786 shares of capital stock held by Dr. Kaldor and (ii) 237,410 shares subject to options held by Dr. Kaldor exercisable within 60 days of September 30, 2020.
- (7) Represents shares of capital stock held by Dr. Murphy.
- (8) Represents shares subject to options held by Mr. Farzan, all of which are exercisable and none of which are vested within 60 days of September 30, 2020.
- (9) Represents shares subject to options held by Mr. Mitchell exercisable within 60 days of September 30, 2020.
- (10) Represents shares subject to options held by Dr. Flaherty exercisable within 60 days of September 30, 2020.
- (11) Consists of the shares described in footnote (3) above. Dr. Gordon disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein, if any.
- (12) Dr. Rome has no voting or investment control over the shares held by entities affiliated with Foresite Capital that are included in footnote (1) above.
- (13) Represents shares subject to options held by Dr. Smaldone Alsup exercisable within 60 days of September 30, 2020.
- (14) Consists of the shares described in footnote (1) above. Dr. Tananbaum disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein, if any.
- (15) Consists of (i) 19,959,761 shares beneficially owned by our current executive officers and directors as of September 30, 2020 and (ii) 2,404,395 shares subject to options exercisable within 60 days of September 30, 2020, of which 347,482 are vested as of such date.

## DESCRIPTION OF CAPITAL STOCK

The following descriptions of our capital stock and certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws are summaries and are qualified by reference to the amended and restated certificate of incorporation and the amended and restated bylaws that will be in effect upon completion of this offering. Copies of these documents will be filed with the SEC as exhibits to our registration statement of which this prospectus forms a part. The descriptions of the common stock and preferred stock reflect changes to our capital structure that will occur upon the completion of this offering.

Immediately prior to the completion of this offering and the filing of our amended and restated certificate of incorporation to be effective upon completion of this offering, our authorized capital stock will consist of 47,000,000 shares of common stock, par value \$0.0001 per share, and 31,790,040 shares of preferred stock, par value \$0.0001 per share.

Immediately prior to the completion of this offering, all the outstanding shares of our convertible preferred stock will automatically convert into an aggregate of 31,824,284 shares of our common stock.

Based on 36,452,278 shares of common stock outstanding as of September 30, 2020, and after giving effect to the automatic conversion of all of our outstanding convertible preferred stock into an aggregate of 31,824,284 shares of common stock immediately prior to the completion of this offering and the issuance of                      shares of common stock in this offering, there will be                      shares of common stock outstanding upon the completion of this offering. As of September 30, 2020, we had 34 stockholders of record.

### **Common Stock**

#### ***Voting Rights***

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our amended and restated certificate of incorporation and amended and restated bylaws to be in effect upon the completion of this offering do not provide for cumulative voting rights. Because of this, the holders of a plurality 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. With respect to matters other than the election of directors, at any meeting of the stockholders at which a quorum is present or represented, the affirmative vote of a majority of the voting power of the shares present in person or represented by proxy at such meeting and entitled to vote on the subject matter shall be the act of the stockholders, except as otherwise required by law. The holders of a majority of the stock issued and outstanding and entitled to vote, present in person or represented by proxy, shall constitute a quorum for the transaction of business at all meetings of the stockholders.

#### ***Dividends***

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

Prior to the completion of this offering, the holders of our Series A convertible preferred stock, Series B convertible preferred stock, and Series C convertible preferred stock in preference to any distributions to the holders of common stock, are entitled to receive dividends at an annual rate of \$0.16 per share for the Series A convertible preferred stock holders, \$0.497 per share for the Series B convertible preferred stock holders and \$0.767 per share for the Series C convertible preferred stock holders. Such dividends are payable only when and if declared by our board of directors and shall not be cumulative. Immediately prior to the completion of this offering, all outstanding shares of our convertible preferred stock will be automatically converted into our common stock and the foregoing dividend preferences will no longer be applicable.



### ***Liquidation***

In the event of our liquidation, dissolution or winding up, holders of our 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.

Prior to the completion of this offering, the holders of our Series A convertible preferred stock, Series B convertible preferred stock, and Series C convertible preferred stock are entitled to receive liquidation preferences at the rate of \$2.00 per share for the Series A convertible preferred stock, \$6.218 per share for the Series B convertible preferred stock, and \$9.584 per share for the Series C convertible preferred stock, in each case plus all accrued and declared but unpaid dividends on the applicable series of stock. Liquidation payments to the holders of the Series A, Series B and Series C convertible preferred stock have priority and are made in preference to any payments to the holders of common stock. After full payment of the liquidation preference to the holders of the Series A, Series B and Series C convertible preferred stock, the remaining assets, if any, will be distributed ratably to the holders of the common stock. Immediately prior to the completion of this offering, all outstanding shares of our convertible preferred stock will be automatically converted into our common stock and the foregoing liquidation preferences will no longer be applicable.

### ***Rights, Preferences and Privileges***

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

### ***Fully Paid and Nonassessable***

All of our outstanding shares of common stock are, and the shares of common stock to be issued in this offering, upon payment and delivery in accordance with the underwriting agreement, will be fully paid and nonassessable.

### ***Preferred Stock***

Upon the completion of this offering, our board of directors will have the authority, without further action by the stockholders, to issue up to \_\_\_\_\_ shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, redemption rights, 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 common stock. The issuance of preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in our control or other corporate action. Upon the completion of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

### ***Options***

As of September 30, 2020, we had outstanding options to purchase an aggregate of 7,037,046 shares of our common stock, with a weighted-average exercise price of \$2.49 per share, under our 2018 Plan.

### ***Registration Rights***

After the completion of this offering, under our investors' rights agreement, as amended, the holders of shares of common stock or their transferees, will have the right to require us to register the offer and sale of their shares or to include their shares in any registration statement we file, in each case as described below.

### ***Demand Registration Rights***

After the completion of this offering, the holders of up to 31,824,284 shares of our common stock will be entitled to certain demand registration rights. At any time beginning after 180 days following the date of effectiveness of the registration statement of which this prospectus forms a part, the holders of at least 30% of the shares having registration rights then outstanding can request that we file a registration statement to register the offer and sale of their shares. We are only obligated to effect up to two such registrations. Each such request for registration must cover securities the anticipated aggregate gross proceeds of which, before deducting underwriting discounts and expenses, is at least \$15 million. These demand registration rights are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under certain circumstances. If we determine that it would be materially detrimental to us and our stockholders to effect such a demand registration, we have the right to defer such registration, not more than twice in any twelve-month period, for a period of up to 90 days.

### ***Form S-3 Registration Rights***

After the completion of this offering, the holders of up to 31,824,284 shares of our common stock will be entitled to certain Form S-3 registration rights. At any time after the completion of this offering when we are eligible to file a registration statement on Form S-3, the holders of at least 20% of the shares having these rights then outstanding can request that we register the offer and sale of their shares of our common stock on a registration statement on Form S-3 so long as the request covers securities the anticipated aggregate public offering price of which is at least \$3 million. These stockholders may make an unlimited number of requests for registration on a registration statement on Form S-3. However, we will not be required to effect a registration on Form S-3 if we have effected two such registrations within the twelve month period preceding the date of the request. These Form S-3 registration rights are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under certain circumstances. Additionally, if we determine that it would be seriously detrimental to us and our stockholders to effect such a demand registration, we have the right to defer such registration, not more than twice in any twelve month period, for a period of up to 90 days.

### ***Piggyback Registration Rights***

After the completion of this offering, the holders of up to 31,824,284 shares of our common stock will be entitled to certain “piggyback” registration rights. If we propose to register the offer and sale of shares of our common stock under the Securities Act, the holders of these shares can request that we include their shares in such registration, subject to certain marketing and other limitations, including the right of the underwriters to limit the number of shares included in any such registration statement under certain circumstances. As a result, whenever we propose to file a registration statement under the Securities Act, other than with respect to (i) a registration solely to employee benefit plans; (ii) a registration relating to the offer and sale of debt securities; (iii) a registration relating to a corporate reorganization or other transaction covered by Rule 145 promulgated under the Securities Act; (iv) a registration on any registration form that does not permit secondary sales; or (v) a registration pursuant to the demand or Form S-3 registration rights described in the preceding two paragraphs above, the holders of these shares are entitled to notice of the registration and have the right, subject to certain limitations, to include their shares in the registration.

### ***Expenses of Registration***

We will pay all expenses relating to any demand registrations, Form S-3 registrations and piggyback registrations, subject to specified exceptions.

### ***Termination***

The registration rights terminate upon the earliest of (i) the date that is four years after the closing of this offering; (ii) immediately prior to the closing of certain liquidation events; and (iii) as to a given holder of registration rights, the date after the closing of this offering when such holder of registration rights can sell all of such holder's registrable securities during any 90-day period pursuant to Rule 144 promulgated under the Securities Act.

**Anti-Takeover Effects of Certain Provisions of Delaware Law, Our Amended and Restated Certificate of Incorporation and Our Amended and Restated Bylaws**

Certain provisions of Delaware law and certain provisions that will be included in our amended and restated certificate of incorporation and amended and restated bylaws summarized below may be deemed to have an anti-takeover effect and may delay, deter or prevent a tender offer or takeover attempt that a stockholder might consider to be in its best interests, including attempts that might result in a premium being paid over the market price for the shares held by stockholders.

***Preferred Stock***

Our amended and restated certificate of incorporation will contain provisions that permit our board of directors to issue, without any further vote or action by the stockholders, shares of preferred stock in one or more series and, with respect to each such series, to fix the number of shares constituting the series and the designation of the series, the voting rights (if any) of the shares of the series and the powers, preferences or relative, participation, optional and other special rights, if any, and any qualifications, limitations or restrictions, of the shares of such series.

***Classified Board***

Our amended and restated certificate of incorporation will provide that our board of directors is divided into three classes, designated Class I, Class II and Class III. Each class will be an equal number of directors, as nearly as possible, consisting of one third of the total number of directors constituting the entire board of directors. The term of initial Class I directors shall terminate on the date of the 2021 annual meeting, the term of the initial Class II directors shall terminate on the date of the 2022 annual meeting, and the term of the initial Class III directors shall terminate on the date of the 2023 annual meeting. At each annual meeting of stockholders beginning in 2021, the class of directors whose term expires at that annual meeting will be subject to reelection for a three-year term.

***Removal of Directors***

Our amended and restated certificate of incorporation will provide that stockholders may only remove a director for cause by a vote of no less than a majority of the shares present in person or by proxy at the meeting and entitled to vote.

***Director Vacancies***

Our amended and restated certificate of incorporation will authorize only our board of directors to fill vacant directorships.

***No Cumulative Voting***

Our amended and restated certificate of incorporation will provide that stockholders do not have the right to cumulate votes in the election of directors.

***Special Meetings of Stockholders***

Our amended and restated certificate of incorporation and amended and restated bylaws will provide that, except as otherwise required by law, special meetings of the stockholders may be called only by an officer at the request of a majority of our board of directors, by the Chair of our board of directors or by our Chief Executive Officer.

***Advance Notice Procedures for Director Nominations***

Our amended and restated bylaws will provide that stockholders seeking to nominate candidates for election as directors at an annual or special meeting of stockholders must provide timely notice thereof in writing. To be timely, a stockholder's notice generally will have to be delivered to and received at our principal executive offices before notice of the meeting is issued by the secretary of the company, with such notice being served not less than 90 nor more than 120 days before the meeting. Although the amended and restated bylaws will not give the board of directors the power to approve or disapprove

stockholder nominations of candidates to be elected at an annual meeting, the amended and restated bylaws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of the company.

#### ***Action by Written Consent***

Our amended and restated certificate of incorporation and amended and restated bylaws will provide that any action to be taken by the stockholders must be effected at a duly called annual or special meeting of stockholders and may not be effected by written consent.

#### ***Amending Our Certificate of Incorporation and Bylaws***

Our amended and restated certificate of incorporation may be amended or altered in any manner provided by the Delaware General Corporation Law (DGCL). Our amended and restated bylaws may be adopted, amended, altered or repealed by stockholders only upon approval of at least majority of the voting power of all the then outstanding shares of the common stock, except for any amendment of the above provisions, which would require the approval of a two-thirds majority of our then outstanding common stock. Additionally, our amended and restated certificate of incorporation will provide that our bylaws may be amended, altered or repealed by the board of directors.

#### ***Authorized but Unissued Shares***

Our authorized but unissued shares of common stock and preferred stock will be available for future issuances without stockholder approval, except as required by the listing standards of , and could be utilized for a variety of corporate purposes, including future offerings to raise additional capital, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved common stock and preferred stock could render more difficult or discourage an attempt to obtain control of the company by means of a proxy contest, tender offer, merger or otherwise.

#### ***Exclusive Jurisdiction***

Our amended and restated bylaws will provide that, unless we consent to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of fiduciary duty, any action asserting a claim arising pursuant to the DGCL, any action regarding our amended and restated certificate of incorporation or amended and restated bylaws, or any action asserting a claim against us that is 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. Our amended and restated bylaws further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in our securities shall be deemed to have notice of and consented to these provisions. Although we believe these provisions benefit us by providing increased consistency in the application of law for the specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits against us or our directors and officers. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings. We also note that stockholders cannot waive compliance (or consent to noncompliance) with the federal securities laws and the rules and regulations thereunder. See the section titled "Risk factors—Our amended and restated bylaws that will become effective upon the closing of this offering provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be 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."

***Business Combinations with Interested Stockholders***

We are governed by Section 203 of the DGCL. Subject to certain exceptions, Section 203 of the DGCL prohibits a public Delaware corporation from engaging in a business combination (as defined in such section) with an “interested stockholder” (defined generally as any person who beneficially owns 15% or more of the outstanding voting stock of such corporation or any person affiliated with such person) for a period of three years following the time that such stockholder became an interested stockholder, unless (i) prior to such time the board of directors of such corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder; (ii) upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of such corporation at the time the transaction commenced (excluding for purposes of determining the voting stock of such corporation outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (1) by persons who are directors and also officers of such corporation and (2) by 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 (iii) at or subsequent to such time the business combination is approved by the board of directors of such corporation and authorized at a meeting of stockholders (and not by written consent) by the affirmative vote of at least 66 2/3% of the outstanding voting stock of such corporation not owned by the interested stockholder.

Our amended and restated certificate of incorporation and our amended and restated bylaws will provide that we must indemnify our directors and officers to the fullest extent authorized by the DGCL. We are expressly authorized to, and do, carry directors’ and officers’ insurance providing coverage for our directors, officers and certain employees for some liabilities. We believe that these indemnification provisions and insurance are useful to attract and retain qualified directors and executive officers.

The limitation on liability and indemnification provisions in our certificate of incorporation and bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duty. These provisions may also have the effect of reducing the likelihood of derivative litigation against directors and officers, even though such an action, if successful, might otherwise benefit us and our stockholders. In addition, each investor’s investment may be adversely affected to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

***Listing***

We intend to apply to list our common stock on \_\_\_\_\_ under the symbol “\_\_\_\_\_.”

***Transfer Agent and Registrar***

Upon completion of this offering, the transfer agent and registrar for our common stock will be \_\_\_\_\_. The transfer agent and registrar’s address is \_\_\_\_\_.

## SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock, and although we expect that our common stock will be approved for listing on the \_\_\_\_\_, we cannot assure investors that there will be an active public market for our common stock following this offering. We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. Future sales of substantial amounts of common stock in the public market, including shares issued upon exercise of outstanding options, or the perception that such sales may occur, however, could adversely affect the market price of our common stock and also could adversely affect our future ability to raise capital through the sale of our common stock or other equity-related securities of ours at times and prices we believe appropriate.

Upon completion of this offering, based on our shares outstanding as of September 30, 2020, and after giving effect to the conversion of all outstanding shares of our convertible preferred stock, \_\_\_\_\_ shares of our common stock will be outstanding, or \_\_\_\_\_ shares of common stock if the underwriters exercise their option to purchase additional shares in full. All of the shares of common stock expected to be sold in this offering will be freely tradable without restriction or further registration under the Securities Act unless held by our "affiliates," as that term is defined in Rule 144 under the Securities Act. The remaining outstanding shares of our common stock will be deemed "restricted securities" as that term is defined under Rule 144. Restricted securities may be sold in the public market only if their offer and sale is registered under the Securities Act or if the offer and sale of those securities qualify for an exemption from registration, including exemptions provided by Rules 144 and 701 under the Securities Act, which are summarized below.

As a result of the lock-up agreements and market stand-off provisions described below and the provisions of Rules 144 or 701, the shares of our common stock that will be deemed "restricted securities" will be available for sale in the public market following the completion of this offering as follows:

- no shares will be eligible for sale on the date of this prospectus; and
- \_\_\_\_\_ shares will be eligible for sale upon expiration of the lock-up agreements and market stand-off provisions described below, following the date that is 180 days after the date of this prospectus.

### Lock-up Agreements and Market Stand-Off Agreements

Our officers, directors and the holders of substantially all of our securityholders have entered into market stand-off agreements with us and have entered into or will enter into lock-up agreements with the underwriters, subject to certain exceptions, not to dispose of or hedge any of their common stock or securities convertible into or exchangeable for shares of common stock during the period from the date of this prospectus continuing through the date 180 days after the date of this prospectus, except with the prior consent of Goldman Sachs & Co. LLC, SVB Leerink LLC and Piper Sandler & Co. See the section titled "Underwriting" for additional information.

### Rule 144

Rule 144, as currently in effect, generally provides that, once we have been subject to the public company reporting requirements of Section 13 or Section 15(d) of the Exchange Act for at least 90 days, a stockholder who is not deemed to have been one of our affiliates at any time during the preceding 90 days and who has beneficially owned the shares of our capital stock proposed to be sold for at least six months is entitled to sell such shares in reliance upon Rule 144 without complying with the volume limitation, manner of sale or notice conditions of Rule 144. If such stockholder has beneficially owned the shares of our capital stock proposed to be sold for at least one year, then such person is entitled to sell such shares in reliance upon Rule 144 without complying with any of the other conditions of Rule 144.



Rule 144 also provides that a stockholder who is deemed to have been one of our affiliates at any time during the preceding 90 days and who has beneficially owned the shares of our common stock proposed to be sold for at least six months is entitled to sell such shares in reliance upon Rule 144 within any three month period beginning 90 days after the date of this prospectus a number of such shares that does not exceed the greater of the following:

- 1% of the number of shares of our capital stock then outstanding, which will equal        shares immediately after the completion of this offering, assuming no exercise by the underwriters of their option to purchase additional shares; or
- the average weekly trading volume of our common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales of our capital stock made in reliance upon Rule 144 by a stockholder who is deemed to have been one of our affiliates at any time during the preceding 90 days are also subject to the current public information, manner of sale and notice conditions of Rule 144.

#### **Rule 701**

Rule 701 generally provides that, once we have been subject to the public company reporting requirements of Section 13 or Section 15(d) of the Exchange Act for at least 90 days, a stockholder who purchased shares of our common stock pursuant to a written compensatory benefit plan or contract and who is not deemed to have been one of our affiliates at any time during the preceding 90 days may sell such shares in reliance upon Rule 144 without complying with the current public information or holding period conditions of Rule 144. Rule 701 also provides that a stockholder who purchased shares of our common stock pursuant to a written compensatory benefit plan or contract and who is deemed to have been one of our affiliates during the preceding 90 days may sell such shares under Rule 144 without complying with the holding period condition of Rule 144. However, all stockholders who purchased shares of our common stock pursuant to a written compensatory benefit plan or contract are required to wait until 90 days after the date of this prospectus before selling such shares pursuant to Rule 701.

#### **Registration Rights**

After the completion of this offering, the holders of up to 31,824,284 shares of our common stock will be entitled to certain rights with respect to the registration of such shares under the Securities Act. The registration of these shares of our common stock under the Securities Act would result in these shares becoming eligible for sale in the public market without restriction under the Securities Act immediately upon the effectiveness of such registration. See the section titled “Description of Capital Stock—Registration Rights” for a description of these registration rights.

#### **Registration Statement**

After the completion of this offering, we intend to file a registration statement on Form S-8 under the Securities Act to register all of the shares of our common stock subject to equity awards outstanding or reserved for issuance under our equity compensation plans. The shares of our common stock covered by such registration statement will be eligible for sale in the public market without restriction under the Securities Act immediately upon the effectiveness of such registration statement, subject to vesting restrictions, the conditions of Rule 144 applicable to affiliates, and any applicable market stand-off agreements and lock-up agreements. See the section titled “Executive Compensation—Employee Benefit and Stock Plans” for a description of our equity compensation plans.

**MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS**

The following is a summary of the material U.S. federal income tax considerations of the ownership and disposition of our common stock acquired in this offering by a “non-U.S. holder” (as defined below), but does not purport to be a complete analysis of all the potential tax considerations relating thereto. This summary is based upon the provisions of the Internal Revenue Code of 1986, as amended (the Code), Treasury Regulations promulgated thereunder, administrative rulings and judicial decisions, all as of the date hereof. These authorities may be changed, possibly retroactively, so as to result in U.S. federal income tax consequences different from those set forth below. We have not sought, and do not intend to seek, any ruling from the Internal Revenue Service (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 summary also does not address the tax considerations arising under the laws of any non-U.S., state or local jurisdiction or under U.S. federal gift and estate tax rules, and does not address tax considerations applicable to an investor's particular circumstances or to investors that may be subject to special tax rules, including, without limitation:

- banks, insurance companies, regulated investment companies, real estate investment trusts or other financial institutions;
- tax-exempt organizations;
- pension plans and tax-qualified retirement plans;
- controlled foreign corporations, passive foreign investment companies and corporations that accumulate earnings to avoid U.S. federal income tax;
- brokers or dealers in securities or currencies;
- traders in securities that elect to use a mark-to-market method of accounting for their securities holdings;
- persons that own, or are deemed to own, more than 5% of our capital stock (except to the extent specifically set forth below);
- certain former citizens or long-term residents of the United States;
- partnerships (or entities or arrangements classified as such for U.S. federal income tax purposes), other pass-through entities, and investors therein;
- persons who hold our common stock as a position in a hedging transaction, “straddle,” “conversion transaction” or other risk reduction transaction;
- persons who hold or receive our common stock pursuant to the exercise of any option or otherwise as compensation;
- persons subject to special tax accounting rules as a result of any item of gross income with respect to our common stock being taken into account in an “applicable financial statement” as defined in Section 451(b) of the Code;
- persons who do not hold our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, property held for investment); or
- persons deemed to sell our common stock under the constructive sale provisions of the Code.

In addition, if a partnership (or an entity or arrangement classified as a partnership for U.S. federal income tax purposes) holds our common stock, the tax treatment of a partner in such partnership or other entity generally will depend on the status of the partner and upon the activities of the partnership or other entity. A partner in a partnership or other such entity that will hold our common stock should consult his, her or its own tax advisor regarding the tax consequences of the ownership and disposition of our common stock through a partnership or other such entity, as applicable.

**You are urged to consult your tax advisor with respect to the application of the U.S. federal income tax laws to your particular situation, as well as any tax consequences of the purchase, ownership and disposition of our common stock arising under the U.S. federal gift or estate tax rules or under the laws of any state, local, non-U.S. or other taxing jurisdiction or under any applicable tax treaty.**

### **Non-U.S. Holder Defined**

For purposes of this discussion, you are a “non-U.S. holder” if you are a beneficial owner of our common stock that, for U.S. federal income tax purposes, is not a partnership (including any entity or arrangement treated as a partnership and the equity holders therein) or:

- an individual who is a citizen or resident of the United States;
- a corporation or other entity taxable as a corporation created or organized in the United States or under the laws of the United States or any political subdivision thereof, or otherwise treated as such for U.S. federal income tax purposes;
- an estate whose income is subject to U.S. federal income tax regardless of its source; or
- a trust (i) whose administration is subject to the primary supervision of a U.S. court and that has one or more U.S. persons who have the authority to control all substantial decisions of the trust or (ii) that has made a valid election under applicable Treasury Regulations to be treated as a U.S. person.

### **Distributions**

As described in the section titled “Dividend Policy,” we have never declared or paid cash dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future. However, if we do make distributions on our common stock, those payments 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. To the extent those distributions exceed both our current and our accumulated earnings and profits, the excess will constitute a return of capital and will first reduce your basis in our common stock, but not below zero, and then will be treated as gain from the sale of stock.

Subject to the discussions below on effectively connected income and in the subsections titled “—Backup Withholding and Information Reporting” and “—Foreign Account Tax Compliance Act (FATCA),” any dividend paid to you generally will be subject to U.S. federal withholding tax either at a rate of 30% of the gross amount of the dividend or such lower rate as may be specified by an applicable income tax treaty between the United States and your country of residence. In order to receive a reduced treaty rate, you must provide us with a properly executed IRS Form W-8BEN or W-8BEN-E or other appropriate version of IRS Form W-8 certifying qualification for the reduced rate. If you are eligible for a reduced rate of U.S. federal withholding tax pursuant to an income tax treaty, you may obtain a refund of any excess amounts withheld by filing an appropriate claim for refund with the IRS. If you hold our common stock through a financial institution or other agent acting on the non-U.S. holder’s behalf, you will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or our paying agent, either directly or through other intermediaries.

Dividends received by you that are treated as effectively connected with your conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, are attributable to a permanent establishment or fixed base maintained by you in the United States) are generally exempt from the 30% U.S. federal withholding tax, subject to the discussion below in the subsections titled “—Backup Withholding and Information Reporting” and “—Foreign Account Tax Compliance Act (FATCA).” In order to obtain this exemption, you must provide us with a properly executed IRS Form W-8ECI or applicable successor form properly certifying such exemption. Such effectively connected dividends, although not subject to U.S. federal withholding tax, are taxed at the same graduated rates applicable to U.S. persons, net of certain deductions and credits, subject to an applicable income tax treaty providing otherwise. In addition, if you are a corporate non-U.S. holder, dividends you receive that are effectively connected with

your conduct of a U.S. trade or business may also be subject to a branch profits tax at a rate of 30% or such lower rate as may be specified by an applicable income tax treaty between the United States and your country of residence. You should consult your tax advisor regarding the tax consequences of the ownership and disposition of our common stock, including any applicable tax treaties that may provide for different rules.

### **Gain on Disposition of Common Stock**

Subject to the discussion in the subsections titled “—Backup Withholding and Information Reporting,” and “—Foreign Account Tax Compliance Act (FATCA),” you generally will not be required to pay U.S. federal income tax on any gain realized upon the sale or other disposition of our common stock unless:

- the gain is effectively connected with your conduct of a U.S. trade or business (and, if an applicable income tax treaty so provides, the gain is attributable to a permanent establishment or fixed base maintained by you in the United States);
- you are an individual who is present in the United States for a period or periods aggregating 183 days or more during the calendar year in which the sale or disposition occurs and certain other conditions 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” (USRPHC), for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding your disposition of, or your holding period for, our common stock, unless our common stock is regularly traded on an established securities market and you hold no more than 5% of our outstanding common stock, directly, indirectly and constructively, at all times, during the shorter of the five-year period ending on the date of the taxable disposition or your holding period for our common stock.

We believe that we are not currently and will not become a USRPHC for U.S. federal income tax purposes, and the remainder of this discussion so assumes. However, because the determination of 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 U.S. and worldwide real property interests plus our other assets used or held for use in a trade or business, there can be no assurance that we will not become a USRPHC in the future. If we are a USRPHC and either our common stock is not regularly traded on an established securities market or you hold, or are treated as holding, more than 5% of our outstanding common stock, directly or indirectly, during the applicable testing period, you will generally be taxed on any gain in the same manner as gain that is effectively connected with the conduct of a U.S. trade or business, except that the branch profits tax generally will not apply. If we are a USRPHC and our common stock is not regularly traded on an established securities market, your proceeds received on the disposition of shares will also generally be subject to withholding at a rate of 15%. You are encouraged to consult your own tax advisors regarding the possible consequences to you if we are, or were to become, a USRPHC.

If you are a non-U.S. holder described in the first bullet above, you will be required to pay tax on the gain derived from the sale (net of certain deductions and credits) under the same graduated U.S. federal income tax rates applicable to U.S. persons, and a corporate non-U.S. holder described in the first bullet above also may be subject to the branch profits tax at a 30% rate, or such lower rate as may be specified by an applicable income tax treaty. If you are an individual non-U.S. holder described in the second bullet above, you will be subject to tax on such gain at 30% (or such lower rate specified by an applicable income tax treaty) on the gain derived from the sale, which gain may be offset by U.S. source capital losses for the year, provided you have timely filed U.S. federal income tax returns with respect to such losses. You should consult your tax advisor regarding any applicable income tax treaties or other agreements that may provide for different rules.

## **Backup Withholding and Information Reporting**

Generally, we must report annually to the IRS the amount of dividends paid to you, your name and address and the amount of tax withheld, if any. A similar report will be sent to you. Pursuant to applicable income tax treaties or other agreements, the IRS may make these reports available to tax authorities in your country of residence.

Payments of dividends on or of proceeds from the disposition of our common stock made to you may also be subject to backup withholding at a current rate of 24% unless you establish an exemption, for example, by properly certifying your non-U.S. status on a properly completed IRS Form W-8BEN or W-8BEN-E or another appropriate version of IRS Form W-8. Notwithstanding the foregoing, backup withholding may apply if either we or our paying agent has actual knowledge, or reason to know, that you are a U.S. person.

Backup withholding is not an additional tax; rather, the U.S. federal income tax liability of persons subject to backup withholding will be reduced by the amount of tax withheld. If withholding results in an overpayment of taxes, a refund or credit may generally be obtained from the IRS, provided that the required information is furnished to the IRS in a timely manner.

## **Foreign Account Tax Compliance Act (FATCA)**

The Foreign Account Tax Compliance Act, Treasury Regulations issued thereunder and official IRS guidance (collectively FATCA), generally impose a U.S. federal withholding tax of 30% on dividends on, and, subject to the discussion of certain proposed Treasury Regulations below, the gross proceeds from a sale or other disposition of our common stock, paid to a "foreign financial institution" (as specially defined under these rules), unless such institution enters into an agreement with the U.S. government to, among other things, withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding the 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 otherwise establishes an exemption. FATCA also generally imposes a U.S. federal withholding tax of 30% on dividends on and, subject to the discussion of certain proposed Treasury Regulations below, the gross proceeds from a sale or other disposition of our common stock paid to a "non-financial foreign entity" (as specially defined under these rules) unless such entity provides the withholding agent with a certification identifying the substantial direct and indirect U.S. owners of the entity, certifies that it does not have any substantial U.S. owners, or otherwise establishes an exemption. The withholding tax will apply regardless of whether the payment otherwise would be exempt from withholding tax, including under the exemptions described above. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. An intergovernmental agreement between the United States and your country of residence may modify the requirements described in this section. Prospective investors should consult with their own tax advisors regarding the application of FATCA withholding to their investment in, and ownership and disposition of, our common stock.

