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As confidentially submitted to the Securities and Exchange Commission on October 30, 2019 as Amendment No. 2 to the draft registration statement submitted on August 23, 2019. This Amendment No. 2 to the draft registration statement has not been publicly filed with the Securities and Exchange **Commission and all information herein remains confidential**.

Registration No. 333–

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1
REGISTRATION STATEMENT

UNDER
THE SECURITIES ACT OF 1933

Black Diamond Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	2836	81-4254660
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification No.)**

Black Diamond Therapeutics, Inc.
139 Main Street
Cambridge, MA 02142
617-252-0848
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

David M. Epstein, Ph.D.
President and Chief Executive Officer
Black Diamond Therapeutics, Inc.
139 Main Street
Cambridge, MA 02142
617-252-0848
(Name, address, including zip code, and telephone number, including area code, of agent for service)

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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, as amended, check the following box. ☐

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

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

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration 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, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed maximum aggregate offering price(1)	Amount of registration fee(2)
Common stock, $0.0001 par value per share	$	$

(1) Estimated solely for the purpose of computing the registration fee in accordance with Rule 457(o) under the Securities Act of 1933, as amended. Includes the aggregate offering price of shares that the underwriters have the option to purchase to cover over-allotments, if any.

(2) Registration fee will be paid when registration statement is first publicly filed 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 files 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 Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the Securities and Exchange Commission declares our registration statement 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 , 2019

Preliminary prospectus

shares

BLACK DIAMOND THERAPEUTICS

Common stock

This is our initial public offering of our common stock. We are offering shares of common stock. Prior to this offering, there has been no public market for our shares. We expect that the initial public offering price will be between $ and $ per share. We intend to apply to list our common stock on The Nasdaq Global Market under the symbol "BDTX."

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

Investing in our common stock involves a high degree of risk. Before buying any shares, you should read carefully the discussion of the material risks of investing in our common stock under the heading "Risk Factors" starting on page 13 of this prospectus.

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

	Per share	Total
Initial public offering price	$	$
Underwriting discount(1)	$	$
Proceeds, before expenses, to Black Diamond Therapeutics, Inc.	$	$

(1) We refer you to "Underwriting" beginning on page 193 of this prospectus for additional information regarding underwriting compensation.

Delivery of the shares of common stock is expected to be made on or about , 2019.

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

J.P. Morgan **Jefferies** **Cowen**

Canaccord Genuity

The date of this prospectus is , 2019.

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Neither we nor the underwriters have authorized anyone to provide you with information different from, or in addition to, that contained in this prospectus, any amendment or supplement to this prospectus and any related 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 assurances as to the reliability of, any information that others may give you. This prospectus is not an offer to sell, nor is it seeking an offer to buy, these securities in any jurisdiction where the offer or sale is not permitted. The information contained in this prospectus or in any free writing prospectus is only accurate as of its date, regardless of its time of delivery or the time of any sale of our common stock. Our business, financial condition, results of operations and future prospects may have changed since that date. No action is being taken in any jurisdiction outside the United States to permit a public offering of our common stock or possession or distribution of this prospectus in that jurisdiction. Persons who come into possession of this prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus applicable to that jurisdiction.

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We have applied for various trademarks that we use in connection with the operation of our business. This prospectus may also contain trademarks, service marks and trade names of third parties, which are the property of their respective owners. Our use or display of third parties' trademarks, service marks, trade names or products in this prospectus is not intended to, and does not imply a relationship with, or endorsement or sponsorship by us. Solely for convenience, the trademarks, service marks and trade names referred to in this prospectus may appear without the ®, TM or SM symbols, but the omission of such references is not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable owner of these trademarks, service marks and trade names.

Until and including , (25 days after the date of this prospectus), all dealers that buy, sell or trade our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the obligation of dealers to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

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Prospectus summary

This summary highlights information contained in greater detail elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including our consolidated financial statements and the related notes thereto included elsewhere in this prospectus. You should also consider, among other things, the information set forth under the sections titled "Risk Factors," "Special Note Regarding Forward-Looking Statements," and "Management's Discussion and Analysis of Financial Condition and Results of Operations," in each case appearing elsewhere in this prospectus. Unless the context otherwise requires, we use the terms "Black Diamond," "Black Diamond Therapeutics," the "Company," "we," "us," "our" and similar designations in this prospectus to refer to Black Diamond Therapeutics, Inc. and, where appropriate, its subsidiary.

Overview

We are a precision oncology medicine company pioneering the discovery and development of small molecule, tumor-agnostic therapies. Our goal is to bring precision oncology medicine to a greater number of patients. We target undrugged mutations in patients with genetically-defined cancers. The foundation of our company is built upon a deep understanding of cancer genetics, protein structure and function, and medicinal chemistry. Our proprietary technology platform, which we refer to as our Mutation-Allostery-Pharmacology, or MAP, platform, is designed to allow us to i) analyze population-level genetic sequencing data to identify oncogenic mutations that promote cancer across tumor types, ii) group these mutations into families and iii) develop a single small molecule therapy in a tumor-agnostic manner that targets a specific family of mutations. We have designed our lead product candidate, BDTX-189, to block the function of an undrugged family of oncogenic proteins defined by mutations which occur across a range of tumor types, and which affect both the epidermal growth factor receptor, or EGFR, and the tyrosine-protein kinase ErbB-2, or HER2. We have designed BDTX-189 to bind to the active site of these mutant kinases and to inhibit their function. BDTX-189 is also designed to spare normal, or wild type, EGFR, which we believe will improve upon the toxicity profiles of current ErbB kinase inhibitors. We are completing Investigational New Drug, or IND, enabling activities for BDTX-189 and plan to start a combined Phase 1/2 clinical trial in the first half of 2020 to pursue a tumor-agnostic development strategy. We are also leveraging our MAP platform to expand the reach of targeted therapies by identifying other families of mutations in genes known to drive disease.

Background of targeted oncology therapies

Cancer is a genetic disease that is caused by changes in DNA that control the way cells function, especially how they grow and divide, and has historically been diagnosed and treated based on a tumor's organ site or tissue of origin. Oncogene addiction, which is the dependency of tumors on genetic drivers for a growth and survival advantage, has enabled the development of targeted therapies that exploit this dependency.

Approved targeted therapies, such as kinase inhibitors, have transformed the treatment of cancers by providing substantial clinical benefit and have emerged as an important part of standard of care for cancer patients. Worldwide sales of kinase inhibitors, one class of targeted therapies, exceeded $25 billion in 2018. Despite the success of these drugs, a recent analysis found that only nine percent of patients with metastatic cancer have tumors with genetic profiles that could make them eligible for treatment with an approved precision oncology medicine.

Genetic sequencing of cancers has become increasingly widespread, leading to the discovery of multiple genetic alterations which were previously unaddressed, unsuccessfully targeted or overlooked. Furthermore,

advancements in genetic sequencing and a better understanding of genetic alterations that drive cancers have facilitated more precise cancer drug development to be conducted in a tumor and histology agnostic manner. We believe our MAP platform will allow us to reveal the oncogenic nature of families of undrugged mutations having similar protein structures, and our approach offers a substantial opportunity to expand the number of patients who could benefit from precision oncology medicines.

The Black Diamond Therapeutics approach

At Black Diamond Therapeutics, our goal is to bring precision oncology medicine to a greater number of patients. Our drug development efforts leverage our novel findings that:

- mutations throughout a gene can drive oncogenic activation and change the drug selectivity profile of their active sites;
- these oncogenic mutations can be grouped as families because they drive similar structural changes, and exhibit a shared selectivity profile; and
- a family of oncogenic proteins can therefore be inhibited by a single small molecule that targets the active site.

We believe we can address certain key limitations of current generation precision medicine therapies in oncology by applying our MAP Platform to identify and target novel classes of oncogenic mutations. We believe this will allow us to design and develop potential therapies for patients for whom there are currently no targeted treatment options.

Our MAP platform

Our proprietary MAP platform was developed to reveal the oncogenic nature of families of undrugged driver mutations, at or outside the active site, and their associated protein structures. We believe there is a substantial opportunity for designing novel classes of tumor-agnostic precision medicines targeting families of mutations.

Our proprietary MAP platform is built on three central pillars:

- ***Discover*** — Through comprehensive analysis of population-level genetic sequencing data, we identify oncogenic mutations among hundreds of unique alterations within a single gene. Our MAP platform algorithm uses genetic and proteomic features to rank mutations for potential oncogenicity. We use our algorithm as a machine learning tool to classify mutations as either pathogenic or benign and predict the probability, or MAP score, that a mutation is pathogenic.

- ***Reveal*** — We confirm the oncogenicity of the identified mutations through cell and tumor models and reveal how these mutations drive conformational changes in proteins. This allows us to group subsets of mutations into families based upon similar protein structures and shared selectivity profiles.

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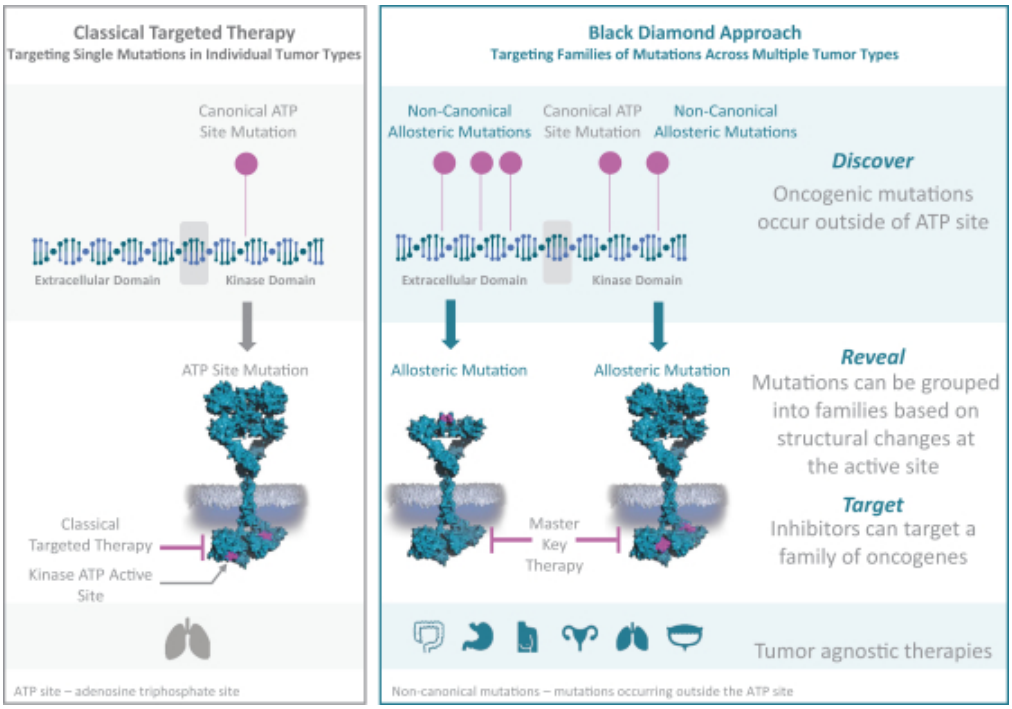
• ***Target*** — Using these shared characteristics, we seek to develop single small molecule product candidates, each designed to inhibit only the intended mutation family.



Our pipeline

Utilizing our proprietary MAP platform, we are developing a pipeline of orally available, potent and selective small molecule kinase inhibitors, each targeting a family of undrugged driver mutations in cancer. An overview of our pipeline of product candidates is shown in the table below.

Oncogene Family	Target	Drug Candidate	Diseases	Discovery[1]	Optimization[2]	IND-enabling[3]	Phase 1	Phase 2	Phase 3	Commercial Rights	Key Anticipated Milestone
ErbB Family	EGFR HER2	BDTX-189	Tumor agnostic								• IND Filing • Phase 1/2 Trial Initiation (1H 2020)
	EGFR	Undisclosed	Glioblastoma								• IND-Enabling Studies (2020)

Completed

(1) In the Discovery stage, we screen compounds against biological assays to identify lead compounds with activity against desired targets.
(2) In the Optimization stage, we synthetically modify an active lead compound to improve potency, selectivity, pharmacokinetic and toxicity parameters and physical chemical properties important for clinical usefulness to support nomination as a development candidate.
(3) In the IND-enabling stage, we conduct preclinical studies, in addition to Good Laboratory Practice, or GLP, compliant toxicology studies and generate chemical manufacture and control information and analytical data, required for an IND submission to the FDA.

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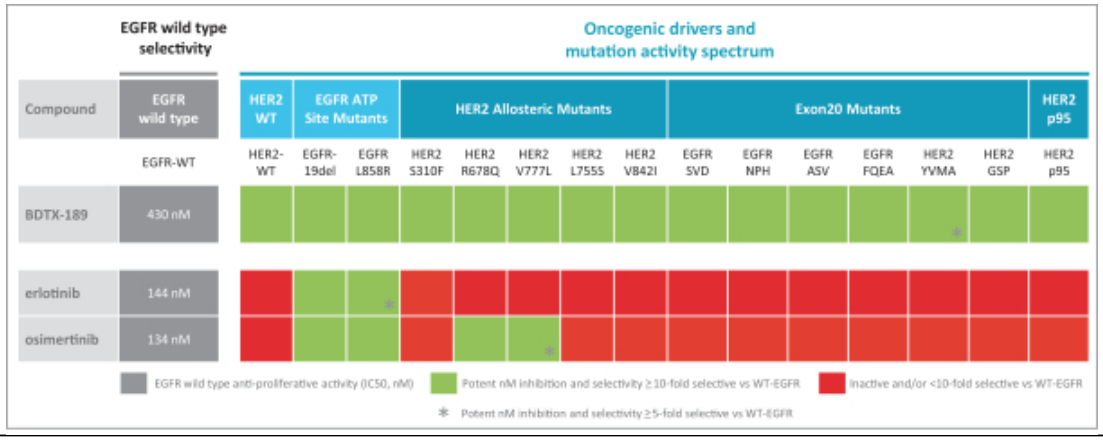
Our BDTX-189 program

BDTX-189 is designed to be an orally available, irreversible small molecule inhibitor that targets undrugged oncogenic driver mutations of the ErbB kinases EGFR and HER2. These include extracellular domain allosteric mutations of HER2 as well as EGFR and HER2 kinase domain exon 20 insertions, and additional activating oncogenic drivers of ErbB. Currently, there are no drugs approved by the FDA to target all of these oncogenic mutations with a single therapy. In preclinical models, BDTX-189 exhibited anti-tumor activity evidenced by potent tumor growth inhibition and tumor regression.

We are completing IND-enabling activities for BDTX-189 and plan to start a combined Phase 1/2 clinical trial in the first half of 2020. The Phase 1 portion of the trial will evaluate escalating doses of BDTX-189 and is designed to determine the recommended Phase 2 dose and to assess preliminary indications of anti-tumor activity. The Phase 2 portion will determine the objective response rate, or ORR, and duration of response in patients with solid tumors that have an allosteric HER2 mutation or EGFR or HER2 exon 20 insertion mutation using next-generation sequencing, or NGS. Depending on results, we plan to pursue an accelerated approval of BDTX-189 for a tumor-agnostic indication in patients with mutations of the ErbB family. The figure below shows the selectivity pattern for BDTX-189 for non-canonical oncogenic mutations and additional oncogenic drivers of ErbB (with wild type for reference) as well as comparable data for erlotinib and osimertinib (each as determined by measuring 50 percent inhibition, or IC50, values). The data in the figure below were generated through head-to-head comparisons of BDTX-189 to erlotinib and osimertinib by determining the *in vitro* anti-proliferative activity for each molecule against a panel of cell lines under the same experimental conditions for each molecule.

BDTX-189 potently inhibited the proliferation of BaF3 cells transformed by allosteric EGFR mutations and allosteric HER2 mutations when evaluated *in vitro*. BDTX-189 additionally inhibited the proliferation of lung cancer patient-derived cells expressing EGFR exon 20 insertions (CUTO-14 and CUTO-17 cell lines), and human tumor cells expressed amplified wild type HER2 (BT-474 cells). BDTX-189 further inhibited the proliferation of BaF3 cells transformed by EGFR ATP-site mutations, including the EGFR exon 19 deletion E745-750 and EGFR-L858R, and extracellular domain EGFR mutations, including EGFR-Viii when evaluated *in vitro*. In each case, BDTX-189 inhibits the targeted ErbB mutation more potently than wild type EGFR.



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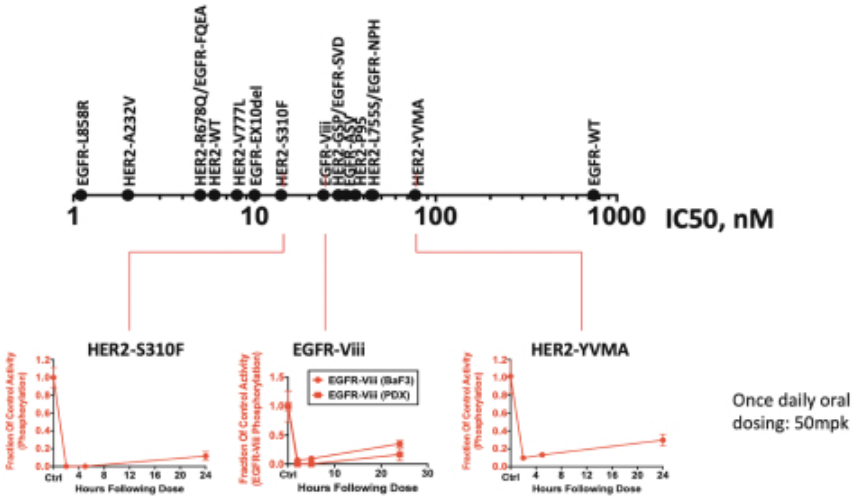
In preclinical animal models, BDTX-189 was observed to have high potency and fast irreversible inactivation of a range of non-canonical oncogenic mutations, as illustrated in the figure below.



BDTX-189 inhibits activity across a range of EGFR and HER2 mutants in vivo (50mpk once a day, or QD, acute oral dosing), including mutants with a range of in vitro 50 percent inhibition, or IC50, values.

Glioblastoma program

Glioblastoma is a difficult-to-treat, aggressive type of cancer that can occur in the brain or spinal cord. Current therapy consists primarily of surgical resection of the tumor, followed by radiation and chemotherapy. Almost 50 percent of glioblastoma tumors express one or more allosteric EGFR mutations that affect the extracellular region of the receptor tyrosine kinase, consequently promoting oncogenic activation. Although the disease appears to be genetically-defined, there are no precision oncology medicines approved to treat these patients. We believe that current targeted therapies have been unsuccessful in treating glioblastoma due to (i) the concurrent expression of these allosteric EGFR mutations within individual patients, (ii) insufficient drug potency for allosteric EGFR mutations and (iii) low levels of brain penetration. Our lead molecules are designed to be potent, allosteric EGFR selective and to be brain penetrant. We have observed measurable brain exposure in animal models. We are completing preclinical characterization of our glioblastoma candidate leads and plan to select a development candidate in 2020.

Early-stage programs

We are also progressing our early stage pipeline programs targeting groups of allosteric mutations in kinases relevant to cancer and/or rare genetic diseases. These programs, which we have developed using our MAP platform, are currently progressing through lead optimization.

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Our history and team

We were founded by Dr. David M. Epstein and Dr. Elizabeth Buck in 2014 and, beginning in 2017, together with Versant Ventures began building the MAP platform and chemistry discovery engine. As of October 30, 2019, we have raised more than $109 million in funding from leading investors including Versant Ventures, New Enterprise Associates, RA Capital Management, NexTech Invest, The Invus Group and Perceptive Advisors.

We have assembled a team with significant expertise in drug discovery and development with particular strengths in the discovery of small molecule protein kinase inhibitors. David M. Epstein, Ph.D., our President and Chief Executive Officer, was previously Chief Scientific Officer at OSI Pharmaceuticals, Inc. and founder of Archemix, where he led the advancement of multiple product candidates into the clinic in multiple therapeutic areas. Thomas Leggett, our Chief Financial Officer, was previously Senior Vice President of Finance and Chief Financial Officer at Axcella Health, Inc. Christopher D. Roberts, our Chief Scientific Officer, was previously Entrepreneur in Residence at S.R. One Limited, the corporate venture capital arm of GlaxoSmithKline plc. Elizabeth Buck, Ph.D., our Executive Vice President of Discovery & Translational Sciences, previously led preclinical pharmacology and oncology translational research at OSI Pharmaceuticals. Karsten Witt, M.D., our Senior Vice President of Clinical Development, previously led clinical development at Array Biopharma Inc. and OSI Pharmaceuticals. Dr. Witt has been involved in eight regulatory approvals, four of which are related to Tarceva (erlotinib), an approved kinase inhibitor for the treatment of certain lung and pancreatic cancers. Brent Hatzis-Schoch, our Chief Operating Officer and General Counsel, was previously General Counsel at Radius Health.

Our strategy

Our goal is to continue building a differentiated, global biopharmaceutical company by discovering, developing and commercializing novel precision medicines for a greater number of patients. The critical components of our strategy include:

- rapidly advancing our lead drug candidate, BDTX-189, through clinical development, as a tumor-agnostic, spectrum-selective small molecule therapy;
- rapidly advancing our glioblastoma program to identify a small molecule lead product candidate and progress it through clinical development;
- expanding our pipeline of potent and selective small molecule inhibitors to fully exploit the potential of our proprietary MAP platform;
- continuing to invest in our proprietary MAP platform to identify and characterize new mutation families; and
- selectively entering into strategic partnerships to maximize the potential of our pipeline and our proprietary MAP platform.

Risks associated with our business

Our ability to implement our business strategy is subject to numerous risks that you should be aware of before making an investment decision. These risks are described more fully in the section entitled “Risk Factors” in this prospectus. These risks include, among others:

- our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability;

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- we have incurred significant losses since inception, and we expect to incur losses over the next several years and may not be able to achieve or sustain revenues or profitability in the future. As of September 30, 2019, we had an accumulated deficit of $41.1 million;
- we have not generated any revenue from our product candidates and may never be profitable;
- we will need substantial additional funding. If we are unable to raise capital when needed, we would be compelled to delay, reduce or eliminate our product development programs or commercialization efforts;
- our discovery and preclinical development is focused on the development of targeted therapeutics for patients with genetically defined cancers, which is a rapidly evolving area of science, and the tumor-agnostic approach we are taking to discover and develop drugs is novel and may never lead to marketable products;
- we are very early in our development efforts. All of our product candidates are still in preclinical development. If we are unable to advance our product candidates to clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed;
- if we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired;
- we do not currently own or in-license any issued patents or non-provisional patent applications relating to our product candidates or technology, including BDTX-189. If we are unable to obtain and maintain patent and other intellectual property protection for BDTX-189, our MAP platform and our other product candidates and technology, or any other product candidates or technology we may develop, or if the scope of intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize BDTX-189 or any other product candidates or technology may be adversely affected;
- we are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy; and
- we have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business.

Corporate information

We were formed as an LLC in December 2014 and we converted to a corporation in September 2016 under the laws of the State of Delaware under the name ASET Therapeutics, Inc. On January 2, 2018, we changed our name to Black Diamond Therapeutics, Inc. Our principal executive offices are located at 139 Main Street, Cambridge, MA 02142, and our telephone number is 617-252-0848. We have one subsidiary located in Canada, Black Diamond Therapeutics (Canada) Inc. Our website address is https://www.blackdiamondtherapeutics.com. The information contained in or accessible from our website is not incorporated into this prospectus, and you should not consider it part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

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Implications of being an emerging growth company and a smaller reporting company

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

- being permitted to 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;
- reduced disclosure about our executive compensation arrangements;
- not being required to hold advisory votes on executive compensation or to obtain stockholder approval of any golden parachute arrangements not previously approved; and
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission (SEC). We may choose to take advantage of some but not all of these exemptions. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock.

We have elected not to "opt out" of the exemption for the delayed adoption of certain accounting standards and, therefore, we will adopt new or revised accounting standards at the time private companies adopt the new or revised accounting standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an emerging growth company.

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.

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The offering

Shares of common stock offered by us	shares.
Shares of our common stock to be outstanding after this offering	shares (or shares if the underwriters exercise their option to purchase additional shares in full).
Underwriters' option to purchase additional shares	We have granted the underwriters a 30-day option to purchase up to additional shares of our common stock at the public offering price, less underwriting discounts and commissions on the same terms as set forth in this prospectus.
Use of proceeds	We estimate that the net proceeds to us from the sale of shares of our common stock in this offering will be approximately $ million, or $ million if the underwriters exercise their option to purchase additional shares in full, assuming an initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds of this offering to fund the Phase 1/2 development of BDTX-189, to identify a lead development candidate and conduct IND-enabling studies in our glioblastoma program and for continued development of our MAP discovery platform and identification of additional targets and development candidates, hiring of additional personnel, capital expenditures, costs of operating as a public company and other general corporate purposes. See "Use of Proceeds."
Proposed Nasdaq Global Market symbol	"BDTX"
Risk factors	Investment in our common stock involves substantial risks. You should read this prospectus carefully, including the section entitled "Risk Factors" and the financial statements and the related notes to those statements included in this prospectus, before investing in our common stock.

The number of shares of our common stock outstanding after this offering is based on 6,695,460 shares of our common stock outstanding as of September 30, 2019, after giving effect to the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 45,419,229 shares of common stock upon the completion of this offering, and excludes:

- 4,850,721 shares of common stock issuable upon exercise of options outstanding under our 2017 Employee, Director and Consultant Equity Incentive Plan at a weighted-average exercise price of $2.22 per share as of September 30, 2019;
- shares of common stock issuable upon the exercise of warrants to purchase common stock at an exercise price of $ per share as of September 30, 2019;

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- 1,460,392 shares of common stock reserved for issuance under our 2017 Employee, Director and Consultant Equity Incentive Plan as of September 30, 2019, which such shares will cease to be available for issuance at the time our 2019 Stock Option and Incentive Plan becomes effective;
- shares of common stock to be reserved for future issuance under our 2019 Stock Option and Incentive Plan to be effective upon the effectiveness of the registration statement of which this prospectus forms a part; and
- shares of common stock to be reserved for future issuance under our 2019 Employee Stock Purchase Plan to be effective upon the effectiveness of the registration statement of which this prospectus forms a part.

Except as otherwise noted, all information in this prospectus:

- gives effect to a 1-for reverse stock split of our common stock effected on , and corresponding adjustments to (i) the rate at which shares of our preferred stock convert into shares of our common stock, (ii) the exercise price of all outstanding stock options and warrants and (iii) the number of shares of our common stock subject to each outstanding option and warrant;
- assumes no exercise of the underwriters' option to purchase up to additional shares of common stock in this offering;
- assumes no exercise of the outstanding options and warrants described above;
- gives effect to the automatic conversion upon the completion of this offering of all of our outstanding shares of preferred stock into an aggregate of shares of common stock; and
- assumes the filing of our amended and restated certificate of incorporation and the effectiveness of our amended and restated bylaws, which will occur upon the closing of this offering.

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Summary consolidated financial data

You should read the following summary consolidated financial data together with our consolidated financial statements and the related notes appearing elsewhere in this prospectus and the "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of this prospectus. We have derived the consolidated statement of operations data for the years ended December 31, 2017 and 2018 from our audited consolidated financial statements appearing elsewhere in this prospectus. The summary consolidated statements of operations data presented below for the nine months ended September 30, 2018 and 2019 and the summary balance sheet data as of September 30, 2019 have been derived from our unaudited financial statements included elsewhere in this prospectus and have been prepared on the same basis as the audited financial information in those statements. In the opinion of management, the unaudited data reflect all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the financial information in those statements. Our historical results are not necessarily indicative of the results that may be expected the future, and our results for any interim period are not necessarily indicative of results that may be expected for any full year.

	Year ended December 31,		Nine months ended September 30,	
	2017	2018	2018	2019
	(in thousands, except share and per share data)			
Consolidated statement of operations data:				
Operating expenses:				
Research and development (inclusive of $1,348, $2,403, $1,595 and $8,497, respectively, with a related party)	$ 3,453	$ 6,950	$ 4,571	$ 14,293
General and administrative (inclusive of $42, $325, $238 and $357, respectively, with a related party)	666	1,954	1,287	4,695
Total operating expenses	4,119	8,904	5,858	18,988
Loss from operations	(4,119)	(8,904)	(5,858)	(18,988)
Other income (expense):				
Interest expense	(65)	—	—	—
Interest income	—	4	2	21
Loss on extinguishment of convertible promissory notes	(282)	—	—	—
Change in fair value of derivative liabilities	(130)	(15)	—	(6,416)
Other income (expense)	(6)	(16)	(9)	—
Total other income (expense), net	(483)	(27)	(7)	(6,395)
Net loss	(4,602)	(8,931)	(5,865)	(25,383)
Net loss attributable to common stockholders	$ (4,602)	$ (8,931)	$ (5,865)	$ (25,383)
Net loss per share attributable to common stockholders—basic and diluted[1]	$ (0.79)	$ (1.47)	$ (0.97)	$ (4.10)
Weighted average common shares outstanding—basic and diluted[1]	5,802,740	6,089,819	6,069,399	6,194,913
Pro forma net loss attributable to common stockholders outstanding—basic and diluted (unaudited)[2]		$ (0.41)		$ (0.37)
Pro forma weighted average common shares outstanding—basic and diluted (unaudited)[2]		21,701,364		51,614,142

(1) See Note 11 to our consolidated financial statements appearing elsewhere in this prospectus for details on the calculation of basic and diluted net loss per share attributable to common stockholders.

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(2) See Note 11 to our consolidated financial statements appearing elsewhere in this prospectus for details on the calculation of basic and diluted pro forma net loss per share attributable to common stockholders.

	As of September 30, 2019		
(in thousands)	**Actual**	**Pro forma[2]**	**Pro forma as adjusted[3]**
Balance sheet data:			
Cash and cash equivalents	$ 78,659	$ 78,659	$
Working capital[1]	74,306	74,306	
Total assets	80,734	80,734	
Derivative liabilities	39	—	
Convertible preferred stock	115,840	—	
Accumulated deficit	(41,095)	(41,095)	
Total stockholders' equity (deficit)	(39,792)	76,087	

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

(2) Pro forma balance sheet data give effect to (i) the automatic conversion of all outstanding shares of convertible preferred stock upon the closing of this offering and (ii) the settlement of our derivative liabilities upon the closing of this offering due to all outstanding warrants to purchase shares of convertible preferred stock becoming warrants to purchase shares of common stock.

(3) The pro forma as adjusted balance sheet data give further effect to the sale by us of shares of our common stock offered in this offering, at the initial public offering price of $ per share, the midpoint of the price range set forth on the cover of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma as adjusted information discussed above is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, working capital, total assets and total 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 estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, an increase (decrease) of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, working capital, total assets and total stockholders' equity (deficit) by $ million, assuming no change in the assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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Risk factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this prospectus, including our financial statements and the related notes thereto and the section of this prospectus titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" before you make an investment decision. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and prospects. As a result, the market price of our common stock could decline, and you may lose all or part of your investment in our common stock.

Risks related to our financial condition and capital requirements

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We are a preclinical stage biotechnology company with a limited operating history. We commenced operations in December 2014, and our operations to date have been limited to organizing and staffing our company, business planning, raising capital, conducting discovery and research activities, filing patent applications, identifying potential product candidates, undertaking preclinical studies and establishing arrangements with third parties for the manufacture of initial quantities of our product candidates and component materials. All of our product candidates are still in preclinical development. We have not yet demonstrated our ability to successfully initiate, conduct or 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, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We expect our financial condition and results of operations to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

We have incurred significant losses since inception, and we expect to incur losses over the next several years and may not be able to achieve or sustain revenues or profitability in the future.