The Treasury Secretary has issued proposed Treasury Regulations, which, if finalized in their present form, would eliminate withholding under FATCA with respect to payment of gross proceeds from a sale or other disposition of our common stock. In its preamble to such proposed Treasury Regulations, the U.S. Treasury stated that taxpayers may generally rely on the proposed Treasury Regulations until final regulations are issued.

**The preceding discussion of U.S. federal tax considerations is for general information only. It is not tax advice to investors in their particular circumstances. Each prospective investor should consult its own tax advisor regarding the particular U.S. federal, state and local and non-U.S. tax consequences of purchasing, holding and disposing of our common stock, including the consequences of any proposed change in applicable laws.**

## UNDERWRITING

We and the underwriters named below have entered into an underwriting agreement with respect to the shares being offered. Subject to certain conditions, each underwriter has severally agreed to purchase the number of shares indicated in the following table. Goldman Sachs & Co. LLC, SVB Leerink LLC and Piper Sandler & Co. are the representatives of the underwriters.

Underwriters	Number of Shares
Goldman Sachs & Co. LLC	
SVB Leerink LLC	
Piper Sandler & Co.	
Wedbush Securities Inc.	
Total	

The underwriters are committed to take and pay for all of the shares being offered, if any are taken, other than the shares covered by the option described below unless and until this option is exercised.

The underwriters have an option to buy up to an additional \_\_\_\_\_ shares from us to cover sales by the underwriters of a greater number of shares than the total number set forth in the table above. They may exercise that option for 30 days. If any shares are purchased pursuant to this option, the underwriters will severally purchase shares in approximately the same proportion as set forth in the table above.

The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters by us. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase up to an \_\_\_\_\_ additional shares from us.

	No Exercise	Full Exercise
Per Share	\$	\$
Total	\$	\$

Shares sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount of up to \$ \_\_\_\_\_ per share from the initial public offering price. After the initial offering of the shares, the representatives may change the offering price and the other selling terms. The offering of the shares by the underwriters is subject to receipt and acceptance and subject to the underwriters' right to reject any order in whole or in part.

We and our officers, directors, and holders of substantially all of our common stock and securities convertible into or exchangeable for our common stock have agreed or will agree with the underwriters, subject to certain exceptions, not to dispose of or hedge any of our or their common stock or securities convertible into or exchangeable for shares of common stock during the period from the date of this prospectus continuing through the date 180 days after the date of this prospectus, except with the prior written consent of Goldman Sachs & Co. LLC, SVB Leerink LLC and Piper Sandler & Co. This agreement does not apply to any existing employee benefit plans. See the section of this prospectus titled "Shares Eligible for Future Sale" for a discussion of certain transfer restrictions.

Prior to the offering, there has been no public market for the shares. The initial public offering price has been negotiated among the company and the representatives. Among the factors to be considered in determining the initial public offering price of the shares, in addition to prevailing market conditions, will be the company's historical performance, estimates of the business potential and earnings prospects of the company, an assessment of our management and the consideration of the above factors in relation to market valuation of companies in related businesses.

We intend to apply to list our common stock on \_\_\_\_\_ under the symbol "\_\_\_\_\_."

In connection with the offering, the underwriters may purchase and sell shares of our common stock in the open market. These transactions may include short sales, stabilizing transactions and purchases to



cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering, and a short position represents the amount of such sales that have not been covered by subsequent purchases. A “covered short position” is a short position that is not greater than the amount of additional shares for which the underwriters’ option described above may be exercised. The underwriters may cover any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to cover 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 additional shares pursuant to the option described above. “Naked” short sales are any short sales that create a short position greater than the amount of additional shares for which the option described above may be exercised. The underwriters must cover any such 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 common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of our common stock, and together with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of our common stock. As a result, the price of our common stock may be higher than the price that otherwise might exist in the open market. The underwriters are not required to engage in these activities and may end any of these activities at any time. These transactions may be effected on \_\_\_\_\_, in the over-the-counter market or otherwise.

We estimate that our share of the total expenses of the offering, excluding underwriting discounts and commissions, will be approximately \$ \_\_\_\_\_. We have agreed to reimburse the underwriters for certain of their expenses in an amount up to \$ \_\_\_\_\_.

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

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Certain of the underwriters and their respective affiliates may in the future provide, a variety of these services to the issuer and to persons and entities with relationships with the issuer, for which they will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and their respective affiliates, officers, directors and employees may purchase, sell or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve or relate to assets, securities and/or instruments of the issuer (directly, as collateral securing other obligations or otherwise) and/or persons and entities with relationships with the issuer. The underwriters and 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 assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities and instruments.

An investment fund associated with SVB Leerink LLC purchased 104,340 shares of our Series C convertible preferred stock in our July 2020 Series C convertible preferred stock financing. The shares of Series C convertible preferred stock that this entity received in the Series C convertible preferred stock financing are excluded from underwriting compensation pursuant to FINRA Rule 5110(d)(5)(C).

## **European Economic Area and United Kingdom**

In relation to each Member State of the European Economic Area and the United Kingdom (each a Relevant State), no shares of common stock (Shares) have been offered or will be offered pursuant to the offering 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:

- (i) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;
- (ii) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or
- (iii) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of Shares shall require 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.

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.

## **United Kingdom**

Each Underwriter has represented and agreed that:

- (i) it has only communicated or caused to be communicated and will only communicate or cause to be communicated 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, the FSMA)) received by it in connection with the issue or sale of the shares in circumstances in which Section 21(1) of the FSMA does not apply to the company; and
- (ii) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares in, from or otherwise involving the United Kingdom.

## **Canada**

The securities may be sold in Canada 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 securities must be made in accordance with an exemption form, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

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

## **Hong Kong**

The shares may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32 of the Laws of Hong Kong) (the Companies Ordinance) or which do not constitute an invitation to the public within the meaning of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong) (the Securities and Futures Ordinance), or (ii) to “professional investors” as defined in the Securities and Futures Ordinance and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a “prospectus” as defined in the Companies Ordinance, and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case 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 in 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” in Hong Kong as defined in the Securities and Futures Ordinance and any rules made thereunder.

## **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 the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor (as defined under Section 4A of the Securities and Futures Act, Chapter 289 of Singapore (the SFA)) under Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) 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, in each case subject to conditions set forth in the SFA.

Where the 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, the securities (as defined in Section 239(1) of the SFA) of that corporation shall not be transferable for 6 months after that corporation has acquired the shares under Section 275 of the SFA except: (i) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA); (ii) where such transfer arises from an offer in that corporation's securities pursuant to Section 275(1A) of the SFA; (iii) where no consideration is or will be given for the transfer; (iv) where the transfer is by operation of law; (v) as specified in Section 276(7) of the SFA; or (vi) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore (Regulation 32)

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a trust (where the trustee is not an accredited investor (as defined in Section 4A of the SFA)) whose sole purpose is to hold investments and each beneficiary of the trust is an accredited investor, the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferable for 6 months after that trust has acquired the shares under Section 275 of the SFA except: (i) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA); (ii) where such transfer arises from an offer that is made on terms that such rights or interest are acquired at a consideration of not less than S\$200,000 (or its equivalent in a foreign currency) for each transaction (whether such amount is to be paid for in cash or by exchange of securities or other assets); (iii) where no consideration is or will be given for the transfer; (iv) where the transfer is by operation of law; (v) as specified in Section 276(7) of the SFA; or (vi) as specified in Regulation 32.

Solely for the purposes of its obligations pursuant to Section 309B of the SFA, we have determined, and hereby notify all relevant persons (as defined in the CMP Regulations 2018), that the shares are

“prescribed capital markets products” (as defined in the CMP Regulations 2018) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).

## **Japan**

The securities have not been and will not be registered under the Financial Instruments and Exchange Act of Japan (Act No. 25 of 1948, as amended), or the FIEA. The securities may not be offered or sold, directly or indirectly, in Japan or to or for the benefit of any resident of Japan (including any person resident in Japan or any corporation or other entity organized under the laws of Japan) or to others for reoffering or resale, directly or indirectly, in Japan or to or for the benefit of any resident of Japan, except pursuant to an exemption from the registration requirements of the FIEA and otherwise in compliance with any relevant laws and regulations of Japan.

## **Australia**

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission (ASIC), in relation to the offering. This offering document does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001 (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 (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 the 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 offering document 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 offering document is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

## **Dubai International Financial Centre**

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

**Switzerland**

We have not and will not register with the Swiss Financial Market Supervisory Authority (FINMA) as a foreign collective investment scheme pursuant to Article 119 of the Federal Act on Collective Investment Scheme of 23 June 2006, as amended (CISA), and accordingly the securities being offered pursuant to this prospectus have not and will not be approved, and may not be licensable, with FINMA. Therefore, the securities have not been authorized for distribution by FINMA as a foreign collective investment scheme pursuant to Article 119 CISA and the securities offered hereby may not be offered to the public (as this term is defined in Article 3 CISA) in or from Switzerland. The securities may solely be offered to “qualified investors,” as this term is defined in Article 10 CISA, and in the circumstances set out in Article 3 of the Ordinance on Collective Investment Scheme of 22 November 2006, as amended (CISO), such that there is no public offer. Investors, however, do not benefit from protection under CISA or CISO or supervision by FINMA. This prospectus and any other materials relating to the securities are strictly personal and confidential to each offeree and do not constitute an offer to any other person. This prospectus may only be used by those qualified investors to whom it has been handed out in connection with the offer described in this prospectus and may neither directly or indirectly be distributed or made available to any person or entity other than its recipients. It may not be used in connection with any other offer and shall in particular not be copied and/or distributed to the public in Switzerland or from Switzerland. This prospectus does not constitute an issue prospectus as that term is understood pursuant to Article 652a and/or 1156 of the Swiss Federal Code of Obligations. We have not applied for a listing of the securities on the SIX Swiss Exchange or any other regulated securities market in Switzerland, and consequently, the information presented in this prospectus does not necessarily comply with the information standards set out in the listing rules of the SIX Swiss Exchange and corresponding prospectus schemes annexed to the listing rules of the SIX Swiss Exchange.

## **LEGAL MATTERS**

The validity of the issuance of our common stock offered in this prospectus will be passed upon for us by Wilson Sonsini Goodrich & Rosati, Professional Corporation, Palo Alto, California. Cooley LLP, San Diego, California, is acting as counsel for the underwriters.

## **EXPERTS**

The financial statements of Kinnate Biopharma Inc. as of December 31, 2018 and 2019, and for the period from January 4, 2018 (inception) to December 31, 2018 and for the year ended December 31, 2019, have been included herein and in the registration statement in reliance upon the report of KPMG LLP, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm 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 our common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement, as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document is not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The SEC also maintains an Internet website that contains the registration statement of which this prospectus forms a part, as well as the exhibits thereto. These documents, along with future reports, proxy statements and other information about us, are available at the SEC's website, [www.sec.gov](http://www.sec.gov).

As a result of this offering, we will become subject to the information and reporting requirements of the Exchange Act and, in accordance with this law, will file periodic reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information will be available for inspection and copying at the SEC's public reference facilities and the website of the SEC referred to above. We also maintain a website at [www.kinnate.com](http://www.kinnate.com) where these materials are available. Upon the completion of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on, or that can be accessible through, our website is not a part of this prospectus and the inclusion of our website address in this prospectus is an inactive textual reference only.



## KINNATE BIOPHARMA INC.

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**Report of Independent Registered Public Accounting Firm**

To the Stockholders and Board of Directors  
Kinnate Biopharma Inc.:

*Opinion on the Financial Statements*

We have audited the accompanying balance sheets of Kinnate Biopharma Inc. (the Company) as of December 31, 2018 and 2019, the related statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows for the period from January 4, 2018 (inception) to December 31, 2018 and for the year ended December 31, 2019, and the related notes (collectively, 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 the period from January 4, 2018 (inception) to December 31, 2018 and for the year ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

*Basis for Opinion*

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. 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/ KPMG LLP

We have served as the Company's auditor since 2020.

San Diego, California  
September 4, 2020

**Kinnate Biopharma Inc.**  
**Balance Sheets**  
(in thousands, except share and par value amounts)

	December 31,	
	2018	2019
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 6,999	\$ 76,453
Related party receivables, net (See Note 8)	1,078	973
Prepaid expenses	—	25
Total current assets	8,077	77,451
Property and equipment	—	154
Total assets	<u>\$ 8,077</u>	<u>\$ 77,605</u>
<b>Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)</b>		
Current liabilities:		
Accounts payable	\$ 442	\$ 956
Accrued expenses	25	989
Total current liabilities	467	1,945
Commitments and contingencies (See Note 10)		
Convertible preferred stock:		
Series A convertible preferred stock, \$0.0001 par value; 9,583,328 shares authorized at December 31, 2019; 9,583,328 shares issued and outstanding at December 31, 2019; aggregate liquidation preference of \$19,167 at December 31, 2019	—	18,942
Series B convertible preferred stock, \$0.0001 par value; 0 and 11,981,343 shares authorized, issued and outstanding at December 31, 2018 and 2019, respectively; aggregate liquidation preference of \$74,500 at December 31, 2019	—	74,204
Stockholders' equity (deficit):		
Series A convertible preferred stock, \$0.0001 par value; 7,000,000 shares authorized at December 31, 2018; 4,586,832 shares issued and outstanding at December 31, 2018	—	—
Common stock, \$0.0001 par value; 20,000,000 and 33,227,000 shares authorized at December 31, 2018 and 2019, respectively; 4,517,500 and 4,524,583 shares issued and outstanding at December 31, 2018 and 2019, respectively	—	—
Additional paid-in capital	15,240	82
Accumulated deficit	(7,630)	(17,568)
Total stockholders' equity (deficit)	7,610	(17,486)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	<u>\$ 8,077</u>	<u>\$ 77,605</u>

*See accompanying notes to financial statements.*

**Kinnate Biopharma Inc.**  
**Statements of Operations and Comprehensive Loss**  
(in thousands, except share and per share amounts)

	For the Period January 4, 2018 (Inception) through December 31, 2018	Year Ended December 31, 2019
Operating expenses:		
Research and development (includes related party amounts of \$1,454 and \$2,301, respectively)	\$ 5,675	\$ 8,955
General and administrative (includes related party amounts of \$1,600 and \$2,609, respectively)	<u>1,955</u>	<u>3,057</u>
Total operating expenses	<u>7,630</u>	<u>12,012</u>
Loss from operations	(7,630)	(12,012)
Other income:		
Interest income	<u>—</u>	<u>43</u>
Total other income	<u>—</u>	<u>43</u>
Net loss and comprehensive loss	<u>\$ (7,630)</u>	<u>\$ (11,969)</u>
Gain on extinguishment of Series A convertible preferred stock	<u>—</u>	<u>2,031</u>
Net loss attributable to common stockholders	<u>\$ (7,630)</u>	<u>\$ (9,938)</u>
Weighted-average shares outstanding, basic and diluted	<u>4,504,024</u>	<u>4,517,713</u>
Net loss attributable to common stockholders per share, basic and diluted	<u>\$ (1.69)</u>	<u>\$ (2.20)</u>
Pro forma weighted-average shares outstanding, basic and diluted (unaudited)		<u>13,333,894</u>
Pro forma net loss attributable to common stockholders per share, basic and diluted (unaudited)		<u>\$ (0.75)</u>