Investment in biopharmaceutical product development is a highly speculative undertaking and entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. We are still in the early stages of development of our product candidates and have not yet initiated our first clinical trial. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. We have financed our operations primarily through private placements of our preferred stock.

We have incurred significant net losses in each period since our inception in December 2014. For the years ended December 31, 2017 and 2018, we reported net losses of $4.6 million and $8.9 million, respectively. For

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the nine months ended September 30, 2019, we reported a net loss of $25.4 million. As of September 30, 2019, we had an accumulated deficit of $41.1 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase substantially if and as we:

- continue our research and development efforts and submit investigational new drug applications, or INDs, for our lead product candidates;
- conduct preclinical studies and clinical trials for our current and future product candidates based on our Mutation—Allostery—Pharmacology, or MAP, platform;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, safety issues or other regulatory challenges;
- establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities, whether alone or with third parties, to commercialize any product candidates for which we may obtain regulatory approval, if any;
- obtain, expand, maintain, enforce and protect our intellectual property portfolio;
- hire additional clinical, regulatory and scientific personnel; and
- operate as a public company.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses we will incur or when, if ever, we will be able to achieve profitability. Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop, seek regulatory approval for and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We have not generated any revenue from our product candidates and may never be profitable.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from any of our product candidates. We do not expect to generate significant revenue unless or until we successfully complete clinical development and obtain regulatory approval of, and then successfully commercialize, at least one of our product candidates. All of our product candidates are in the preclinical stages of development and will require additional preclinical studies, clinical development, regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. BDTX-189, our most advanced product candidate targeting ErbB family receptors, has yet to complete IND-enabling studies. Our other product candidates are in early preclinical stages. We have not yet administered any of our product candidates in humans and, as such, we face significant translational risk as our product candidates advance to the clinical stage, as promising results in preclinical studies may not be replicated in subsequent clinical trials, and testing on animals may not accurately predict human experience. Our ability to generate revenue depends on a number of factors, including, but not limited to:

- timely completion of our preclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;

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- our ability to complete IND-enabling studies and successfully submit INDs or comparable applications;
- whether we are required by the U.S. Food and Drug Administration, or the FDA, or similar foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;
- our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities the safety, potency, purity, efficacy and acceptable risk to benefit profile of our product candidates or any future product candidates and such regulatory authorities' acceptance of our tumor-agnostic development strategy (i.e., our pursuit of approval based on a biomarker rather than a specific cancer indication);
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates or future product candidates, if any;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- the willingness of physicians, operators of clinics and patients to utilize or adopt any of our product candidates or future product candidates over alternative or more conventional therapies, such as chemotherapy, to treat solid tumors;
- the actual and perceived availability, cost, risk profile and side effects and efficacy of our product candidates, if approved, relative to existing and future alternative cancer therapies and competitive product candidates and technologies;
- our ability and the ability of third parties with whom we contract to manufacture adequate clinical and commercial supplies of our product candidates or any future product candidates, remain in good standing with regulatory authorities and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices, cGMP;
- our ability to successfully develop a commercial strategy and thereafter commercialize our product candidates or any future product candidates in the United States and internationally, if approved for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- patient demand for our product candidates and any future product candidates, if approved; and
- our ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates.

Many of the factors listed above are beyond our control and could cause us to experience significant delays or prevent us from obtaining regulatory approvals or commercializing our product candidates. Even if we are able to commercialize our product candidates, we may not achieve profitability soon after generating product sales, if ever. If we are unable to generate sufficient revenue through the sale of our product candidates or any future product candidates, we may be unable to continue operations without continued funding.

We will need substantial additional funding. If we are unable to raise capital when needed, we would be compelled to delay, reduce or eliminate our product development programs or commercialization efforts.

We expect our expenses to increase in parallel with our ongoing activities, particularly as we continue our discovery and preclinical development activities to identify new product candidates and initiate clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Furthermore, upon the closing of this offering, we expect to incur

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significant additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. However, we have estimated our current additional funding needs based on assumptions that may prove to be wrong. Additionally, changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We cannot be certain that additional funding will be available on acceptable terms, or at all. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of public or private equity offerings, debt financings, governmental funding, collaborations, strategic partnerships and alliances or marketing, distribution or licensing arrangements with third parties. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our discovery and preclinical development programs or any future commercialization efforts.

We had cash and cash equivalents of $78.7 million as of September 30, 2019. We estimate that our net proceeds from this offering will be $ million, based on an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We believe that, based upon our current operating plan, our existing capital resources, together with the net proceeds from this offering will be sufficient to fund our anticipated operations for at least , including the Phase 1/2 development of BDTX-189, the identification of a lead product candidate and IND-enabling studies in our glioblastoma program, with additional resources for continued development of our MAP platform. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of discovery, preclinical development and clinical trials for our product candidates;
- the extent to which we enter into collaboration arrangements with regard to product discovery or acquire or in-license products or technologies;
- our ability to establish discovery collaborations on favorable terms, if at all;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval; and
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining, enforcing and protecting our intellectual property rights and defending intellectual property-related claims.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

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If we do not obtain adequate capital funding or improve our financial performance, we may not be able to continue as a going concern.

The report of our independent registered public accounting firm for the year ended December 31, 2018 included herein contains an explanatory paragraph indicating that there is substantial doubt as to our ability to continue as a going concern as a result of recurring losses from operations. Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States, which contemplate that we will continue to operate as a going concern. Our ability to continue as a going concern will be determined by our ability to complete this offering, which will enable us to fund our expansion plans and realize our business objectives. In addition, we have incurred a net loss in each period since our inception and expect to incur losses in future periods as we continue to increase our expenses in order to position us to grow our business. If we are unable to obtain adequate funding from this proposed offering or in the future, or if we are unable to grow our revenue substantially to achieve and sustain profitability, we may not be able to continue as a going concern.

Risks related to the development of our product candidates

Our discovery and preclinical development is focused on the development of precision medicines for patients with genetically 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 marketable products.

The discovery and development of precision medicines for patients with genetically 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 mutations targeted by our programs are oncogenic drivers, clinical results may not confirm this hypothesis or may only confirm it for certain mutations or certain tumor types. The patient populations for our product candidates are limited to those with specific target mutations 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 the targeted mutations. Successful identification of patients is dependent on several factors, including achieving certainty as to how specific genetic alterations respond to our product candidates and developing companion diagnostics to identify such genetic 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 products and achieve profitability. In addition, even if our approach is successful in showing clinical benefit for tumors harboring the targeted mutations affecting the ErbB proteins EGFR and HER2, we may never successfully identify additional oncogenic mutations for other receptor tyrosine kinases. Therefore, we do not know if our approach of treating patients with genetically defined cancers will be successful, and if our approach is unsuccessful, our business will suffer.

In addition, we are pursuing a tumor-agnostic development strategy (i.e., pursuing approval based on a biomarker rather than a specific cancer indication). There is currently a limited number of approved tumor-agnostic therapies. We may not receive approval for a tumor-agnostic indication or may be delayed in receiving tumor-agnostic approval.

We are very early in our development efforts and are substantially dependent on our lead product candidate, BDTX-189. If we are unable to advance BDTX-189 or any of our other product candidates through clinical development, obtain regulatory approval and ultimately commercialize BDTX-189 or any of our other 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 human subjects. Our ability to generate product revenues, which we do not

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expect will occur for many years, if ever, will depend heavily on the successful clinical development and eventual commercialization of BDTX-189 and one or more of our other product candidates. In addition, our drug development programs contemplate the development of companion diagnostics, which are assays or tests to identify an appropriate patient population. Companion diagnostics are subject to regulation as medical devices and must themselves be approved for marketing by the FDA or certain other foreign regulatory agencies before we may commercialize our product candidates. The success of our product candidates will depend on several factors, including the following:

- successful completion of preclinical studies;
- approval of INDs for our planned clinical trials or future clinical trials;
- FDA acceptance of our proposed Phase 1/2 clinical trial design for BDTX-189 and our tumor-agnostic development strategy;
- successful initiation of clinical trials;
- successful patient enrollment in and completion of clinical trials;
- successful development of companion diagnostics for use with our product candidates;
- safety, tolerability and efficacy profiles for our product candidates that are satisfactory to the FDA or any foreign regulatory authority for marketing approval;
- receipt of marketing approvals for our product candidates and any companion diagnostics from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our product candidates, if any product candidates are approved;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other cancer therapies;
- obtaining and maintaining third-party coverage and adequate reimbursement; and
- maintaining a continued acceptable safety profile of our products following approval.

There is no guarantee that the results obtained in current preclinical studies or our planned open-label Phase 1/2 clinical trial of BDTX-189 will be sufficient to obtain regulatory approval or marketing authorization for such product candidate. Negative results in the development of our lead product candidate may also impact our ability to obtain regulatory approval for our other product candidates, either at all or within anticipated timeframes because, although other product candidates may target different indications, the underlying technology platform, manufacturing process and development process is the same for all of our product candidates. Accordingly, a failure in any one program may affect the ability to obtain regulatory approval to continue or conduct clinical programs for other product candidates. For example, although we believe based on

our preclinical studies that the conformational change to the active site receptor is similar for all of the genetic mutations we are targeting and therefore the chemical structure of BDTX-189 will suffice to bind adequately to such receptor for all such mutations, this may not prove true in clinical testing of BDTX-189 for all or any of the targeted mutations. Moreover, anti-tumor activity may be different in each of the different tumor types we plan on evaluating in the clinical trial. Therefore, even though we plan on pursuing tumor agnostic clinical development of BDTX-189, the tumor response may be low in patients with some cancers compared to others. This may result in discontinuation of development of BDTX-189 for patients with these tumor types and/or mutations due to insufficient clinical benefit while continuing development for a more limited population of patients more likely to benefit. As a consequence, we may have to negotiate with the FDA to reach agreement on defining the optimal patient population, study design and size in order to obtain regulatory approval, any of which may require significant additional resources and delay the timing of our clinical trials and ultimately the approval, if any, of any of our product candidates.

In addition, because we have limited financial and personnel resources and are placing significant focus on the development of our lead product candidate, we may forgo or delay pursuit of opportunities with other future product candidates that later prove to have greater commercial potential. 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 programs and other future product candidates for specific indications may not yield any commercially viable future product candidates. If we do not accurately evaluate the commercial potential or target market for a particular future product candidate, we may relinquish valuable rights to those future product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such future product candidates.

Difficulty in enrolling patients could delay or prevent clinical trials of our product candidates. We may find it difficult to enroll patients in our open-label Phase 1/2 clinical trial for BDTX-189 with the genetic mutations that BDTX-189 is designed to target.

Identifying and qualifying patients to participate in clinical studies of our product candidates is critical to our success. The timing of completion of our clinical studies depends in part on the speed at which we can recruit patients to participate in testing our product candidates, and we may experience delays in our clinical trials if we encounter difficulties in enrollment. 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 as required by the FDA or similar regulatory authorities outside the United States. In particular, because we are focused on patients with specific genetic mutations, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. For example, with respect to BDTX-189, we cannot be certain how many patients will have each of the genetic mutations that BDTX-189 is designed to target or that the number of patients enrolled for each mutation will suffice for regulatory approval and inclusion of each such mutation in the approved label. In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

In addition to the potentially small populations, the eligibility criteria of our planned clinical trials will further limit the pool of available study participants as we will require that patients have specific characteristics that we can measure to assure their disease is either severe enough or not too advanced to include them in a study. Additionally, the process of finding and diagnosing patients may prove costly. We also may not be able to identify, recruit and enroll a sufficient number of patients to complete our clinical studies because of the perceived risks and benefits of the product candidate under study, the availability and efficacy of competing therapies and clinical trials, the proximity and availability of clinical study sites for prospective patients, the availability of genetic sequencing information for patient tumors so that we can identify patients with the targeted genetic mutations, and the patient referral practices of physicians. If patients are unwilling to

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participate in our studies for any reason, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of potential products may be delayed.

We intend to engage third parties to develop companion diagnostics for use in our clinical trials, but such third parties may not be successful in developing such companion diagnostics, furthering the difficulty in identifying patients with the targeted genetic mutations for our clinical trials. Further, if we are unable to include patients with the targeted genetic mutations, this could compromise our ability to seek participation in FDA's expedited review and development programs, including Breakthrough Therapy Designation and Fast Track Designation, or otherwise seek to accelerate clinical development and regulatory timelines.

The enrollment of patients further depends on many factors, including:

- the proximity of patients to clinical trial sites;
- the design of the clinical trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents;
- reporting of the preliminary results of any of our clinical trials; and
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before clinical trial completion.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us because some patients who might have opted to enroll in our clinical trials may instead opt to enroll in a clinical trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment and because our product candidates have not been tested in humans before, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy, rather than enroll patients in any future clinical trial. Additionally, because our clinical trials are in patients with relapsed/refractory cancer, the patients are typically in the late stages of their disease and may experience disease progression independent from our product candidates, making them unevaluable for purposes of the clinical trial and requiring additional patient enrollment.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenue from any of these product candidates could be delayed or prevented.

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, we cannot be certain that our ongoing preclinical studies will be completed on time or if the 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, contract research organizations, or 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. For our lead product candidate, BDTX-189, we recently entered in to a master services agreement with a CRO to lead our

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first-in-human planned open label Phase 1/2 clinical trial. There can be no assurance that we will be able to negotiate and enter into any additional master services agreement with other CROs, as necessary, on terms that are acceptable to us on a timely basis or at all.

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

Before obtaining regulatory approvals for the commercial sale of our product candidates, including BDTX-189, 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 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 and early clinical trials of our product candidates 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, potency, purity 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. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of potency or efficacy, insufficient durability of potency or 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.

Any preclinical studies or clinical trials that we may conduct may not demonstrate the safety, potency, purity 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, potency, purity 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, potency, purity 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. While we have not yet initiated clinical trials for any of our product candidates, as is the case with all oncology drugs, it is likely that there may be side effects associated with their use. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. 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.

Further, our product candidates could cause undesirable side effects in clinical trials related to on-target toxicity. For example, other EGFR inhibitors have experienced dose limiting toxicities due to rash in patients

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and, although we have designed BDTX-189 to be “wild-type” sparing to limit the risk of similar toxicities, clinical results may differ and patients may also experience similar or different toxicities that limit the dose and/or efficacy of BDTX-189. If on-target toxicity is observed, or if our product candidates have characteristics that are unexpected, we may need to 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. Many compounds that initially showed promise in early stage testing for treating cancer have later been found to cause side effects that prevented further development of the compound.

We may not be able to file INDs or IND amendments to commence additional 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 BDTX-189 in time to commence the Phase 1/2 trial for BDTX-189 in the first half of 2020. However, we may not be able to file the IND 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 further clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, we cannot guarantee that such regulatory authorities will not change their 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 trials may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all.

Failure to successfully validate, develop and obtain regulatory approval for companion diagnostics for our product candidates could harm our drug development strategy and operational results.

As one of the central elements of our business strategy and approach, we seek to screen and identify subsets of patients with a genetic alteration who may derive meaningful benefit from our development product candidates. To achieve this, our product development program is dependent on the development and commercialization of a companion diagnostic by us or by third party collaborators. Companion diagnostics are developed in conjunction with clinical programs for the associated product and are subject to regulation as medical devices. Each agency that approves a product candidate will independently need to approve the companion diagnostic before or concurrently with its approval of the product candidate, and before a product can be commercialized. The approval of a companion diagnostic as part of the product label will also limit the use of the product candidate to only those patients who express the specific genetic alteration it was developed to detect.

Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and require separate clearance or approval prior to their commercialization. To date, the FDA has required premarket approval of all companion diagnostics for cancer therapies. We and our third-party 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 of our related product candidates.

Since the number of patients that we plan to dose in our planned open-label Phase 1/2 clinical trial of BDTX-189 is small, the results from such clinical trial, once completed, may be less reliable than results achieved in larger clinical trials, which may hinder our efforts to obtain regulatory approval for our product candidates.

In our planned open-label Phase 1/2 clinical trial of BDTX-189, we plan to evaluate the safety profile of BDTX-189 and establish the recommended Phase 2 dose in patients with bladder cancer, endometrial cancer, breast cancer, gastric cancer, colon cancer and non-small cell lung cancer, or NSCLC, and other solid tumors.

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The Phase 1 portion of the trial is expected to enroll up to 80 patients with solid tumors that have alterations likely to be associated with anti-tumor activity based on preclinical studies as well as some patients with the targeted genetic mutations and is designed to establish the recommended dose for the Phase 2 portion of the trial. The Phase 1 portion may have to evaluate different dosing schedules if the pharmacokinetic or safety data suggest once daily dosing is suboptimal. This may delay initiation of the Phase 2 portion. The open-label Phase 2 portion of the trial is expected to enroll up to 100 patients with the targeted mutations to evaluate efficacy as determined by objective response rate, or ORR, a measure of tumor response and tumor duration response, or DOR. This portion may need to be expanded to provide additional safety and efficacy data to support an application for accelerated approval even if tumor response and duration is adequate. The preliminary results of clinical trials with smaller sample sizes, such as our planned open-label Phase 1/2 clinical trial of BDTX-189, can be disproportionately influenced by various biases associated with the conduct of small clinical trials, such as the potential failure of the smaller sample size to accurately depict the features of the broader patient population, which limits the ability to generalize the results across a broader community, thus making the clinical trial results less reliable than clinical trials with a larger number of patients. As a result, there may be less certainty that such product candidates would achieve a statistically significant effect in any future clinical trials. If we conduct any future clinical trials of BDTX-189, we may not achieve a statistically significant result or the same level of statistical significance, if any, that we might have anticipated based on the results observed in our initial open-label Phase 1/2 clinical trial.

Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the drug candidate. If our product candidates receive marketing approval and we or others identify undesirable side effects caused by such product candidates (or any other similar drugs) after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such product candidates;
- regulatory authorities may require the addition of labeling statements, such as a “boxed” warning or a contraindication;
- we may be required to change the way such product candidates are distributed or administered, conduct additional clinical trials or change the labeling of the product candidates;
- regulatory authorities may require a Risk Evaluation and Mitigation Strategy, or REMS, plan to mitigate risks, which 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;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to remove such product candidates from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking our product candidates; and
- our reputation may suffer.

We believe that any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidates and could substantially increase the costs of commercializing our product candidates, if approved, and significantly impact our ability to successfully commercialize our product candidates and generate revenues.

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Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future clinical trial results. We may encounter substantial delays in clinical trials, or may not be able to conduct or complete clinical trials on the expected timelines, if at all. If our preclinical studies and clinical trials are not sufficient to support regulatory approval of any of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate.

All of our lead product candidates are in preclinical development and their risk of failure is high. It is impossible to predict when or if any of our product candidates will prove effective and safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any drug candidate, we must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical development testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. 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 product candidates. Our pre-clinical studies and future clinical trials may not be successful.

We cannot be certain that our preclinical study and clinical trial results will be sufficient to support regulatory approval of our product candidates. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Failure or delay can occur at any time during the clinical trial process.

Additionally, some of the clinical trials we conduct may be open-label in study design and may be conducted at a limited number of clinical sites on a limited number of patients. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. Moreover, patients selected for early clinical studies often include the most severe sufferers and their symptoms may have been bound to improve notwithstanding the new treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. Given that our planned open-label Phase 1/2 clinical trial of BDTX-189 includes an open-label dosing design, the results from this clinical trial may not be predictive of future clinical trial results with this or other product candidates for which we conduct an open-label clinical trial when studied in a controlled environment with a placebo or active control.

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We may experience delays in obtaining the FDA's authorization to initiate clinical trials under future INDs, completing ongoing preclinical studies of our other product candidates, and initiating our planned preclinical studies and clinical trials. Additionally, we cannot be certain that preclinical studies or clinical trials for our product candidates will begin on time, not require redesign, enroll an adequate number of subjects on time, or be completed on schedule, if at all. Clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to:

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- the FDA or comparable foreign regulatory authorities disagreeing with our tumor-agnostic development strategy;
- delays in obtaining regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining IRB approval at each clinical trial site;
- recruiting an adequate number of suitable patients to participate in a clinical trial;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate;
- having subjects complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from clinical trial protocol or dropping out of a clinical trial;
- addressing subject safety concerns that arise during the course of a clinical trial;
- adding a sufficient number of clinical trial sites; or
- obtaining sufficient product supply of product candidate for use in preclinical studies or clinical trials from third-party suppliers.

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

- we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon our research efforts for our other product candidates;
- clinical trials of our product candidates may not produce differentiated or clinically significant results across tumor types or indications;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of our clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements, fail to maintain adequate quality controls or be unable to provide us with sufficient product supply to conduct and complete preclinical studies or clinical trials of our product candidates in a timely manner, or at all;

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- we or our investigators might have to suspend or terminate clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate, for example, if we experiences delays or challenges in identifying patients with the mutations required for our clinical trials, we may have to reimburse sites for genetic sequencing costs in order to encourage sequencing of additional patients;
- the quality of our product candidates or other materials necessary to conduct preclinical studies or clinical trials of our product candidates may be insufficient or inadequate, and any transfer of manufacturing activities may require unforeseen manufacturing or formulation changes;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and
- future collaborators may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

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, if the results of these trials or tests are not positive or are only moderately positive or if there are safety concerns, our business and results of operations may be adversely affected and we may incur significant additional costs.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such clinical trials are being conducted, by the Data Safety Monitoring Board, if any, for such clinical trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from the product candidates, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Moreover, principal investigators for our future clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

If we experience delays in the completion, or termination, of any preclinical study or clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed, and our ability to generate revenues from any of these product candidates will be delayed or not realized at all. In addition, any delays in completing our preclinical studies or clinical trials may increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate

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revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. If one or more of our product candidates generally prove to be ineffective, unsafe or commercially unviable, our entire pipeline and MAP platform would have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

We may in the future conduct clinical trials for product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We may in the future choose to conduct one or more clinical trials outside the United States, including in Europe. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to good clinical practice, or GCP, regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

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 MAP platform to build a pipeline of product candidates with commercial value.

A key element of our strategy is to use and expand our MAP platform to build a pipeline of product candidates and progress these product candidates through clinical development for the treatment of various cancers. Although our research and development efforts to date have resulted in our discovery and preclinical development of BDTX-189, BDTX-189 may not be safe or effective as a cancer treatment, and we may not be able to develop any other product candidates. Our MAP platform 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 genetic mutations which are oncogenic and which can be "basketed" into a group that is large enough to present a sufficient commercial opportunity or that is druggable with one chemical compound. Even if we are successful in building our 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 products that will receive marketing approval from the FDA 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 stock price.

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We will rely on third parties to manufacture our clinical product supplies, and we may rely on third parties to produce and process our product candidates, if approved.

We do not currently own any facility that may be used as our clinical scale manufacturing facility and expect to rely on outside vendors to manufacture supplies of our product candidates. We will need to negotiate and maintain contractual arrangements with these outside vendors for the supply of our product candidates and we may not be able to do so on favorable terms. We have not yet caused any product candidates to be manufactured on a commercial scale and may not be able to do so for any of our product candidates.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA or other foreign regulatory authorities following inspections that will be conducted after we submit an application to the FDA or other foreign regulatory authorities. We may not control the manufacturing process of, and may be completely dependent on, our contract manufacturing partners for compliance with cGMPs and any other regulatory requirements of the FDA or other regulatory authorities for the manufacture of our product candidates. Beyond periodic audits, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any approval in the future, we may need to find alternative manufacturing facilities, which would require the incurrence of significant additional costs and significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Similarly, if any third-party manufacturers on which we will rely fail to manufacture quantities of our product candidates at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows us to achieve profitability, our business, financial condition and prospects could be materially and adversely affected.

Manufacturing our product candidates is complex and we may encounter difficulties in production. If we encounter such difficulties, our ability to provide supply of our product candidates for preclinical studies and clinical trials or for commercial purposes could be delayed or stopped.

The process of manufacturing of our product candidates is complex and highly regulated.

We rely on third parties for the manufacture of our product candidates. These third-party manufacturers may incorporate their own proprietary processes into our product candidate manufacturing processes. We have limited control and oversight of a third party's proprietary process, and a third party may elect to modify its process without our consent or knowledge. These modifications could negatively impact our manufacturing, including product loss or failure that requires additional manufacturing runs or a change in manufacturer, both of which could significantly increase the cost of and significantly delay the manufacture of our product candidates.

As our product candidates progress through preclinical studies and clinical trials towards approval and commercialization, it is expected that various aspects of the manufacturing process will be altered in an effort to optimize processes and results. Such changes may require amendments to be made to regulatory applications which may further delay the timeframes under which modified manufacturing processes can be used for any of our product candidates and additional bridging studies or trials may be required.

We do not have our own clinical-scale manufacturing facility and are currently reliant on a limited number of manufacturers for our product candidates. These third-party manufacturing providers may not be able to provide adequate resources or capacity to meet our needs.

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The market opportunities for our product candidates may be relatively small as it will be limited to those patients who are ineligible for or have failed prior treatments and our estimates of the prevalence of our target patient populations may be inaccurate.

Cancer therapies are sometimes characterized as first line, second line, or third line, and the FDA often approves new therapies initially only for a particular line of use. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first line therapy, usually chemotherapy, antibody drugs, tumor-targeted small molecules, hormone therapy, radiation therapy, surgery, or a combination of these, proves unsuccessful, second line therapy may be administered. Second line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor-targeted small molecules, or a combination of these. Third line therapies can include chemotherapy, antibody drugs and small molecule tumor-targeted therapies, more invasive forms of surgery and new technologies. We expect 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 relapsed or refractory metastatic cancer. Subsequently, for those product candidates that prove to be sufficiently safe and beneficial, if any, we would expect to seek approval as a second line therapy and potentially as a first line therapy, but there is no guarantee that our product candidates, even if approved as a second or 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.

Our projections of both the number of people who have the cancers we are targeting, who may have their tumors genetically sequenced, 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 therapies may change the estimated incidence or prevalence of the cancers that we are targeting. Consequently, even if our product candidates are approved for a second or third line of therapy, 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.

We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, if approved, we may not be able to generate product revenue.

We currently have no sales, marketing or distribution capabilities and have no experience in marketing products. We intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue arrangements with third-party sales, marketing, and distribution collaborators regarding the sales and marketing of our products, if approved. However, there can be no assurance that we will be able to establish or maintain such arrangements on favorable terms or if at all, or if we are able to do so, that these third-party arrangements will provide effective sales forces or marketing and distribution capabilities. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

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There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or overseas.

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

We plan to 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 in foreign countries, for example, no country other than the United States has a pathway for accelerated drug approval and so obtaining regulatory approvals outside of the United States will take longer and be more costly than obtaining approval in the United States;
- 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 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;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 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.

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

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we must focus on a limited number of research programs and product candidates and on specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. 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 discovery and preclinical development programs and product candidates for specific indications may not yield any commercially viable products.

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

The biotechnology and pharmaceutical industries utilize rapidly advancing technologies and are characterized by intense competition. While we believe that our scientific knowledge, platform technology and development expertise provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceuticals, specialty pharmaceuticals and biotechnology companies, academic institutions and government agencies, and public and private research institutes that conduct research, development, manufacturing and commercialization. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, regulatory approvals and product marketing than we do. Our competitors may compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result, our competitors may discover, develop, license or commercialize products before or more successfully than we do.

Product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. Specifically, we expect that BDTX-189 will compete against approved drugs, including neratinib, which is marketed by Puma Biotechnology under the trade name Nerlynx and osimertinib, which is marketed by AstraZeneca plc under the trade name Tagrisso. In the allosteric HER2 patient population we expect competition from drugs in late-stage clinical development, including trastuzumab deruxtecan (DS-8201), which is under development by Daiichi Sankyo Company Ltd. and AstraZeneca plc. and ZW25 and ZW49, which is under development by Zymeworks Inc. and Beigene Co., Ltd. We also expect BDTX-189 will compete in exon20 insertion patient population against drugs under development, including poziotinib, which is under development by Spectrum Pharmaceuticals, Inc.; tarloxitinib, which is under development by Rain Therapeutics Inc.; and TAK-788, which is under development by Takeda Pharmaceutical Company Ltd.

If our drug candidates, including BDTX-189, are approved for the indications for which we are currently planning clinical trials, they will likely compete with the competitor drugs mentioned above and with other drugs that are currently in development. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products. Our competitors may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. The availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. For additional information regarding our competition, see “Business—Competition.”

Risks related to government regulation

We are very early in our development efforts. All of our product candidates are still in preclinical development. If we are unable to advance our product candidates to clinical development, obtain regulatory approval and ultimately commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.

We are very early in our development efforts, and all of our product candidates are still in preclinical development. We have invested substantially all of our efforts and financial resources in the identification and preclinical development of our product candidates, including the development of our initial product candidate, BDTX-189. Our ability to generate product revenues, which we do not expect will occur for many years, if ever,

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will depend on the successful development, approval and eventual commercialization of our product candidates, which may never occur. We currently generate no revenue from sales of any products, and we may never be able to develop or commercialize a marketable product. The success of our product candidates will depend on several factors, including the following:

- successful completion of preclinical studies;
- FDA acceptance of our proposed phase 1/2 clinical trial design for BDTX-189 and our tumor-agnostic development strategy;
- approval of INDs for our planned clinical trials or future clinical trials;
- successful enrollment in future clinical trials;
- positive results from future clinical trials that are supportive of safety and efficacy in the intended patient populations;
- successful development of companion diagnostics for use with certain of our product candidates;
- receipt of regulatory approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers for clinical supply and commercial manufacturing;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of the product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining third-party insurance coverage and adequate reimbursement;
- obtaining, enforcing and defending intellectual property rights and claims; and
- maintaining a continued acceptable safety profile of the product candidates following approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Before we can commercialize any of our product candidates, we must obtain marketing approval. Depending on results from

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our planned open-label Phase 1/2 clinical trial for BDTX-189, we expect, subject to discussions with FDA, to either expand the Phase 2 portion of the trial or initiate a second Phase 2 trial in order to seek accelerated approval from the FDA for the treatment of patients with advanced solid tumors that harbor one or more of the targeted genetic mutations detected by an NGS test requiring contemporaneous FDA clearance or approval, who have progressed or relapsed following prior treatment and who have no satisfactory treatment options. Whether the results from our planned open-label Phase 1/2 clinical trial and other trials will suffice to obtain accelerated approval will be a review issue and the FDA may not grant accelerated approval and may require that we conduct one or more controlled, randomized Phase 3 clinical trials to obtain approval. In addition, because there is limited experience of the FDA with the approval of tumor-agnostic cancer treatments and since we will need to show that there is no available therapy for each of the tumors tested in our open-label Phase 1/2 clinical trial, we may experience challenges in obtaining accelerated approval across all such tumor types. To date, we have had no interactions with regulatory authorities outside of the United States. We intend to engage with the European Medicines Agency, or EMA, following the results of the Phase 2 portion of the planned trial regarding regulatory requirements for registration in the European Union, or EU. There is limited experience of regulatory authorities outside of the United States with the approval of tumor-agnostic precision cancer medicines.

Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Further, our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining regulatory approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted IND, New Drug Application, or NDA, or equivalent application types, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries 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 studies. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials, including our proposed phase 1/2 clinical trial design for BDTX-189;
- the FDA or comparable foreign regulatory authorities may disagree with our tumor-agnostic development strategy;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a drug candidate is safe and effective for its proposed indication or a related companion diagnostic is suitable to identify appropriate patient populations;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate’s clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;

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- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects.

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

To obtain the requisite regulatory approvals to market and sell any of our product candidates, including BDTX-189 and any other future product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our products are safe and effective in humans. Our product candidates may fail to demonstrate efficacy in humans, and particularly across tumor types. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process and our future clinical trial results may not be successful. Further, the process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications, patient population and regulatory agency. Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we or our potential future collaborators must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA, the EMA or other comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses.

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

Even if the trials are successfully completed, clinical data are often susceptible to varying interpretations and analyses, and we cannot guarantee that the FDA, the EMA, or other comparable foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. We cannot guarantee that the FDA, the EMA or other comparable foreign regulatory authorities will view our product candidates as having sufficient efficacy to support a tumor-agnostic indication even if positive results are observed in clinical trials. To the extent that the results of the trials are not satisfactory to the FDA, the EMA or other comparable foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Additionally, any safety or efficacy concerns observed in any tumor-specific

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subgroup of our clinical trials could limit the prospects for regulatory approval of our product candidates for a tumor-agnostic indication, which could have a material adverse effect on our business, financial condition and results of operations.

We may in the future seek orphan drug status for BDTX-189 and some of our other future product candidates, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug status, including market exclusivity, which may cause our revenue, if any, to be reduced.

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting an NDA. 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. After the FDA grants orphan drug designation, the generic identity of the drug 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 drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including an NDA, to market the same biologic for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. As a result, even if one of our product candidates receives orphan exclusivity, the FDA can still approve other drugs that have a different active ingredient for use in treating the same indication or disease. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product.

We may seek orphan drug designation for BDTX-189 and some or all of our other future product candidates in additional orphan indications in which there is a medically plausible basis for the use of these products. Even when we obtain orphan drug designation, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. In addition, although we intend to seek orphan drug designation for other product candidates, we may never receive such designations. For example, the FDA has expressed concerns regarding the regulatory considerations for orphan drug designation as applied to tissue agnostic therapies, and the FDA may interpret the federal Food, Drug and Cosmetic Act, as amended, or the FD&C Act, and regulations promulgated thereunder in a way that limits or blocks our ability to obtain orphan drug designation or orphan drug exclusivity, if our product candidates are approved, for our targeted indications.

On August 3, 2017, the Congress passed the FDA Reauthorization Act of 2017, or FDARA. FDARA, among other things, codified the FDA's pre-existing regulatory interpretation, to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. The legislation reverses prior precedent holding that the Orphan Drug Act unambiguously requires that the FDA recognize the orphan exclusivity period regardless of a showing of clinical superiority. The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in

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the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

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 BDTX-189 and some or all of our 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 intend to seek Breakthrough Therapy designation for BDTX-189 and some or all of our future product candidates for the treatment of various cancers, there can be no assurance that we will receive breakthrough therapy designation.

A Fast Track designation by the FDA, even if granted for BDTX-189 or any other future product candidates, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive marketing approval.

If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA Fast Track designation for a particular indication. We may seek Fast Track designation for BDTX-189 and certain of our future product candidates, but there is no assurance that the FDA will grant this status to any of our proposed product candidates. Marketing applications filed by sponsors of products in Fast Track development may qualify for priority review under the policies and procedures offered by the FDA, but the Fast Track designation does not assure any such qualification or ultimate marketing approval by the FDA. The FDA has broad discretion whether or not to grant Fast Track designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a Fast Track designation does not provide assurance of ultimate FDA approval. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. In addition, the FDA may withdraw any Fast Track designation at any time.

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Accelerated approval by the FDA, even if granted for BDTX-189 or any other future 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 plan to seek approval of BDTX-189, and may seek approval of future product candidates using the FDA's accelerated approval pathway. A product may 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. 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. These confirmatory trials must be completed with due diligence. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Even if we do receive accelerated approval, we may not experience a faster development or regulatory review or approval process, and receiving accelerated approval does not provide assurance of ultimate full FDA approval.

If we are unable to successfully validate, develop and obtain regulatory approval for companion diagnostic tests for our drug candidates that are required or experience significant delays in doing so, we may not realize the full commercial potential of these drug candidates.

In connection with the clinical development of our drug candidates for certain indications, we intend to engage third parties to develop or obtain access to *in vitro* companion diagnostic tests to identify patient subsets within a disease category who may derive selective and meaningful benefit from our drug candidates. Such companion diagnostics would be used during our clinical trials as well as in connection with the FDA approval of our product candidates. To be successful, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. The FDA regulates *in vitro* companion diagnostics as medical devices and, under that regulatory framework, will require the test to be analytically validated and used for patient selection in the clinical trial, which we expect will require separate regulatory clearance or approval prior to commercialization if not already approved.

We intend to rely on third parties for the design, development and manufacture of companion diagnostic tests for our therapeutic drug 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 therapeutic 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 these therapeutic drug candidates, or experience delays in doing so, the development of these therapeutic drug candidates may be adversely affected, these therapeutic drug candidates may not obtain marketing approval, and we may not realize the full commercial potential of any of these therapeutics 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 our 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 therapeutic candidates.

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, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, 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.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

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

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, 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 continued compliance with cGMPs, good laboratory practice, or GLP, regulations and GCPs, for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market or voluntary or mandatory product recalls;
- manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance requiring remediation;

- 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;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's 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.

The FDA 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 and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, if approved. In particular, while the FDA permits the dissemination of truthful and non-misleading information about an approved product, a manufacturer may not promote a product for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we are found to have promoted such off-label uses, we may become subject to significant liability. The 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, corporate integrity agreements or permanent injunctions under which specified promotional conduct must be 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.

The insurance coverage and reimbursement status of newly-approved products is uncertain. Our product candidates may become subject to unfavorable pricing regulations, third-party coverage and reimbursement practices, or healthcare reform initiatives, which would harm our business. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs vary widely from country to country. In the United States, recently enacted legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets,

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prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates we may develop obtain marketing approval.

Patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments such as gene therapy products. Sales of these or other product candidates that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If coverage and adequate 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 a sufficient return on our investment.

Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor’s determination that use of a product is:

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

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines, 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 products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement

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for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. No uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may 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 applied consistently or obtained in the first instance. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours. Reimbursement agencies in Europe may be more conservative than CMS. For example, a number of cancer drugs have been approved for reimbursement in the United States and have not been approved for reimbursement in certain European countries. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates, and our overall financial condition.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates third-party payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. In order to obtain reimbursement, physicians may need to show that patients have superior treatment outcomes with our products compared to standard of care drugs, including lower-priced generic versions of standard of care drugs. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

Additionally, we may develop companion diagnostic tests for use with our product candidates. We, or our collaborators, may be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our product candidates, once approved. Even if we obtain regulatory approval or clearance for such companion diagnostics, there is significant uncertainty regarding our ability to obtain coverage and adequate reimbursement for the same reasons applicable to our product candidates. Medicare reimbursement methodologies, whether under Part A, Part B, or clinical laboratory fee schedule may be amended from time to time, and we cannot predict what effect any change to these methodologies would have on any product candidate or companion diagnostic for which we receive approval.

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Our inability to promptly obtain coverage and adequate reimbursement from both third-party payors for the companion diagnostic tests that we develop and for which we obtain regulatory approval could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.

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

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower-cost biosimilars, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D.

Members of the U.S. Congress and the Trump administration have expressed an intent to pass legislation or adopt executive orders to fundamentally change or repeal parts of the Affordable Care Act. While Congress has not passed repeal legislation to date, the Tax Cuts and Jobs Act of 2017, or TCJA, repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” On December 14, 2018, a federal district court in Texas ruled the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the TCJA, the remaining provisions of the ACA are invalid as well. The Trump Administration and CMS have both stated that the ruling will have no immediate effect, and on December 30, 2018, the Texas District Court Judge issued an order staying the judgment pending appeal. A Fifth Circuit US Court of Appeals hearing to determine whether certain states and the House of Representatives have standing to appeal the lower court decision was held on July 9, 2019, but it is unclear when a Court will render its decision on this hearing, and what effect it will have on the status of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. We will continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from, or delay the implementation of any provision of the Affordable Care Act that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or

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manufacturers of pharmaceuticals or medical devices. On October 13, 2017, President Trump signed an Executive Order terminating the cost-sharing subsidies that reimburse insurers under the Affordable Care Act. The Trump administration has concluded that cost-sharing reduction, or CSR, payments to insurance companies required under the ACA have not received necessary appropriations from Congress and announced that it will discontinue these payments immediately until those appropriations are made. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017.

Moreover, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so called “Cadillac” tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, also amended the ACA, effective January 1, 2019, by increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and closing the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole.” CMS published a 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. In addition, CMS has recently published a final rule that would give states greater flexibility, starting in 2020, in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation’s automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, and, due to subsequent legislative amendments, will remain in effect through 2027 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, or ATRA, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration’s budget for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 legislative session, or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the Trump administration released a “Blueprint” to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of HHS, has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. For example, in August 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy, or ST, a type of prior

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authorization, or PA, for Medicare Part B drugs beginning January 1, 2019. In May 2019, CMS issued a final rule under which Medicare Advantage Plans may implement ST for Part B drugs as a recognized utilization management tool.

At the state level, individual states are increasingly aggressive in passing legislation and implementing 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. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future, including repeal, replacement or significant revisions to the Affordable Care Act. 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.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new 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 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

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recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. 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.

For example, over the last several years, including beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, 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 employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to: comply with the regulations of the FDA and other similar foreign regulatory authorities, provide true, complete and accurate information to the FDA and other similar foreign regulatory authorities, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws and regulations will increase significantly, and our costs associated with compliance with such laws and regulations are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. 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. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;

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- federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claims Act, which impose criminal and civil penalties, including through civil "qui tam" or "whistleblower" actions, 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 False Claims Act, 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;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new 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, or 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 Payment Sunshine Act, created under the Affordable Care Act 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 transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; 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

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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.

Effective upon the closing of this offering, we will adopt a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct 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 be in compliance with such laws or regulations.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations 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 these laws or any other governmental regulations that may apply to us, we may be subject to significant criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment, and exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, and we may be required to curtail or restructure our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of EU Member States, such as the U.K. Bribery Act 2010, or the Bribery Act. Infringement of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain EU Member States must be publicly disclosed.

Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States.

These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States.

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Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

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

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

In addition, California recently enacted the California Consumer Privacy Act, or 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 will require 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. The CCPA goes into effect on January 1, 2020, and the California Attorney General may bring enforcement actions for violations beginning July 1, 2020. The CCPA was amended on September 23, 2018, and it remains unclear what, if any, further modifications will be made to this legislation or how it will be interpreted. As currently written, the CCPA 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. Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity 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. 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.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

Risks related to our intellectual property

We do not currently own or in-license any issued patents or non-provisional patent applications relating to our product candidates or technology, including BDTX-189. If we are unable to obtain and maintain patent and other intellectual property protection for BDTX-189, our MAP platform and our other product candidates and technology, or any other product candidates or technology we may develop, or if the scope of intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize BDTX-189 or any other product candidates or technology may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our product candidates, including BDTX-189, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment and development that are important to our business, as well as successfully defending
these patents against third-party challenges. If we do not adequately protect our intellectual property rights, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability.

We intend to rely upon a combination of patent applications, confidentiality agreements, trade secret protection and license agreements to protect the intellectual property related to our product candidates and technologies. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. We, or any future partners, collaborators, or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to establish our patent position.

To protect our proprietary position, we plan to file patent applications in the United States and abroad relating to our product candidates and MAP platform that are important to our business; we may in the future also

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license or purchase patents or patent applications owned by others. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. If we are unable to secure or maintain patent protection with respect to BDTX-189, our MAP platform or any other proprietary products and technology we develop, our business, financial condition, results of operations, and prospects would be materially harmed.

We do not currently own or in-license any issued patents or non-provisional patent applications relating to BDTX-189, including its composition of matter, and we do not currently own or in-license any issued patents or non-provisional patent applications relating to any of our other product candidates or technology. We own one Patent Cooperation Treaty, or PCT, patent application that covers the composition of matter for BDTX-189, as well as methods of using and making BDTX-189. This PCT application may never result in an issued patent. This pending PCT patent application is not eligible to become an issued patent until, among other things, we file a national stage patent application within 30 months in the countries in which we seek patent protection. If we do not timely file any national stage patent applications, we may lose our priority date with respect to our PCT patent application and any patent protection on the inventions disclosed in such PCT patent application. While we intend to timely file a national stage patent application relating to our PCT patent application, we cannot predict whether any of our future patent applications for BDTX-189 or any of our other product candidates will result in the issuance of patents that effectively protect BDTX-189 or our other product candidates. If we do not successfully obtain patent protection, or, even if we do obtain patent protection, if the scope of the patent protection we or our potential licensors obtain with respect to BDTX-189 or our other product candidates and technology is not sufficiently broad, we will be unable to prevent others from using our technology or from developing or commercializing technology and products similar or identical to ours or other competing products and technologies. Any failure to obtain or maintain patent protection with respect to BDTX-189 and our other product candidates would have a material adverse effect on our business, financial condition, results of operations and prospects.

The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any patents we may own or in-license in the future will have, or that any of our patent applications that mature into issued patents will include, claims with a scope sufficient to protect our current and future product candidates or otherwise provide any competitive advantage. In addition, to the extent that we license intellectual property in the future, we cannot assure you that those licenses will remain in force. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Furthermore, patents have a limited lifespan, and the term of any patents we may own or in-license in the future may be inadequate to protect our competitive position of our product candidates or technology for an adequate amount of time. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. 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.

Even if they are unchallenged, our patent applications, if issued, and any patents we may own or in-license in the future, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent any patents we may own or in-license in the future by developing similar or alternative technologies or therapeutics in a non-infringing manner. For example, a third party may develop a competitive therapy that provides benefits similar to one or more of our product candidates but that uses a formulation and/or a device that falls outside the scope of any patent protection we may have in the future. If the patent protection provided by our patent applications or any patents we may pursue with respect to our

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product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected, which would harm our business. Although we currently own our patent applications, similar risks would apply to any patents or patent applications that we may own or in-license in the future.

Patent positions of life sciences companies can be uncertain and involve complex factual and legal questions. Changes in either the patent laws or their interpretation in any jurisdiction that we seek patent protection may diminish our ability to protect our inventions, maintain and enforce our intellectual property rights; and, more generally, may affect the value of our intellectual property, including the narrowing of the scope of our patent applications or any patents we may own or in-license in the future.

The patent prosecution process is complex, expensive, time-consuming and inconsistent across jurisdictions. Patent license negotiations also can be complex and protracted, with uncertain results. We may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent rights at a commercially reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. It is possible that we will fail to identify important patentable aspects of our research and development efforts in time to obtain appropriate or any patent protection. While we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development efforts, including for example, our employees, corporate collaborators, external academic scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose results before a patent application is filed, thereby endangering our ability to seek patent protection. In addition, publications of discoveries in the scientific and scholarly literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Consequently, we cannot be certain that we were the first to file for patent protection on the inventions claimed in our patent applications.

It is possible that defects of form in the preparation or filing of our patent applications, or any patents we may own or in-license in the future, may exist or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our partners, collaborators, licensees or licensors fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our partners, collaborators, licensees or licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patent applications or patents we may own or in-license in the future, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

Additionally, we cannot be certain that the claims in our patent applications covering composition of matter of our product candidates or technology will be considered patentable by the USPTO, or by patent offices in foreign countries, or that the claims in any issued patents we may own or in-license in the future will be considered patentable by courts in the United States or foreign countries.

Method of use patents protect the use of a product for the specified method. These types of patents do not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products “off-label.” Although off-label prescriptions may induce or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

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The patent position of pharmaceutical and biotechnology companies generally is highly uncertain and involves complex legal and factual questions for which many legal principles remain unresolved. In recent years, patent rights have been the subject of significant litigation. As a result, the issuance, scope, validity, enforceability and commercial value of any rights we may have from our patent applications are highly uncertain. Our patent applications may not result in patents being issued in the United States or in other jurisdictions which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. Moreover, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art, including our own previously filed patent applications and scientific publications, allow our inventions to be patentable over the prior art. Even if our patent applications issue as patents, third parties could challenge the validity of such patents based on such scientific publications and we could potentially lose valuable patent rights. Further, the scope of the invention claimed in a patent application can be significantly reduced before the patent is issued, and this scope can be reinterpreted after issuance. Even where patent applications we currently own or that we may 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 a competitive advantage. Any patents that eventually issue may be challenged, narrowed or invalidated by third parties. Consequently, we do not know whether any of our product candidates will be protectable or remain protected by valid and enforceable patent rights. Our competitors or other third parties may be able to evade any rights we may have from our patent applications by developing new compounds or alternative technologies or products in a non-infringing manner.

The issuance or grant of a patent is not irrefutable as to its inventorship, scope, validity or enforceability, and any patents we may own or in-license in the future may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in the patent claims of any patents we may own or in-license being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. We may in the future, become subject to a third-party pre-issuance submission of prior art or opposition, derivation, revocation, re-examination, post-grant and *inter partes* review, or interference proceeding and other similar proceedings challenging any rights we may have from our patent applications or the patent rights of others in the U.S. Patent and Trademark Office, or USPTO, or other foreign patent office, or in declaratory judgment actions or counterclaims. An unfavorable determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, any rights we may have from our patent applications, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or extinguish our ability to manufacture or commercialize products without infringing third-party patent rights.

In addition, 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.

Moreover, some of our intellectual property, including any patents we may own or in-license in the future, may be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such intellectual property, including patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we or our future licensors may need the cooperation of

any such co-owners of our owned and in-licensed intellectual property, including patents and patent applications, in order to enforce such intellectual property against third parties, and such cooperation may not be provided to us or our future licensors. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

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

If we fail to comply with our obligations in any future agreements under which we may 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.

In the future, we may be party to license or collaboration agreements with third parties to advance our research or allow commercialization of product candidates. Such future agreements may impose numerous obligations, such as development, diligence, payment, commercialization, funding, milestone, royalty, sublicensing, insurance, patent prosecution, enforcement and other obligations on us and may require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses. In spite of our best efforts, our future licensors might conclude that we have materially breached our future license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technologies covered by these license agreements.

Any termination of these licenses, or if the underlying patents fail to provide the intended exclusivity, could result in the loss of significant rights and could harm our ability to commercialize our product candidates, and competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to ours and we may be required to cease our development and commercialization of certain of our product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Disputes may also 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, misappropriate or otherwise violate intellectual property rights of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- the priority of invention of any patented technology; and
- the 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.

In addition, the agreements under which we may license intellectual property or technology from third parties in the future are likely to be 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

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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 may license in the future prevent or impair our ability to maintain future licensing arrangements on 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.

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

In addition to the protection afforded by patents we may own or in-license in the future, we seek to rely on trade secret protection, confidentiality agreements, and license agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes, including our MAP platform that involve proprietary know-how, information, or technology that is not covered by patents. Although we require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, trade secrets can be difficult to protect and we have limited control over the protection of trade secrets used by our collaborators and suppliers. We cannot be certain that we have or will obtain these agreements in all circumstances and we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary information.

Moreover, any of these parties might breach the agreements and intentionally or inadvertently disclose our trade secret information and we may not be able to obtain adequate remedies for such breaches. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights and trade secrets to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, financial condition, results of operations and future prospects.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. For example, significant elements of our MAP platform, including aspects of oncogenicity computational algorithms, in vivo experiments to validate mechanisms and pharmacology, drug design, and related processes, are based on unpatented trade secrets that are not publicly disclosed. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us.

Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept

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confidential and not disclosed to third parties except in specific circumstances. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. Although we require all of our employees to assign their inventions to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Third-party claims of intellectual property infringement, misappropriation or other violations may be costly and time consuming and may prevent or delay our product discovery and development efforts.

The intellectual property landscape around precision medicine is crowded, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business. Our commercial success depends upon our ability to develop, manufacture, market and sell our current and future product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including derivation, interference, reexamination, *inter partes* review, and post grant review proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We or any of our future licensors or strategic partners may be party to, exposed to, or threatened with, future adversarial proceedings or litigation by third parties having patent or other intellectual property rights alleging that our current or future product candidates and/or proprietary technologies infringe, misappropriate or otherwise violate their intellectual property rights. We cannot assure you that our product candidates and other technologies that we have developed, are developing or may develop in the future do not or will not infringe, misappropriate or otherwise violate existing or future patents or other intellectual property rights owned by third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

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

- infringement, misappropriation and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business and may impact our reputation;
- substantial damages for infringement, misappropriation or other violations, which we may have to pay if a court decides that the product candidate or technology at issue infringes, misappropriates or violates the

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third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;

- a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, including BDTX-189, or from using our proprietary technologies, unless the third party licenses its product rights to us, which it is not required to do, on commercially reasonable terms or at all;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products, or the license to us may be non-exclusive, which would permit third parties to use the same intellectual property to compete with us;
- redesigning our product candidates or processes so they do not infringe, misappropriate or violate third party intellectual property rights, which may not be possible or may require substantial monetary expenditures and time; and
- there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

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

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

Third parties may assert that we are employing their proprietary technology without authorization. Patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof. There may be issued third-party patents of which we are currently unaware with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Patent applications can take many years to issue. In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications covering our product candidates or technology. If any such patent applications issue as patents, and if such patents have priority over our patent applications or patents we may own or in-license, we may be required to obtain rights to such patents owned by third parties which may not be available on commercially reasonable terms or at all, or may only be available on a non-exclusive basis. There may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our product candidates or other technologies, could be found to be infringed by our product candidates or other technologies. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, we

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may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, exhausted, or not infringed by our activities. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be nonexclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patent applications or any patents we may own or in-license in the future is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

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

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

Presently we own one PCT patent application related to BDTX-189. Because additional product candidates may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights.

Our product candidates may also require specific formulations to work effectively and efficiently and these rights may be held by others. Similarly, efficient production or delivery of our product candidates may also require specific compositions or methods, and the rights to these may be owned by third parties. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be

nonexclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. Moreover, the molecules that will be used with our product candidates may be covered by the intellectual property rights of others.

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

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

We may be involved in lawsuits to protect or enforce our intellectual property rights, including any patents we may own or in-license in the future, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe any patents we may own or in-license in the future. In addition, any patents we may own or in-license also may become involved in inventorship, priority, validity or unenforceability disputes. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, in an infringement proceeding, a court may decide that one or more of any patents we may own or in-license in the future is not valid or is unenforceable or that the other party's use of our technology that may be patented falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). There is also the risk that, even if the validity of these patents is upheld, the court may refuse to stop the other party from using the technology at issue on the grounds that any patents we may own or in-license in the future do not cover the technology in question or that such third party's activities do not infringe our patent applications or any patents we may own or in-license in the future. An adverse result in any litigation or defense proceedings could put one or more of any patents we may own or in-license in the future at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and

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monetary expenditure. 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 and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Post-grant proceedings provoked by third parties or brought by the USPTO may be necessary to determine the validity or priority of inventions with respect to our patent applications or any patents we may own or in-license in the future. These proceedings are expensive and an unfavorable outcome could result in a loss our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. In addition to potential USPTO review proceedings, we may become a party to patent opposition proceedings in the European Patent Office, or EPO, or similar proceedings in other foreign patent offices, where either our foreign patents are challenged. The costs of these opposition or similar proceedings could be substantial, and may result in a loss of scope of some claims or a loss of the entire patent. An unfavorable result at the USPTO, EPO or other patent office may result in the loss of our right to exclude others from practicing one or more of our inventions in the relevant country or jurisdiction, which could have a material adverse effect on our business.

Litigation or post-grant proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

We may not be able to detect infringement against any patents we may own or in-license in the future. Even if we detect infringement by a third party of any patents we may own or in-license in the future, we may choose not to pursue litigation against or settlement with the third party. If we later sue such third party for patent infringement, the third party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defenses may make it impossible for us to enforce any patents we may own or in-license against such third party.

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

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and following the issuance of a patent. While an inadvertent lapse can in some cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in

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abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market with similar or identical products or platforms, which could have a material adverse effect on our business prospects and financial condition.

Any issued patents we may own or in-license in the future covering our product candidates could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad, including the USPTO.

If we or our future licensors or strategic partners initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of patentable subject matter, lack of written description, lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, *inter partes* review, post grant review and equivalent proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in revocation or amendment to our patent applications or any patents we may own or in-license in the future in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, any rights we may have from our patent applications or any patents we may own or in-license in the future, allow third parties to commercialize our product candidates or other technologies 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, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our or priority of invention or other features of patentability with respect to our patent applications and any patents we may own or in-license. 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 and other technologies. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we or our future licensing partners and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates.

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. If we are unsuccessful in any such proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are

unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of the product candidates we may develop. The loss of exclusivity or the narrowing of our patent application claims could limit our ability to stop others from using or commercializing similar or identical technology and products. Any of the foregoing could have a material adverse effect on our business, results of operations, financial condition and prospects.

Changes to patent law in the United States and in foreign jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we might obtain in the future. For example, in the case *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.,* the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. Any adverse changes in the patent laws of other jurisdictions could have a material adverse effect on our business and financial condition. Changes in the laws and regulations governing patents in other jurisdictions could similarly have an adverse effect on our ability to obtain and effectively enforce any rights we may have in our patent applications or any patents we may own or in-license in the future.

Recent or future patent reform legislation could also increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any patents we may own or in-license in the future. The United States has enacted and implemented wide-ranging patent reform legislation. On September 16, 2011, the Leahy-Smith America Invents Act, or America Invents Act, was signed into law, which includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation, establish a new post-grant review system and switch the U.S. patent system from a “first-to-invent” system to a “first-to-file” system. Under a “first-to-file” system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or other technologies or (ii) invent any of the inventions claimed in our patent applications or any patents we may own or in-license. These changes also allow third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. 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. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing

third-party patent rights. Accordingly, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any issued patents we may own or in-license in the future, all of which could have a material adverse effect on our business and financial condition.

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

We may not be able to pursue generic coverage of our product candidates or MAP platform outside of the United States. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and 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 where enforcement is not as strong as that in the United States. These products may compete with our product candidates and in jurisdictions where we do not have any issued patents our patent applications or other intellectual property rights may not be effective or sufficient to prevent them from competing. Our patent portfolio is at the very early stage. We will need to decide whether and in which jurisdictions to pursue protection for the various inventions in our portfolio prior to applicable deadlines.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of any patents we may own or in-license in the future or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce any rights we may have in our patent applications or any patents we may own or in-license in the future in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put any patents we may own or in-license in the future at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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 we may own or license in the future that are relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

We may be subject to claims challenging the inventorship or ownership of any intellectual property, including any patents we may own or in-license in the future.

We may be subject to claims that former employees, collaborators or other third parties have an interest in any patents we may own or in-license in the future, trade secrets, or other intellectual property as an inventor or

co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates or other technologies. We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, those agreements may not be honored and may not effectively assign intellectual property rights to us. Moreover, there may be some circumstances, where we are unable to negotiate for such ownership rights. Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. If we are subject to a dispute challenging our rights in or to patents or other intellectual property, such a dispute could be expensive and time consuming. Litigation may be necessary to defend against these and other claims challenging inventorship of any patents we may own or in-license in the future, trade secrets or other intellectual property. If we were unsuccessful, in addition to paying monetary damages, we could lose valuable rights in intellectual property that we regard as our own, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates and other technologies. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We are party to a services agreement with Ridgeline Therapeutics GmbH, or the Ridgeline Services Agreement, pursuant to which Ridgeline provides certain drug discovery and development services. Pursuant to the Ridgeline Services Agreement, we own all rights in and to all patent, copyright and other intellectual property rights generated by Ridgeline in the course of performing the specified services. If it is unclear whether certain intellectual property generated by Ridgeline is our property, we may be subject to conflicting claims of ownership.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information or alleged trade secrets of third parties or competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

We have received confidential and proprietary information from third parties. In addition, as is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors, in some cases until recently. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information or trade secrets of these third parties or our employees' former employers or our consultants' or contractors' current or former clients or customers. In addition, we have been and may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation or arbitration may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims and possible aftermath could result in substantial cost and be a distraction to our management and employees. Any litigation or the threat thereof may adversely affect our ability to hire employees. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product candidates, which could have an adverse effect on our business, results of operations and financial condition. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we

can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

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

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

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

Our trademarks or trade names may be challenged, infringed, diluted, circumvented or declared generic or determined to be infringing on other marks. We intend to rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During the trademark registration process, we may receive Office Actions from the USPTO objecting to the registration of our trademark. Although we would be given an opportunity to respond to those objections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and/or to seek the cancellation of registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to obtain a registered trademark or establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.

The degree of future protection afforded by our intellectual property rights, whether owned or in-licensed, is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- patent applications that we own or may in-license in the future may not lead to issued patents;
- patents, should they issue, that we may own or in-license in the future, may not provide us with any competitive advantages, may be narrowed in scope, or may be challenged and held invalid or unenforceable;

- others may be able to develop and/or practice technology, including compounds that are similar to the chemical compositions of our product candidates, that is similar to our technology or aspects of our technology but that is not covered by the claims of any patents we may own or in-license in the future, should any patents issue;
- third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we, or our future licensors or collaborators, might not have been the first to make the inventions covered by a patent application that we own or may in-license in the future;
- we, or our future licensors or collaborators, might not have been the first to file patent applications covering a particular invention;
- others may independently develop similar or alternative technologies without infringing, misappropriating or otherwise violating our intellectual property rights;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not be able to obtain and/or maintain necessary licenses on reasonable terms or at all;
- third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights, or any rights at all, over that intellectual property;
- 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 trade secrets or know-how;
- we may not be able to maintain the confidentiality of our trade secrets or other proprietary information;
- we may not develop or in-license additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

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

Risks related to our reliance on third parties

We plan to rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We plan to utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, contract manufacturing organizations, or CMOs, and strategic partners to conduct and support our preclinical studies and clinical trials under agreements with us. For example, we contract with Ridgeline for services related to our drug discovery and preclinical work, but we are continuing to build our internal chemistry, manufacturing and controls, biology and preclinical development capabilities to assume activities conducted by Ridgeline on our behalf. We expect to transition from our current service model to a more limited consulting arrangement with Ridgeline. As part of this transition, we may incur additional costs or experience delays in engaging directly with other third-party CROs and CMOs.

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We expect to have to negotiate budgets and contracts with CROs, 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. We will rely heavily on these third parties over the course of our preclinical studies and clinical trials, and we control only certain aspects of their activities. As a result, we will have less direct control over the conduct, timing and completion of these 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 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. We and these third parties are required to comply with GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with pharmaceutical product produced under 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.

Any third parties conducting our clinical trials are not and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing, clinical and non-clinical product candidates. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. 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.

Switching or adding third parties to conduct our preclinical studies and clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

We may form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such collaborations, alliances or licensing arrangements.

We may form or seek strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. 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.

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In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our 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 our product candidates as having the requisite potential to demonstrate safety, potency, purity and efficacy and obtain marketing approval.

Further, collaborations involving our product candidates are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization of our product candidates based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, 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;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause 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; and
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, if we enter into additional collaboration agreements and strategic partnerships or license our product candidates, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

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We currently rely and expect to rely in the future on the use of manufacturing suites in third-party facilities or third parties to manufacture our product candidates. Our business could be harmed if we are unable to use third-party manufacturing suites or if the third party manufacturers fail to provide us with sufficient quantities of our product candidates or fail to do so at acceptable quality levels or prices.

We do not currently own any facility that may be used as our clinical-scale manufacturing and processing facility and must currently rely on outside vendors to manufacture our product candidates. We have not yet caused our product candidates to be manufactured on a commercial scale and may not be able to do so for any of our product candidates.