*See accompanying notes to financial statements.*

**Kinnate Biopharma Inc.**  
**Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)**  
(in thousands, except share amounts)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series A Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at January 4, 2018 (Inception)	—	\$ —	—	\$ —	—	\$ —	—	\$ —	—	\$ —	\$ —
Issuance of common stock	—	—	—	—	—	—	4,500,000	—	—	—	—
Issuance of Series A convertible preferred stock, net of issuance costs of \$136	—	—	—	—	4,586,832	—	—	—	15,198	—	15,198
Stock-based compensation expense	—	—	—	—	—	—	—	—	39	—	39
Exercise of stock options	—	—	—	—	—	—	17,500	—	3	—	3
Net loss	—	—	—	—	—	—	—	—	—	(7,630)	(7,630)
Balance at December 31, 2018	—	—	—	—	4,586,832	—	4,517,500	—	15,240	(7,630)	7,610
Issuance of Series A convertible preferred stock in merger	—	—	—	—	1,996,496	—	—	—	—	—	—
Extinguishment of Series A convertible preferred stock	—	—	—	—	—	—	—	—	(2,031)	2,031	—
Issuance of Series A convertible preferred stock, net of issuance costs of \$225	—	—	—	—	3,000,000	—	—	—	5,775	—	5,775
Issuance of Series B convertible preferred stock, net of issuance costs of \$296	—	—	11,981,343	74,204	—	—	—	—	—	—	—
Reclassification of Series A convertible preferred stock from permanent equity to mezzanine equity	9,583,328	18,942	—	—	(9,583,328)	—	—	—	(18,942)	—	(18,942)
Stock-based compensation expense	—	—	—	—	—	—	—	—	39	—	39
Exercise of stock options	—	—	—	—	—	—	7,083	—	1	—	1
Net loss	—	—	—	—	—	—	—	—	—	(11,969)	(11,969)
Balance at December 31, 2019	<u>9,583,328</u>	<u>\$18,942</u>	<u>11,981,343</u>	<u>\$74,204</u>	<u>—</u>	<u>\$ —</u>	<u>4,524,583</u>	<u>\$ —</u>	<u>\$ 82</u>	<u>\$(17,568)</u>	<u>\$(17,486)</u>

See accompanying notes to financial statements.

**Kinnate Biopharma Inc.**  
**Statements of Cash Flows**  
(In thousands)

	For the Period January 4, 2018 (Inception) through December 31, 2018	Year Ended December 31, 2019
<b>Cash flows from operating activities:</b>		
Net loss	\$ (7,630)	\$(11,969)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	39	39
Changes in operating assets and liabilities:		
Related party receivables, net	(1,078)	(49)
Prepaid expenses	—	(25)
Accounts payable and accrued expenses	467	1,478
Net cash used in operating activities	<u>(8,202)</u>	<u>(10,526)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of Series A convertible preferred stock, net of issuance costs	15,198	5,775
Proceeds from issuance of Series B convertible preferred stock, net of issuance costs	—	74,204
Proceeds from stock option exercises	3	1
Net cash provided by financing activities	<u>15,201</u>	<u>79,980</u>
Net increase in cash and cash equivalents	<u>6,999</u>	<u>69,454</u>
Cash and cash equivalents at the beginning of the period	—	6,999
Cash and cash equivalents at the end of the year	<u>\$ 6,999</u>	<u>\$ 76,453</u>
<b>Supplemental non-cash investing activity:</b>		
Property and equipment included in related party receivables, net	<u>\$ —</u>	<u>\$ 154</u>

*See accompanying notes to financial statements.*



**1) Organization and Basis of Presentation**

**a) Organization and Nature of Operations**

Kinnate Biopharma Inc. (Kinnate or the Company) was incorporated in the State of Delaware in January 2018 and is headquartered in San Diego, California. On April 15, 2019, the Company merged with Immanate Therapeutics Inc. (Immanate), a Delaware corporation formed in February 2018, with Kinnate being the surviving entity (the Merger). The Company is a biopharmaceutical company focused on the discovery and development of small molecule kinase inhibitors for difficult-to-treat, genomically defined cancers.

Since its inception, the Company has devoted substantially all of its resources to research and development activities, business planning, establishing and maintaining its intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these operations. It has incurred losses and negative cash flows from operations since commencement of its operations. The Company had an accumulated deficit of \$17.6 million and cash and cash equivalents of \$76.5 million as of December 31, 2019. From its inception through December 31, 2019, the Company has financed its operations primarily through private placements of its convertible preferred stock.

As the Company continues to pursue its business plan, it expects to finance its operations through the sale of equity, debt financings or other capital resources, which could include income from collaborations, strategic partnerships or marketing, distribution, licensing or other strategic arrangements with third parties, or from grants. However, there can be no assurance that any additional financing or strategic transactions will be available to the Company on acceptable terms, if at all. If events or circumstances occur such that the Company does not obtain additional funding, it may need to delay, reduce or eliminate its product development or future commercialization efforts, which could have a material adverse effect on the Company's business, results of operations or financial condition. The accompanying financial statements do not include any adjustments that might be necessary if it were unable to continue as a going concern. Management believes that it has sufficient working capital on hand to fund operations through at least the next twelve months from the date these financial statements were available to be issued, which includes the proceeds from the Series C convertible preferred stock issuance (see Note 11).

**b) Basis of Presentation**

The Company's financial statements are prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP). The accompanying financial statements include the accounts of the Company (the receiving entity) and Immanate, prior to the Merger. The Company and Immanate were entities under the common control of Fount Therapeutics, LLC (FTL) as a result of, among others, FTL's: (i) ownership of a majority of the outstanding capital stock of both companies and (ii) control of the boards of directors of both companies at the time of the Merger. As the merged entities were under common control, the financial statements report the financial position, results of operations and cash flows of the Company and Immanate as though the transfer of net assets and equity interests had occurred at January 4, 2018 (Inception). All intercompany accounts and transactions have been eliminated in combination.

**2) Summary of Significant Accounting Policies**

**a) 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 and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Accounting estimates and management judgments reflected in the financial statements include: normal recurring accruals, including the accrual of research and development expenses; valuation of deferred tax assets; fair value of common stock and preferred stock and stock-based compensation. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may materially differ from these estimates and assumptions.

**b) Concentration of Credit Risk**

Financial instruments, which potentially subject the Company to concentration of credit risk, consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. Management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. The Company has not experienced any losses on deposits since inception.

**c) Fair Value of Financial Instruments**

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value, and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability.

The carrying amounts of cash, prepaid expenses, accounts payable and accrued other liabilities are reasonable estimates of their fair value because of the short maturity of these items.

**d) Cash and Cash Equivalents**

The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents. Cash equivalents primarily represent funds invested in readily available money market accounts. As of December 31, 2018 and 2019, the Company had cash and cash equivalents balances deposited at major financial institutions.

**e) Property and Equipment**

Property and equipment are stated at cost. Depreciation, which includes amortization of leasehold improvements, is computed primarily using straight-line depreciation over the estimated useful lives or the term of the lease, whichever is shorter for the respective assets. Estimated useful lives for the various asset classes were as follows:

	Estimated Useful Lives (in years)
Furniture and fixtures	3-10
Computers and equipment	3-5
Computer software	3-5

**f) Impairment of Property and Equipment**

The Company accounts for the impairment of long-lived assets by reviewing these assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If circumstances require a long-lived asset or asset group to be tested for possible impairment, the Company first compares undiscounted cash flows expected to be generated by that asset or asset group to its carrying value. If the carrying value of the long-lived asset or asset group is not recoverable on an undiscounted-cash-flow basis, an impairment is recognized to the extent that the carrying value exceeds its fair value. The Company did not recognize impairment losses for the periods ended December 31, 2018 and 2019.

**g) Research and Development**

Research and development expenses are expensed in the periods in which they are incurred. External expenses consist primarily of payments to outside consultants and contract research organizations in connection with the Company's discovery and preclinical activities, process development, manufacturing activities, regulatory and other services. External expenses are recognized based on an evaluation of the progress to completion of specific tasks using information provided to the Company by its service providers or the estimate of the level of service that has been performed at each reporting

date. In addition to those external costs, the Company incurred research and development expenses through the management services agreements described below. Research and development expenses amounted to \$5.7 million and \$9.0 million for the periods ended December 31, 2018 and 2019, respectively.

***h) Commitments and Contingencies***

The Company recognizes a liability with regard to loss contingencies when it believes it is probable a liability has been incurred, and the amount can be reasonably estimated. If some amount within a range of loss appears at the time to be a better estimate than any other amount within the range, the Company accrues that amount. When no amount within the range is a better estimate than any other amount the Company accrues the minimum amount in the range. The Company has not recorded any such liabilities as of December 31, 2018 and 2019.

***i) Income Taxes***

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

As of December 31, 2018 and 2019, the Company maintained valuation allowances against its deferred tax assets as the Company concluded it had not met the "more likely than not" to be realized threshold. Changes in the valuation allowance when they are recognized in the provision for income taxes would result in a change in the estimated annual effective tax rate.

***j) Stock-Based Compensation***

Stock-based compensation expense represents the cost of the grant date fair value of employee, officer, director and non-employee stock option grants, estimated in accordance with the applicable accounting guidance, recognized on a straight-line basis over the vesting period. The vesting period generally approximates the expected service period of the awards. The Company recognizes forfeitures as they occur.

The fair value of stock options is estimated using a Black-Scholes valuation model on the date of grant. This method requires certain assumptions be used as inputs, such as the fair value of the underlying common stock, expected term of the option before exercise, expected volatility of the Company's common stock, risk-free interest rate and expected dividend. Options granted have a maximum contractual term of ten years. The Company has limited historical stock option activity and therefore estimates the expected term of stock options granted using the simplified method, which represents the arithmetic average of the original contractual term of the stock option and its weighted-average vesting term. The expected volatility of stock options is based upon the historical volatility of a number of publicly traded companies in similar stages of clinical development. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available. The risk-free interest rates used are based on the U.S. Treasury

yield in effect at the time of grant for zero-coupon U.S. treasury notes with maturities approximately equal to the expected term of the stock options. The Company has historically not declared or paid any dividends and does not currently expect to do so in the foreseeable future, and therefore has estimated the dividend yield to be zero.

**k) Common Stock Valuation**

Due to the absence of an active market for the Company's common stock, the Company utilized methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants' Audit and Accounting Practice Guide: *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 fair value of the common stock as of the grant date. The fair value of the common stock has been determined based upon a variety of factors, including the prices at which the Company sold shares of its convertible preferred stock to outside investors in arms-length transactions, and the superior rights, preferences and privileges of the preferred stock relative to the common stock at the time of each grant; the progress of the Company's research and development programs, including their stages of development, and the Company's business strategy; external market and other conditions affecting the biotechnology industry, and trends within the biotechnology industry; the Company's financial position, including cash on hand, and its historical and forecasted performance and operating results; the lack of an active public market for the Company's common stock; the likelihood of achieving a liquidity event for the Company's securityholders, such as an initial public offering or a sale of the company, taking into consideration prevailing market conditions; the hiring of key personnel and the experience of management; and the analysis of initial public offerings and the market performance of peer companies in the biopharmaceutical industry, as well as completed mergers and acquisitions of peer companies.

Significant changes to the key assumptions underlying the factors used could result in different fair values of common stock at each valuation date.

**l) Deferred Offering Costs**

The Company capitalizes costs that are directly associated with in-process equity financings until such financings are consummated at which time such costs are recorded against the gross proceeds of the offering. Should an in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the statement of operations and comprehensive loss. The Company did not record any deferred offering costs as of December 31, 2018 and 2019.

**m) Comprehensive Loss**

Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources, including unrealized gains and losses on investments and foreign currency gains and losses. Net loss and comprehensive loss were the same for all periods presented.

**n) Net Loss Per Share**

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, the Company's outstanding convertible preferred stock and common stock options are considered to be potentially dilutive securities. Basic and diluted net loss attributable to common stockholders per share is presented in conformity with the two-class method required for participating securities as the convertible preferred stock is considered a participating security. The Company's

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participating securities do not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to common stockholders. As the Company has reported a net loss for all periods presented, diluted net loss per common share is the same as basic net loss per common share for those periods.

The following table sets forth the computation of the basic and diluted net loss per share attributable to common stockholders (in thousands, except share and per share amounts).

	For the Period January 4, 2018 (Inception) through December 31, 2018	Year Ended December 31, 2019
<b>Numerator</b>		
Net loss and comprehensive loss	\$ (7,630)	\$ (11,969)
Gain on extinguishment of Series A convertible preferred stock	—	2,031
Net loss attributable to common stockholders	<u>\$ (7,630)</u>	<u>\$ (9,938)</u>
<b>Denominator</b>		
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	4,504,024	4,517,713
Net loss attributable to common stockholders per share, basic and diluted	<u>\$ (1.69)</u>	<u>\$ (2.20)</u>

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented because including them would have been anti-dilutive:

	As of December 31,	
	2018	2019
Options to purchase common stock	1,660,000	1,710,208
Convertible preferred stock	4,586,832	21,564,671
Total	<u>6,246,832</u>	<u>23,274,879</u>

### ***o) Unaudited Pro Forma Net Loss Per Share***

Unaudited pro forma basic and diluted net loss per share is calculated to give effect to the one-for-one conversion of all outstanding shares of the Company's convertible preferred stock into shares of its common stock in using the as-converted method as though the conversion had occurred as of the beginning of the period presented or the date of issuance, if later.

The following table sets forth the computation of the basic and diluted unaudited pro forma net loss per share (in thousands, except share and per share amounts):

	Year Ended December 31, 2019
<b>Numerator</b>	
Net loss attributable to common stockholders	\$ (9,938)
<b>Denominator</b>	
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	4,517,713
Adjust: Assumed weighted-average effect of conversion of convertible preferred stock	<u>8,816,181</u>
Weighted-average shares outstanding used in computing pro forma net loss per share, basic and diluted	<u>13,333,894</u>
Pro forma net loss per share, basic and diluted	<u>\$ (0.75)</u>

**p) Recently Issued Accounting Standards**

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which outlines a single, principle-based revenue recognition model that will supersede and replace nearly all existing U.S. GAAP revenue recognition guidance. Entities will recognize revenue in a manner that depicts the transfer of goods or services to customers at an amount that reflects the consideration to which the entity expects to be entitled to receive in exchange for goods and services. The model provides that entities follow five steps: (i) identify the contract with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations, and (v) recognize revenue. The Company adopted this standard as of January 4, 2018 (inception). As the Company has yet to generate revenues, the adoption of this standard did not have any impact on the Company's financial statements and related disclosures.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Non-employee Share-Based Payment Accounting*, which expands the scope of Topic 718 to include all share-based payment transactions for acquiring goods and services from nonemployees and simplifies the accounting for nonemployee share-based payment transactions. The accounting for share-based payments to nonemployees and employees will be substantially aligned because of this update. This ASU specifies that Topic 718 applies to all share-based payment transactions in which the grantor acquires goods and services to be used or consumed in its own operations by issuing share-based payment awards. This ASU also clarifies that Topic 718 does not apply to share-based payments used to effectively provide (i) financing to the issuer or (ii) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under Topic 606. The transition method provided by ASU No. 2018-07 is a modified retrospective basis, which recognizes a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. For public business entities, this ASU is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted but may take place no earlier than a company's adoption date of Topic 606, *Revenue from Contracts with Customers*. The Company adopted the guidance for the year ended December 31, 2018. The adoption of this ASU did not have a material impact on the Company's financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* (ASU 2016-02), which supersedes FASB Accounting Standards Codification (ASC) Topic 840, *Leases (Topic 840)*, and provides principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method for finance leases or on a straight-line basis over the term of the lease for operating leases. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of classification. Leases with a term of 12 months or less will be accounted for similar to existing guidance for operating leases. For companies that are not emerging growth companies, ASU 2016-02 is effective for fiscal years beginning after December 15, 2018. For emerging growth companies, the ASU was to be effective for fiscal years beginning after December 15, 2019. However, in November 2019, the FASB issued ASU 2019-10, *Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815) and Leases (Topic 842): Effective Dates* (ASU 2019-10), which included a one-year deferral of the effective date of ASU 2016-02 for certain entities. As a result, the ASU is now effective for emerging growth companies for fiscal years beginning after December 15, 2020, and interim periods within fiscal years beginning after December 15, 2021. The Company expects to adopt the new standard in the first quarter of 2021 using the modified retrospective method, under which the Company will apply Topic 842 to existing and new leases as of January 1, 2021, but prior periods will not be restated and will continue to be reported under Topic 840 guidance in effect during those periods. The Company is currently evaluating the impact the adoption of these ASUs will have on its financial statements and related disclosures.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes - Simplifying the Accounting for Income Taxes* (ASU 2019-12). Among other items, the amendments in ASU 2019-12 simplify the accounting treatment of tax law changes and year-to-date losses in interim periods. An entity generally recognizes the



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effects of a change in tax law in the period of enactment; however, there is an exception for tax laws with delayed effective dates. Under current guidance, an entity may not adjust its annual effective tax rate for a tax law change until the period in which the law is effective. This exception was removed under ASU 2019-12, thereby providing that all effects of a tax law change are recognized in the period of enactment, including adjustment of the estimated annual effective tax rate. Regarding year-to-date losses in interim periods, an entity is required to estimate its annual effective tax rate for the full fiscal year at the end of each interim period and use that rate to calculate its income taxes on a year-to-date basis. However, current guidance provides an exception that when a loss in an interim period exceeds the anticipated loss for the year, the income tax benefit is limited to the amount that would be recognized if the year-to-date loss were the anticipated loss for the full year. ASU 2019-12 removes this exception and provides that, in this situation, an entity would compute its income tax benefit at each interim period based on its estimated annual effective tax rate. ASU 2019-12 is effective for fiscal years beginning after December 15, 2020, including interim periods within those annual periods. Early adoption is permitted. The Company does not expect the ASU to have a material impact on its financial statements and related disclosures.

### 3) Property and Equipment

Property and equipment consisted of the following (in thousands):

	December 31,	
	2018	2019
Furniture and fixtures	\$ —	\$ 72
Computers and equipment	—	48
Computer software	—	34
Total	<u>\$ —</u>	<u>\$154</u>

There was no depreciation and amortization expense for property and equipment during 2019 as the equipment was purchased on December 31, 2019.

### 4) Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31,	
	2018	2019
Accrued research and development	\$ —	\$681
Accrued legal fees	—	217
Accrued audit fees	—	66
Other accruals	<u>25</u>	<u>25</u>
Total	<u>\$ 25</u>	<u>\$989</u>

### 5) Fair Value Measurements

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets;

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and



Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

At December 31, 2018 and 2019, the carrying amounts of the Company's financial instruments, which include cash, accounts payable and accrued expenses, approximate fair value because of their short maturities.

Included in cash and cash equivalents at December 31, 2018 and 2019 are money market funds with a carrying value and fair value of \$0 and \$75.5 million, respectively, based upon a Level 1 fair value assessment.

As of December 31, 2018 and 2019, the Company did not hold any Level 2 or Level 3 financial assets measured on a recurring basis.

## **6) Stockholders' Equity**

Under its Amended and Restated Articles of Incorporation dated December 12, 2019, the Company had a total of 54,791,671 shares of capital stock authorized for issuance, consisting of 33,227,000 shares of common stock, par value of \$0.0001 per share, and 21,564,671 shares of convertible preferred stock, par value of \$0.0001 per share. Shares of authorized convertible preferred stock are designated as 9,583,328 shares of Series A convertible preferred stock and 11,981,343 shares of Series B convertible preferred stock.

### **a) Convertible Preferred Stock**

In March, June and October 2018, Kinnate issued an aggregate of 3,489,982 shares of its Series A convertible preferred stock at a price of \$3.3429 per share, resulting in total net proceeds of approximately \$11.6 million including issuance costs of \$0.1 million.

In March 2018, Immanate issued 1,096,850 shares of its Series A convertible preferred stock at a price of \$3.3429 per share resulting in total net proceeds of approximately \$3.6 million including issuance costs of \$0.1 million. Additionally, during 2018, Immanate issued 4,500,000 shares of its common stock at a purchase price of \$0.0001 per shares. Due to the Merger with Kinnate, in April 2019, 4,500,000 shares of Immanate's common stock were cancelled along with then outstanding options for 1,660,000 shares of Immanate's stock. The 1,096,850 shares of Immanate's Series A convertible preferred stock were converted to shares of Kinnate's Series A convertible preferred stock at a rate of 0.683776 per share, resulting in a total of 750,000 shares of Kinnate Series A convertible preferred stock.

In connection with the Merger and the repricing of the Series A convertible preferred stock from \$3.429 per share to \$2.00 per share in April 2019, the rights preferences and privileges of the Series A preferred stock were modified and resulted in the following changes: (i) the original issue price, conversion price and liquidation preference were reduced from \$3.3429 per share to \$2.00 per share and (ii) the dividend rate was reduced from \$0.267432 to \$0.16 per share. As a result of these changes, the Company concluded substantive changes were made to the contractual terms of the Series A convertible preferred stock and that the repricing of the Series A convertible preferred stock, along with the issuance of 2,343,346 additional shares for no consideration, was an extinguishment. The extinguishment resulted in the removal of the carrying value of the Series A convertible preferred stock pre-merger and the difference between the fair value of consideration paid and the carrying value was recognized as a gain to the common stockholders and an adjustment within stockholders' equity (deficit) of \$2.0 million during the year ended December 31, 2019.

Further, in April 2019, the Company granted existing investors 2,343,346 additional shares of its Series A convertible preferred stock for no additional consideration. These shares, plus the 750,000 shares converted, minus the 1,096,850 shares of Immanate Series A convertible preferred stock, have been presented net as a single line item, "Issuance of Series A convertible preferred stock in merger" on the statements of convertible preferred stock and stockholders' equity (deficit) in the amount of 1,996,496 for the period ended December 31, 2019. The Company determined the fair value based on the per share cash purchase price based on a comparable transaction with third parties in April 2019 where Series A convertible preferred stock was sold at a price of \$2.00 per share. The inputs used to determine the fair value were determined to be level 2 of the fair value hierarchy.

Additionally, in April 2019, the Company issued 3,000,000 shares of its Series A convertible preferred stock at a price of \$2.00 per share resulting in net proceeds of approximately \$5.8 million including \$0.2 million of issuance costs.

In December 2019, the Company issued 11,981,343 shares of its Series B convertible preferred stock at a price of \$6.218 per share resulting in net proceeds of approximately \$74.2 million including issuance costs of \$0.3 million.

As of December 31, 2018, the Company's Series A convertible preferred stock was classified within permanent equity in the accompanying balance sheets as the holders could not cause the Company to redeem the convertible preferred stock. As of December 31, 2019, the Company's Series A and Series B convertible preferred stock have been classified as temporary equity in the accompanying balance sheets given that a majority of the Company's board of directors seats are held by convertible preferred stockholders and they could cause certain events to occur that are outside of the Company's control whereby the Company could be obligated to redeem the convertible preferred stock. The Company has not adjusted the carrying values of the convertible preferred stock to the respective liquidation preferences of such shares as the instruments are currently not redeemable and the Company believes it is not probable that the instruments will become redeemable at this point in time. Adjustments to increase the carrying values to the respective liquidation preferences will be made if and when it becomes probable that an event would occur obligating the Company to pay such amounts.

The Company's convertible preferred stock has the following characteristics:

*1) Dividends*

Holders of the Series A and Series B convertible preferred stock, in preference to any distributions to the holders of common stock, shall be entitled to receive dividends at an annual rate of \$0.16 per share for the Series A convertible preferred stock holders and \$0.497 per share for the Series B convertible preferred stock holders. Such dividends shall be payable only when and if declared by the Company's board of directors and shall not be cumulative.

No such dividends have been declared or paid through December 31, 2019.

*2) Preference on Liquidation*

The holders of the Series A and Series B convertible preferred stock are entitled to receive liquidation preferences at the Series A and Series B original issue prices of \$2.00 and \$6.218, respectively, plus all accrued and declared but unpaid dividends. Liquidation payments to the holders of the Series A and Series B convertible preferred stock have priority and are made in preference to any payments to the holders of common stock.

After full payment of the liquidation preference to the holders of the Series A and Series B convertible preferred stock, the remaining assets, if any, will be distributed ratably to the holders of the common stock.

*3) Conversion Rights*

The shares of Series A and Series B convertible preferred stock are convertible into an equal number of shares of common stock, at the option of the holder, subject to certain anti-dilution adjustments. The conversion rate for the convertible preferred stock is determined by dividing the original issue price, as adjusted for stock splits, by the conversion price. The conversion price is initially the original issue price, but is subject to adjustment for dividends, stock splits, and other distributions. The conversion rate at December 31, 2019 for the Series A and Series B convertible preferred stock was 1:1.

Each share of Series A and Series B convertible preferred stock will be automatically converted into common stock at the then effective conversion rate (i) immediately upon the closing of a firmly underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, covering the offer and sale of common stock for the account of the Company in which the gross cash proceeds to the Company are at least \$50.0 million or (ii) upon written request for such conversion from the Requisite Investors (defined as at least 64% of the holders of preferred stock).

4) *Redemption Rights*

The holders of Series A and Series B convertible preferred stock do not have any redemption rights.

5) *Voting*

The holder of each share of Series A and Series B convertible preferred stock generally vote together with the shares of common stock as a single class, but also have class vote approval rights as provided by the Company's certificate of incorporation or as required by applicable law.

**b) Common Stock**

As of December 31, 2018, and 2019, of the authorized 20,000,000 and 33,227,000 shares of common stock, 4,517,500 and 4,524,583 shares were issued and outstanding, respectively. The fair value of the Company's common stock was \$0.14 and \$2.08 as of December 31, 2018, and 2019, respectively, and was determined in part based on third-party valuations.

The voting, dividend, and liquidation rights of the holders of the common stock are subject to, and qualified by, the rights, preferences and privileges of the holders of the convertible preferred stock. The holders of the common stock are entitled to one vote for each share of common stock held at all meetings of stockholders.

Common stock reserved for future issuance consisted of the following:

	As of December 31,	
	2018	2019
Convertible preferred stock	4,586,832	21,564,671
Common stock options granted and outstanding	1,660,000	1,710,208
Common stock reserved for future option grants	<u>322,500</u>	<u>3,840,051</u>
Total common stock reserved for future issuance	<u>6,569,332</u>	<u>27,114,930</u>

**7) Stock-Based Compensation**

In March 2018, the Company adopted the 2018 Equity Incentive Plan (the Plan), which allowed for the issuance of incentive stock options (ISOs), nonstatutory stock options (NSOs), stock appreciation rights, restricted stock and restricted stock units. The Plan was established to enable the Company to attract and retain the best available personnel, to provide additional incentive to its employees, directors, and consultants of the Company and to promote the financial success and progress of the Company. Under the Plan, the Company can offer ISOs to employees and NSOs to employees, non-employee directors, and consultants. The Plan allows the Company to issue options for shares of its common stock up to a total of 5,579,842 shares (the Option Pool), subject to appropriate adjustments for stock splits, combinations and other similar events for issuance pursuant to awards made under the Plan.

Under the Plan, the exercise price of each ISO shall be established in the sole discretion of the Company's board of directors (or any of the committees of the Company's board of directors) ; provided, however, that (i) the exercise price per share for an ISO shall not be less than the fair market value for shares of the Company's common stock on the date of grant and (ii) the exercise price per share of an ISO granted to an optionee who on the date of the grant owns stock possessing more than 10% of the total combined voting power of all classes of the Company's stock shall not be less than 110% of the fair market value of a share of its common stock on the date of grant.

The options that are granted under the 2018 Plan are exercisable at various dates as determined upon grant and terminate within 10 years of the date of grant, unless the optionee owns 10% or more of the common shares at which point the expiration period is 5 years, or upon the employee's termination (whereupon the terminated employee has thirty days after termination to exercise vested options from the date of termination). The vesting period generally occurs over three to four years unless there is a specific performance vesting trigger at which time those shares will vest when the performance trigger is probable to occur.

Stock option activity under the Plan, is as follows:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2019	1,660,000	\$0.14	9.5	
Granted	170,000	0.27	9.7	
Forfeited	(112,709)	0.19	9.1	
Exercised	(7,083)	0.14	8.5	
Outstanding at December 31, 2019	<u>1,710,208</u>	<u>\$0.15</u>	<u>8.6</u>	<u>\$3,302</u>
Exercisable at December 31, 2019	<u>437,187</u>	<u>\$0.15</u>	<u>8.6</u>	<u>\$ 840</u>

All exercisable options are vested and all outstanding options are vested or expected to vest.

The Company estimated the fair value of stock options using the Black-Scholes valuation model. The Company accounts for any forfeitures of options when they occur. Previously recognized compensation expense for an award is reversed in the period that the award is forfeited. The fair value of stock options was estimated using the following assumptions:

	As of December 31	
	2018	2019
Expected term (in years)	10	10
Expected volatility	110.5 - 110.7%	95.9 - 98.7%
Risk-free interest rate	2.90 - 2.99%	1.80 - 2.64%
Expected dividend	0%	0%

The Company recorded \$39,000 in stock-based compensation expense for each of the periods ended December 31, 2018 and 2019.

As of December 31, 2019, there was approximately \$0.1 million of total unrecognized stock-based compensation expense related to nonvested stock-based compensation arrangements granted under the Plan, which is expected to be recognized over a weighted-average period of approximately 2.54 years.

## 8) Related Party Transactions

### a) *Management Service Agreement with Fount Therapeutics, LLC and Fount Service Corp.*

Effective June 22, 2018, the Company entered into a Master Service Agreement with FTL and Fount Service Corp. (FSC), a wholly owned subsidiary of FTL. Under this agreement, FTL and FSC agreed to perform various management and other services to the Company, either directly or via arrangements with third parties. These services included research and development and general and administrative functions, such as finance, audit, accounting, human resources, technology, facilities, and other management services necessary for the Company's operations. For all services performed, directly or indirectly, which generally included FTL and FSC payroll costs and other third-party costs incurred by FTL and FSC, a five percent markup was charged as a management service fee to the Company.