Our anticipated reliance on a limited number of third-party manufacturers exposes us to a number of risks, including the following:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must inspect any manufacturers for current cGMP compliance as part of our marketing application;
- a new manufacturer would have to be educated in, or develop substantially equivalent processes for, the production of our product candidates;
- our third-party manufacturers might be unable to timely manufacture our product candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- contract manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately;
- our future contract manufacturers may not perform as agreed, may not devote sufficient resources to our product candidates or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute our products, if any;
- manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards and we have no control over third-party manufacturers' compliance with these regulations and standards;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates;
- our third-party manufacturers could breach or terminate their agreements with us;
- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects;
- our contract manufacturers and critical reagent suppliers may be subject to inclement weather, as well as natural or man-made disasters; and
- our contract manufacturers may have unacceptable or inconsistent product quality success rates and yields, and we have no direct control over our contract manufacturers' ability to maintain adequate quality control, quality assurance and qualified personnel.

Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our product candidates by the FDA, result in higher costs or adversely impact commercialization of our product

candidates. In addition, we will rely on third parties to perform certain specification tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and the FDA could place significant restrictions on our company until deficiencies are remedied.

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 our own facility or at a third party's facility, 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 our third-party manufacturers use hazardous and biological 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 and biological 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.

Risks related to managing growth and employee matters

We are highly dependent on our key personnel and anticipate hiring new key personnel. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly

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dependent on our management, scientific and medical personnel, including our Chief Executive Officer and President, our newly-hired Chief Financial Officer and Chief Scientific Officer, our Executive Vice President of Discovery and Translational Sciences and our Senior Vice President, Clinical Development. Our Senior Vice President, Clinical Development, Karsten Witt, M.D., is not our employee and provides services under a consulting agreement. We plan to transition from our current service model with Ridgeline to a more limited consulting arrangement. While we expect to engage in an orderly transition process as we integrate newly appointed officers and managers, we face a variety of risks and uncertainties relating to management transition, including diversion of management attention from business concerns, failure to retain other key personnel or loss of institutional knowledge. In addition, the loss of the services of any of our executive officers, other key employees and other scientific and medical advisors, and an inability to find suitable replacements could result in delays in product development and harm our business.

We conduct our operations at our facilities in Cambridge, MA, New York, NY, Stony Brook, NY, Toronto, Canada, and at the Ridgeline facilities in Switzerland. The Massachusetts region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. Changes to U.S. immigration and work authorization laws and regulations, including those that restrain the flow of scientific and professional talent, can be significantly affected by political forces and levels of economic activity. Our business may be materially adversely affected if legislative or administrative changes to immigration or visa laws and regulations impair our hiring processes and goals or projects involving personnel who are not U.S. citizens.

To encourage valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

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

As of October 30, 2019, we had 23 full-time employees. We also contract for the services of six full-time equivalent employees through our agreement with Ridgeline. We intend to hire new employees to assume activities and responsibilities from Ridgeline personnel and conduct our research and development activities in the future. Any delay in hiring such new employees or disruption in the transition of activities and responsibilities from Ridgeline personnel could result in delays in our research and development activities and would harm our business. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel, as well as additional facilities to expand our operations. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;

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- managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our 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 substantially all aspects of regulatory approval, clinical trial management 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 consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, or we are not able to effectively build out new facilities to accommodate this expansion, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our internal computer systems, or those used by our third-party CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of the development programs of our product candidates.

Despite the implementation of security measures, our internal computer systems and those of our current and future CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, and telecommunication and electrical failures. While we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of data from completed or future preclinical studies and clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our CROs, CMOs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business

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interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

Even if we obtain regulatory approval of our product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community.

The use of precision medicines as a potential cancer treatment is a recent development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers and others in the medical community. Various factors will influence whether our product candidates are accepted in the market, including:

- the clinical indications for which our product candidates are licensed;
- physicians, hospitals, cancer treatment centers and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- our ability to demonstrate the advantages of our product candidates over other cancer medicines;
- the prevalence and severity of any side effects;
- the prevalence and severity of any side effects for other precision medicines and public perception of other precision medicines;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

If our product candidates are licensed but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue.

In addition, although our product candidates differ in certain ways from other precision medicine approaches, serious adverse events or deaths in other clinical trials involving precision medicines, even if not ultimately attributable to our product or product candidates, could result in increased government regulation, unfavorable public perception and publicity, potential regulatory delays in the testing or licensing of our product candidates, stricter labeling requirements for those product candidates that are licensed, and a decrease in demand for any such product candidates.

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Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the planned clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates or products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in our share price.

Failure to obtain or retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with corporate collaborators. Although we have clinical trial insurance, our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

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

On December 22, 2017, President Trump signed into law the TCJA, which significantly reformed the Internal Revenue Code of 1986, as amended. The TCJA, among other things, contains significant changes to corporate and individual taxation, some of which could adversely impact an investment in our common stock. You are urged to consult your tax adviser regarding the implications of the TCJA on an investment in our common stock.

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Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership by 5% stockholders over a three-year period), the corporation's ability to use its pre- change net operating loss carryforwards and other pre-change tax attributes to offset its post-change taxable income may be limited. As a result of our most recent private placements and other transactions that have occurred over the past three years, we may have experienced, and, upon closing of this offering, may experience, an "ownership change." We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As of December 31, 2018, we had U.S. federal net operating loss carryforwards of $2.6 million and U.S. federal research and development tax credit carryforwards of $0.5 million, each of which will begin to expire at various dates through 2037 and which could be limited if we experience an "ownership change." The reduction of the corporate tax rate under the TCJA may cause a reduction in the economic benefit of our net operating loss carryforwards and other deferred tax assets available to us. Under the TCJA, federal net operating losses generated after December 31, 2017 will not be subject to expiration but will not be permitted to be carried back. In addition, under the TCJA, the amount of post 2017 net operating losses that we are permitted to deduct in any taxable year is limited to 80% of our taxable income in such year, where taxable income is determined without regard to the net operating loss deduction itself. As of December 31, 2018, we had a U.S. federal net operating loss carryforward of $8.5 million, which does not expire but is limited to an annual deduction equal to 80% of annual taxable income.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

As widely reported, global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive.

Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

We may be unable to adequately protect our information systems from cyberattacks, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure.

We rely on information technology systems that we or our third-party providers operate to process, transmit and store electronic information in our day-to-day operations. In connection with our MAP platform and product discovery efforts, we may collect and use a variety of personal data, such as name, mailing address, email addresses, phone number and clinical trial information. A successful cyberattack could result in the theft or destruction of intellectual property, data, or other misappropriation of assets, or otherwise compromise our

confidential or proprietary information and disrupt our operations. Cyberattacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial-of-service, social engineering fraud or other means to threaten data security, confidentiality, integrity and availability. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. Although we devote resources to protect our information systems, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent information security breaches that would result in business, legal, financial or reputational harm to us, or would have a material adverse effect on our results of operations and financial condition. Any failure to prevent or mitigate security breaches or improper access to, use of, or disclosure of our clinical data or patients' personal data could result in significant liability under state (*e.g.*, state breach notification laws), federal (*e.g.*, HIPAA, as amended by HITECH), and international law (*e.g.*, the GDPR) and may cause a material adverse impact to our reputation, affect our ability to conduct new studies and potentially disrupt our business.

In addition, the computer systems of various third parties on which we rely, including our CROs and other contractors, consultants and law and accounting firms, may sustain damage from computer viruses, unauthorized access, data breaches, phishing attacks, cybercriminals, natural disasters (including hurricanes and earthquakes), terrorism, war and telecommunication and electrical failures. We rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. If we or our third-party providers fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems, we or our third-party providers could have difficulty preventing, detecting and controlling such cyber-attacks and any such attacks could result in losses described above as well as disputes with physicians, patients and our partners, regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows. Any failure by such third parties to prevent or mitigate security breaches or improper access to or disclosure of such information could have similarly adverse consequences for us. If we are unable to prevent or mitigate the impact of such security or data privacy breaches, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business.

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 you to sell your shares of our common stock.

Prior to this offering, there was no public trading market for shares of our common stock. Although we have applied to list our common stock on The Nasdaq Global Market, an active trading market for our shares may never develop or be sustained following this offering. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. The initial public offering price for our common stock will be determined through negotiations with the underwriters, and the negotiated price may not be indicative of the market price of the common stock after the offering. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the initial public offering price. Further, 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 partnerships or acquire companies or products by using our shares of common stock as consideration.

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

The trading price of our common stock following this offering is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this prospectus, these factors include:

- the results of our ongoing, planned or any future preclinical studies, clinical trials or clinical development programs;
- the commencement, enrollment, or results of clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- adverse results or delays in preclinical studies and clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial;
- any delay in our regulatory filings or any adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers or our manufacturing plans;
- our inability to obtain adequate product supply for any licensed product or inability to do so at acceptable prices;
- our inability to establish collaborations if needed;
- our failure to commercialize our product candidates;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth of our initial cancer target markets;
- our ability to successfully treat additional types of cancers or at different stages;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or immunotherapy in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;

- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to intellectual property or proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including intellectual property or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the market for biopharmaceutical 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. If the market price of our common stock after this offering does not exceed the initial public offering price, you may not realize any return on your investment in us and may lose some or all of your investment. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, financial condition, results of operation and future prospects.

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

The initial public offering price will be substantially higher than the net tangible book value per share of our common stock. Investors purchasing common stock in this offering will pay a price per share that substantially exceeds the book value of our tangible assets after subtracting our liabilities. As a result, investors purchasing common stock in this offering will incur immediate dilution of $ per share, based on 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. Further, investors purchasing common stock in this offering will contribute approximately % of the total amount invested by stockholders since our inception, but will own only approximately % of the total number of shares of our common stock outstanding after this offering.

This dilution is due to our investors who purchased shares prior to this offering having paid substantially less when they purchased their shares than the price offered to the public in this offering, and the exercise of stock options granted to our employees. To the extent that outstanding stock options or warrants are exercised, there will be further dilution to new investors. As a result of the dilution to investors purchasing common stock in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation. For a further description of the dilution that you will experience immediately after this offering, see the section of this prospectus entitled "Dilution."

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Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our 2019 Stock Option and Incentive Plan, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, expanded research and development activities, and costs associated with operating as a public company. To raise capital, we may sell common stock, convertible securities, or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities, or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences, and privileges senior to the holders of our common stock, including shares of common stock sold in this offering.

Pursuant to our 2019 Stock Option and Incentive Plan, or 2019 Plan, which will become effective upon the effectiveness of the registration statement of which this prospectus is a part, our management is authorized to grant stock options to our employees, directors, and consultants.

Initially, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under the 2019 Plan will be shares, less the shares of common stock remaining available for issuance under our 2015 Stock Option and Grant Plan as of the business day immediately prior to the effective date of the registration statement of which this prospectus forms a part. The number of shares of our common stock reserved for issuance under the 2019 Plan shall be cumulatively increased on January 1, 2021 and each January 1 thereafter by % of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year or a lesser number of shares determined by our board of directors. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us.

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

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section entitled “Use of Proceeds,” and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management might not apply our net proceeds in ways that ultimately increase or maintain the value of your investment.

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

We currently anticipate that we will retain future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, we may enter into agreements that prohibit us from paying cash dividends without prior written consent from our contracting parties, or which other terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited to the appreciation of their stock, which may never occur.

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

Prior to this offering, our executive officers, directors, and 5% stockholders beneficially owned approximately % of our voting stock as of September 30, 2019, and, assuming the sale by us of shares of common stock in this offering, based on an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and not accounting for any shares purchased in this offering by certain of our existing stockholders (or their affiliates), we anticipate that same group will hold approximately % of our outstanding voting stock following this offering (assuming no exercise of the underwriters' option to purchase additional shares). Therefore, even after this offering, these stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

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, or JOBS Act, enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or Sarbanes-Oxley Act, 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 votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following the year in which we complete this offering, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of this offering, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period.

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 not "opt out" of this exemption from complying with new or revised accounting standards and, therefore, we will adopt new or revised accounting standards at the time private companies adopt the new or revised accounting standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an emerging growth company.

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

As a public company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which will require, among other things, that we file with the Securities and Exchange Commission, or SEC, annual, quarterly, and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and The Nasdaq Global Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas, such as "say on pay" and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the pricing of this offering. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment, and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, and results of operations. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees, or as executive officers.

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

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lockup and other legal restrictions on resale discussed in this prospectus lapse, the trading price of our common stock could decline. Based on the number of shares of common stock outstanding as of September 30, 2019, upon the closing of this offering, we will have outstanding a total of shares of

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common stock. Of these shares, only the shares of common stock sold in this offering by us, plus any shares sold upon exercise of the underwriters' option to purchase additional shares, will be freely tradable without restriction in the public market immediately following this offering. In connection with this offering, our officers, directors and substantially all of our stockholders have agreed to be subject to a contractual lock-up with the underwriters, which will expire 180 days after the date of this prospectus. The lock-up agreements contain important exceptions that govern their applicability. J.P. Morgan Securities LLC, Jefferies LLC and Cowen and Company, LLC, however, may, in their sole discretion, permit our officers, directors and other stockholders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our 2019 Plan and our 2019 Employee Stock Purchase Plan, each to be effective upon the effectiveness of the registration statement of which this prospectus forms a part, will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act of 1933, as amended, or the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

After this offering, the holders of shares of our common stock will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the 180-day lock-up agreements described above. See "Description of Capital Stock— Registration Rights." Registration of these shares under the Securities Act would result in such shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

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

Our amended and restated certificate of incorporation and amended and restated bylaws, which are to become effective upon the closing of this offering, will contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairperson of the board of directors, the chief executive officer, or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and

- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These antitakeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer, or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our bylaws to be effective upon the consummation of this offering designate certain courts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our bylaws that will become effective upon the completion of this offering provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers, and employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein. This exclusive forum provision will not apply to any causes of action arising under the Exchange Act. In addition, our amended and restated bylaws will provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions. We recognize that the forum selection clause in our bylaws may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware. Additionally, the forum selection clauses in our amended and restated bylaws may limit our stockholders' ability to bring a claim in a forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. The Court of Chancery of the State of Delaware may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business.

In preparation of our financial statements to meet the requirements of this offering, we determined that material weaknesses in our internal control over financial reporting existed during fiscal 2017 and remained unremediated as of December 31, 2018. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material

misstatement of a company's annual and interim financial statements will not be detected or prevented on a timely basis.

The material weaknesses we identified are related to the design and maintenance of an effective control environment commensurate with our financial reporting requirements. Specifically, we lacked a sufficient complement of professionals with an appropriate level of accounting knowledge, training and experience to appropriately analyze, record and disclose accounting matters timely and accurately and we did not design and maintain controls to ensure adequate segregation of duties within our financial reporting function including the preparation and review of journal entries.

The material weaknesses contributed to the restatement of our previously issued 2017 annual financial statements. Specifically, the material weaknesses resulted in errors in our accounting for and reporting of derivative liabilities, loss on extinguishment of convertible promissory notes and expense classification.

Prior to the completion of this offering, we have been a private company with limited accounting personnel to adequately execute our accounting processes. We are in the process of building a finance organization and implementing measures designed to improve our internal control over financial reporting and remediate the control deficiencies that led to these material weaknesses, including hiring additional finance and accounting personnel and the establishment of controls to account for and disclose complex transactions.

If we are unable to successfully remediate our existing or any future material weaknesses in our internal control over financial reporting, or identify any additional material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports and applicable Nasdaq Global Market listing requirements, investors may lose confidence in our financial reporting, and our share price may decline as a result. In addition, we could become subject to investigations by Nasdaq, the SEC or other regulatory authorities, which could require additional financial and management resources.

If we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. In connection with this offering, we intend to begin the process of documenting, reviewing, and improving our internal controls and procedures for compliance with Section 404 of the Sarbanes-Oxley Act, which will require annual management assessment of the effectiveness of our internal control over financial reporting. We have begun recruiting additional finance and accounting personnel with certain skill sets that we will need as a public company.

Implementing any appropriate changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes, and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm our stock price and make it more difficult for us to effectively market and sell our service to new and existing customers.

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

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

After the completion of this offering, we may be at an increased risk of securities class action litigation.

Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

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Special note regarding forward-looking statements

This prospectus, including the sections entitled “Prospectus Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and “Business,” contains express or implied forward-looking statements that are based on our management’s belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this prospectus include, but are not limited to, statements about:

- the initiation, timing, progress and results of our research and development programs, preclinical studies, any clinical trials and IND and other regulatory submissions;
- our ability to obtain and maintain regulatory approval for BDTX-189 or any of our other current or future product candidates that we may identify or develop;
- our need to raise additional funding before we can expect to generate any revenues from product sales;
- our ability to identify and develop product candidates for treatment of additional disease indications;
- the rate and degree of market acceptance and clinical utility for any product candidates we may develop;
- the effects of competition with respect to BDTX-189 or any of our other current or future product candidates, as well as innovations by current and future competitors in our industry;
- the implementation of our strategic plans for our business, any product candidates we may develop and our MAP platform;
- our ability to successfully develop companion diagnostics for use with our product candidates;
- our intellectual property position, including the scope of protection we are able to establish, maintain and enforce for intellectual property rights covering our product candidates and MAP platform;
- our ability to use the proceeds of this offering in ways that increase the value of your investment;
- our financial performance and our ability to effectively manage our anticipated growth;
- our estimates regarding the market opportunities for our product candidates;
- our ability to remediate our existing material weaknesses and to design and maintain an effective system of internal controls; and
- other risks and uncertainties, including those listed under the section titled “Risk Factors.”

In some cases, you can identify forward-looking statements by terminology such as “may,” “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue” or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section titled “Risk Factors” and elsewhere in this prospectus. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-

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looking statement is a guarantee of future performance. You should read this prospectus and the documents that we reference in this prospectus and have filed with the Securities and Exchange Commission as exhibits to the registration statement, of which this prospectus forms a part, completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

The forward-looking statements in this prospectus represent our views as of the date of this prospectus. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this prospectus.

This prospectus also contains estimates, projections and other information concerning our industry, our business and the markets for our product candidates. 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. Unless otherwise expressly stated, we obtained this industry, business, market, and other data from our own internal estimates and research as well as from reports, research surveys, studies, and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources. While we are not aware of any misstatements regarding any third-party information presented in this prospectus, their estimates, in particular, as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties and are subject to change based on various factors, including those discussed under the section titled “Risk Factors” and elsewhere in this prospectus.

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Use of proceeds

We estimate that the net proceeds to us from the sale of shares of our common stock in this offering will be $ million, or $ if the underwriters exercise in full their option to purchase additional shares, 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 estimated underwriting discounts and commissions and estimated offering expenses payable by us.

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us from this offering by $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase (decrease) of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us from this offering by $ million, assuming no change in the assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We do not expect that a change in the offering price or the number of shares by these amounts would have a material effect on our intended uses of the net proceeds from this offering, although it may impact the amount of time prior to which we may need to seek additional capital.

As of September 30, 2019, we had a cash and cash equivalents balance of $78.7 million. We currently intend to use the net proceeds from this offering as follows:

- approximately $ million to fund the Phase 1/2 development of BDTX-189;
- approximately $ million to identify a lead development candidate and conduct IND-enabling studies in our glioblastoma program; and
- the remaining proceeds for continued development of our MAP platform and identification of additional targets and development candidates, hiring of additional personnel, capital expenditures, costs of operating as a public company and other general corporate purposes.

Based on our current plans, we believe our existing cash, together with the net proceeds from this offering, will be sufficient to fund our operations and capital expenditure requirements through .

This expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. 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 closing of this offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual expenditures and the extent of clinical development may vary significantly depending on numerous factors, including the progress of our development, the status of and results from preclinical studies or clinical trials we may commence in the future, as well as any collaborations that we may enter into with third parties for our product candidates or strategic opportunities that become available to us, and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Pending our use of proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation instruments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities.

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Dividend policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain any future earnings to fund the development and expansion of our business, and therefore we do not anticipate paying cash dividends on our common stock in the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors and will depend on our results of operations, financial condition, capital requirements, contractual restrictions and other factors deemed relevant by our board of directors.

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Capitalization

The following table sets forth our cash and capitalization as of September 30, 2019:

- on an actual basis;
- on a pro forma basis to give effect to (i) the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 45,419,229 shares of common stock upon the closing of this offering, (ii) the settlement of our derivative liabilities upon the closing of this offering and (iii) the filing and effectiveness of our amended and restated certificate of incorporation, which will occur upon the closing of this offering; and
- on a pro forma as-adjusted basis to give further effect to the sale and issuance by us of shares of our common stock in this offering at an assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table below with our consolidated financial statements and the related notes appearing elsewhere in this prospectus and the "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of this prospectus.

	As of September 30, 2019		
	Actual	Pro forma	Pro forma as adjusted
	(In thousands, except share and per share data)		
Cash and cash equivalents	$ 78,659	$ 78,659	$
Derivative liabilities[1]	39	—	—
Convertible preferred stock (Series A and B), $0.0001 par value; 45,451,685 shares authorized and 45,419,229 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma; no shares authorized, issued or outstanding, pro forma as adjusted	115,840	—	—
Stockholders' equity (deficit):			
Preferred stock, $0.0001 par value; 45,451,685 shares authorized, issued and outstanding, actual; shares authorized and no shares issued and outstanding, pro forma and pro forma as adjusted	—	—	—
Common stock, $0.0001 par value; 58,803,522 shares authorized, 6,695,460 shares issued and outstanding, actual; 58,803,522 shares authorized, 52,114,689 shares issued and outstanding, pro forma; shares authorized, shares issued and outstanding, pro forma as adjusted	1	5	
Additional paid-in capital	1,302	117,177	
Accumulated deficit	(41,095)	(41,095)	
Total stockholders' equity (deficit)	(39,792)	76,087	
Total capitalization	$ 76,087	$ 76,087	$

(1) The derivative liabilities will be settled upon the closing of this offering due to all outstanding warrants to purchase shares of convertible preferred stock becoming warrants to purchase shares of common stock.

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

The table above excludes each of the following:

- 4,850,721 shares of common stock issuable upon exercise of options outstanding under our 2017 Employee, Director and Consultant Equity Incentive Plan, as amended, at a weighted-average exercise price of $2.22 per share as of September 30, 2019;
- shares of common stock issuable upon the exercise of warrants to purchase common stock at the exercise price of $ per share as of September 30, 2019;
- 1,460,392 shares of common stock reserved for issuance under our 2017 Employee, Director and Consultant Equity Incentive Plan as of September 30, 2019, which such shares will cease to be available for issuance at the time our 2019 Stock Option and Incentive Plan becomes effective;
- shares of common stock to be reserved for future issuance under our 2019 Stock Option and Incentive Plan to be effective upon the effectiveness of the registration statement of which this prospectus forms a part; and
- shares of common stock to be reserved for future issuance under our 2019 Employee Stock Purchase Plan to be effective upon the effectiveness of the registration statement of which this prospectus forms a part.

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Dilution

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock after this offering. As of September 30, 2019, our historical net tangible book value (deficit) was $(41.4) million, or $(6.18) per share of common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets less our total liabilities and the carrying value of our convertible preferred stock, which is not included in stockholders' deficit. Historical net tangible book value (deficit) per share represents historical net tangible book value (deficit) divided by 6,695,460 shares of common stock outstanding as of September 30, 2019.

Our pro forma net tangible book value as of September 30, 2019 was $74.5 million, or $1.43 per share of common stock, after giving effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 45,419,229 shares of our common stock upon the closing of this offering and (ii) the settlement of our derivative liabilities upon the closing of this offering due to all outstanding warrants to purchase shares of convertible preferred stock becoming warrants to purchase shares of common stock. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares of common stock outstanding as of September 30, 2019, after giving effect to the pro forma adjustment described above.

After giving further effect to our issuance and sale of shares of our common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of September 30, 2019 would have been $ million, or $ per share of common stock. This represents an immediate increase in pro forma as adjusted net tangible book value of $ per share to existing stockholders and an immediate dilution of $ in pro forma as adjusted net tangible book value per share to new investors purchasing common stock in this offering. Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the assumed initial public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share		$
Historical net tangible book value (deficit) per share as of September 30, 2019	$(6.18)	
Increase per share attributable to the pro forma adjustments described above	7.61	
Pro forma net tangible book value per share as of September 30, 2019, before giving effect to this offering	1.43	
Increase in pro forma as adjusted net tangible book value per share attributable to new investors purchasing common stock in this offering		
Pro forma as adjusted net tangible book value per share after giving effect to this offering		
Dilution in pro forma as adjusted net tangible book value per share to new investors purchasing common stock in this offering		$

The dilution information discussed above is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth

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

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

The following table summarizes, on a pro forma as adjusted basis as of September 30, 2019, the total number of shares of common stock purchased from us on an as converted basis, the total consideration paid or to be paid and the average price per share paid, or to be paid by existing stockholders and by new investors in this offering, based on the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover of this prospectus before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares purchased		Total consideration		Average price per share
	Number	Percent	Amount	Percent	
Existing stockholders		%	$	%	$
New investors					
Total		100.0%	$	100.0%	

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the total consideration paid by new investors by $ million, would increase (decrease) the total consideration paid by new investors by $ million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by percentage points, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase (decrease) of 1,000,000 shares in the number of shares offered by us in this offering would increase (decrease) the total consideration paid by new investors in this offering by $ million, and, in the case of an increase, would increase the percentage of total consideration paid by new investors by percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by percentage points, assuming no change in the assumed initial public offering price of $ per share, the

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midpoint of the price range set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The table above assumes no exercise of the underwriters' option to purchase additional shares in this offering. If the underwriters exercise their option to purchase additional shares of our common stock 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.

The foregoing tables and calculations exclude:

- 4,850,721 shares of common stock issuable upon exercise of options outstanding under our 2017 Employee, Director and Consultant Equity Incentive Plan at a weighted-average exercise price of $2.22 per share as of September 30, 2019;
- shares of common stock issuable upon the exercise of warrants to purchase common stock at an exercise price of $ per share as of September 30, 2019;
- 1,460,392 shares of common stock reserved for issuance under our 2017 Employee, Director and Consultant Equity Incentive Plan as of September 30, 2019, which such shares will cease to be available for issuance at the time our 2019 Stock Option and Incentive Plan becomes effective;
- shares of common stock to be reserved for future issuance under our 2019 Stock Option and Incentive Plan to be effective upon the effectiveness of the registration statement of which this prospectus forms a part; and
- shares of common stock to be reserved for future issuance under our 2019 Employee Stock Purchase Plan to be effective upon the effectiveness of the registration statement of which this prospectus forms a part.

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

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Selected consolidated financial data

You should read the following selected consolidated financial data together with our consolidated financial statements and the related notes appearing elsewhere in this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this prospectus. We have derived the consolidated statement of operations data for the years ended December 31, 2017 and 2018 and the consolidated balance sheet data as of December 31, 2017 and 2018 from our audited consolidated financial statements appearing elsewhere in this prospectus. The consolidated statements of operations data for the nine months ended September 30, 2018 and 2019 and the balance sheet data as of September 30, 2019 are derived from our unaudited financial statements included elsewhere in this prospectus and have been prepared on the same basis as the audited financial statements. In the opinion of management, the unaudited data reflects all adjustments, consisting only of normal recurring adjustments, necessary for a fair statement of the financial information in those statements. Our historical results are not necessarily indicative of the results that may be expected in the future, and our results for any interim period are not necessarily indicative of results that may be expected for any full year.

	Year ended December 31,		Nine months ended September 30,	
	2017	2018	2018	2019
	(in thousands, except share and per share data)			
Consolidated statement of operations data:				
Operating expenses:				
Research and development (inclusive of $1,348, $2,403, $1,595 and $8,497, respectively, with a related party)	$ 3,453	$ 6,950	$ 4,571	$ 14,293
General and administrative (inclusive of $42, $325, $238 and $357, respectively, with a related party)	666	1,954	1,287	4,695
Total operating expenses	4,119	8,904	5,858	18,988
Loss from operations	(4,119)	(8,904)	(5,858)	(18,988)
Other income (expense):				
Interest expense	(65)	—	—	—
Interest income	—	4	2	21
Loss on extinguishment of convertible promissory notes	(282)	—	—	—
Change in fair value of derivative liabilities	(130)	(15)	—	(6,416)
Other income (expense)	(6)	(16)	(9)	—
Total other income (expense), net	(483)	(27)	(7)	(6,395)
Net loss	(4,602)	(8,931)	(5,865)	(25,383)
Net loss attributable to common stockholders	$ (4,602)	$ (8,931)	$ (5,865)	$ (25,383)
Net loss per share attributable to common stockholders—basic and diluted[1]	$ (0.79)	$ (1.47)	$ (0.97)	$ (4.10)
Weighted average common shares outstanding—basic and diluted[1]	5,802,740	6,089,819	6,069,399	6,194,913
Pro forma net loss attributable to common stockholders outstanding—basic and diluted (unaudited)[2]		$ (0.41)		$ (0.37)
Pro forma weighted average common shares outstanding—basic and diluted (unaudited)[2]		21,701,364		51,614,142

(1) See Note 11 to our consolidated financial statements appearing elsewhere in this prospectus for details on the calculation of basic and diluted net loss per share attributable to common stockholders.

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(2) See Note 11 to our consolidated financial statements appearing elsewhere in this prospectus for details on the calculation of basic and diluted pro forma net loss per share attributable to common stockholders.

	As of December 31,		As of September 30,
	2017	2018	2019
			(in thousands)
Consolidated balance sheet data:			
Cash and cash equivalents	$ 7,878	$ 51,660	$ 78,659
Working capital[1]	5,684	49,109	74,306
Total assets	8,021	51,826	80,734
Derivative liabilities	8	4,023	39
Convertible preferred stock	12,458	60,770	115,840
Accumulated deficit	(6,781)	(15,712)	(41,095)
Total stockholders' equity (deficit)	(6,675)	(15,542)	(39,732)

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

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

You should read the following discussion and analysis of our financial condition and results of operations together with the "Selected Consolidated Financial Data" section of this prospectus and our consolidated financial statements and related notes appearing elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this prospectus, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a precision oncology medicine company pioneering the discovery and development of small molecule, tumor-agnostic therapies. We target undrugged oncogenic driver mutations in patients with genetically-defined cancers. The foundation of our company is built upon a deep understanding of cancer genetics, protein structure and function, and medicinal chemistry. Our proprietary technology platform, which we refer to as our Mutation-Allostery-Pharmacology, or MAP, platform, is designed to allow us to analyze population-level genetic sequencing data to discover oncogenic mutations that promote cancer across tumor types. Our goal is to identify families of mutations that can be inhibited with a single small molecule therapy in a tumor-agnostic manner. We have designed our lead product candidate, BDTX-189, to potently and selectively inhibit a family of oncogenic proteins defined by mutations which occur outside the adenosine triphosphate, or ATP site, and which we refer to as non-canonical mutations. Non-canonical mutations occur across a range of tumor types that affect both the epidermal growth factor receptor, or EGFR, and the tyrosine-protein kinase ErbB-2, or HER2. We have designed BDTX-189 to bind to the active site of these mutant Kinases and inhibit their function. BDTX-189 is also designed to spare normal, or wild type, EGFR, which we believe will improve upon the toxicity profiles of current ErbB kinase inhibitors. We are completing Investigational New Drug, or IND, enabling activities for BDTX-189 and plan to start a combined Phase 1/2 clinical trial in the first half of 2020 to pursue a tumor-agnostic development strategy. We are also leveraging our MAP platform to identify other families of non-canonical mutations in validated oncogenes beyond ErbB, which has the potential to expand the reach of targeted therapies.

Since our inception in 2014, we have devoted substantially all of our efforts and financial resources to organizing and staffing our company, business planning, raising capital, acquiring, discovering product candidates and securing related intellectual property rights and conducting research and development activities for our programs. We do not have any products approved for sale and have not generated any revenue from product sales. We may never be able to develop or commercialize a marketable product. We have not yet successfully completed any pivotal clinical trials, obtained any regulatory approvals, manufactured a commercial-scale drug, or conducted sales and marketing activities. Through September 30, 2019, we had received net proceeds of $115.8 million from sales of our preferred stock and net cash proceeds of $1.8 million from borrowings under convertible promissory notes.

We have incurred significant operating losses since inception. Our net losses were $4.6 million and $8.9 million for the years ended December 31, 2017 and 2018, respectively, and $5.9 million and $25.4 million for the nine months ended September 30, 2018 and 2019, respectively. As of September 30, 2019, we had an accumulated deficit of $41.1 million. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current or future product

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candidates. We expect that our expenses and capital requirements will increase substantially in connection with our ongoing activities, particularly if and as we:

- continue preclinical studies and initiate clinical trials for BDTX-189, our glioblastoma program and other product candidates;
- advance the development of our product candidate pipeline;
- continue to develop and expand our proprietary MAP platform to identify additional product candidates;
- obtain, maintain, expand and protect our intellectual property portfolio;
- seek marketing approvals for our product candidates that successfully complete clinical trials, if any;
- hire additional clinical, scientific and commercial personnel;
- acquire or in-license additional product candidates;
- expand our infrastructure and facilities to accommodate our growing employee base; and
- add operational, financial and management information systems and personnel, including personnel to support our research and development programs, any future commercialization efforts and our transition to operating as a public company following the completion of this offering.

Furthermore, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company.

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

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

As of September 30, 2019, we had cash and cash equivalents of $78.7 million. We believe that the anticipated net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements through . We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See "—Liquidity and capital resources." Our future viability beyond that point is dependent on our ability to raise additional capital to finance our operations.

Without giving effect to the net proceeds from this offering, we expect that our cash and cash equivalents balance at September 30, 2019 will enable us to fund our operating expenses and capital requirements through the third quarter of 2020. To finance our operations beyond that point, we will need to raise additional capital, which cannot be assured. We have concluded that this circumstance raises substantial doubt about our ability

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to continue as a going concern within one year after the August 22, 2019 issuance date of our consolidated financial statements for the year ended December 31, 2018, and within one year after the October 30, 2019 issuance date of our interim consolidated financial statements for the nine months ended September 30, 2019. See Note 1 to our consolidated financial statements appearing at the end of this prospectus for additional information on our assessment.

In its report on our consolidated financial statements for the year ended December 31, 2018, our independent registered public accounting firm included an explanatory paragraph stating that our recurring losses from operations and required additional funding to finance our operations raise substantial doubt about our ability to continue as a going concern.

Components of our results of operations

Revenue

To date, we have not generated any revenue from any sources, including from product sales, and we do not expect to generate any revenue from the sale of products in the foreseeable future. If our development efforts for our product candidates are successful and result in regulatory approval, or license agreements with third parties, we may generate revenue in the future from product sales. However, there can be no assurance as to when we will generate such revenue, if at all.

Operating expenses

Research and development expenses (inclusive of amounts with a related party)

Research and development expenses consist primarily of costs incurred for our research activities, including our drug discovery efforts and the development of our product candidates. We expense research and development costs as incurred, which include:

- expenses incurred under our services agreement with Ridgeline Therapeutics GmbH, or Ridgeline;
- expenses incurred to conduct the necessary preclinical studies and clinical trials required to obtain regulatory approval;
- expenses incurred under agreements with contract research organizations, or CROs, that are primarily engaged in the oversight and conduct of our drug discovery efforts and preclinical studies, clinical trials and contract manufacturing organizations, or CMOs, that are primarily engaged to provide preclinical and clinical drug substance and product for our research and development programs;
- other costs related to acquiring and manufacturing materials in connection with our drug discovery efforts and preclinical studies and clinical trial materials, including manufacturing validation batches, as well as investigative sites and consultants that conduct our clinical trials, preclinical studies and other scientific development services;
- payments made in cash or equity securities under third-party licensing, acquisition and option agreements;
- employee-related expenses, including salaries and benefits, travel and stock-based compensation expense for employees engaged in research and development functions;
- costs related to compliance with regulatory requirements; and
- allocated facilities-related costs, depreciation and other expenses, which include rent and utilities.

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We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers. 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. Any nonrefundable advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such amounts are expensed as the related goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered.

We do not track our research and development expenses on a program-by-program basis. Our direct external research and development expenses consist primarily of external costs, such as fees paid to outside consultants, CROs, CMOs and research laboratories in connection with our preclinical development, process development, manufacturing and clinical development activities. Our direct research and development expenses also include fees incurred under license, acquisition and option agreements. We do not allocate employee costs, costs associated with our discovery efforts, laboratory supplies, and facilities, including depreciation or other indirect costs, to specific programs because these costs are deployed across multiple programs and, as such, are not separately classified. We use internal resources primarily to conduct our research and discovery as well as for managing our preclinical development, process development, manufacturing and clinical development activities. These employees work across multiple programs and, therefore, we do not track their costs by program.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect that our research and development expenses will increase substantially over the next several years as we commence our planned clinical trials for BDTX-189, as well as conduct other preclinical and clinical development, including submitting regulatory filings for our other product candidates. Historically, many of our research and development activities have been conducted pursuant to our services agreement with Ridgeline, a related party, and we expect to transition many of these activities internally as we increase our internal capacity. While we expect the service fee we have historically paid under our Ridgeline Services Agreement to reduce significantly as a result of that transition, we expect that we will incur increased personnel and overhead costs associated with moving those functions in-house, which we expect will offset that reduction in Ridgeline services fees. In addition, we expect our discovery research efforts and our related personnel costs will increase and, as a result, we expect our research and development expenses, including costs associated with stock-based compensation, will increase above historical levels. In addition, we may incur additional expenses related to milestone and royalty payments payable to third parties with whom we may enter into license, acquisition and option agreements to acquire the rights to future product candidates.

At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates or when, if ever, material net cash inflows may commence from any of our product candidates. The successful development and commercialization of our product candidates is highly uncertain. This uncertainty is due to the numerous risks and uncertainties associated with product development and commercialization, including the uncertainty of the following:

- the scope, progress, outcome and costs of our preclinical development activities, clinical trials and other research and development activities;
- establishing an appropriate safety and efficacy profile with Investigational New Drug, or IND, enabling studies;
- successful patient enrollment in and the initiation and completion of clinical trials;

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- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities including the U.S. Federal Drug Administration, or FDA and non-U.S. regulators;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- establishing clinical and commercial manufacturing capabilities or making arrangements with third-party manufacturers in order to ensure that we or our third-party manufacturers are able to make product successfully;
- development and timely delivery of clinical-grade and commercial-grade drug formulations that can be used in our clinical trials and for commercial launch;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- significant and changing government regulation;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others; and
- maintaining a continued acceptable safety profile of our product candidates following approval, if any, of our product candidates.

Any changes in the outcome of any of these variables with respect to the development of our product candidates in preclinical and clinical development could mean a significant change in the costs and timing associated with the development of these product candidates. For example, if the FDA or another regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect or if we experience significant delays in enrollment in any of our planned clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development of that product candidate.

General and administrative expenses (inclusive of amounts with a related party)

General and administrative expenses consist primarily of salaries and benefits, travel and stock-based compensation expense for personnel in executive, business development, finance, human resources, legal, information technology, pre-commercial and support personnel functions. General and administrative expenses also include direct and allocated facility-related costs as well as insurance costs and professional fees for legal, patent, consulting, investor and public relations, accounting and audit services.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our product candidates and prepare for potential commercialization activities. We also anticipate that we will incur significantly increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with operating as a public company. Additionally, if and when we believe a regulatory approval of a product candidate appears likely, we anticipate an increase in payroll and other employee-related expenses as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of that product candidate.

Other income (expense)

Interest expense

Interest expense consists of interest accrued on our convertible promissory notes which were converted into shares of Series A preferred stock during March 2017. As a result, in periods subsequent to this conversion, we no longer incurred interest expense.

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Interest income

Interest income consists of income earned on our cash balance. Our interest income has not been significant due to low balances and low interest earned on those balances.

Loss on the extinguishment of convertible promissory notes

In March 2017, in connection with the conversion of our convertible promissory notes into Series A preferred stock, we recorded a loss on extinguishment of convertible promissory notes of $0.3 million.

Change in fair value of derivative liabilities

We issued convertible promissory notes that contained a conversion feature, which met the definition of a derivative instrument. We classified this derivative instrument as a liability on our consolidated balance sheet. We remeasured this derivative liability to fair value at each reporting date and recognized changes in the fair value of the derivative liability in our consolidated statement of operations.

In March 2017, in connection with the issuance of our Series A preferred stock, the outstanding convertible promissory notes were automatically converted into shares of our Series A preferred stock. Subsequent to this conversion, no convertible promissory notes remained outstanding and therefore we no longer have a derivative liability related to the convertible promissory notes.

Additionally, our issuance of Series A and Series B preferred stock provided investors the right to participate in subsequent offerings of Series A and Series B preferred stock, respectively, in the event specified developmental and regulatory milestones were achieved (see Note 7 to our consolidated financial statements). We classified the tranche rights as derivative liabilities on our consolidated balance sheets. We remeasured the derivative liabilities associated with tranche rights to fair value at each reporting date, and recognized changes in the fair value of the derivative liabilities in the consolidated statements of operations.

Other income (expense)

Other income (expense) consists primarily of realized and unrealized foreign currency transaction gains and losses.

Income taxes

Since our inception, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in each year or for our earned research and development tax credits, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our net operating loss carryforwards and tax credits will not be realized. As of December 31, 2018, we had U.S. federal and state net operating loss carryforwards of $2.6 million and $11.1 million, respectively, which expire at various dates through 2037 and 2038, respectively. As of December 31, 2018, we had federal and state research and development tax credit carryforwards of approximately $0.5 million available to reduce future tax liabilities, which expire at various dates through 2038. As of December 31, 2018, we had a U.S. federal net operating loss carryforward of $8.5 million, which does not expire but is limited in usage to an annual deduction equal to 80% of annual taxable income. We have recorded a full valuation allowance against our net deferred tax assets at each balance sheet date.

On December 22, 2017, the Tax Cuts and Jobs Act, or TCJA, was signed into United States law. The TCJA includes a number of changes to existing tax law, including, among other things, a permanent reduction in the federal

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corporate income tax rate from 35% to 21%, effective as of January 1, 2018, as well as limitation of the deduction for net operating losses to 80% of annual taxable income and elimination of net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such net operating losses may be carried forward indefinitely). The tax rate change resulted in (i) a reduction in the gross amount of our deferred tax assets as of December 31, 2017, without an impact on the net amount of our deferred tax assets, which are recorded with a full valuation allowance, and (ii) no income tax expense or benefit being recognized as of the enactment date of the TCJA.

The staff of the Securities and Exchange Commission issued Staff Accounting Bulletin No. 118 to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the TCJA. In connection with the initial analysis of the impact of the TCJA, the Company remeasured its deferred tax assets and liabilities based on the rates at which they are expected to reverse in the future, which is generally 21% for federal tax purposes. The remeasurement of the Company's deferred tax assets and liabilities was offset by a change in the valuation allowance.

Comparison of the nine months ended September 30, 2018 and 2019

The following table summarizes our results of operations for the nine months ended September 30, 2018 and 2019:

	Nine months ended September 30,		
	2018	**2019**	**Change**
			(in thousands)
Operating expenses:			
Research and development (inclusive of $1,595 and $8,497 respectively, with a related party)	$ 4,571	$ 14,293	$ 9,722
General and administrative (inclusive of $238 and $357, respectively, with a related party)	1,287	4,695	3,408
Total operating expenses	5,858	18,988	13,130
Loss from operations	(5,858)	(18,988)	(13,130)
Interest income	2	21	19
Change in fair value of derivative liabilities	—	(6,416)	(6,416)
Other income (expense)	(9)	—	9
Total other income (expense), net	(7)	(6,395)	(6,388)
Net loss	$(5,865)	$(25,383)	$(19,518)

Research and development expenses (inclusive of amounts with a related party)

Research and development expenses were $4.6 million for the nine months ended September 30, 2018, compared to $14.3 million for the nine months ended September 30, 2019. The increase of $9.7 million was primarily due to an increase in external fees related to the continued development of our MAP platform and our product candidates, including BDTX-189. We do not currently track expenses on a program-by-program basis.

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General and administrative expenses (inclusive of amounts with a related party)

General and administrative expenses were $1.3 million for the nine months ended September 30, 2018, compared to $4.7 million for the nine months ended September 30, 2019. The increase of $3.4 million was primarily a result of higher personnel-related costs due to additional headcount and higher legal and other professional fees.

Interest income

Interest income was less than $0.1 million for the nine months ended September 30, 2018, compared to less than $0.1 million for the nine months ended September 30, 2019.

Change in fair value of derivative liabilities

The change in the fair value of derivative liabilities was $6.4 million for the nine months ended September 30, 2019, compared to $0 for the nine months ended September 30, 2018. The increase was due to the remeasurement of derivative liabilities related to the tranche right on our Series B preferred stock primarily due to an increase in the probability of a liquidity event during the nine months ended September 30, 2019. We did not have any derivative liabilities during the nine months ended September 30, 2018.

Other income (expense)

Other income (expense) was less than $0.1 million for the nine months ended September 30, 2018, compared to less than $0.1 million for the nine months ended September 30, 2019.

Comparison of the years ended December 31, 2017 and 2018

The following table summarizes our results of operations for the years ended December 31, 2017 and 2018:

	Year ended December 31,		
	2017	2018	Change
			(in thousands)
Operating expenses:			
Research and development (inclusive of $1,348 and $2,403, respectively, with a related party)	$ 3,453	$ 6,950	$ 3,497
General and administrative (inclusive of $42 and $325, respectively, with a related party)	666	1,954	1,288
Total operating expenses	4,119	8,904	4,785
Loss from operations	(4,119)	(8,904)	(4,785)
Interest expense	(65)	—	65
Interest income	—	4	4
Loss on the extinguishment of convertible promissory notes	(282)	—	282
Change in fair value of derivative liabilities	(130)	(15)	115
Other income (expense)	(6)	(16)	(10)
Total other income (expense), net	(483)	(27)	456
Net loss	$(4,602)	$(8,931)	$ (4,329)

Research and development expenses (inclusive of amounts with a related party)

Research and development expenses were $3.5 million for the year ended December 31, 2017, compared to $7.0 million for the year ended December 31, 2018. The increase of $3.5 million was primarily due to an increase

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in external fees related to the continued development of our MAP platform and our product candidates, including BDTX-189.

General and administrative expenses (inclusive of amounts with a related party)

General and administrative expenses were $0.7 million for the year ended December 31, 2017, compared to $2.0 million for the year ended December 31, 2018. The increase of $1.3 million was primarily a result of higher personnel-related costs due to additional headcount and higher legal and other professional fees incurred in connection with financing activities.

Interest expense

Interest expense was $0.1 million for the year ended December 31, 2017, compared to $0 for the year ended December 31, 2018. The decrease of $0.1 million was due to the conversion of our convertible promissory notes into shares of our Series A preferred stock during March 2017 and, therefore, no interest expense being incurred during 2018.

Loss on the extinguishment of convertible promissory notes

Loss on extinguishment of convertible promissory notes was $0.3 million for the year ended December 31, 2017, compared to $0 for the year ended December 31, 2018. The decrease of $0.3 million was due to the conversion of our convertible promissory notes into shares of our Series A preferred stock during March 2017, which resulted in a loss on extinguishment of debt.

Change in fair value of derivative liabilities

The change in the fair value of derivative liabilities was $0.1 million for the year ended December 31, 2017, compared to less than $0.1 million for the year ended December 31, 2018. The decrease was primarily due to the derivative liabilities related to the conversion option, our convertible promissory notes, and tranche rights on our Series A preferred stock being settled during 2017.

Other income (expense)

Other income (expense) was less than $0.1 million for the year ended December 31, 2017, compared to less than $0.1 million for the year ended December 31, 2018.

Liquidity and capital resources

Since our inception, we have not generated any revenue from any product sales or any other sources, and have incurred significant operating losses and negative cash flows from our operations. We have not yet commercialized any of our product candidates and we do not expect to generate revenue from sales of any product candidates for several years, if at all. We have funded our operations to date primarily with proceeds from the sale of preferred stock and borrowings under convertible promissory notes. Through September 30, 2019, we had received net cash proceeds of $115.8 million from sales of our preferred stock and net cash proceeds of $1.8 million from borrowings under convertible promissory notes.

As of September 30, 2019 we had cash and cash equivalents of $78.7 million.

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Cash flows

The following table summarizes our cash flows for each of the years presented:

	Year ended December 31,		Nine months ended September 30,	
	2017	2018	2018	2019
	(in thousands)		(in thousands)	
Net cash used in operating activities	$(2,351)	$ (8,454)	$ (6,070)	$ (17,163)
Net cash used in investing activities	(77)	(76)	(71)	(44)
Net cash provided by financing activities	9,974	52,312	4,987	44,261
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 7,546	$43,782	$ (1,154)	$ 27,054

Operating activities

During the nine months ended September 30, 2018, we used cash in operating activities of $6.1 million, primarily resulting from our net loss of $5.9 million, partially offset by a decrease in amounts due to related parties due to payments to Ridgeline.

During the nine months ended September 30, 2019, we used cash in operating activities of $17.2 million, primarily resulting from our net loss of $25.4 million, partially offset by the non-cash charge related to the change in fair value of derivative liabilities of $6.4 million, an increase in prepaid expenses and other current assets primarily due to payments for research services and a decrease in amounts due to related parties due to payments to Ridgeline.

During the year ended December 31, 2017, we used cash in operating activities of $2.4 million, primarily resulting from our net loss of $4.6 million, partially offset by the non-cash interest expense related to our convertible promissory notes and an increase in amounts due to related parties due to amounts owed to Ridgeline.

During the year ended December 31, 2018, we used cash in operating activities of $8.5 million, primarily resulting from our net loss of $8.9 million, partially offset by an increase in accrued expenses.

Changes in accounts payable and accrued expenses in all periods were generally due to growth in our business, the advancement of our product candidates, and the timing of vendor invoicing and payments.

Investing activities

During the nine months ended September 30, 2018, we used cash in investing activities of $0.1 million, consisting solely of purchases of equipment.

During the nine months ended September 30, 2019, we used cash in investing activities of less than $0.1 million, consisting primarily of increases in security deposits related to our lease agreements.

During the year ended December 31, 2017, we used cash in investing activities of $0.1 million, consisting solely of purchases of equipment.

During the year ended December 31, 2018, we used cash in investing activities of $0.1 million, consisting solely of purchases of equipment.

Financing activities

During the nine months ended September 30, 2018, we had cash provided by financing activities of $5.0 million from the issuance of convertible preferred stock.

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During the nine months ended September 30, 2019, we had cash provided by financing activities of $44.3 million from the issuance of convertible preferred stock.

During the year ended December 31, 2017, we had cash provided by financing activities of $10.0 million, consisting primarily of proceeds from the issuance of our preferred stock.

During the year ended December 31, 2018, we had cash provided by financing activities of $52.3 million, consisting primarily of proceeds from the issuance of our preferred stock.

Funding requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our product candidates. In addition, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company. The timing and amount of our operating expenditures will depend largely on our ability to:

- advance preclinical development of our early-stage programs, including BDTX-189;
- manufacture, or have manufactured on our behalf, our preclinical and clinical drug material and develop processes for late state and commercial manufacturing;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval and intend to commercialize on our own;
- hire additional clinical, quality control and scientific personnel;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company; and
- obtain, maintain, expand and protect our intellectual property portfolio.

As of September 30, 2019, we had cash and cash equivalents of $78.7 million. We believe that the anticipated net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements through . We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We anticipate that we will require additional capital as we seek regulatory approval of our product candidates and if we choose to pursue in-licenses or acquisitions of other product candidates. If we receive regulatory approval for BDTX-189 or our other product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize.

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

- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical and clinical trials;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs, timing and ability to manufacture our product candidates to supply our clinical and preclinical development efforts and our clinical trials;

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- 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 product and necessary inventory to support commercial launch;
- the ability to receive additional non-dilutive funding, including grants from organizations and foundations;
- the revenue, if any, received from commercial sale of our products, should any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining, expanding and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all; and
- the extent to which we acquire or in-license other product candidates and technologies.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of public or private equity offerings, debt financings, governmental funding, collaborations, strategic partnerships and alliances or marketing, distribution or licensing arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. In addition, debt financing would result in fixed payment obligations.

If we raise additional funds through governmental funding, collaborations, strategic partnerships and alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual obligations and commitments

As of December 31, 2018, our future minimum lease payments under non-cancelable operating lease commitments, which are all due during the year ending December 31, 2019, totaled $0.1 million. The following table summarizes our contractual obligations as of September 30, 2019 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods:

	Payments due by period				
	Less than 1 year	1 to 3 years	4 to 5 years	More than 5 years	Total
					(in thousands)
Operating lease commitments	$ 235	$ 343	$ —	$ —	$ 578
Total	$ 235	$ 343	$ —	$ —	$ 578

We enter into contracts in the normal course of business with CMOs, CROs and other third parties for the manufacture of our product candidates and to support clinical trials and preclinical research studies and

testing. These contracts are generally cancelable by us. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation. These payments are not included in the preceding table as the amount and timing of such payments are not known.

Similarly, we have not included the monthly service fee payments under our services agreement with Ridgeline, as although the amount and timing are known, we cannot currently determine the final termination date of that agreement and, as a result, we cannot determine the total amount of such payment.

Critical accounting policies and significant judgments and estimates

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

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

Accrued research and development expenses (including amounts due to related party)

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

- vendors, including research laboratories, in connection with preclinical development activities;
- CROs and investigative sites in connection with preclinical studies and clinical trials; and
- CMOs in connection with drug substance and drug product formulation of preclinical studies and clinical trial materials.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple research institutions and CROs that supply, conduct and manage preclinical studies and clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. 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 prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Stock-based compensation

We measure stock options and other stock-based awards granted to employees and directors based on their fair value on the date of the grant and recognize the corresponding compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. We have only issued stock options and restricted share awards with service-based vesting conditions and record the expense for these awards using the straight-line method. We would apply the graded-vesting method to all stock-based awards with performance-based vesting conditions or to awards with both service-based and performance-based vesting conditions.

For stock-based awards granted to consultants and non-employees, we recognize compensation expense over the period during which services are rendered by such consultants and non-employees until completed. At the end of each financial reporting period prior to the completion of the service, the fair value of these awards is remeasured using the then-current fair value of our common stock and updated assumption inputs in the Black-Scholes option-pricing model.

We estimate the fair value of each stock option grant using the Black-Scholes option-pricing model, which uses as inputs the fair value of our common stock and assumptions we make for the volatility of our common stock, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield.

Determination of the fair value of common stock

As there has been no public market for our common stock to date, the estimated fair value of our common stock has been determined by our board of directors as of the date of each option grant, with input from management, considering our most recently available third-party valuations of common stock, and our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. Our common stock valuations were prepared using either an option pricing method, or OPM, or a hybrid method, both of which used market approaches to estimate our enterprise value. The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceeded the value of the preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. A discount for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock. The hybrid method is a probability-weighted expected return method, or PWERM, where the equity value in one or more scenarios is calculated using an OPM. The PWERM is a scenario-based methodology that estimates the fair value of our common stock based upon an analysis of our future values, assuming various outcomes. The common stock value is based on the

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probability-weighted present value of expected future investment returns considering each of the possible outcomes available 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 an indication of value for the common stock. These third-party valuations were performed at various dates, which resulted in valuations of our common stock of $0.24 per share as of August 31, 2018, $1.06 per share as of December 21, 2018, $1.37 per share as of June 12, 2019, $2.13 per share as of July 30, 2019 and $3.60 per share as of September 9, 2019. In addition to considering the results of these third-party valuations, 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 preferred stock and the superior rights and preferences of the preferred stock relative to our common stock at the time of each grant;
- the progress of our research and development programs, including the status and results of preclinical studies and clinical trials for our product candidates;
- our stage of development and commercialization and our business strategy;
- external market conditions affecting the biopharmaceutical industry and trends within the biopharmaceutical industry;
- our financial position, including cash on hand, and our historical and forecasted performance and results of operations;
- the lack of an active public market for our common stock and our preferred stock;
- offers we have received to be purchased by prospective buyers;
- the likelihood of achieving a liquidity event, such as an initial public offering, or IPO, or sale of our company in light of prevailing market conditions; and
- the analysis of IPOs and the market performance of similar companies in the biopharmaceutical industry.

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

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

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Awards granted

The following table sets forth by grant date the number of shares subject to options and restricted stock granted from January 1, 2017 through the date of this prospectus, the per share purchase prices and exercise prices, the fair value of common stock per share on each grant date, and the per share estimated fair value of the awards:

Grant Date	Type of award	Number of shares subject to award	Per share exercise price of options or purchase price of restricted stock	Per share fair value of common stock on grant date	Per share estimated fair value of award on grant date
March 14, 2017	Option	10,000	$ 0.10	$ 0.10	$ 0.06
March 14, 2017	Option	10,000	$ 0.10	$ 0.10	$ 0.07
December 11, 2017	Restricted stock	276,500	$ 0.10	$ 0.10	$ 0.10(2)
September 13, 2018	Option	73,970	$ 0.24	$ 0.24	$ 0.14
September 13, 2018	Option	50,000	$ 0.24	$ 0.24	$ 0.12
October 8, 2018	Restricted stock	278,960	$ 0.24	$ 0.24	$ 0.24(2)
March 4, 2019	Option	15,000	$ 1.06	$ 1.06	$ 0.58
March 4, 2019	Option	88,199	$ 1.06	$ 1.06	$ 0.62
March 4, 2019	Restricted stock	140,000	$ 1.06	$ 1.06	$ 1.06(2)
June 12, 2019(1)	Option	39,000	$ 1.06	$ 1.37	$ 0.86
June 12, 2019(1)	Option	78,000	$ 1.06	$ 1.37	$ 0.88
June 12, 2019(1)	Option	1,154,839	$ 1.06	$ 1.37	$ 0.92
August 8, 2019	Option	117,200	$ 2.13	$ 2.13	$ 1.22
August 14, 2019	Option	1,745,870	$ 2.13	$ 2.13	$ 1.22
September 9, 2019	Option	100,000	$ 3.60	$ 3.60	$ 1.89
September 9, 2019	Option	1,368,643	$ 3.60	$ 3.60	$ 2.06

(1) For options granted on June 12, 2019, the board of directors determined that the fair value of our common stock was $1.06 per share as of the grant date. However, the fair value of our common stock at the date of the grant was adjusted in connection with a retrospective fair value assessment solely for accounting purposes.

(2) For purposes of recording stock-based compensation for grants of options or restricted stock to non-employees, we measure the fair value of the award on the service completion date (vesting date). At the end of each reporting period prior to completion of the services, we remeasure the value of any unvested portion of the award based on the then-current fair value of the award and adjust the expense accordingly. Amounts in this column reflect only the grant-date fair value of awards to non-employees.

Valuation of derivative liabilities

Conversion feature

We issued convertible promissory notes that contained a conversion feature, which met the definition of a derivative instrument as it was not clearly and closely related to the economic characteristics and risks of the convertible promissory notes because the conversion feature provided for the accelerated repayment of the convertible promissory notes at a substantial premium upon the occurrence of specified events. We classified the instrument as a derivative liability, which was initially recorded at its fair value upon issuance of the convertible promissory notes and was subsequently remeasured to fair value at each reporting date with changes in the fair value recognized in our consolidated statement of operations.

The fair value of the derivative liability was determined using a with and without analysis within a PWERM which considered as inputs the type, timing and probability of occurrence of a future equity financing; the

potential amount of the payment under each of the potential settlement scenarios (with and without the conversion feature); and the discount rate reflecting the expected risk profile for each of the potential settlement scenarios. The estimates were based, in part, on subjective assumptions. Changes to these assumptions could have had a significant impact on the fair value of the derivative liability.

In March 2017, in connection with the sale of our Series A preferred stock, all of the outstanding principal and accrued interest under the convertible promissory notes automatically converted into shares of Series A preferred stock. As a result, subsequent to this conversion, we no longer have a derivative liability recorded on our consolidated balance sheet and we no longer recognize changes in the fair value of the derivative liability in our consolidated statement of operations.

Tranche rights

Our issuance of Series A and Series B preferred stock (see Note 7 to our consolidated financial statements) provided investors the right to participate in subsequent offerings of Series A and Series B preferred stock, respectively, in the event specified developmental and regulatory milestones were or are achieved. We classify the tranche rights as derivative liabilities on our consolidated balance sheets as we determined that the tranche rights met the definition of a freestanding financial instrument since they are legally detachable. We also determined that such instruments represent forward sale contracts on redeemable shares and, accordingly, the instrument should be accounted for as a liability separate from the convertible preferred stock. We remeasure the derivative liabilities associated with tranche rights to fair value at each reporting date, and recognize changes in the fair value of the derivative liabilities in our consolidated statements of operations.

The fair value of the derivative liabilities was determined using a back solve approach based on the price paid for the underlying preferred stock and the derivative liability. The derivative liabilities were valued as forward contracts which considered inputs including, but not limited to, the probability of attaining milestones, market-based assumptions for expected term and the risk free rate. Changes to these assumptions could have a significant impact on the fair value of the derivative liabilities.

Off-balance sheet arrangements

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

Recently issued accounting pronouncements

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

Internal control over financial reporting

In preparation of our financial statements to meet the requirements of this offering, we determined that material weaknesses in our internal control over financial reporting existed during fiscal 2017 and remain unremediated. See “Risk factors—We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business.”

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Quantitative and qualitative disclosures about market risks

Interest rate risk

We are exposed to market risk related to changes in interest rates. As of December 31, 2017 and 2018 and September 30, 2019, our cash and cash equivalents were held in savings accounts at banking institutions and a money market fund that invests in U.S. Government securities. 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 nature of the instruments in our portfolio, an immediate 10% change in the interest rate would not have a material impact on the fair market value of our investment portfolio or on our financial position or results of operations.

As of December 31, 2017 and 2018 and September 30, 2019, we had no debt outstanding and are therefore not subject to interest rate risk related to debt.

Foreign currency exchange risk

Our primary exposure to market risk is foreign exchange rate sensitivity to the Canadian dollar (CAD), the currency used in Canada, where our wholly owned subsidiary, Black Diamond Therapeutics (Canada), Inc., which was incorporated in September 2018, is located. For the year ended December 31, 2018 and the nine months ended September 30, 2019, we recognized foreign currency transaction losses of less than $0.1 million. These foreign currency transaction losses were recorded as a component of other income (expense) in our consolidated statements of operations. An immediate 5% change in CAD exchange rate would not have any material effect on our results of operations.

As we continue to grow our business, our results of operations and cash flows will be subject to fluctuations due to changes in foreign currency exchange rates, which could adversely impact our results of operations. To date, we have not entered into any foreign currency hedging contracts to mitigate our exposure to foreign currency exchange risk.

Emerging growth company and smaller reporting company status

The Jumpstart Our Business Startups Act of 2012 permits an “emerging growth company” such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected to not “opt out” of this provision and, as a result, we will adopt new or revised accounting standards at the time private companies adopt the new or revised accounting standard and will do so until such time that we either (i) irrevocably elect to “opt out” of such extended transition period or (ii) no longer qualify as an emerging growth company.

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.