Certain services performed and expenses incurred by FTL discussed above are performed by other wholly owned subsidiaries of FTL. When this occurs, FTL's management allocates expenses to the respective entities based on its best estimate of the expenses incurred by each entity. The Company recognized management fee expenses of approximately \$3.1 million and \$4.9 million for the periods ended December 31, 2018 and 2019, respectively, which are included in the Company's statements of operations and comprehensive loss.

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The following table set forth the amounts included in the Company's statements of operations and comprehensive loss (in thousands):

	For the Period January 4, 2018 (Inception) through December 31, 2018	Year Ended December 31, 2019
FTL included in research and development	\$ —	\$ —
FTL included in general and administrative	617	841
Total FTL related party expense	617	841
FSC included in research and development	1,454	2,301
FSC included in general and administrative	983	1,768
Total FSC related party expense	2,437	4,069
Total related party expenses	<u>\$3,054</u>	<u>\$4,910</u>

The following table set forth the amounts included as related party receivables, net on the Company's balance sheets (in thousands):

	As of December 31,	
	2018	2019
FTL related party receivables	\$ 1,750	\$ 250
FTL related party payables	(1,315)	(20)
FTL related party receivables, net	435	230
FSC related party receivables	6,000	2,283
FSC related party payables	(5,357)	(1,540)
FSC related party receivables, net	643	743
Total related party receivables, net	<u>\$ 1,078</u>	<u>\$ 973</u>

### **b) Management Services Agreement with Subveho, LLC**

Effective March 21, 2018, FTL entered into a Management Service Agreement (the Subveho MSA) with Subveho, LLC (Subveho), pursuant to which Subveho agreed to perform various services such as, but not limited to, research and development, manufacturing activities, general and administrative, business development, advisory, and other management services necessary for the operations of the Company. Such services were performed on behalf of Subveho by an individual who was a partial owner of Subveho and who acted in the capacity of an officer of the Company based on the nature of such services. Pursuant to the Subveho MSA, in June 2018, the Company issued to Subveho options to purchase 600,000 shares of the Company's common stock at an exercise price of \$0.14 per share. In addition, FTL agreed to pay Subveho \$75,000 per quarter for services up to an agreed upon hour limit. Services outside of this agreed upon hour limit were to be billed separately. Total expenses FTL paid to Subveho under the Subveho MSA for services provided to the Company were \$0.2 million and \$0.3 million for the periods ended December 31, 2018 and 2019, respectively, which are included in the total management fee expenses in Note 8(a).

## 9) Income Taxes

Significant components of the Company's provision for income taxes and income taxes computed using the U.S. federal statutory corporate tax rate were as follows (in thousands):

	For the Period January 4, 2018 (Inception) through December 31, 2018	Year Ended December 31, 2019
Income taxes computed at the statutory rate	\$(1,602)	\$(2,513)
State income taxes, net of federal benefit	(532)	(825)
Permanent items	4	25
Stock-based compensation	—	2
Change in valuation allowance	2,130	3,311
Provision for income taxes	<u>\$ —</u>	<u>\$ —</u>

Significant components of the Company's deferred taxes were as follows (in thousands):

	As of December 31,	
	2018	2019
Deferred tax assets:		
Net operating loss carryforward	\$ 2,093	\$ 5,404
Accruals and other	37	37
Gross deferred tax assets:	2,130	5,441
Less valuation allowance	(2,130)	(5,441)
Total deferred tax assets	—	—
Deferred tax liabilities:		
Fixed assets	—	—
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company has established a valuation allowance against net deferred tax assets due to the uncertainty that such assets will be realized. The Company periodically evaluates the recoverability of its deferred tax assets. Due to the Company's history of losses management cannot conclude that the deferred tax asset will be realized. The change in the valuation allowance for the year ended December 31, 2019 was an increase of \$3.3 million.

At December 31, 2019, the Company has federal and California net operating loss carryforwards of approximately \$19.3 million and \$19.3 million, respectively.

As a result of the Tax Cuts and Jobs Act of 2017, as amended by the Coronavirus Aid, Relief, and Economic Security Act, for U.S. income tax purposes, net operating losses generated in taxable years beginning after December 31, 2017 can be carried forward indefinitely, but for taxable years beginning after December 31, 2020 the deductibility of such NOLs is limited to 80% of current year taxable income. The California net operating losses will begin to expire in 2038.

Pursuant to the Internal Revenue Code, as amended (IRC) Sections 382 and 383, annual use of the Company's NOL and research and development credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. The Company has not completed an ownership change analysis pursuant to IRS Section 382. If ownership changes have occurred or occurs in the future, the amount of remaining tax attribute carryforwards available to offset taxable income and income tax expense in future years may be restricted or eliminated. If eliminated, the related asset would be removed from deferred tax assets with a corresponding reduction in the valuation allowance. Due to the existence of the valuation allowance, limitations created by future ownership changes, if any, will not impact the Company's effective tax rate.

The Company has not yet conducted a study to document whether its research activities may qualify for the research and development tax credit. Such a study may result in the creation of a research and

development credit carryforward; however, until a study is completed, no amount is being presented as a deferred tax asset or as an uncertain tax position. Any research and development credit carryforward identified and claimed if and when such study is complete would be offset by an adjustment to the valuation allowance.

Uncertain tax positions are evaluated based upon the facts and circumstances that exist at each reporting period. Subsequent changes in judgement based upon new information may lead to changes in recognition, derecognition, and measurement. Adjustment may result, for example, upon resolution of an issue with the taxing authorities or expiration of a statute of limitations barring an assessment for an issue.

The Company recognizes a tax benefit from an uncertain tax position when it is more likely than not that the position will be sustained upon examination by tax authorities. As of December 31, 2018, and 2019, the Company did not have gross unrecognized tax benefits.

The Company is subject to taxation in the United States and California. All of the Company's tax years from inception are subject to examination by federal and state tax authorities. The Company's practice is to recognize interest and penalties related to income tax matters in income tax expense. The Company had no accrued interest or penalties related to income tax matters in the Company's balance sheets at December 31, 2018 and 2019 and has not recognized interest or penalties in the Company's statements of operations and comprehensive income for the years ended December 31, 2018 and 2019. Further, the Company is not currently under examination by any federal, state or local tax authority.

## **10) Commitments and Contingencies**

### ***Litigation***

The Company, from time to time, is involved in legal proceedings, regulatory actions, claims and litigation arising in the ordinary course of business. The Company was not a defendant in any lawsuit for the periods ending December 31, 2018 and 2019.

### ***Leases***

The Company leases certain office space in San Diego, California under a short-term lease with base monthly rent payments of \$13,000 that expires December 31, 2020, which the Company will renew or arrange for alternatives to that space before such date.

## **11) Subsequent Events**

The Company evaluated the effect subsequent events would have on the financial statements through September 4, 2020, which is the date the financial statements were available to be issued.

Subsequent to the balance sheet date, the World Health Organization declared the outbreak of COVID-19, a novel strain of coronavirus, a pandemic. The coronavirus outbreak is disrupting supply chains, affecting production and impacting businesses and sales across a range of industries. The extent of the impact of the COVID-19 pandemic on the Company's business, operations and development timelines and plans remains uncertain, and will depend on certain developments, including the duration and spread of the outbreak and its impact on the Company's development activities, planned clinical trial enrollment, future trial sites, contract research organizations, third-party manufacturers and other third parties with whom the Company does business, as well as its impact on regulatory authorities and the Company's key scientific and management personnel. The financial statements do not reflect any adjustments as a result of the subsequent increase in economic uncertainty.

In July and August 2020, an aggregate of 10,225,369 shares of the Company's Series C convertible preferred stock were issued at a price of \$9.584 per share, resulting in aggregate gross proceeds of \$98.0 million.

In March 2020, the Company appointed Nima Farzan as its President and Chief Executive Officer.

In March 2020, the Subveho MSA was terminated.

In April 2020, the Company appointed Mark Meltz as its Chief Operating Officer and General Counsel.

In June 2020, the Company appointed Dr. Richard Williams as its Chief Medical Officer.

In August 2020, Laurie Smaldone Alsup, M.D. and Dean Mitchell were elected to the Company's board of directors.



**Kinnate Biopharma Inc.**  
**Condensed Balance Sheets**  
(in thousands, except share and par value amounts)

	December 31, 2019	September 30, 2020	Pro Forma As of September 30, 2020
			(unaudited)
<b>Assets</b>			
Current assets:			
Cash and cash equivalents	\$ 76,453	\$156,859	
Related party receivables, net (See Note 8)	973	—	
Prepaid expenses	25	620	
Total current assets	77,451	157,479	—
Property and equipment	154	316	
Deferred offering costs	—	1,347	
Other assets	—	55	
Total assets	<u>\$ 77,605</u>	<u>\$159,197</u>	<u>\$ —</u>
<b>Liabilities, Convertible Preferred Stock and Stockholders' (Deficit) Equity</b>			
Current liabilities:			
Accounts payable	\$ 956	\$ 2,328	
Accrued expenses	989	4,371	
Total current liabilities	<u>1,945</u>	<u>6,699</u>	<u>—</u>
Commitments and contingencies (See Note 9)			
Convertible preferred stock:			
Series A convertible preferred stock, \$0.0001 par value; 9,583,328 shares authorized, issued and outstanding at December 31, 2019 and September 30, 2020, respectively; aggregate liquidation preference of \$19,167 at September 30, 2020, no shares issued and outstanding, pro forma	18,942	18,942	—
Series B convertible preferred stock, \$0.0001 par value; 11,981,343 shares authorized, issued and outstanding at December 31, 2019 and September 30, 2020, respectively; aggregate liquidation preference of \$74,500 at September 30, 2020, no shares issued and outstanding, pro forma	74,204	74,187	—
Series C convertible preferred stock, \$0.0001 par value; 0 and 10,225,369 shares authorized at December 31, 2019 and September 30, 2020, respectively; 0 and 10,225,369 shares issued and outstanding at December 31, 2019 and September 30, 2020, respectively; aggregate liquidation preference of \$98,000 at September 30, 2020, no shares issued and outstanding, pro forma	—	97,706	—
Stockholders' (deficit) equity:			
Common stock, \$0.0001 par value; 33,227,000 and 47,000,000 shares authorized at December 31, 2019 and September 30, 2020, respectively; 4,524,583 and 4,664,062 shares issued at December 31, 2019 and September 30, 2020, respectively; 4,524,583 and 4,627,994 shares outstanding at December 31, 2019 and September 30, 2020, respectively; 36,452,278 shares issued and outstanding, pro forma	—	—	4
Additional paid—in capital	82	1,360	192,191
Treasury stock at cost, 0 and 36,068 shares of common stock at December 31, 2019 and September 30, 2020, respectively	—	(75)	(75)
Accumulated deficit	<u>(17,568)</u>	<u>(39,622)</u>	<u>(39,622)</u>
Total stockholders' (deficit) equity	<u>(17,486)</u>	<u>(38,337)</u>	<u>152,498</u>
Total liabilities, convertible preferred stock and stockholders' (deficit) equity	<u>\$ 77,605</u>	<u>\$159,197</u>	<u>—</u>

*See accompanying notes to unaudited condensed financial statements.*

**Kinnate Biopharma Inc.**  
**Condensed Statements of Operations and Comprehensive Loss**  
(unaudited)  
(in thousands, except share and per share amounts)

	Nine Months Ended September 30,	
	2019	2020
Operating expenses:		
Research and development (includes related party amounts of \$1,551 and \$0, respectively)	\$ 5,896	\$ 17,261
General and administrative (includes related party amounts of \$1,827 and \$92, respectively)	2,131	5,021
Total operating expenses	8,027	22,282
Loss from operations	(8,027)	(22,282)
Other income:		
Interest income	—	228
Total other income	—	228
Net loss and comprehensive loss	\$ (8,027)	\$ (22,054)
Gain on extinguishment of Series A convertible preferred stock	2,031	—
Net loss attributable to common stockholders	\$ (5,996)	\$ (22,054)
Weighted-average shares outstanding, basic and diluted	4,517,500	4,578,904
Net loss attributable to common stockholders per share, basic and diluted	\$ (1.33)	\$ (4.82)
Pro forma weighted-average shares outstanding, basic and diluted		28,743,251
Pro forma net loss attributable to common stockholders per share, basic and diluted		\$ (0.77)

*See accompanying notes to unaudited condensed financial statements.*

**Kinnate Biopharma Inc.**  
**Condensed Statements of Convertible Preferred Stock and Stockholders' (Deficit) Equity**  
(unaudited)  
(in thousands, except share amounts)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Series A Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Treasury Stock		Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amounts			Shares	Amount	
Balance at January 1, 2019	—	\$ —	—	\$ —	—	\$ —	4,586,832	\$—	4,517,500	\$—	\$15,240	\$ (7,630)	—	\$ —	7,610
Issuance of Series A convertible preferred stock in merger	—	—	—	—	—	—	1,996,496	—	—	—	—	—	—	—	—
Extinguishment of Series A convertible preferred stock	—	—	—	—	—	—	—	—	—	—	(2,031)	2,031	—	—	—
Issuance of Series A convertible preferred stock, net of issuance costs of \$163	—	—	—	—	—	—	3,000,000	—	—	—	5,930	—	—	—	5,930
Net loss	—	—	—	—	—	—	—	—	—	—	—	(8,027)	—	—	(8,027)
Balance at September 30, 2019	—	\$ —	—	\$ —	—	\$ —	9,583,328	\$—	4,517,500	\$—	\$19,139	\$ (13,626)	—	\$ —	\$ 5,513
Balance at January 1, 2020	9,583,328	\$18,942	11,981,343	\$74,204	—	\$ —	—	\$—	4,524,583	\$—	\$ 82	\$ (17,568)	—	\$ —	(17,486)
Series B convertible preferred stock issuance costs	—	—	—	(17)	—	—	—	—	—	—	—	—	—	—	—
Issuance of Series C convertible preferred stock, net of issuance costs of \$294	—	—	—	—	10,225,369	\$97,706	—	—	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	1,252	—	—	—	1,252
Exercise of stock options	—	—	—	—	—	—	—	—	139,479	—	26	—	—	—	26
Treasury stock	—	—	—	—	—	—	—	—	—	—	—	—	(36,068)	(75)	(75)
Net loss	—	—	—	—	—	—	—	—	—	—	—	(22,054)	—	—	(22,054)
Balance at September 30, 2020	9,583,328	\$18,942	11,981,343	\$74,187	10,225,369	\$97,706	—	\$—	4,664,062	\$—	\$ 1,360	\$ (39,622)	(36,068)	\$ (75)	\$ (38,337)

See accompanying notes to unaudited condensed financial statements.