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Business

Overview

We are a precision oncology medicine company pioneering the discovery and development of small molecule, tumor-agnostic therapies. We target undrugged oncogenic driver mutations in patients with genetically-defined cancers. The foundation of our company is built upon a deep understanding of cancer genetics, protein structure and function, and medicinal chemistry. Our proprietary technology platform, which we refer to as our Mutation-Allostery-Pharmacology, or MAP, platform, is designed to allow us to analyze population-level genetic sequencing data to discover oncogenic mutations that promote cancer across tumor types. Our goal is to identify families of mutations that can be inhibited with a single small molecule therapy in a tumor-agnostic manner. We have designed our lead product candidate, BDTX-189, to potently and selectively inhibit a family of oncogenic proteins defined by mutations which occur outside the adenosine triphosphate, or ATP site, and which we refer to as non-canonical mutations. Non-canonical mutations occur across a range of tumor types that affect both the epidermal growth factor receptor, or EGFR, and the tyrosine-protein kinase ErbB-2, or HER2. We have designed BDTX-189 to bind to the active site of these mutant Kinases and inhibit their function. BDTX-189 is also designed to spare normal, or wild type, EGFR, which we believe will improve upon the toxicity profiles of current ErbB kinase inhibitors. We are completing Investigational New Drug, or IND, enabling activities for BDTX-189 and plan to start a combined Phase 1/2 clinical trial in the first half of 2020 to pursue a tumor-agnostic development strategy. We are also leveraging our MAP platform to identify other families of non-canonical mutations in validated oncogenes beyond ErbB, which has the potential to expand the reach of targeted therapies.

Approved targeted therapies, such as kinase inhibitors, have transformed the treatment of cancers and demonstrated a significant benefit to certain patients by treating active site mutations in a single tumor type. Improved genetic sequencing of cancers has led to the discovery of additional genetic alterations responsible for cancer development and growth. These genetic alterations were previously unaddressed, unsuccessfully targeted or overlooked. We believe our MAP platform will allow us to reveal the oncogenic nature of families of undrugged driver mutations and their associated protein conformations. We believe this approach offers a substantial opportunity to expand the number of patients who could benefit from precision oncology medicines.

Our proprietary MAP platform is built on three central pillars:

- **Discover**—Through comprehensive analysis of population-level genetic sequencing data, we identify oncogenic mutations among hundreds of unique alterations within a single gene. Our MAP platform algorithm uses genetic and proteomic features to rank mutations for potential oncogenicity. We use our algorithm as a machine learning tool to classify mutations as either pathogenic or benign and predict the probability, or MAP score, that a mutation is pathogenic.
- **Reveal**—We confirm the oncogenicity of the identified mutations through cell and tumor models and reveal how these mutations drive conformational changes in proteins. This allows us to group subsets of mutations into families based upon similar protein structures and shared selectivity profiles.

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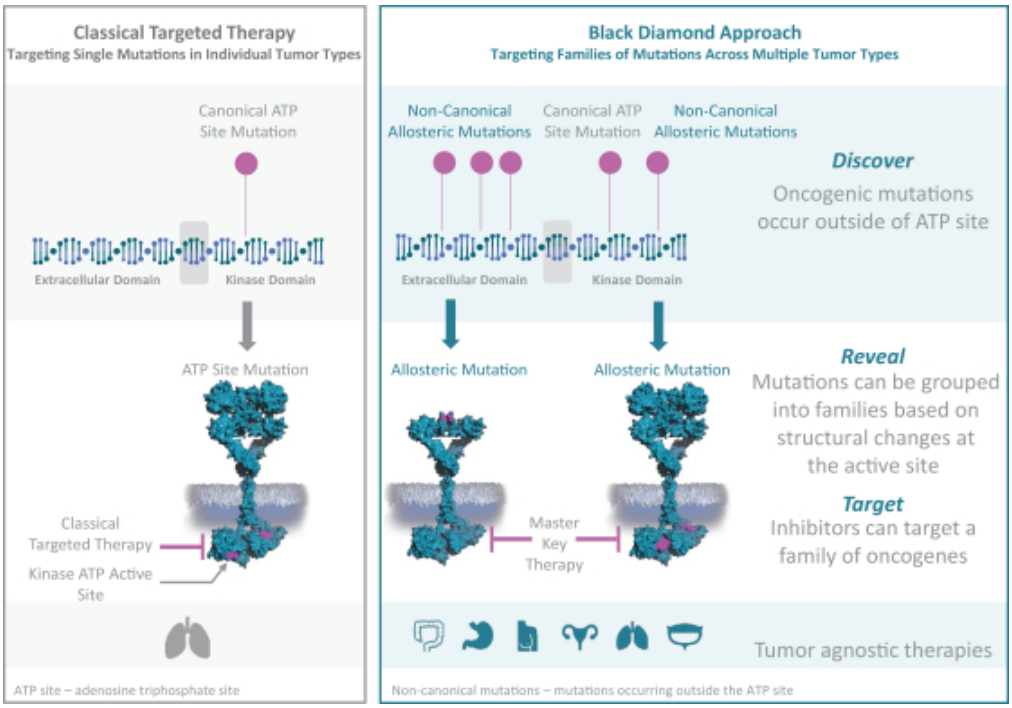
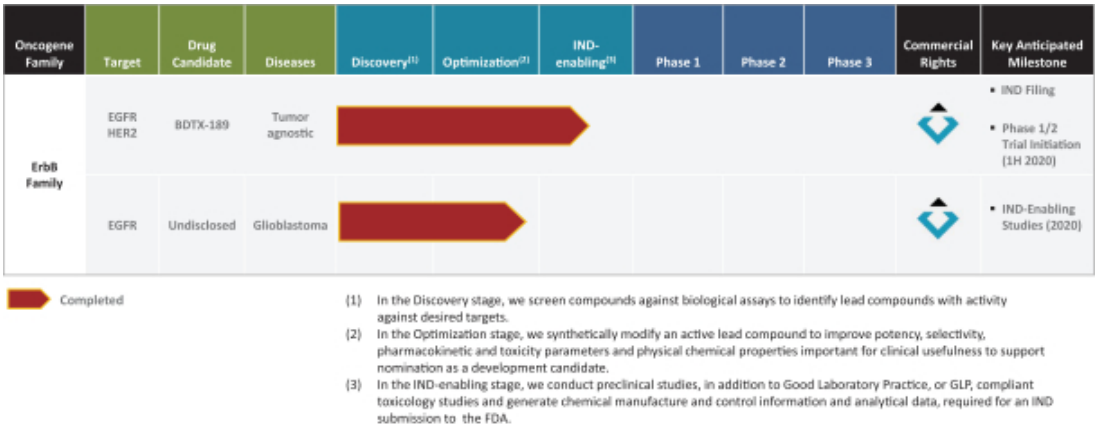
- **Target**—Using these shared characteristics, we seek to develop single small molecule product candidates, each designed to inhibit only the intended mutation family.



Our pipeline

Utilizing our proprietary MAP platform, we are developing a pipeline of orally available, potent and selective small molecule kinase inhibitors that target a range of driver mutations in cancer. An overview of our pipeline of product candidates is shown in the table below.



BDTX-189: An inhibitor of non-canonical and additional oncogenic mutations of ErbB

BDTX-189 is designed to be an orally available, irreversible small molecule inhibitor that targets a family of non-canonical and canonical driver mutations of the ErbB kinases EGFR and HER2. These mutations are

prevalent in bladder, breast, endometrial, gastric and colon cancers and non-small cell lung cancer, or NSCLC. Currently, there are no drugs approved by the U.S. Food and Drug Administration, or FDA, that target all of these oncogenic mutations with a single therapy.

BDTX-189 is designed to be a highly selective, potent inhibitor that targets this family of oncogenic proteins defined by the non-canonical ErbB driver mutations, while also sparing wild type EGFR. In preclinical models, BDTX-189 exhibited anti-tumor activity evidenced by potent tumor growth inhibition and tumor regression. We are completing IND-enabling activities for BDTX-189 and plan to start a combined Phase 1/2 clinical trial in the first half of 2020. The Phase 1 portion of the trial will evaluate escalating doses of BDTX-189 and is designed to determine the recommended Phase 2 dose and to assess preliminary indications of anti-tumor activity. The Phase 2 portion will determine the ORR and duration of response in patients with solid tumors that have an allosteric HER2 mutation, or EGFR or HER2 exon 20 insertion mutation using NGS, or next-generation sequencing. Depending on results from the Phase 1/2 trial, we may either expand the Phase 2 portion of the trial or initiate a second Phase 2 trial in order to pursue an accelerated approval of BDTX-189, subject to discussions with FDA, for patients with mutations of the ErbB family across one or more solid tumor types as a tumor agnostic indication.

Glioblastoma program: Allosteric-EGFR mutation inhibitors

Glioblastoma is a difficult-to-treat, aggressive type of cancer that can occur in the brain or spinal cord. Current therapy consists primarily of surgical resection of the tumor followed by radiation and chemotherapy and has only a 25 percent survival rate two years after diagnosis.

Almost 50 percent of glioblastoma tumors express one or more allosteric EGFR mutations that affect the extracellular region of the receptor tyrosine kinase, consequently promoting oncogenic activation. We believe that current targeted therapies have been unsuccessful in treating glioblastoma due to (i) the concurrent expression of these allosteric EGFR mutations within individual patients, (ii) insufficient drug potency for allosteric EGFR mutations and (iii) low levels of brain penetration. We have shown that the mechanism of activation for these allosteric EGFR mutations involves the formation of a constitutive dimer, and a shared conformation by the family of allosteric EGFR mutations expressed in glioblastoma. Our lead molecules potently and selectively inhibited this family of allosteric mutants and achieved tumor-growth inhibition and regression in the *in vivo* animal models we have utilized. Additionally, our lead molecules are designed to be brain penetrant and we have observed measurable brain exposure in animal models. We are completing preclinical characterization of our glioblastoma candidate leads and plan to select a development candidate in 2020.

Early-stage programs

We are also progressing our early stage pipeline programs targeting groups of allosteric mutations in kinases relevant to cancer and/or rare genetic diseases that we have developed utilizing our MAP platform. These programs are currently progressing through lead optimization.

Our strategy

Our vision is to build a differentiated, global biopharmaceutical company by discovering, developing and commercializing novel precision medicines for every genetically-defined patient. We are advancing the field of precision medicines through improved understanding of mutant protein conformations to (i) identify novel oncogenic driver mutations and (ii) target families of mutations with individual small molecule therapies. We believe our strategy will enable us to become an industry leader in precision oncology medicine and advance a

portfolio of tumor-agnostic product candidates aimed at delivering safe and effective medicines to patients. The critical components of our strategy include:

- **Rapidly advance our lead drug candidate, BDTX-189, through clinical development, as a tumor-agnostic, spectrum-selective small molecule therapy.** We believe BDTX-189 has the potential to treat multiple tumors independent of tissue of origin and become the first agent approved to address allosteric ErbB mutations. We intend to advance BDTX-189 into a combined Phase 1/2 clinical trial in solid tumors with genetically defined allosteric mutations in EGFR and HER2. We plan to conduct our clinical studies in a genetically-defined patient population and leverage learnings from recently approved tumor-agnostic drugs to inform the clinical and regulatory pathways for BDTX-189 in order to mitigate potential development risks. If successful in achieving clinically meaningful anti-tumor activity across a range of allosteric ErbB mutations and solid tumor types, we plan to meet with regulatory authorities to discuss expedited regulatory approval strategies.
- **Rapidly advance our glioblastoma program to identify a lead small molecule product candidate and progress it through clinical development.** We believe that the lead molecules in our glioblastoma program could overcome the limitations of current therapies by potently and selectively inhibiting the family of allosteric EGFR kinases expressed in glioblastoma tumors with a brain penetrant compound. We plan to select a development candidate in 2020.
- **Expand our pipeline of potent and selective small molecule inhibitors to fully exploit the potential of our proprietary MAP platform.** We believe that the general principles for mutation-driven conformational change that we have identified for the ErbB family can also apply to other oncogenic proteins. We also believe that our MAP platform has identified undrugged driver mutations for cancer for which we intend to design and develop highly selective and potent inhibitors to block the activity of these oncogenic proteins. We are advancing several early-stage programs focused on targeting a range of driver mutations, including allosteric activating mutations.
- **Continue to invest in our proprietary MAP platform to identify and characterize new mutation families.** We plan to expand our MAP platform to enable new insights into canonical and non-canonical mutations and to accelerate our ability to identify other mutational drivers, including those involved in rare diseases, as well as oncology. We will continue to enhance our proprietary computational algorithms by leveraging our extensive in-house expertise in allosteric mutations and deep understanding of chemistry. By continuing to strengthen and expand our MAP platform, we believe we can exploit the growing amount of genetic sequencing data to characterize mutations underlying human disease.
- **Selectively enter into strategic partnerships to maximize the potential of our pipeline and our proprietary MAP platform.** Given our potential to generate novel product candidates addressing a wide variety of cancers and rare diseases, we may opportunistically enter into strategic partnerships around certain targets, product candidates or disease areas. These collaborations could advance and accelerate our development programs to maximize their market potential and expand our MAP platform capabilities.

Our history and team

We were founded by Dr. David M. Epstein and Dr. Elizabeth Buck in 2014 and, beginning in 2017, together with Versant Ventures began building the MAP platform and chemistry discovery engine. As of October 30, 2019, we have raised more than $109 million in funding from leading investors including Versant Ventures, New Enterprise Associates, RA Capital Management, NexTech Invest, The Invus Group and Perceptive Advisors.

We have assembled a team with significant expertise in drug discovery and development with particular strengths in the discovery of small molecule protein kinase inhibitors. David M. Epstein, Ph.D., our President

and Chief Executive Officer, was previously Chief Scientific Officer at OSI Pharmaceuticals, Inc. and founder of Archemix, where he led the advancement of multiple product candidates into the clinic in multiple therapeutic areas. Thomas Leggett, our Chief Financial Officer, was previously Senior Vice President of Finance and Chief Financial Officer at Axcella Health, Inc. Christopher D. Roberts, our Chief Scientific Officer, was previously Entrepreneur in Residence at S.R. One Limited, the corporate venture capital arm of GlaxoSmithKline plc. Elizabeth Buck, Ph.D., our Executive Vice President of Discovery & Translational Sciences, previously led preclinical pharmacology and oncology translational research at OSI Pharmaceuticals. Karsten Witt, M.D., our Senior Vice President of Clinical Development, previously led clinical development at Array Biopharma Inc. and OSI Pharmaceuticals. Dr. Witt has been involved in eight regulatory approvals, four of which are related to Tarceva (erlotinib), an approved kinase inhibitor for the treatment of certain lung and pancreatic cancers. Brent Hatzis-Schoch, our Chief Operating Officer and General Counsel, was previously General Counsel at Radius Health.

Background on and limitations of previous generations of targeted therapies

Background on targeted therapies

Cancer is a genetic disease that is caused by changes in DNA that control the way cells function, especially how they grow and divide, and has historically been diagnosed and treated based on a tumor's organ site or tissue of origin. Oncogene addiction, which is the dependency of tumors on genetic drivers for their growth and survival advantage, has enabled the pharmacological development of targeted therapies that exploit this dependency. Recent advances in genetic sequencing and a better understanding of genetic alterations that drive cancers have facilitated more precise and histologically agnostic cancer drug development.

These targeted therapies have transformed the treatment of some cancers by providing substantial clinical benefit and have emerged as an important part of standard of care for cancer patients. Worldwide sales of kinase inhibitors, one class of targeted therapies, exceeded $25 billion in 2018. Furthermore, patients with tumors driven by oncogene addiction typically show rapid and measurable tumor shrinkage when exposed to drugs targeting the relevant alteration. Such clinical responses can be dramatic enough in many cases to support expedited regulatory approval of these targeted therapies. Yet, a recent analysis found that only nine percent of patients with metastatic cancer have tumors with genetic profiles that could make them eligible for treatment with an approved precision oncology medicine.

Existing targeted therapies have been effective because they target genetically-defined cancers driven by a single mutation. Genetic sequencing of tumors reveals that many mutations remain uncharacterized, suggesting that there are additional mutations that can lead to oncogene addiction. In 2018, larotrectinib, or Vitrakvi, was approved for neurotrophic tropomyosin receptor kinase, or NTRK, driven cancers, making it the first drug to be developed and approved to treat a specific genetic alteration in a tissue agnostic fashion. In addition, pembrolizumab, or Keytruda, was one of the first targeted oncology treatments approved for any solid tumor based on a molecular profile, regardless of the tumor's site of origin. We believe that these approvals represent a fundamental change in the development of targeted therapies and will increasingly lead to cancer being characterized for treatment in a genetic, rather than in a tissue-specific manner.

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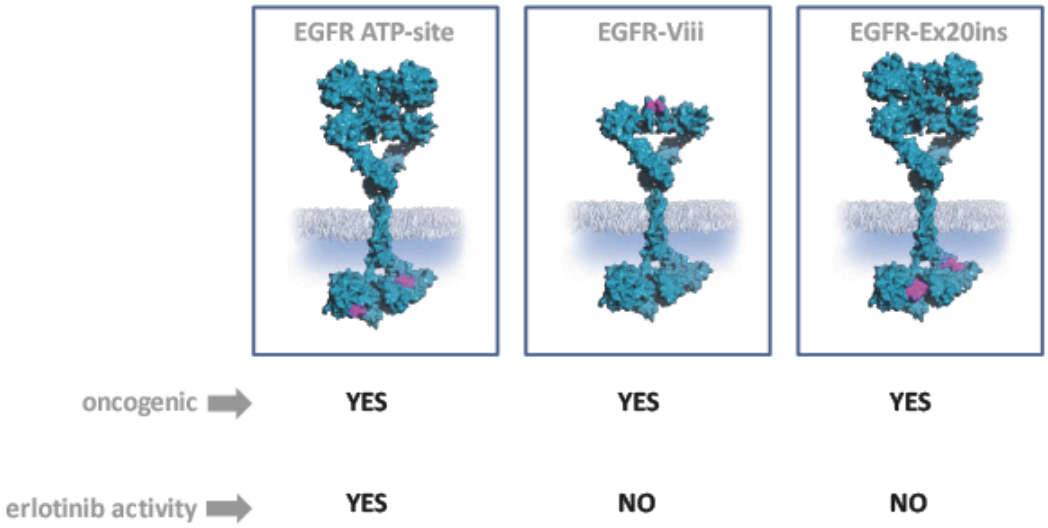
Limitations of current targeted therapies

Current targeted therapies provide clinical benefit to patients expressing the ATP-site mutations but not to patients expressing other EGFR mutations. Numerous mutations beyond active site mutations are known to the oncology clinical and research community, but those mutations are not currently targeted by approved inhibitors. While EGFR-targeted therapies, including erlotinib and osimertinib, have proven to be effective in patients with ATP-site mutations, limited response has been observed to these inhibitors when treating patients with cancers expressing other types of oncogenic EGFR mutations, including those expressed outside of the ATP site, such as EGFR exon 20 insertions and extracellular domain mutations. There remains a significant unmet medical need for new drugs that can extend precision medicines to these patients expressing non-ATP site or non-canonical mutations. The figure below depicts the oncogenic EGFR mutations, shown in magenta. These include the ATP-site mutations, EGFR exon 19 deletions and L858R (left panel), as well as an additional spectrum of mutations occurring outside of the ATP site, including EGFR-Viii (middle panel) and EGFR exon 20 insertions (right panel).



Emergence of genetic sequencing as standard of care in treating cancer

Cancer treatment is evolving rapidly and there is now widespread recognition that cancer is a disease of genetics, as much as it is a disease defined by histology or anatomical location. This shift has been driven by the increased use of genetic sequencing coupled with the availability of approved targeted therapies. The FDA has approved Foundation Medicine's comprehensive genetic profiling test FoundationOne CDx and the Centers for Medicare & Medicaid Services announced coverage of next generation genetic sequencing tests, which we believe will further drive the use of genetic testing. A recent study demonstrated that 75 percent of oncologists in the United States employ genetic sequencing. As technological advancements in genetic sequencing improve and an increasing number of targeted therapies are developed, we believe that physicians will require molecular information about their patients' cancers to determine the optimal course of treatment. Not only have advances in genetic sequencing changed the standard of care for oncology patients, they are leading to transformations in the discovery and development of oncology drugs.

We believe that genetic sequencing enables the discovery of additional targets for drug development. More than 400 cancer-associated genes are routinely sequenced, and analysis of this data has shown that mutations

are not restricted to specific regions, but rather are spread more broadly throughout entire sequences of genes. We believe that such mutations have not yet been systematically studied as potential drug targets or their oncogenic proteins targeted in drug discovery efforts, and that our ability to do so represents a significant opportunity to develop precision medicines in areas of major unmet medical need.

The Black Diamond Therapeutics approach

At Black Diamond Therapeutics, our goal is to bring precision oncology medicine to a greater number of patients. Our drug development efforts leverage our novel findings that:

- mutations throughout a gene can drive oncogenic activation and change the drug selectivity profile of their active sites;
- these oncogenic mutations can be grouped as families because they drive similar protein structural changes, and exhibit a shared selectivity profile; and
- a family of oncogenic proteins can therefore be inhibited by a single small molecule that targets the active site.

We believe we can address certain key limitations of current generation precision medicine therapies in oncology by applying our MAP platform to identify and target novel classes of oncogenic mutations. We believe this will allow us to design and develop potential therapies for patients for whom there are currently no targeted treatment options.

Our MAP platform

Our MAP platform is built on three central pillars: Discover—Reveal—Target.

Discover—identify mutations and rank for potential oncogenicity

Our discovery process begins by identifying oncogenic mutations. We use population-level cancer genetic data obtained from all tumor types, to identify potential families of mutations that occur within individual oncogenes.

We have developed unique insights into the specific structural features of a protein that are associated with oncogenic mutations. The algorithm underlying our MAP platform scores each mutation for its potential oncogenicity, which we refer to as a MAP score. This algorithm is designed to identify potential oncogenic mutations within the vast landscape of potentially insignificant mutations. We map these mutations onto the 3-dimensional structure of a protein to determine which of the many mutations expressed by human tumors occur at sites associated with oncogenicity.

For HER2 and EGFR, we observed that oncogenic mutations are distributed nearly uniformly throughout the sequence of these two genes, revealing many mutations occurring outside of the ATP site, which have not been targeted by drugs.

For example, applying our algorithm to all currently known mutations in HER2 alone reveals a subset of mutations with high MAP scores, which we believe is a predictor of oncogenicity. For the ErbB family, we observed 3,868 unique mis-sense mutations (935 mutations in EGFR, 670 mutations in HER2, 794 mutations in HER3 and 1469 mutations in HER4). These mutations are distributed throughout the target sequence. As illustrated in the figure below, we observed 670 unique mutations expressed in HER2, detected within a combined human tumor data set of approximately 70,000 cases (GENIE 5.0 and TCGA data sets). Through this

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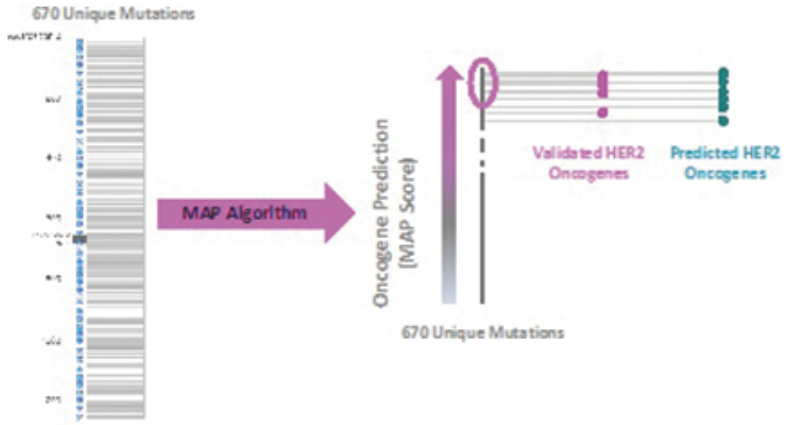
analysis, we re-identified or confirmed the known HER2 allosteric oncogenic mutations, which are the mutations that we targeted with our BDTX-189 product candidate. We also identified an additional subset of mutations with high MAP scores, and we are currently validating these putative oncogenic mutations experimentally. Our goal is to expand our targeted mutation family to potentially include this additional group of non-canonical mutations.



Our genetic sequencing analysis has identified a family of 50 non-canonical mutations in both the extracellular and kinase domains of EGFR and HER2. The figure below is a compilation of the non-canonical EGFR and HER2 oncogenic mutations that we are targeting in both of our ErbB programs. Each dot represents a unique non-canonical EGFR and HER2 oncogenic mutation found in individual tumors while the height of each dot represents the frequency at which such mutation was found. The sites of two mutations defined as canonical mutations are indicated. The frequency for EGFR oncogenic mutations expressed in glioblastoma (was calculated as relative frequency within glioblastoma. The frequency for all other EGFR and HER2 mutations was calculated relative to all solid tumors (approximately 70,000 tumors within project GENIE 5.0 / TCGA dataset). Specifically, the figure shows the prevalence of various types of alterations of EGFR expressed in glioblastoma (EGFR-Viii, EGFR-Vii, EGFR-Vvi, three mutations affecting EGFR-A289 and two mutations affecting EGFR-G598) and various types of EGFR and HER2 alterations expressed across solid tumors (two mutations affecting HER2-S310, HER2-R678Q, six unique mutations affecting HER2-L755, four unique mutations affecting HER2-V777, HER2-V842I, 46 unique mutations that are deletions within exon 19, and 28 unique mutations that are insertions within exon 20 and EGFR-L858R).

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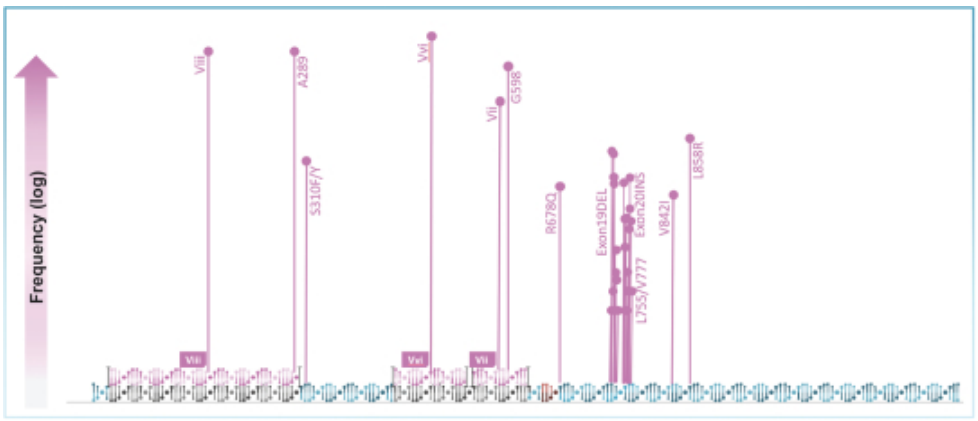
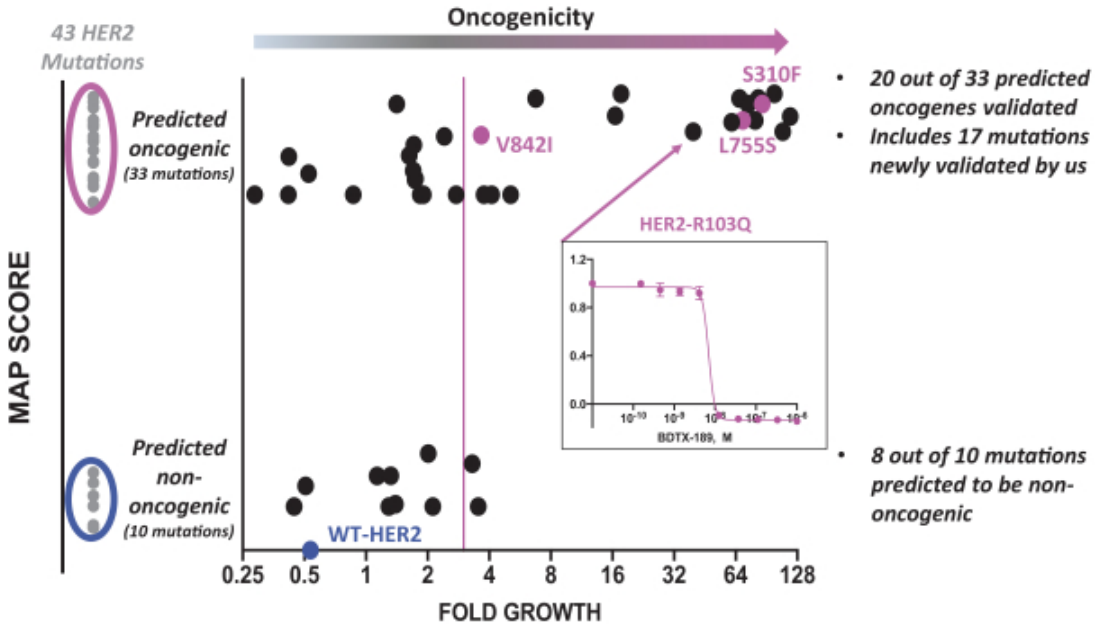


We selected 43 additional HER2 mutations to experimentally test for oncogenicity using the BaF3 transformation assay. Thirty three of the 43 mutations tested had high MAP scores and were therefore predicted to have oncogenic behavior, while ten of the 43 mutations had low MAP scores and were therefore not predicted to be oncogenic. In this screen, we also tested wild type HER2 and three HER2 mutations that we had already observed to have oncogenic behavior. Wild type HER2 was unable to transform BaF3 cells to IL-3 independent proliferation, while all three validated HER2 oncogenic mutations (HER2-V842I, L755S and S310F) successfully transformed cells, as evidenced by greater than three-fold proliferation over a seven day period. Of the 33 mutations with high MAP scores that were predicted to be oncogenic, 17 were transformative. In contrast, among the group of mutations with low MAP scores that were not predicted to have oncogenic behavior, only three transformed BaF3 cells to proliferate greater than three fold over seven days. We found newly-characterized mutations to be sensitive to BDTX-189, as evidenced below with potent inhibition of proliferation against cells transformed by the HER2-R103Q mutation.



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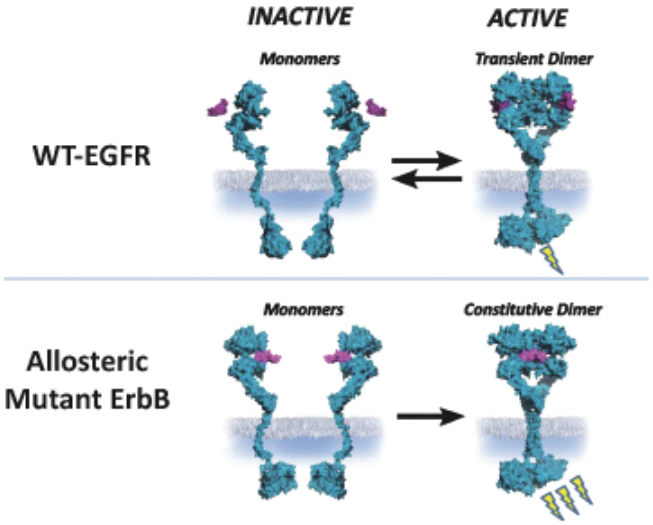
Reveal—understanding the mechanism for oncogenic activation

We evaluate the oncogenicity of these mutations occurring outside of the ATP site, which have not been targeted and use our preclinical models to reveal how mutations drive protein conformation change to promote oncogenicity. Furthermore, we use these models to determine whether the drug sensitivity profile, or pharmacology, of the ATP site is altered. We use this information to group mutations into oncogene families that share a similar ATP site pharmacology. The drug selectivity patterns of mutant EGFR and HER2 kinases provide evidence of unique conformational states driven by mutation. As illustrated in the figure below, dimerization is required for receptor activation, an important step in oncogenic signaling. In wild type EGFR, the binding of a ligand to the extracellular domain promotes an active dimer conformation. In the case of wild type EGFR, this is a transient dimer conformation. We have discovered that a family of EGFR and HER2 mutations activate these kinases and promote oncogenicity by stabilizing the kinase in a unique constitutive dimer conformation. Importantly, the constitutive dimer conformation results in a change in selectivity for drugs which bind to the ATP site, potentially reducing the effectiveness of currently approved targeted therapies, such as erlotinib.



The protein conformation for the active form of allosteric mutant ErbB receptors is unique from the conformation of wild type EGFR. Wild type EGFR is inactive in its monomeric form, and activated upon the binding of an EGF ligand (shown in dark purple) to the extracellular domain, forming an active transient dimer conformation. Allosteric ErbB mutations (highlighted in magenta in this example) can promote a constitutive dimer conformation which has high activity and is oncogenic.

Target—develop mutation spectrum-selective drugs to our targets

Our team of experienced medicinal chemists seek to design and identify small molecules that bind to the active site and inhibit the target only when it is in the unique conformation promoted by the non-canonical oncogenic mutations we identified. Using a multidimensional medicinal chemistry lead identification and optimization strategy and leveraging our proprietary know-how in drug design, we aim to identify small molecules with bespoke selectivity against the entire desired spectrum of mutations as a family, while at the same time sparing inhibition of the wild-type form of the protein or other unwanted targets.

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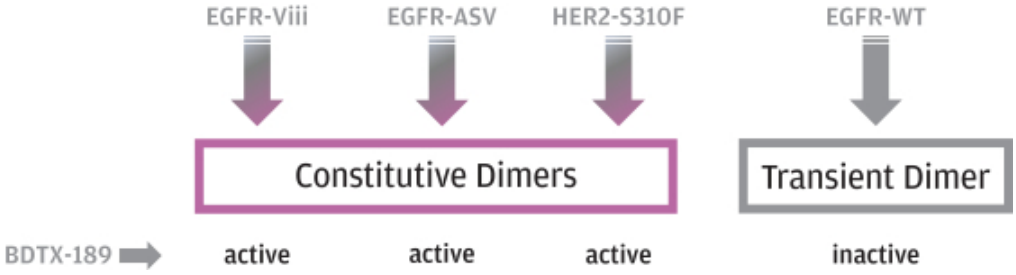
We utilized the cell and tumor models developed under our “Reveal” pillar as biological screens which recapitulate the tumor biology for these mutations. We used these models to identify our ErbB clinical candidate, BDTX-189. BDTX-189 binds to the ATP-site to inhibit the constitutive dimer in a family of EGFR and HER2 mutations, while at the same time sparing inhibition of the normal wild type EGFR. We have validated the activity for BDTX-189 against the most commonly occurring mutations representing each of these types of mutations (HER2-S310F, HER2-R678Q, HER2-L755S, HER2-V777L, HER2-V842I, the EGFR Exon 20 insertions EGFR-ASV/SVD/NPH/FQEA, the HER2 Exon 20 insertions HER2-YVMA/GSP, the EGFR Exon 19 deletion EGFR-746-750, and EGFR-L858R).



Our product candidates and development programs

We are leveraging our MAP platform to develop a drug pipeline of orally available, potent and spectrum-selective small molecule kinase inhibitors that target genetic drivers in several cancers. We own worldwide commercial rights to all of our product candidates.

BDTX-189: An inhibitor of non-canonical mutations and additional oncogenic drivers of ErbB

Overview

Allosteric ErbB mutations are found in one to two percent of a large variety of solid tumors but are overexpressed in tumors such as advanced NSCLC, invasive breast, bladder and endometrial cancer, where incidence ranges from two to eight percent. Currently available EGFR and HER2 tyrosine kinase inhibitors or monoclonal antibodies have limited or no anti-tumor activity against these genetic alterations due to insufficient potency or lack of selectivity, which results in toxicity before adequate exposures can be achieved. There remains a significant unmet medical need for new drugs that can extend targeted therapies to patients expressing non-canonical mutations outside of the ATP site.

BDTX-189 is designed to be an orally available irreversible, small molecule inhibitor that targets undrugged oncogenic driver mutations of ErbB kinases in HER2 and EGFR. These include extracellular domain allosteric mutations of HER2, as well as EGFR and HER2 kinase domain exon 20 insertions, and additional activating oncogenic drivers of ErbB. Currently, there are no FDA approved drugs that targets all of these mutations with a single small molecule therapy. We are completing IND-enabling activities for BDTX-189 and plan to start a combined Phase 1/2 clinical trial in the first half of 2020. As part of our IND-enabling studies for BDTX-189, we have conducted GLP safety pharmacological and toxicological studies of BDTX-189 in laboratory animals. We believe that the results of these studies to-date suggest that BDTX-189 has an acceptable safety profile for the conduct of our planned Phase 1/2 trial. The results of these studies have also informed our selection of a starting dose for testing in humans. The Phase 1 portion of the trial is expected to evaluate escalating doses of BDTX-189 and is designed to determine the recommended Phase 2 dose and to assess preliminary indications of anti-tumor activity. The open-label Phase 2 portion is expected to determine the objective response rate, or ORR, and duration of response in patients with solid tumors that have an allosteric HER2 mutation, or EGFR or

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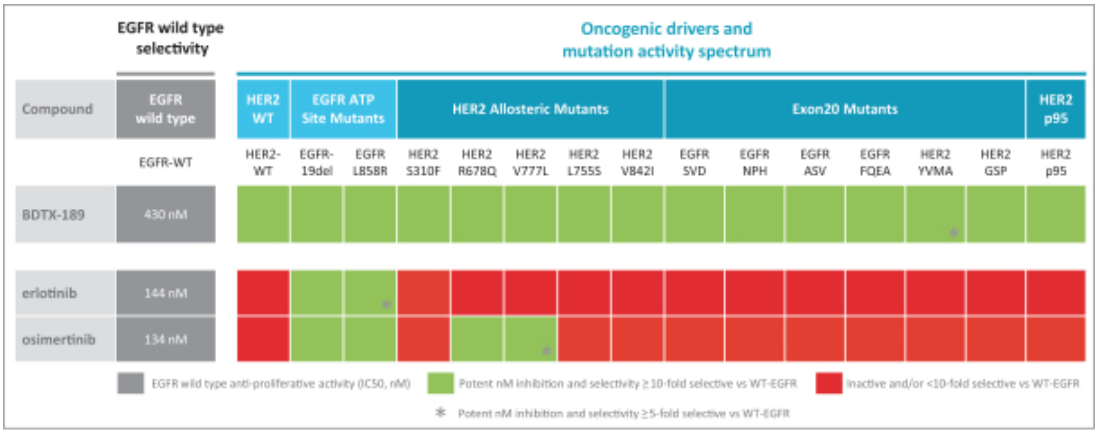
HER2 exon 20 insertion mutation using NGS, or next-generation sequencing. Depending on results from the Phase 1/2 trial, we anticipate that, subject to discussions with FDA, we may either expand the Phase 2 portion of the trial or initiate a second Phase 2 trial in order to pursue an accelerated approval, if available, of BDTX-189 for patients with mutations of the ErbB family across one or more solid tumor types as a tumor agnostic indication.

The figure below shows the selectivity pattern for BDTX-189 for non-canonical oncogenic mutations and additional oncogenic drivers of ErbB (with wild type for reference) as well as comparable data for erlotinib and osimertinib (each as determined by measuring 50 percent inhibition, or IC50, values). The data in the figure below were generated through head-to-head comparisons of BDTX-189 to erlotinib and osimertinib. We conducted the head-to-head comparisons by determining the *in vitro* anti-proliferative activity for each molecule against a panel of cell lines, which included BaF3 transformants for various EGFR and HER2 mutations, patient-derived cell lines expressing EGFR mutations and cells expressing either wild type EGFR or wild type HER2. The head-to-head comparisons were conducted under the same experimental conditions for each molecule.

BDTX-189 potently inhibited the proliferation of BaF3 cells transformed by allosteric EGFR mutations and allosteric HER2 mutations when evaluated *in vitro*. BDTX-189 additionally inhibited the proliferation of lung cancer patient-derived cells expressing EGFR exon 20 insertions (CUTO-14 and CUTO-17 cell lines), and human tumor cells expressed amplified wild type HER2 (BT-474 cells). BDTX-189 further inhibited the proliferation of BaF3 cells transformed by EGFR ATP-site mutations, including the EGFR exon 19 deletion E745-750 and EGFR-L858R, and extracellular domain EGFR mutations, including EGFR-Viii, when evaluated *in vitro*. In each case, BDTX-189 inhibits the targeted ErbB mutation more potently than wild type EGFR.



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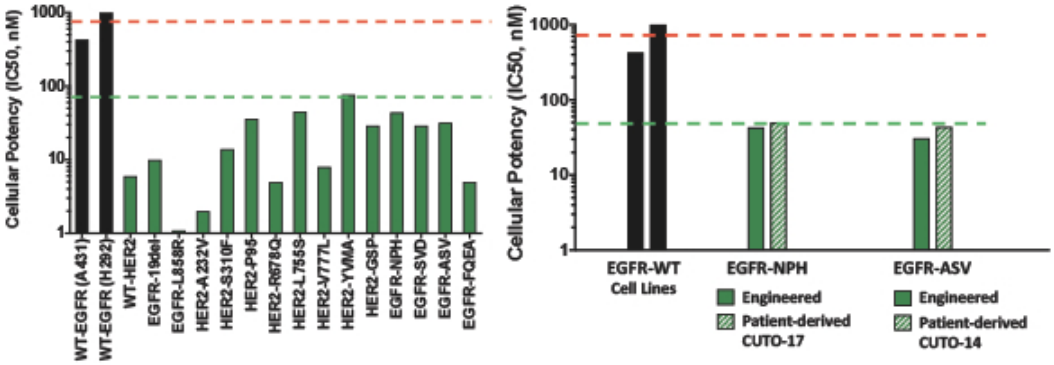
As shown in the figure below, BDTX-189 has been observed to inhibit the proliferation of BaF3 cells transformed by many oncogenic EGFR and HER2 mutants, with selectivity versus cells expressing the normal wild type EGFR (A431 and H292) (left chart). Cellular potency, or anti-proliferative IC50, was determined by measuring the effect of various concentrations on the proliferation of cells over a 72-hour time period. BDTX-189 also inhibited the proliferation of both BaF3 transformants (engineered cell lines) and patient derived cell lines expressing the EGFR Exon 20 insertion mutants EGFR-NPH and EGFR-ASV (right chart).



A favorable therapeutic window over wild type EGFR was a key design goal in the ErbB program. BDTX-189 achieved high selectivity for cells expressing the targeted allosteric EGFR and HER2 mutants and the compound spares cells expressing wild type EGFR (A431 and H292).

We believe BDTX-189 has an excellent kinome selectivity profile, as determined using the DiscoverX KINOMEscan methodology testing 468 kinases. BDTX-189 exhibited binding affinity for the isolated kinase domains of EGFR and HER2 of less than 1nM. All but seven kinases outside of the ErbB family showed no or very poor binding when BDTX-189 was tested at a single concentration of 100nM, with selectivity determined to be greater than 200-fold. The selectivity for ErbB kinases versus a small subset of kinases (BLK, BTK, LCK, LOK, MEK5, and YES) was determined to be greater than 10-fold. The only kinase that was bound with less than 10-fold selectivity is RIPK2, and this activity is not expected to be dose limiting.

In preclinical animal models, BDTX-189 was observed to have high potency and fast irreversible inactivation of the desired mutations. BDTX-189 displayed a favorable pharmacokinetic profile with fast absorption, good exposure and subsequent swift elimination, together with the drug's rapid irreversible target inhibition. As illustrated in the figures below, BDTX-189 was observed to be well suited to engage and inactivate the allosteric ErbB mutants *in vivo*. In acute dose pharmacokinetic/pharmacodynamic, or PK/PD, studies, oral administration of BDTX-189 to athymic nude mice bearing a range of HER2-S310F, EGFR-Viii (both BaF3 and GBM6 patient derived glioblastoma tumors) or HER2-YVMA BaF3 allograft tumors resulted in potent and sustained suppression of target phosphorylation for at least 24 hours following dosing.

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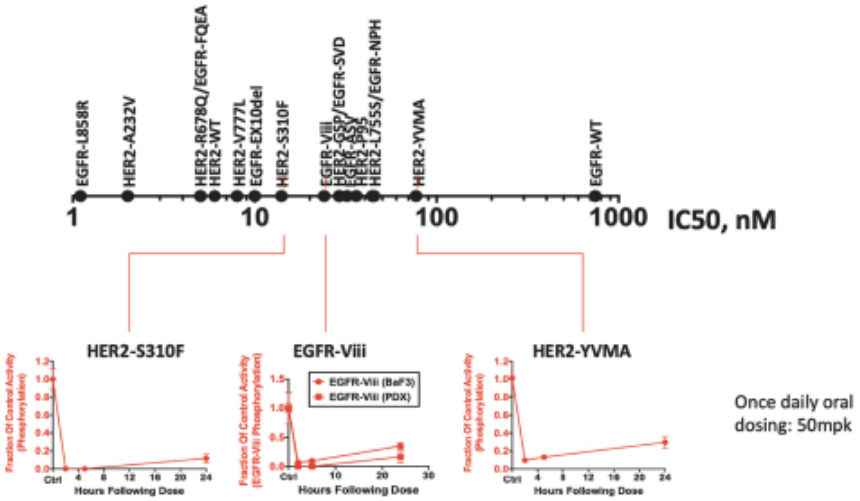
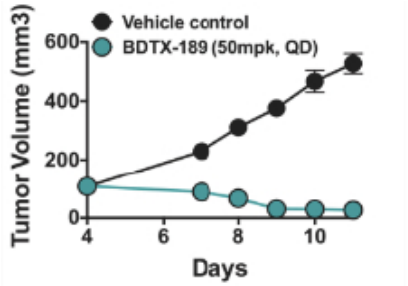
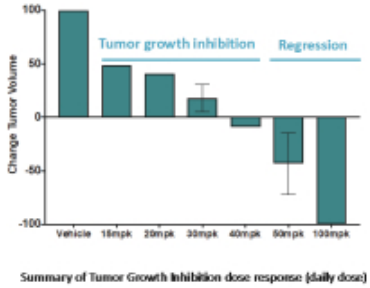


BDTX-189 inhibits the activity across a range of EGFR and HER2 mutants in vivo (50mpk QD acute oral dosing), including mutants with a range of in vitro IC50 values.

BDTX-189 has been observed to exhibit anti-tumor activity against allosteric HER2 mutant tumors, evidenced by both potent tumor growth inhibition and regression. Daily dosing of BDTX-189 was well tolerated in athymic nude mice bearing HER2-S310F BaF3 allograft tumors up to 100mg/kg. BDTX-189 demonstrated dose-dependent tumor growth inhibition (median tumor volume) at daily doses ranging from 15 mg/kg to 100 mg/kg. BDTX-189 also demonstrated dose-dependent tumor regression at doses ranging from 30 mg/kg to 100 mg/kg.





We used a PK/PD analysis of the HER2-S310F BaF3 allograft tumor inhibition studies to assess the PK/PD driver for efficacy using different doses and dose regimens to project expected human exposures to be associated with anti-tumor activity.

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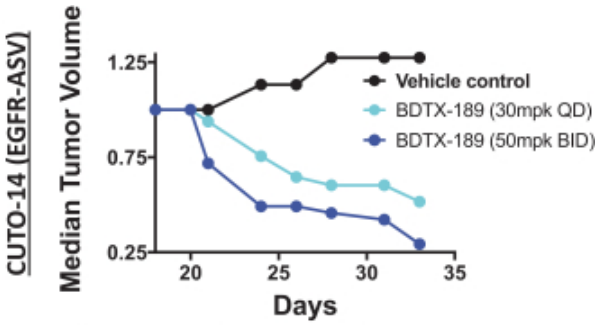
BDTX-189 has also been observed to exhibit anti-tumor activity in athymic nude mice bearing patient derived xenografts, or PDX, expressing allosteric EGFR exon 20 insertion mutants. BDTX-189, administered at a daily oral dose of 30mpk or 50mpk, demonstrated growth regression of CUTO-14 PDX tumors that express the EGFR mutation EGFR-ASV.



	Dose	% Regression
BDTX-189	50mpk BID	71%
	30mpk QD	48%

Clinical development plan

We are currently completing IND-enabling studies and plan to start a combined Phase 1/2 clinical trial in the first half of 2020. We intend to pursue a tumor agnostic development strategy. We have designed the initial study to be a combined Phase 1/2 clinical trial which is intended to allow a seamless transition from the Phase 1 dose-escalation portion into a Phase 2 portion to expedite development of this product candidate. The Phase 1 portion is designed to evaluate multiple ascending oral doses of BDTX-189 to assess the safety, tolerability and pharmacokinetic profile in order to determine the recommended Phase 2 dose. We have designed our Phase 1 portion to allow for greater flexibility and precision to determine the appropriate dose for further clinical evaluation. The Phase 1 trial is a two-step process where step one is a single-patient cohort, accelerated dose-escalation process until grade 2 drug-related adverse events are observed. Step 2 is designed to provide the flexibility to enroll three or more patients, which is intended to allow evaluation of drug tolerability as well as enrollment of patients with allosteric ErbB mutations at relevant exposures to evaluate early anti-tumor proof-of-concept. The study is planned to primarily evaluate once daily dosing, but may also assess more frequent dosing schedules, such as twice daily, if the drug pharmacology or patient tolerability suggest this could be a better approach. In the Phase 1 portion, we plan to enroll up to 80 patients with advanced or metastatic solid tumors for whom no standard therapy is available or for whom standard therapy is considered unsuitable or intolerable, as determined by the investigator. In the Phase 1 portion, we plan to enroll patients with solid tumors that have alterations that may be associated with BDTX-189 anti-tumor activity based on preclinical data such as allosteric HER2 or HER3 mutation, EGFR/HER2 exon 20 insertion mutation, HER2 amplified/overexpressing tumor, EGFR exon 19 deletion or L858R mutation. We are targeting completion of the Phase 1 dose-escalation portion by the first half of 2021. Preliminary efficacy data from Phase 1 patients with targeted allosteric mutations may further inform the optimal population for the Phase 2 portion of the trial.

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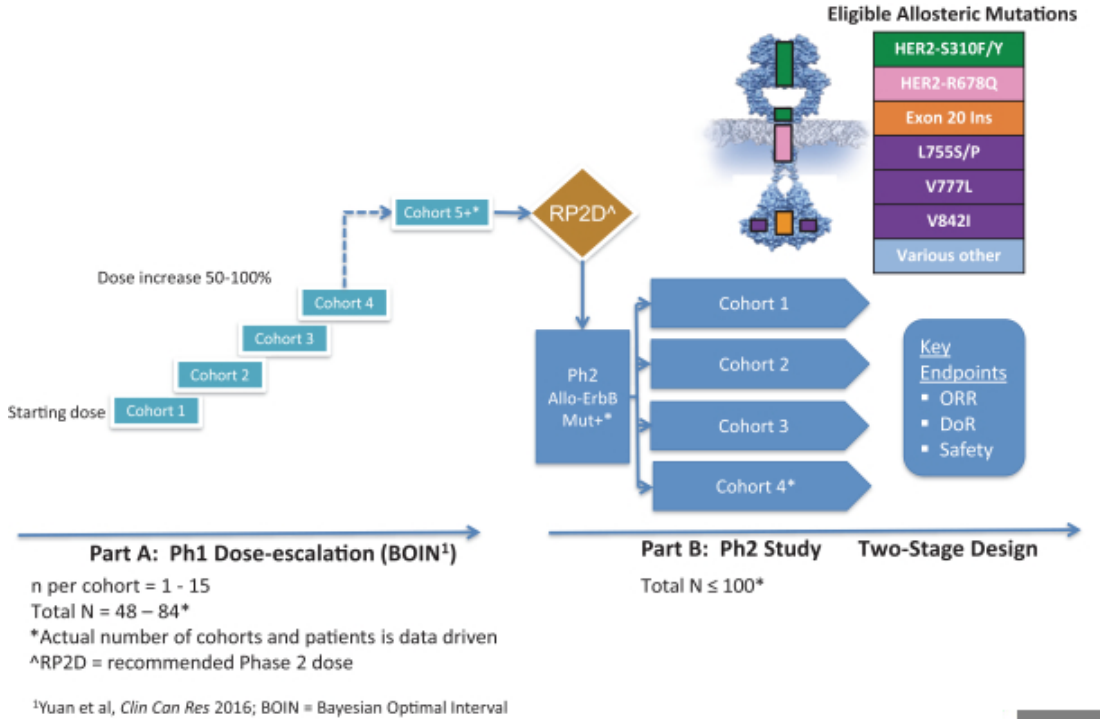
The open-label Phase 2 portion is expected to enroll up to 100 patients in multiple cohorts with solid tumors that have allosteric HER2 mutations, or EGFR or HER2 exon 20 insertion mutations confirmed using NGS, or next-generation sequencing. The patient population will already have been treated with standard approved cancer therapies and have either relapsed or failed to respond to those therapies. To be enrolled, patients must also be willing to provide tumor tissue for confirmatory mutation testing in order to facilitate our development of a companion diagnostic test. We expect to enroll a population with a variety of different advanced or metastatic cancers including lung, breast, colon, bladder, endometrial, and many other solid tumors. The planned primary objective of the Phase 2 portion is to determine the anti-tumor activity of BDTX-189 in patients preselected with allosteric ErbB mutations and evaluate this in each of the cohorts.



If the combined efficacy data from the Phase 1 and 2 portions of the trial show adequate anti-tumor activity across the mutation spectrum and tumor types, we anticipate that we may either expand the Phase 2 portion or initiate a second Phase 2 trial in order to pursue an accelerated approval path, if available, with the FDA for a tumor agnostic indication similar to the precedent established by Keytruda in MSI-high/dMMR cancers and Vitrakvi or entrectinib, or Rozlytrek, in NTRK fusions cancers. A larger sample size may be needed for some mutations and/or tumor types to achieve this goal. Our regulatory strategy includes periodic dialogue with the FDA regarding the study design, patient population, study endpoint and companion diagnostic strategy for the BDTX-189 development program. For example, we submitted a pre-IND meeting request to FDA and received written feedback from the FDA regarding our nonclinical plan and the proposed patient population, patient selection criteria and study endpoints for the planned Phase 1/2 trial for BDTX-189. We believe that objective response rate, or ORR, and duration of response combined with a favorable safety profile may, subject to discussions with FDA, support filing for accelerated approval provided we can obtain data from a sufficiently large sample size across the mutation spectrum and tumor types. While an accelerated approval path cannot be guaranteed, if we obtain accelerated approval based on the outlined plan, FDA will still require the conduct of a post-approval study to confirm clinical benefit. Should the anti-tumor activity in certain subgroups be

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inadequate to support further development, we may not pursue the broader tumor agnostic population and instead limit enrollment to patients with tumor types and/or mutations that appear to derive the greatest clinical benefit. We believe, subject to discussion with FDA, that this may be achieved by either amending the Phase 2 portion of the planned study or opening a separate pivotal Phase 2 study to support accelerated approval. We may also seek Fast Track or Breakthrough Therapy designation by the FDA. We plan on using one of the existing FDA-approved companion diagnostic tests which already include the allosteric ErbB mutations of interest to identify patients or to collaborate with a partner on development of a new test.

BDTX-189 has demonstrated *in vitro* activity against the canonical activating EGFR mutations (exon 19 deletion and L858R mutation), as well as potent HER2 wild-type activity, or HER2-positive. We continue to evaluate BDTX-189's activity in areas where we believe there may be additional opportunities.

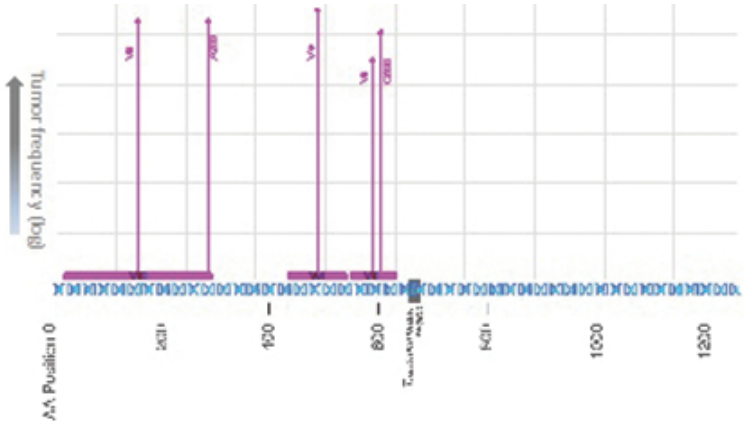
Glioblastoma program: Allosteric-EGFR mutation inhibitors

Overview

According to the National Cancer Institute, there were an estimated 24,000 new cases of brain cancer in the United States in 2018. Fifteen percent of patients with brain cancer have glioblastoma, a particularly aggressive form, and most of those patients die within 15 months of diagnosis.

Almost 50 percent of glioblastoma tumors express one or more allosteric EGFR mutations that affect the extracellular region of the receptor kinase and promote oncogenic activation. These include large deletions of portions of the extracellular domain, including the mutants EGFR-Viii, EGFR-Vvi, and EGFR-Vii. These also include any one of a number of short variant, single amino acid substitutions affecting the extracellular domain, the most common of which are substitutions at position A289. These mutants are constitutively activated, exhibit sustained signaling that is resistant to downregulation, and are both transforming and tumorigenic. Their expression has been associated with metastasis and with poor long term overall survival.

EGFR oncogenic mutations are expressed throughout the target sequence. The figure below shows the frequency for EGFR oncogenic mutations expressed in glioblastoma (EGFR-Viii, EGFR-Vii, EGFR-Vvi, EGFR-G598 mutations, EGFR-A289V mutations) which was calculated as relative frequency within glioblastoma (Brennan et al Cell 2013). Each dot represents a unique oncogenic mutation found in individual tumors and the height of each dot represents the frequency with which it was found. A given glioblastoma tumor may co-express multiple different EGFR oncogenic mutations. Therefore we believe a critical challenge to overcome in drug discovery and clinical development of targeted therapies is to develop precision medicines for GBM to efficiently block the oncogenic activity of all of these various allosteric-EGFR species.



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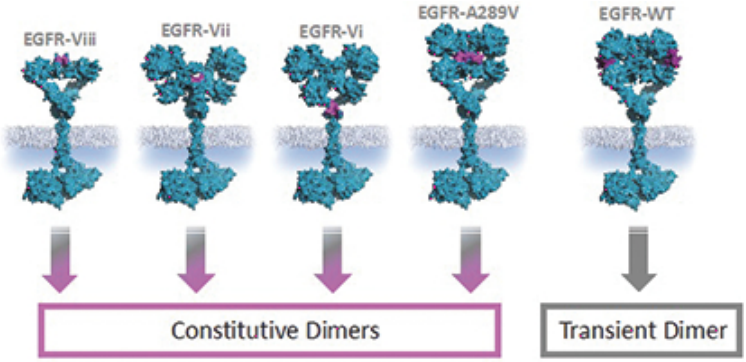
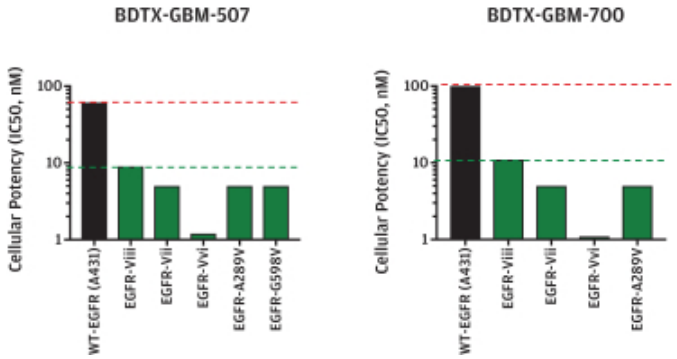
We have shown that the mechanism of activation for these EGFR mutants requires formation of a covalent dimer, which is always active, also known as a constitutive dimer. The formatting of these constitutive dimers is essential for oncogenicity. No current generation EGFR-directed therapy has thus proved effective in treating patients that express these mutations. We believe this is due to (i) inability to inhibit the entire group of allosteric glioblastoma mutations expressed in a given tumor, (ii) the inability to target the constitutive dimer conformation and (iii) poor brain penetration. The figure below illustrates distinct allosteric EGFR oncogenic mutations (EGFR-Viii, EGFR-Vii, EGFR-Vi, EGFR-A289V) that similarly promote a constitutive dimer conformation, which is different from the transient dimer conformation for wild type EGFR. For mutants, the region surrounding each mutation site is highlighted in magenta. For wild type EGFR, bound EGF ligand in shown in dark purple.

4 unique EGFR mutants share a unifying constitutive dimer conformation



We have applied our platform and our proprietary chemistry know-how to design and develop potent and selective inhibitors targeting a group of glioblastoma constitutive dimer EGFR mutations described above.

We have identified several orally available, irreversible small molecule inhibitors, including BDTX-GBM-507 and BDTX-GBM-700, as development candidate lead molecules that have been observed to potently inhibit the group of extracellular domain allosteric mutants, as illustrated in the figure below, that form the constitutive dimer conformation. Importantly, these development candidate leads have not been observed to potently inhibit the transient dimer conformation for the wild type EGFR. Our glioblastoma development candidate leads were optimized to achieve brain penetration in preclinical PK studies. For example, a lead compound also demonstrated good brain penetration in mouse PK studies with a favorable total brain-to-plasma ratio.



BDTX-GBM-507 and BDTX-GBM-700 have been observed in vitro to inhibit the proliferation of BaF3 cells transformed by EGFR mutants expressed in glioblastoma tumors, with selectivity versus cells expressing the normal wild type EGFR (A431 cells). Cellular IC50 values are shown.

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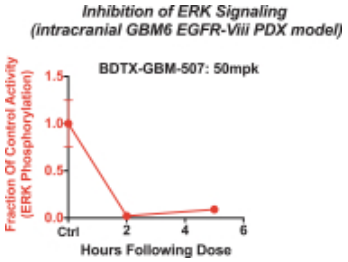
We evaluated activity of our development candidate leads against glioblastoma EGFR mutants *in vivo*. Acute oral dosing of lead molecule BDTX-GBM-507 in athymic nude mice bearing intracranial patient derived glioblastoma tumors (GBM6) showed effective suppression of ERK phosphorylation.



BDTX-GBM-507, administered orally at 50mpk to athymic nude mice bearing intracranial GBM6 patient derived xenografts expressing EGFR-Viii, was observed to result in inhibition of ERK signaling in tumor.

We are completing preclinical characterization our glioblastoma candidate leads and plan to nominate a development candidate in 2020.

Early-stage programs

We are applying our MAP platform to the analysis of the mutation landscape of more than 300 genes, including 92 kinases within Foundation Medicine's FoundationOne CDx test panel. Of these 92 kinases, we applied our MAP scoring algorithm to six kinases, including all ErbB family members, other RTKs (FGFR3) and a non-receptor kinase (BRAF). We are advancing several early programs focused on targeting a range of driver mutations, including allosteric activating mutations. We believe these general principles also apply to targets associated with diseases outside of oncology. We are currently evaluating additional groups of targets, including allosteric FGFR3 mutations and allosteric BRAF mutations, among others, for drug discovery. As part of our on-going efforts to leverage our know-how regarding mutations in the ErbB family, we also continue to investigate novel potent and selective compounds directed against this family of targets.

Our collaboration with Ridgeline Therapeutics

During our initial years of operation, we built and conducted our research and development activities via a collaborative model with Ridgeline Therapeutics GmbH, or Ridgeline, a wholly-owned subsidiary of Versant Ventures, our largest shareholder. Ridgeline is a company incubator and discovery engine of Versant focused on providing drug discovery expertise. By leveraging Ridgeline's deep experience in the areas of discovery, drug design and medicinal chemistry together with our biology expertise, we were able to accelerate the discovery and development of spectrum selective and highly potent small molecule inhibitors targeting the oncogenic driver mutations in our lead programs. Alexander Mayweg, one of our founders and a member of our board of directors, is a managing director of Ridgeline and a partner of Versant, and Fang Ni, our former interim Chief Business Officer, is a principal of Versant.