**Kinnate Biopharma Inc.**  
**Condensed Statements of Cash Flows**  
(unaudited)  
(in thousands)

	Nine Months Ended September 30,	
	2019	2020
Cash flows from operating activities:		
Net loss	\$(8,027)	\$(22,054)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	—	1,252
Depreciation expense	—	59
Changes in operating assets and liabilities:		
Related party receivables, net	422	1,127
Prepaid expenses and other assets	—	(650)
Accounts payable and accrued expenses	425	3,861
Net cash used in operating activities	<u>(7,180)</u>	<u>(16,405)</u>
Cash flows from investing activities:		
Purchases of property and equipment	—	(359)
Net cash used in investing activities	—	(359)
Cash flows from financing activities:		
Proceeds from issuance of Series A convertible preferred stock, net of issuance costs	5,930	—
Series B convertible preferred stock issuance costs	—	(17)
Proceeds from issuance of Series C convertible preferred stock, net of issuance costs	—	97,706
Payment of deferred offering costs	—	(470)
Purchase of treasury stock	—	(75)
Proceeds from stock option exercises	—	26
Net cash provided by financing activities	<u>5,930</u>	<u>97,170</u>
Net (decrease) increase in cash and cash equivalents	(1,250)	80,406
Cash and cash equivalents at the beginning of the period	<u>6,999</u>	<u>76,453</u>
Cash and cash equivalents at the end of the period	<u>\$ 5,749</u>	<u>\$156,859</u>
Supplemental non-cash investing and financing activity:		
Property and equipment included in accounts payable and accrued expenses	\$ —	\$ 16
Deferred offering costs included in accounts payable and accrued expenses	<u>\$ —</u>	<u>\$ 876</u>

*See accompanying notes to unaudited condensed financial statements.*

**Kinnate Biopharma Inc.**  
**Notes to Condensed Financial Statements**  
(unaudited)

**1) Organization and Basis of Presentation**

**a) Organization and Nature of Operations**

Kinnate Biopharma Inc. (Kinnate or the Company) was incorporated in the State of Delaware in January 2018 and is headquartered in San Diego, California. On April 15, 2019, the Company merged with Immanate Therapeutics Inc. (Immanate), a Delaware corporation formed in February 2018, with Kinnate being the surviving entity (the Merger). The Company is a biopharmaceutical company focused on the discovery and development of small molecule kinase inhibitors for difficult-to-treat, genomically defined cancers.

Since its inception, the Company has devoted substantially all of its resources to research and development activities, business planning, establishing and maintaining its intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these operations. It has incurred losses and negative cash flows from operations since commencement of its operations. The Company had an accumulated deficit of \$39.6 million and cash and cash equivalents of \$156.9 million as of September 30, 2020. From its inception through September 30, 2020, the Company has financed its operations primarily through private placements of its convertible preferred stock.

As the Company continues to pursue its business plan, it expects to finance its operations through the sale of equity, debt financings or other capital resources, which could include income from collaborations, strategic partnerships or marketing, distribution, licensing or other strategic arrangements with third parties, or from grants. However, there can be no assurance that any additional financing or strategic transactions will be available to the Company on acceptable terms, if at all. If events or circumstances occur such that the Company does not obtain additional funding, it may need to delay, reduce or eliminate its product development or future commercialization efforts, which could have a material adverse effect on the Company's business, results of operations or financial condition. The accompanying financial statements do not include any adjustments that might be necessary if it were unable to continue as a going concern. Management believes that it has sufficient working capital on hand to fund operations through at least the next twelve months from the date these financial statements are available to be issued.

**b) Basis of Presentation**

The Company's financial statements are prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP). The accompanying financial statements include the accounts of the Company (the receiving entity) and Immanate, prior to the Merger. The Company and Immanate were entities under the common control of Fount Therapeutics, LLC (FTL) as a result of, among others, FTL's: (i) ownership of a majority of the outstanding capital stock of both companies and (ii) control of the boards of directors of both companies at the time of the Merger. As the merged entities were under common control, the financial statements report the financial position, results of operations and cash flows of the Company and Immanate as though the transfer of net assets and equity interests had occurred at January 4, 2018 (Inception). All intercompany accounts and transactions have been eliminated in combination.

**2) Summary of Significant Accounting Policies**

The Company's significant accounting policies are disclosed in the audited financial statements for the periods ended December 31, 2018 and 2019, included elsewhere in this prospectus. Since the date of those financial statements, there have been no changes to its significant accounting policies, except as noted below.

**a) Unaudited Interim Financial Information**

The interim condensed balance sheet as of September 30, 2020, the condensed statements of operations and comprehensive loss and of cash flows for the nine months ended September 30, 2019 and 2020, and statements of changes in convertible preferred stock and stockholders' equity (deficit) for the nine months ended September 30, 2019 and 2020 are unaudited. In the opinion of management, the unaudited data reflects all adjustments, which include only normal recurring adjustments necessary for the fair statement of the Company's financial position as of September 30, 2020 and the results of its operations and comprehensive loss and its cash flows for the nine months ended September 30, 2019 and 2020. The financial data and other information disclosed in these notes related to the nine months ended September 30, 2019 and 2020 are also unaudited. The results for the nine months ended September 30, 2020 are not necessarily indicative of results to be expected for the year ending December 31, 2020, any other interim periods, or any future year or period. Certain disclosures have been condensed or omitted from the interim financial statements. These condensed financial statements should be read in conjunction with the Company's audited financial statements as of and for the periods ended December 31, 2018 and 2019 and the notes thereto, included elsewhere in this prospectus.

**b) Deferred Offering Costs**

Deferred offering costs consist primarily of legal fees, which are direct and incremental fees related to the Company's planned initial public offering (the "IPO"). The deferred offering costs will be offset against the IPO proceeds upon the consummation of the IPO. In the event the offering is aborted, the deferred offering costs will be expensed. As of December 31, 2019 and September 30, 2020, the Company had incurred \$0 and \$1.3 million, respectively, in deferred offering costs, which are reported on the balance sheet as non-current assets.

**3) Property and Equipment**

Property and equipment consisted of the following (in thousands):

	December 31, 2019	September 30, 2020
Furniture and fixtures	\$ 72	\$ 72
Computers and equipment	48	199
Computer software	<u>34</u>	<u>104</u>
Total property and equipment	154	375
Accumulated depreciation	<u>—</u>	<u>(59)</u>
Total property and equipment, net	<u>\$154</u>	<u>\$316</u>

Depreciation and amortization expense for property and equipment was \$0 and \$59,000 for the nine months ended September 30, 2019 and 2020, respectively.

**4) Accrued Expenses**

Accrued expense consisted of the following (in thousands):

	December 31, 2019	September 30, 2020
Accrued research and development	\$681	\$2,476
Accrued legal fees	217	848
Accrued audit fees	66	116
Accrued payroll and related expenses	—	739
Other accruals	<u>25</u>	<u>192</u>
Total	<u>\$989</u>	<u>\$4,371</u>

## **5) Fair Value Measurements**

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets;

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

As of December 31, 2019 and September 30, 2020, the carrying amounts of the Company's financial instruments, which include cash, accounts payable and accrued expenses, approximate fair value because of their short maturities.

Included in cash and cash equivalents as of December 31, 2019 and September 30, 2020 are money market funds with a carrying value and fair value of \$75.5 million and \$156.2 million, respectively, based upon a Level 1 fair value assessment.

As of December 31, 2019 and September 30, 2020, the Company did not hold any Level 2 or Level 3 financial assets measured on a recurring basis.

## **6) Stockholders' Equity**

Under its Amended and Restated Articles of Incorporation dated August 24, 2020, the Company had a total of 78,790,040 shares of capital stock authorized for issuance, consisting of 47,000,000 shares of common stock, par value of \$0.0001 per share, and 31,790,040 shares of convertible preferred stock, par value of \$0.0001 per share. Shares of authorized convertible preferred stock are designated as 9,583,328 shares of Series A convertible preferred stock, 11,981,343 shares of Series B convertible preferred stock and 10,225,369 shares of Series C convertible preferred stock.

### **a) *Convertible Preferred Stock***

In July and August 2020, the Company issued an aggregate of 10,225,369 shares of its Series C convertible preferred stock at a price of \$9.584 per share, resulting in total net proceeds of approximately \$97.7 million including issuance costs of \$0.3 million.

As of December 31, 2019 and September 30, 2020, the Company's convertible preferred stock has been classified as temporary equity in the accompanying balance sheets given that a majority of the Company's shares are held by the convertible preferred stockholders and they could cause certain events to occur that are outside of the Company's control whereby the Company could be obligated to redeem the convertible preferred stock. The Company has not adjusted the carrying values of the convertible preferred stock to the respective liquidation preferences of such shares as the instruments are currently not redeemable and the Company believes it is not probable that the instruments will become redeemable at this point in time. Adjustments to increase the carrying values to the respective liquidation preferences will be made if and when it becomes probable that an event would occur obligating the Company to pay such amounts.



The Company's convertible preferred stock has the following characteristics:

*1) Dividends*

Holders of the Series A, Series B and Series C convertible preferred stock, in preference to any distributions to the holders of common stock, shall be entitled to receive dividends at an annual rate of \$0.16 per share for the Series A convertible preferred stock holders, \$0.497 per share for the Series B convertible preferred stock holders and \$0.767 per share for the Series C convertible preferred stock holders. Such dividends shall be payable only when and if declared by the Company's board of directors and shall not be cumulative.

No such dividends have been declared or paid through September 30, 2020.

*2) Preference on Liquidation*

The holders of the Series A, Series B and Series C convertible preferred stock are entitled to receive liquidation preferences at the Series A, Series B and Series C original issue prices of \$2.00, \$6.218 and \$9.584, respectively, plus all accrued and declared but unpaid dividends. Liquidation payments to the holders of the Series A, Series B and Series C convertible preferred stock have priority and are made in preference to any payments to the holders of common stock.

After full payment of the liquidation preference to the holders of the Series A, Series B and Series C convertible preferred stock, the remaining assets, if any, will be distributed ratably to the holders of the common stock.

*3) Conversion Rights*

The shares of Series A, Series B and Series C convertible preferred stock are convertible into an equal number of shares of common stock, at the option of the holder, subject to certain anti-dilution adjustments. The conversion rate for the convertible preferred stock is determined by dividing the original issue price, as adjusted for stock splits, by the conversion price. The conversion price for Series A and Series B convertible preferred stock is initially the original issue price, but is subject to adjustment for dividends, stock splits, and other distributions. The conversion price for Series C convertible preferred stock is \$9.552, but is subject to adjustment for dividends, stock splits, and other distributions. The conversion rate at September 30, 2020 for the Series A Series B convertible preferred stock was one share of common stock for each share of preferred stock and for the Series C convertible preferred stock is 1.0033 shares of common stock for each share of preferred stock.

Each share of Series A, Series B and Series C convertible preferred stock will be automatically converted into common stock at the then effective conversion rate (i) immediately upon the closing of a firmly underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, covering the offer and sale of common stock for the account of the Company in which the gross cash proceeds to the Company are at least \$50.0 million or (ii) upon written request for such conversion from the Requisite Investors (defined as at least 71% of the holders of Series A and Series B convertible preferred stock) or written request for such conversion from at least two thirds of the Series C convertible preferred stock holders.

*4) Redemption Rights*

The holders of Series A, Series B and Series C convertible preferred stock do not have any redemption rights.

*5) Voting*

The holder of each share of Series A, Series B and Series C convertible preferred stock generally vote together with the shares of common stock as a single class, but also have class vote approval rights as provided by the Company's certificate of incorporation or as required by applicable law.

**b) Common Stock**

As of December 31, 2019, and September 30, 2020, of the authorized 33,227,000 and 47,000,000 shares of common stock, 4,524,583 and 4,664,062 shares were issued and 4,524,583 and 4,627,994 shares were outstanding, respectively. The fair value of the Company's common stock was \$2.08 and \$6.79 as of December 31, 2019, and September 30, 2020, respectively, and was determined in part based on third-party valuations.

The voting, dividend, and liquidation rights of the holders of the common stock are subject to, and qualified by, the rights, preferences and privileges of the holders of the convertible preferred stock. The holders of the common stock are entitled to one vote for each share of common stock held at all meetings of stockholders.

Common stock reserved for future issuance consisted of the following:

	December 31, 2019	September 30, 2020
Convertible preferred stock	21,564,671	31,824,284
Common stock options granted and outstanding	1,710,208	7,037,046
Common stock reserved for future option grants	<u>3,840,051</u>	<u>1,379,209</u>
Total common stock reserved for future issuance	<u>27,114,930</u>	<u>40,240,539</u>

**7) Stock-Based Compensation**

Following is a summary of the Company's stock option plan activity and related information for the nine months ended September 30, 2020:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2020	1,710,208	\$0.15	8.6	
Granted	6,321,837	2.76	9.6	
Forfeited	(855,520)	0.14	7.8	
Exercised	<u>(139,479)</u>	<u>0.18</u>	<u>7.9</u>	
Outstanding at September 30, 2020	<u>7,037,046</u>	<u>\$2.49</u>	<u>9.4</u>	<u>\$30,231</u>
Exercisable at September 30, 2020	<u>709,823</u>	<u>\$1.01</u>	<u>8.6</u>	<u>\$ 4,102</u>

All exercisable options are vested and all outstanding options are vested or expected to vest.

The aggregate intrinsic value of options exercised during the nine months ended September 30, 2020 was \$0.3 million, determined as of the date of exercise. No options were exercised during the nine months ended September 30, 2019.

The Company estimated the fair value of stock options using the Black-Scholes valuation model. The Company accounts for any forfeitures of options when they occur. Previously recognized compensation expense for an award is reversed in the period that the award is forfeited. The fair value of stock options was estimated using the following assumptions:

	As of September 30,	
	2019	2020
Stock price	\$0.14 - \$0.27	\$2.08 - \$4.56
Expected term (in years)	10	6 - 7
Expected volatility	95.9 - 98.7%	87.5 - 89.2%
Risk-free interest rate	1.80 - 2.64%	0.37 - 1.57%
Expected dividend	0%	0%

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The Company recorded stock-based compensation expense of \$0 and \$1.3 million for the nine months ended September 30, 2019 and 2020, respectively.

As of September 30, 2020, there was \$12.0 million of total unrecognized stock-based compensation expense related to nonvested stock-based compensation arrangements granted under the Company's 2018 Equity Incentive Plan, which is expected to be recognized over a weighted-average period of approximately 3.5 years.

### 8) Related Party Transactions

#### a) *Management Services Agreement with Fount Therapeutics, LLC and Fount Service Corp.*

Effective June 22, 2018, the Company entered into a Master Service Agreement with FTL and Fount Service Corp. (FSC), a wholly owned subsidiary of FTL. Under this agreement, FTL and FSC agreed to perform various management and other services to the Company, either directly or via arrangements with third parties. These services included research and development and general and administrative functions, such as finance, audit, accounting, human resources, technology, facilities, and other management services necessary for the Company's operations. For all services performed, directly or indirectly, which generally included FTL and FSC payroll costs and other third-party costs incurred by FTL and FSC, a five percent markup was charged as a management service fee to the Company.

Certain services performed and expenses incurred by FTL discussed above are performed by other wholly owned subsidiaries of FTL. When this occurs, FTL's management allocates expenses to the respective entities based on its best estimate of the expenses incurred by each entity. The Company recognized management fee expenses of approximately \$3.4 million and \$92,000 for the nine months ended September 30, 2019 and 2020, respectively, which are included in the Company's statements of operations and comprehensive loss. During 2020, the Company discontinued using the services of FTL and FSC.

The following table sets forth the amounts included in the Company's statements of operations and comprehensive loss (in thousands):

	Nine Months Ended September 30,	
	2019	2020
FTL included in research and development	\$ —	\$—
FTL included in general and administrative	627	80
Total FTL related party expense	627	80
FSC included in research and development	1,551	—
FSC included in general and administrative	1,200	12
Total FSC related party expense	2,751	12
Total related party expenses	\$3,378	\$92

The following table sets forth the amounts included as related party receivables, net on the Company's balance sheets (in thousands):

	December 31, 2019	September 30, 2020
FTL related party receivables	\$ 250	\$—
FTL related party payables	(20)	—
FTL related party receivables, net	230	—
FSC related party receivables	2,283	—
FSC related party payables	(1,540)	—
FSC related party receivables, net	743	—
Total related party receivables, net	\$ 973	\$—

**b) Management Services Agreement with Subveho, LLC**

Effective March 21, 2018, FTL entered into a Management Service Agreement (the Subveho MSA) with Subveho, LLC (Subveho), pursuant to which Subveho agreed to perform various services such as, but not limited to, research and development, manufacturing activities, general and administrative, business development, advisory, and other management services necessary for the operations of the Company. Such services were performed on behalf of Subveho by an individual who was a partial owner of Subveho and who acted in the capacity of an officer of the Company based on the nature of such services. Pursuant to the Subveho MSA, in June 2018, the Company issued to Subveho options to purchase 600,000 shares of the Company's common stock at an exercise price of \$0.14 per share. In addition, FTL agreed to pay Subveho \$75,000 per quarter for services up to an agreed upon hour limit. Services outside of this agreed upon hour limit were to be billed separately. Total expenses FTL paid to Subveho under the Subveho MSA for services provided to the Company were \$0.2 million and \$75,000 for each of the nine months ended September 30, 2019 and 2020, respectively, which are included in the total management fee expenses in Note 8(a). The Subveho MSA was terminated effective March 2020.

**9) Commitments and Contingencies**

**Litigation**

The Company, from time to time, is involved in legal proceedings, regulatory actions, claims and litigation arising in the ordinary course of business. The Company was not a defendant in any lawsuits for the nine months ending September 30, 2019 and 2020.

**Leases**

The Company leases certain office space in San Diego, California under a short-term lease with base monthly rent payments of \$13,000 that expires December 31, 2020, which the Company will renew or arrange for alternatives to that space before such date.

**10) Net Loss and Pro Forma Net Loss Per Share**

**a) Net Loss per Share**

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share amounts):

	Nine Months Ended September 30,	
	2019	2020
<b>Numerator</b>		
Net loss and comprehensive loss	\$ (8,027)	\$ (22,054)
Gain on extinguishment of Series A convertible preferred stock	2,031	—
Net loss attributable to common stockholders	<u>\$ (5,996)</u>	<u>\$ (22,054)</u>
<b>Denominator</b>		
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	4,517,500	4,578,904
Net loss attributable to common stockholders per share, basic and diluted	<u>\$ (1.33)</u>	<u>\$ (4.82)</u>

The Company's potentially dilutive securities, which include preferred stock and common 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 shares of common stock outstanding used to calculate both basic and diluted net loss per share attributable to common

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stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Nine Months Ended September 30,	
	2019	2020
Options to purchase common stock	1,762,500	7,037,046
Convertible preferred stock	9,583,328	31,824,284
Total	<u>11,345,828</u>	<u>38,861,330</u>

### b) Pro Forma Net Loss Per Share

The unaudited pro forma basic and diluted net loss per share attributable to common stockholders, for the nine months ended September 30, 2020 has been prepared to give effect, upon a Qualified IPO, to the automatic conversion of the shares of all outstanding shares of preferred stock into common stock as if such conversion had occurred on the later of January 1, 2020 or the issuance date of the preferred Stock (in thousands, except share and per share amounts):

	Nine Months Ended September 30, 2020
<b>Numerator</b>	
Net loss attributable to common stockholders	\$ (22,054)
<b>Denominator</b>	
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	4,578,904
Adjust: Assumed weighted-average effect of conversion of convertible preferred stock	<u>24,164,347</u>
Weighted-average shares outstanding used in computing pro forma net loss per share, basic and diluted	<u>28,743,251</u>
Pro forma net loss per share, basic and diluted	<u>\$ (0.77)</u>

### 11) Subsequent Events

The Company evaluated the effect subsequent events would have on the financial statements through November 3, 2020, which is the date the financial statements were available to be issued.

In October 2020, Melissa Epperly was elected to the Company's board of directors.

Shares

## Kinnate Biopharma Inc.

Common Stock



Goldman Sachs & Co. LLC

SVB Leerink

Piper Sandler

Wedbush PacGrow

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Through and including \_\_\_\_\_, 2020 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

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## Part II

### Information Not Required in the Prospectus

#### Item 13. Other Expenses of Issuance and Distribution

The following table sets forth the expenses to be incurred in connection with the offering described in this Registration Statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimates except the Securities and Exchange Commission (SEC) registration fee, the Financial Industry Regulatory Authority, Inc. (FINRA) filing fee and the listing fee.

	Amount Paid or to Be Paid
SEC registration fee	\$ *
FINRA filing fee	*
listing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer agent and registrar fees	*
Miscellaneous expenses	*
<b>Total</b>	<b>\$ *</b>

\* To be provided by amendment.

#### Item 14. Indemnification of Directors and Officers

Section 145 of the Delaware General Corporation Law empowers a corporation to indemnify its directors and officers and to purchase insurance with respect to liability arising out of their capacity or status as directors and officers, provided that the person acted in good faith and in a manner the person reasonably believed to be in our best interests, and, with respect to any criminal action, had no reasonable cause to believe the person's actions were unlawful. The Delaware General Corporation Law further provides that the indemnification permitted thereunder shall not be deemed exclusive of any other rights to which the directors and officers may be entitled under the corporation's bylaws, any agreement, a vote of stockholders or otherwise. The certificate of incorporation of the registrant to be in effect upon the completion of this offering provides for the indemnification of the registrant's directors and officers to the fullest extent permitted under the Delaware General Corporation Law. In addition, the bylaws of the registrant to be in effect upon the completion of this offering require the registrant to fully 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) by reason of the fact that such person is or was a director or officer of the registrant, or is or was a director or officer of the registrant serving at the registrant's request as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorney's fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, to the fullest extent permitted by applicable law.

Section 102(b)(7) of the Delaware General Corporation Law permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except (1) for any breach of the director's duty of loyalty to the corporation or its stockholders, (2) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (3) for payments of unlawful dividends or unlawful stock repurchases or redemptions or (4) for any transaction from which the director derived an improper personal benefit. The registrant's certificate of incorporation to be in effect upon the completion of this offering provides that the registrant's directors shall not be personally liable to it or its stockholders for monetary damages for breach of fiduciary duty as a director



and that if the Delaware General Corporation Law is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of the registrant's directors shall be eliminated or limited to the fullest extent permitted by the Delaware General Corporation Law, as so amended.

Section 174 of the Delaware General Corporation Law provides, among other things, that a director who willfully or negligently approves of an unlawful payment of dividends or an unlawful stock purchase or redemption may be held liable for such actions. A director who was either absent when the unlawful actions were approved, or dissented at the time, may avoid liability by causing his or her dissent to such actions to be entered in the books containing minutes of the meetings of the board of directors at the time such action occurred or immediately after such absent director receives notice of the unlawful acts.

As permitted by the Delaware General Corporation Law, the registrant has entered into separate indemnification agreements with each of the registrant's directors and executive officers which would require the registrant, among other things, to indemnify them against certain liabilities which may arise by reason of their status as directors or executive officers.

The registrant expects to obtain and maintain insurance policies under which its directors and officers are insured, within the limits and subject to the limitations of those policies, against certain expenses in connection with the defense of, and certain liabilities which might be imposed as a result of, actions, suits or proceedings to which they are parties by reason of being or having been directors or officers. The coverage provided by these policies may apply whether or not the registrant would have the power to indemnify such person against such liability under the provisions of the Delaware General Corporation Law.

These indemnification provisions and the indemnification agreements entered into between the registrant and the registrant's officers and directors may be sufficiently broad to permit indemnification of the registrant's officers and directors for liabilities (including reimbursement of expenses incurred) arising under the Securities Act of 1933, as amended.

The underwriting agreement between the registrant and the underwriters filed as Exhibit 1.1 to this registration statement provides for the indemnification by the underwriters of the registrant's directors and officers and certain controlling persons against specified liabilities, including liabilities under the Securities Act with respect to information provided by the underwriters specifically for inclusion in the registration statement. The investors' rights agreement with certain holders of our capital stock also provides for cross-indemnification in connection with the registration of the registrant's common stock on behalf of such holders.

#### **Item 15. Recent Sales Of Unregistered Securities**

The following list sets forth information regarding all unregistered securities sold by us since January 1, 2017. No underwriters were involved in the sales and the certificates representing the securities sold and issued contain legends restricting transfer of the securities without registration under the Securities Act or an applicable exemption from registration.

- (1) In March 2018, June 2018 and October 2018, we issued and sold an aggregate of 3,489,982 shares of our Series A convertible preferred stock at a purchase price of \$3.3429 per share for an aggregate purchase price of \$11.7 million.
- (2) In April 2019, we entered into an amended and restated Series A Preferred Stock Purchase Agreement pursuant to (i) which the number of shares issued in such 2018 financings was amended and restated to a new total of 5,833,328 and (ii) we issued and sold an additional 3,000,000 shares of our Series A convertible preferred stock at an updated purchase price of \$2.00 per share for an aggregate purchase price of \$6.0 million.
- (3) In April 2019, we entered into an Agreement and Plan of Merger with Immanate Therapeutics Inc. (Immanate), pursuant to which we acquired Immanate in exchange for the issuance of 750,000 shares of our Series A convertible preferred stock. At the effective time of the merger,

the outstanding shares of Immanate preferred stock were exchanged for the shares of our Series A convertible preferred stock and the outstanding shares of Immanate common stock and options to purchase Immanate common stock were canceled

- (3) In December 2019, we issued and sold 11,981,343 shares of our Series B convertible preferred stock at a purchase price of \$6.218 per share for an aggregate purchase price of \$74.5 million.
- (4) In July and August 2020, we issued and sold 10,225,369 shares of our Series C convertible preferred stock at a purchase price of \$9.584 per share for an aggregate purchase price of \$98.0 million. These shares are convertible into an aggregate of 10,259,613 shares of common stock.
- (5) From January 2017 through , 2020, we granted stock options to purchase an aggregate of shares of common stock upon the exercise of options under our 2018 Plan at exercise prices per share ranging from \$ to \$ , for an aggregate exercise price of approximately \$ .
- (6) From January 2017 through , 2020, we issued and sold to certain service providers of ours an aggregate of shares of common stock upon the exercise of options under our 2018 Plan at exercise prices per share ranging from \$ to \$ , for an aggregate exercise price of approximately \$ .

The offers, sales and issuances of the securities described in Items 15(1), 15(2), 15(3) and 15(4) were exempt from registration under the Securities Act under Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder as transactions by an issuer not involving a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited person and had adequate access, through employment, business or other relationships, to information about the registrant.

The offers, sales and issuances of the securities described in Items 15(5) and 15(6) were exempt from registration under the Securities Act under either (1) Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701 or (2) Section 4(a)(2) of the Securities Act as transactions by an issuer not involving any public offering. The recipients of such securities were the registrant's employees, consultants or directors and received the securities under our 2018 Plan. The recipients of securities in each of these transactions represented their intention to acquire the securities for investment only and not with view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions.

#### **Item 16. Exhibit and Financial Statement Schedules**

##### ***(a) Exhibits.***

See the Exhibit Index immediately preceding the signature page hereto for a list of exhibits filed as part of this registration statement on Form S-1, which Exhibit Index is incorporated herein by reference.

##### ***(b) Financial Statement Schedules.***

Schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

#### **Item 17. Undertakings**

The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreements, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

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Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities 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 Securities Act and will be governed by the final adjudication of such issue.

The undersigned hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act, 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 of 1933 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, 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.

**Exhibit Index**

<b>Exhibit number</b>	<b>Description</b>
1.1*	Form of Underwriting Agreement.
3.1^	Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect.
3.2*	Form of Amended and Restated Certificate of Incorporation of the Registrant, to be in effect upon the completion of this offering.
3.3^	Bylaws of the Registrant, as currently in effect.
3.4*	Form of Amended and Restated Bylaws of the Registrant, to be in effect upon the completion of this offering.
4.1^	Amended and Restated Investors' Rights Agreement by and among the Registrant and certain of its stockholders, dated August 24, 2020.
4.2*	Specimen common stock certificate of the Registrant.
5.1*	Opinion of Wilson Sonsini Goodrich & Rosati, Professional Corporation.
10.1+*	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.
10.2+*	2018 Equity Incentive Plan, as amended, and forms of agreement thereunder.
10.3+*	2020 Equity Incentive Plan and forms of agreements thereunder, to be in effect upon the completion of this offering.
10.4+*	2020 Employee Stock Purchase Plan and forms of agreements thereunder, to be in effect upon the completion of this offering.
10.5+*	Employment Letter between the Registrant and Nima Farzan.
10.6+*	Employment Letter between the Registrant and Mark Meltz.
10.7+*	Employment Letter between the Registrant and Eric Murphy, Ph.D.
10.8+*	Employment Letter between the Registrant and Richard Williams, Ph.D.
10.9+*	Executive Incentive Compensation Plan.
10.10+*	Change in Control and Severance Policy.
10.11+*	Outside Director Compensation Policy.
10.12^	Office Lease between the Registrant and Realty Income Properties 14, LLC, dated May 2, 2018, as amended by Amendment Number One dated May 5, 2020 and Amendment Number Two dated August 26, 2020, and the consent and assignment related thereto.
23.1*	Consent of KPMG LLP, Independent Registered Public Accounting Firm.
23.2*	Consent of Wilson Sonsini Goodrich & Rosati, Professional Corporation (included in Exhibit 5.1).
24.1*	Power of Attorney (see page II- to this Form S-1).

^ Previously submitted.

\* To be filed by amendment.

+ Indicated management contract or compensatory plan.

**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 the City of San Diego, California, on \_\_\_\_\_, 2020.

KINNATE BIOPHARMA INC.

By: \_\_\_\_\_

Nima Farzan  
President and Chief Executive Officer

**Power of attorney**

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Nima Farzan and Mark Meltz as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and substitution, for him or her and in his or her name, place and stead, in any and all capacities to sign any or all amendments (including post-effective amendments) to this registration statement and any and all additional registration statements pursuant to Rule 462(b) of the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as they, he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agents or any of them, or their, his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
_____	President, Chief Executive Officer and Director ( <i>Principal Executive Officer</i> )	_____, 2020
Nima Farzan		
_____	<i>Principal Financial and Accounting Officer</i>	_____, 2020
_____	Chair of the Board	_____, 2020
Dean Mitchell		
_____	Director	_____, 2020
Melissa Epperly		
_____	Director	_____, 2020
Keith Flaherty, M.D.		
_____	Director	_____, 2020
Carl Gordon, Ph.D.		
_____	Director	_____, 2020
Stephen Kaldor, Ph.D.		
_____	Director	_____, 2020
Michael Rome, Ph.D.		
_____	Director	_____, 2020
Laurie Smaldone Alsup, M.D.		
_____	Director	_____, 2020
Jim Tananbaum, M.D.		