We entered into a services agreement with Ridgeline in March 2017, amended in November 2017 and December 2018. BDTX-189, our lead product candidate for which we are completing IND-enabling studies, as well as the lead compounds for our glioblastoma program have been developed under this collaboration with Ridgeline. All results, inventions, and products and any related intellectual property arising from services provided by Ridgeline are owned by us. In consideration for the services provided under the agreement, we pay Ridgeline $950,000 a month, which is reconciled on a quarterly basis with actual expenses incurred by Ridgeline on our behalf and a corresponding reconciling payment is made by us to (or received by us from) Ridgeline each quarter. Certain executives and employees of Ridgeline have also received equity grants from the Company. No milestone or

royalty payments are owed to Ridgeline. The Ridgeline services agreement has a one-year term and automatically renews for successive one-year terms unless either we or Ridgeline elect to terminate the agreement.

During 2019 we continued to build our internal chemistry, manufacturing and controls, biology and preclinical development capabilities through key additional hires to assume activities conducted by Ridgeline on our behalf and expect to transition from our current service model to a more limited consulting arrangement with Ridgeline by 2020.

Competition

Our industry is intensely competitive and subject to rapid and significant technological change. While we believe that our knowledge, experience and scientific resources provide us with competitive advantages, we face substantial competition from major pharmaceutical companies and biotechnology companies worldwide. Many of our competitors have significantly greater financial, technical and human resources. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. As a result, our competitors may discover, develop, license or commercialize products before or more successfully than we do.

We face competition with respect to our current product candidates, and will face competition with respect to future product candidates, from segments of the pharmaceutical, biotechnology and other related markets that pursue targeted therapies for patients with undrugged, genetically-defined cancers. For example, a number of biopharmaceutical companies, including Loxo Oncology, Inc. (recently acquired by Eli Lilly and Company), Blueprint Medicines Corporation, Spectrum Pharmaceuticals, Inc., Deciphera Pharmaceuticals, Inc., Turning Point Therapeutics, Inc. and Mirati Therapeutics, Inc., are developing precision medicines. If BDTX-189 or our future product candidates do not offer sustainable advantages over competing products, we may otherwise not be able to successfully compete against current and future competitors.

Our competitors may obtain regulatory approval of their products more rapidly than we may or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than us in manufacturing and marketing their products.

In addition, we will likely need to develop our product candidates in collaboration with diagnostic companies, and we will face competition from other companies in establishing these collaborations. Our competitors will also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Furthermore, we also face competition more broadly across the market for cost-effective and reimbursable cancer treatments. The most common methods of treating patients with cancer are surgery, radiation and drug therapy, including chemotherapy, hormone therapy and targeted drug therapy or a combination of such methods. There are a variety of available drug therapies marketed for cancer. In many cases, these drugs are administered in combination to enhance efficacy. While our product candidates, if any are approved, may compete with these existing drug and other therapies, to the extent they are ultimately used in combination with or as an adjunct to these therapies, our product candidates may not be competitive with them. Some of these drugs are branded and subject to patent protection, and others are available on a generic basis. Insurers and other third-party payors may also encourage the use of generic products or specific branded products. We expect that if our product candidates are approved, they will be priced at a significant premium over competitive generic, including branded generic, products. As a result, obtaining market acceptance of, and a gaining significant share of the market for, any of our product candidates that we successfully introduce to the

market will pose challenges. In addition, many companies are developing new therapeutics, and we cannot predict what the standard of care will be as our product candidates progress through clinical development.

The acquisition or licensing of pharmaceutical products is also very competitive. If we seek to acquire or license products, we will face substantial competition from a number of more established companies, some of which have acknowledged strategies to license or acquire products and many of which are bigger than us and have more institutional experience and greater cash flows than we have. These more established companies may have competitive advantages over us, as may other emerging companies taking similar or different approaches to product licenses and/or acquisitions. In addition, a number of established research-based pharmaceutical and biotechnology companies may acquire products in late stages of development to augment their internal product lines, which may provide those companies with an even greater competitive advantage.

Manufacturing

We do not have any manufacturing facilities or personnel. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates undergoing preclinical testing, as well as for clinical testing if our IND for BDTX-189 is accepted and commercial manufacture if our product candidates receive marketing approval.

All of our drug candidates are small molecules and are manufactured in synthetic processes from available starting materials. The chemistry appears amenable to scale up and does not currently require unusual equipment in the manufacturing process. We expect to continue to develop product candidates that can be produced cost-effectively at contract manufacturing facilities.

We generally expect to rely on third parties for the manufacture of companion diagnostics for our products, which are assays or tests to identify an appropriate patient population. Depending on the technology solutions we choose, we may rely on multiple third parties to manufacture and sell a single test.

Commercialization

Subject to receiving marketing approvals, we expect to commence commercialization activities by building a focused sales and marketing organization in the United States to sell our products. We believe that such an organization will be able to address the community of oncologists who are the key specialists in treating the patient populations for which our product candidates are being developed. Outside the United States, we expect to enter into distribution and other marketing arrangements with third parties for any of our product candidates that obtain marketing approval.

We also plan to build a marketing and sales management organization to create and implement marketing strategies for any products that we market through our own sales organization and to oversee and support our sales force. The responsibilities of the marketing organization would include developing educational initiatives with respect to approved products and establishing relationships with researchers and practitioners in relevant fields of medicine.

Intellectual property

We seek to protect the intellectual property and proprietary technology that we consider important to our business, including by pursuing patent applications that cover our product candidates and methods of using the same, as well as any other relevant inventions and improvements that are considered commercially important to the development of our business. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position. Our commercial success depends, in part, on our ability to obtain, maintain, enforce and protect our intellectual property and other

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proprietary rights for the technology, inventions and improvements we consider important to our business, and to defend any patents we may own or in-license in the future, prevent others from infringing any patents we may own or in-license in the future, preserve the confidentiality of our trade secrets, and operate without infringing, misappropriating or otherwise violating the valid and enforceable patents and proprietary rights of third parties.

As with other biotechnology and pharmaceutical companies, our ability to maintain and solidify our proprietary and intellectual property position for our product candidates and technologies will depend on our success in obtaining effective patent claims and enforcing those claims if granted. However, our pending provisional and PCT patent applications, and any patent applications that we may in the future file or license from third parties, may not result in the issuance of patents and any issued patents we may obtain do not guarantee us the right to practice our technology in relation to the commercialization of our products. We also cannot predict the breadth of claims that may be allowed or enforced in any patents we may own or in-license in the future. Any issued patents that we may own or in-license in the future may be challenged, invalidated, circumvented or have the scope of their claims narrowed. For example, we cannot be certain of the priority of inventions covered by pending third-party patent applications. If third parties prepare and file patent applications in the United States that also claim technology or therapeutics to which we have rights, we may have to participate in interference proceedings in the USPTO to determine priority of invention, which could result in substantial costs to us, even if the eventual outcome is favorable to us, which is highly unpredictable. In addition, because of the extensive time required for clinical development and regulatory review of a product candidate we may develop, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby limiting the protection such patent would afford the respective product and any competitive advantage such patent may provide.

The term of individual patents depends 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 most countries, including the United States, the patent term is 20 years from the earliest filing date of a non-provisional patent application. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier filed patent. The term of a patent claiming a new drug product may also be eligible for a limited patent term extension when FDA approval is granted, provided statutory and regulatory requirements are met. The restoration period granted on a patent covering a product is typically one-half the time between the effective date of a clinical investigation involving human beings is begun and the submission date of an application, plus the time between the submission date of an application and the ultimate approval date. 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. Only one patent applicable to an approved product is eligible for the extension, and only those claims covering the approved product, a method for using it, or a method for manufacturing it may be extended. Additionally, the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The United States Patent and Trademark Office reviews and approves the application for any patent term extension or restoration in consultation with the FDA. In the future, if our product candidates receive approval by the FDA, we expect to apply for patent term extensions on any issued patents covering those products, depending upon the length of the clinical studies for each product and other factors. There can be no assurance that our pending provisional or PCT patent applications will issue or that we will benefit from any patent term extension or favorable adjustments to the terms of any patents we may own or in-license in the future. In addition, 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

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validity and enforceability of the patent. Patent term may be inadequate to protect our competitive position on our products for an adequate amount of time.

We currently do not own or in-license any issued patents or non-provisional patent applications with respect to BDTX-189, our MAP platform or our Glioblastoma program, and our intellectual property portfolio is in its very early stages. We do not currently own or in-license any issued patents or provisional or non-provisional patent applications covering our other product candidates or technology.

BDTX-189

As of October 30, 2019, we own one Patent Cooperation Treaty, or PCT, patent application that covers the composition of matter for BDTX-189, as well as methods of using and making BDTX-189. Any U.S. or foreign patent issued from this PCT patent application would be scheduled to expire in 2039, excluding any additional term for patent term adjustment or patent term extension, and assuming national phase entries are timely made based upon the pending PCT application and payment of all applicable maintenance or annuity fees.

MAP platform

As of October 30, 2019, we own one U.S. provisional patent application that covers our MAP platform and the use thereof in developing and applying therapeutics. We are continuing to assess whether we will convert this U.S. provisional patent application into a non-provisional patent application and ultimately seek patent protection for our MAP platform, or instead maintain the intellectual property described in this provisional patent application as a trade secret. Any U.S. or foreign patent issued from this U.S. provisional patent application would be scheduled to expire in 2040, excluding any additional term for patent term adjustment or patent term extension.

Glioblastoma program

As of October 30, 2019, we own one U.S. provisional patent application that covers our glioblastoma program, which is directed to the composition of matter for the drug candidates of the program, analogs thereof, as well as methods of using and making these compounds. Any U.S. or foreign patent issued from this U.S. provisional patent application would be scheduled to expire in 2040, excluding any additional term for patent term adjustment or patent term extension.

Prosecution for these patent applications has not commenced and will not commence unless and until they are timely converted into U.S. non-provisional or national stage applications. Prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the USPTO are often significantly narrowed by the time they issue, if they issue at all. Any U.S. or foreign patent issuing from these provisional or PCT patent applications (if timely converted to U.S. non-provisional or foreign patent applications and such non-provisional or foreign applications are granted as issued patents), would be scheduled to expire in 2039 or 2040, excluding any additional term for patent term adjustment or patent term extension, and assuming national phase entries are timely made based upon the pending PCT application and payment of all applicable maintenance or annuity fees. Any of our pending PCT patent applications are not eligible to become issued patents until, among other things, we file national stage patent applications within 30 months in the countries in which we seek patent protection. If we do not timely file any national stage patent applications, we may lose our priority date with respect to our PCT patent applications and any patent protection on the inventions disclosed in such PCT patent applications. Our provisional patent applications may never result in issued patents and are not eligible to become issued patents until, among other things, we file a non-provisional patent application within 12 months of filing the related provisional patent application. If we do not timely file non-provisional patent applications, we may lose our priority date with respect to our provisional patent

applications and any patent protection on the inventions disclosed in our provisional patent applications. While we intend to timely file non-provisional and national stage patent applications relating to our provisional and PCT patent applications, we cannot predict whether any of our future patent applications for BDTX-189 or any of our other product candidates or technology will result in the issuance of patents that effectively protect BDTX-189 or our other product candidates or technology. If we do not successfully obtain patent protection, or, even if we do obtain patent protection, if the scope of the patent protection we or our potential licensors obtain with respect to BDTX-189 or our other product candidates or technology is not sufficiently broad, we will be unable to prevent others from using our technology or from developing or commercializing technology and products similar or identical to ours or other competing products and technologies. For more information regarding the risks related to our intellectual property, please see “Risk Factors—Risks Related to our Intellectual Property.”

In addition to patent applications, we rely on unpatented trade secrets, know-how and continuing technological innovation to develop and maintain our competitive position. However, trade secrets and confidential know-how are difficult to protect. In particular, we anticipate that with respect to the building of our compound library, our trade secrets and know-how will over time be disseminated within the industry through independent development and public presentations describing the methodology. We seek to protect our proprietary information, in part, by executing confidentiality agreements with our collaborators and scientific advisors and non-competition, non-solicitation, confidentiality and invention assignment agreements with our employees and consultants. We have also executed agreements requiring assignment of inventions with selected consultants, scientific advisors and collaborators. The confidentiality agreements we enter into are designed to protect our proprietary information and the agreements or clauses requiring assignment of inventions to us are designed to grant us ownership of technologies that are developed through our relationship with the respective counterparty. We cannot guarantee that we will have executed such agreements with all applicable employees and contractors, or that these agreements will afford us adequate protection of our intellectual property and proprietary information rights. In addition, our trade secrets and/or confidential know-how may become known or be independently developed by a third party, or misused by any collaborator to whom we disclose such information. These agreements may also be breached, and we may not have an adequate remedy for any such breach. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or to obtain or use information that we regard as proprietary. Although we take steps to protect our proprietary information, third parties may independently develop the same or similar proprietary information or may otherwise gain access to our proprietary information. As a result, we may be unable to meaningfully protect our trade secrets and proprietary information. For more information regarding the risks related to our intellectual property, please see “Risk Factors—Risks Related to our Intellectual Property.”

Government regulation

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of drugs. We, along with our vendors, contract research organizations and contract manufacturers, will be required to navigate the various preclinical, clinical, manufacturing and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval of our product candidates. The process of obtaining regulatory approvals of drugs and ensuring subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources.

In the United States, where we are initially focusing our drug development, the FDA regulates drug products under the FD&C Act, its implementing regulations and other laws. Our product candidates are early-stage and

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none of our product candidates has been approved by the FDA for marketing in the United States. If we fail to comply with applicable FDA or other requirements at any time with respect to product development, clinical testing, approval or any other legal requirements relating to product manufacture, processing, handling, storage, quality control, safety, marketing, advertising, promotion, packaging, labeling, export, import, distribution, or sale, we may become subject to administrative or judicial sanctions or other legal consequences. These sanctions or consequences could include, among other things, the FDA's refusal to approve pending applications, issuance of clinical holds for ongoing studies, suspension or revocation of approved applications, warning or untitled letters, product withdrawals or recalls, product seizures, relabeling or repackaging, total or partial suspensions of manufacturing or distribution, injunctions, fines, civil penalties or criminal prosecution.

The process required by the FDA before our product candidates are approved as drugs for therapeutic indications and may be marketed in the United States generally involves the following:

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with GLP requirements;
- submission to the FDA of an IND application, which must become effective before clinical trials may begin;
- approval by an IRB or independent ethics committee at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled clinical trials in accordance with applicable IND regulations, GCP requirements and other clinical trial-related regulations to establish the safety and efficacy of the investigational product for each proposed indication;
- submission to the FDA of an NDA;
- a determination by the FDA within 60 days of its receipt of an NDA, to accept the filing for review;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the drug will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- potential FDA audit of the clinical trial sites that generated the data in support of the NDA;
- payment of user fees for FDA review of the NDA;
- 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

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

Preclinical and clinical trials for drugs

Before testing any drug in humans, the product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluations of drug chemistry, formulation and stability, as well as *in vitro* and animal studies to assess safety and in some cases to establish the rationale for therapeutic use. The conduct of preclinical studies is subject to federal and state regulations and requirements, including GLP requirements for safety/toxicology studies. The results of the preclinical studies, together with manufacturing information and analytical data must be submitted to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans, and must become effective before clinical trials may begin. Some long-term preclinical testing may continue after the IND is submitted. The IND automatically

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becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks, and imposes a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Submission of an IND may result in the FDA not allowing clinical trials to commence or not allowing clinical trials to commence on the terms originally specified in the IND. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development of a product candidate, and the FDA must grant permission, either explicitly or implicitly by not objecting, before each clinical trial can begin.

The clinical stage of development involves the administration of the product candidate 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 requirements 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 and criteria to be used in monitoring safety and evaluating effectiveness. 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 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 related to the anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative, and must monitor the clinical trial until completed. The FDA, the IRB, or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trials to public registries. Information about clinical trials, including clinical trials results, must be submitted within specific timeframes for publication on the www.clinicaltrials.gov website.

While we plan to conduct any international clinical trials under our INDs we obtain with the FDA in the future, 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 must submit data from the clinical trial to the FDA in support of an NDA. The FDA will accept a well-designed and well-conducted foreign clinical study not conducted under an IND if the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Clinical trials to evaluate therapeutic indications to support NDAs for marketing approval are typically conducted in three sequential phases, which may overlap.

- *Phase 1*—Phase 1 clinical trials involve initial introduction of the investigational product into healthy human volunteers or patients with the target disease or condition. These studies are typically designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, excretion the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.
- *Phase 2*—Phase 2 clinical trials typically involve administration of the investigational product to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks.
- *Phase 3*—Phase 3 clinical trials typically involve administration of the investigational product to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval and physician labeling.

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In August 2018, the FDA released a draft guidance entitled “Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics,” which outlines how drug developers can utilize an adaptive trial design commonly referred to as a seamless trial design in early stages of oncology drug development (i.e., the first-in-human clinical trial) to compress the traditional three phases of trials into one continuous trial called an expansion cohort trial. Information to support the design of individual expansion cohorts are included in IND applications and assessed by FDA. Expansion cohort trials can potentially bring efficiency to drug development and reduce developmental costs and time.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and are commonly intended to generate additional safety data regarding use of the product in a clinical setting. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition 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 and written IND safety reports must be submitted to the FDA and the investigators fifteen days after the trial sponsor determines the information qualifies for reporting for serious and unexpected suspected adverse events, findings from other studies or animal or *in vitro* testing that suggest a significant risk for human volunteers and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must also notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than seven calendar days after the sponsor’s initial receipt of the information.

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

U.S. marketing approval for drugs

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, together with detailed information relating to the product’s chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. An NDA is a request for approval to market a new drug for one or more specified indications and must contain proof of the drug’s safety and efficacy. The marketing application may 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 marketed in the United States.

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, and such decision could include a refusal to file by the FDA. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the NDA. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured,

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processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity. Under the goals and polices agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA targets ten 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 for priority review. The FDA does not always meet its PDUFA goal dates for standard or priority NDAs, and the review process is often extended by FDA requests for additional information or clarification.

Further, under PDUFA, as amended, each NDA must be accompanied by a user fee. FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA also may require submission of a REMS plan to ensure that the benefits of the drug outweigh its risks. The REMS plan could include medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, or other risk-minimization tools.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, which reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the Sponsor product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP and other requirements and the integrity of the clinical data submitted to the FDA.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product, depending on the specific risk(s) to be addressed it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

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Orphan drug designation and exclusivity

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making the product available in the United States for the disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting an NDA. Orphan designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, though companies developing orphan products are eligible for certain incentives, including tax credits for qualified clinical testing and waiver of application fees.

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 a seven-year period of marketing exclusivity during which the FDA may not approve any other applications to market the same therapeutic agent for the same indication, except in limited circumstances, such as a subsequent product's showing of clinical superiority over the product with orphan exclusivity or where the original applicant cannot produce sufficient quantities of product. Competitors, however, may receive approval of different therapeutic agents for the indication for which the orphan product has exclusivity or obtain approval for the same therapeutic agent for a different indication than that for which the orphan product has exclusivity. Orphan product exclusivity could block the approval of one of our products for seven years if a competitor obtains approval for the same therapeutic agent for the same indication before we do, unless we are able to demonstrate that our product is clinically superior. If an orphan designated product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan exclusivity. Further, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Rare pediatric disease designation and priority review vouchers

Under the FD&C Act, the FDA incentivizes the development of drugs that meet the definition of a "rare pediatric disease," defined to mean a serious or life-threatening disease in which the serious of life-threatening manifestations primarily affect individuals aged from birth to 18 years and the disease affects fewer than 200,000 individuals in the United States or affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making in the United States a drug for such disease or condition will be received from sales in the United States of such drug. The sponsor of a product candidate for a rare pediatric disease may be eligible for a voucher that can be used to obtain a priority review for a subsequent human drug application after the date of approval of the rare pediatric disease drug product, referred to as a priority review voucher, or PRV. A sponsor may request rare pediatric disease designation from the FDA prior to the submission of its NDA. A rare pediatric disease designation does not guarantee that a sponsor will receive a PRV upon approval of its NDA. Moreover, a sponsor who chooses not to submit a rare pediatric disease designation request may nonetheless receive a PRV upon approval of their marketing application if they request such a voucher in their original marketing application and meet all of the eligibility criteria. If a PRV is received, it may be sold or transferred an unlimited number of times. Congress has extended the PRV program until September 30, 2020, with the potential for PRVs to be granted until 2022.

Expedited development and review programs for drugs

The FDA maintains several programs intended to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening diseases or conditions. These programs include Fast Track designation, Breakthrough Therapy designation, Priority Review and Accelerated

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Approval, and the purpose of these programs is to either expedite the development or review of important new drugs to get them to patients earlier than under standard FDA development and review procedures.

A new drug is eligible for Fast Track designation if it is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for such disease or condition. Fast Track designation provides increased opportunities for sponsor interactions with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed, meaning that the agency may review portions of the marketing application before the sponsor submits the complete application, as well as Priority Review, discussed below. In addition, a new drug may be eligible for Breakthrough Therapy designation if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough Therapy designation provides all the features of Fast Track designation in addition to intensive guidance on an efficient drug development program beginning as early as Phase 1, and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate.

Any product submitted to the FDA for approval, including a product with Fast Track or Breakthrough Therapy designation, may also be eligible for additional FDA programs intended to expedite the review and approval process, including Priority Review designation and accelerated approval. A product is eligible for Priority Review if it has the potential to provide a significant improvement in safety or effectiveness in the treatment, diagnosis or prevention of a serious disease or condition. Under priority review, the FDA must review an application in six months compared to ten months for a standard review. Additionally, products are eligible for accelerated approval if they can be shown to have an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or an effect on a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality which is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.

Accelerated approval is usually contingent on a sponsor’s agreement to conduct additional post-approval studies to verify and describe the product’s clinical benefit. The FDA may withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, unless otherwise informed by the FDA, the FDA currently requires, as a condition for accelerated approval, that all advertising and promotional materials that are intended for dissemination or publication within 120 days following marketing approval be submitted to the agency for review during the pre-approval review period, and that after 120 days following marketing approval, all advertising and promotional materials must be submitted at least 30 days prior to the intended time of initial dissemination or publication.

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 the time period for FDA review or approval may not be shortened. Furthermore, Fast Track designation, Breakthrough Therapy designation, Priority Review and Accelerated Approval do not change the scientific or medical standards for approval or the quality of evidence necessary to support approval but may expedite the development or review process.

Pediatric information and pediatric exclusivity

Under the Pediatric Research Equity Act, or PREA, certain NDAs and certain supplements to an NDA must contain data to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial

waivers. The Food and Drug Administration Safety and Innovation Act, or FDASIA, amended the FD&C Act to require that a sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs.

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

U.S. post-approval requirements for drugs

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, reporting of adverse experiences with the product, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as “off-label use”) and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use or first publication. 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 impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-market testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product’s safety and effectiveness after commercialization.

In addition, drug manufacturers and their subcontractors involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP, which impose certain procedural and documentation requirements upon us and our contract manufacturers. Failure to comply with statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, product seizures, injunctions, civil penalties or criminal prosecution. There is also a continuing, annual prescription drug product program user fee.

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, requirements for post-market

studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a REMS. 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;
- safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; and
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs; or mandated modification of promotional materials and labeling and issuance of corrective information.

Regulation of companion diagnostics

We believe that the success of certain of our product candidates may depend, in part, on the development and commercialization of a companion diagnostic. Companion diagnostics identify patients who are most likely to benefit from a particular therapeutic product; identify patients likely to be at increased risk for serious side effects as a result of treatment with a particular therapeutic product; or monitor response to treatment with a particular therapeutic product for the purpose of adjusting treatment to achieve improved safety or effectiveness. Companion diagnostics are regulated as medical devices by the FDA. In the United States, the FD&C Act and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Unless an exemption or FDA exercise of enforcement discretion applies, diagnostic tests generally require marketing clearance or approval from the FDA prior to commercialization. The two primary types of FDA marketing authorization applicable to a medical device are clearance of a premarket notification, or 510(k), application, and approval of a premarket approval, or PMA, application.

To obtain 510(k) clearance for a medical device, or for certain modifications to devices that have received 510(k) clearance, a manufacturer must submit a premarket notification demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device or to a preamendment device that was in commercial distribution before May 28, 1976, or a predicate device, for which the FDA has not yet called for the submission of a PMA. In making a determination that the device is substantially equivalent to a predicate device, the FDA compares the proposed device to the predicate device or predicate devices and assesses whether the subject device is comparable to the predicate device or predicate devices with respect to intended use, technology, design and other features which could affect safety and effectiveness. If the FDA determines that the subject device is substantially equivalent to the predicate device or predicate devices, the subject device may be cleared for marketing. The 510(k) premarket notification pathway generally takes from three to twelve months from the date the application is completed, but can take significantly longer.

PMA applications must be supported by valid scientific evidence, which typically requires extensive data, including technical, preclinical, clinical and manufacturing data, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. For diagnostic tests, a PMA application typically includes data regarding

analytical and clinical validation studies. As part of its review of the PMA, the FDA will conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the Quality System Regulation, or QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures. The FDA's review of an initial PMA application is required by statute to take between six to ten months, although the process typically takes longer, and may require several years to complete. If the FDA evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure the final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny the approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. Once granted, PMA approval may be withdrawn by the FDA if compliance with post-approval requirements, conditions of approval or other regulatory standards is not maintained or problems are identified following initial marketing.

On July 31, 2014, the FDA issued a final guidance document addressing the development and approval process for "In Vitro Companion Diagnostic Devices." According to the guidance document, for novel therapeutic products that depend on the use of a diagnostic test and where the diagnostic device could be essential for the safe and effective use of the corresponding therapeutic product, the premarket application for the companion diagnostic device should be developed and approved or cleared contemporaneously with the therapeutic, although the FDA recognizes that there may be cases when contemporaneous development may not be possible. However, in cases where a drug cannot be used safely or effectively without the companion diagnostic, the FDA's guidance indicates it will generally not approve the drug without the approval or clearance of the diagnostic device. The FDA also issued a draft guidance in July 2016 setting forth the principles for co-development of an in vitro companion diagnostic device with a therapeutic product. The draft guidance describes principles to guide the development and contemporaneous marketing authorization for the therapeutic product and its corresponding in vitro companion diagnostic.

Once cleared or approved, the companion diagnostic device must adhere to post-marketing requirements including the requirements of the FDA's quality system regulation, adverse event reporting, recalls and corrections along with product marketing requirements and limitations. Like drug makers, companion diagnostic makers are subject to unannounced FDA inspections at any time during which the FDA will conduct an audit of the product(s) and the company's facilities for compliance with its authorities.

Other regulatory matters

Manufacturing, sales, promotion and other activities of product candidates following product approval, where applicable, or commercialization are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, which may include the Centers for Medicare & Medicaid Services, or CMS, other divisions of the Department of Health and Human Services, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments and governmental agencies.

Other healthcare laws

Healthcare providers, physicians, and third-party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our business operations and any current or future arrangements with third-party payors, healthcare providers and physicians 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 develop, market, sell and distribute any drugs for

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which we obtain marketing approval. In the United States, these laws include, without limitation, state and federal anti-kickback, false claims, physician transparency, and patient data privacy and security laws and regulations, including but not limited to those described below.

- The federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving or providing any remuneration (including any kickback, bride, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid; a person or entity need not have actual knowledge of the federal Anti-Kickback 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 that includes 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 civil and criminal false claims laws, including the civil False Claims Act, or FCA, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false, fictitious or fraudulent; knowingly making, using, or causing to be made or used, a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. 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 False Claims Act, 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.
- The federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer or remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state health care program, unless an exception applies.
- The Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for knowingly and willfully executing a scheme, or attempting to execute a scheme, to defraud any healthcare benefit program, including private payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, or falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, imposes, among other things, specified requirements on covered entities and their business associates relating to the privacy and security of individually identifiable health information including mandatory contractual terms and required implementation of technical safeguards of such information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates in some cases, 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.

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- The Physician Payments Sunshine Act, enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, imposed new annual reporting requirements for certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, for certain payments and "transfers of value" provided 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. In addition, many states also require reporting of payments or other transfers of value, many of which differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts.
- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.
- Analogous state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, which may be broader in scope and apply regardless of payor. These laws are enforced by various state agencies and through private actions. Some state laws require pharmaceutical companies implement compliance to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant federal government compliance guidance, require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, and restrict marketing practices or require disclosure of marketing expenditures and pricing information. State and foreign laws also govern the privacy and security of health information in some circumstances. These data privacy and security laws may differ from each other in significant ways and often are not pre-empted by HIPAA, which may complicate compliance efforts.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations 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 these laws or any other related governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, disgorgement, exclusion from government funded healthcare programs, such as Medicare and Medicaid, reputational harm, additional oversight and reporting obligations if we become subject to a corporate integrity agreement or similar settlement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to similar actions, penalties and sanctions. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from its business.

Insurance Coverage and Reimbursement

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Thus, even if a product candidate is approved, sales of the product will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide

coverage, and establish adequate reimbursement levels for, the product. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. No uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Additionally, companies may also need to provide discounts to purchasers, private health plans or government healthcare programs. Nonetheless, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover a product could reduce physician utilization once the product is approved and have a material adverse effect on sales, our operations and financial condition. Additionally, a third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of products have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. 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 a company or its collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Current and future healthcare reform legislation

In the United States and some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering the cost of healthcare. For example, in March 2010, the United States Congress enacted the Affordable Care Act, which, among other things, includes changes to the coverage and payment for products under government health care programs. The Affordable Care Act includes provisions of importance to our potential product candidates that:

- created an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic products, apportioned among these entities according to their market share in certain government healthcare programs;
- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;

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- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices;
- addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- expanded the types of entities eligible for the 340B drug discount program;
- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide point-of-sale-discounts off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D; and
- created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Some of the provisions of the Affordable Care Act have yet to be implemented, and there have been judicial and Congressional challenges to certain provisions of the Affordable Care Act, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the Affordable Care Act. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the Affordable Care Act such as removing penalties, starting January 1, 2019, for not complying with the Affordable Care Act's individual mandate to carry health insurance, delaying the implementation of certain Affordable Care Act-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. The Trump administration and CMS have stated that the ruling will have no immediate effect pending appeal of the decision, and on December 30, 2018 the Texas District Court Judge issued an order staying the judgment pending appeal. A Fifth Circuit US Court of Appeals hearing to determine whether certain states and the House of Representatives have standing to appeal the lower court decision was held on July 9, 2019, but it is unclear when a Court will render its decision on this hearing, and what effect it will have on the status of the ACA. Litigation and legislation related to the ACA are likely to continue, with unpredictable and uncertain results. We will continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products, which has resulted in several Congressional inquiries and proposed

and enacted state and federal 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 pharmaceutical products. For example, at the federal level, the Trump administration's budget for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 legislative session, or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of HHS, has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy (ST) for Medicare Part B drugs beginning January 1, 2019. Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

On May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act, but the manufacturer must develop an internal policy and respond to patient requests according to that policy.

Outside the United States, ensuring coverage and adequate payment for a product also involves challenges. Pricing of prescription pharmaceuticals is subject to government control in many countries. Pricing negotiations with government authorities can extend well beyond the receipt of regulatory approval for a product and may require a clinical trial that compares the cost-effectiveness of a product to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in commercialization.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its member states to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other member states allow companies to fix their own prices for products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. The downward pressure on healthcare costs in general, particularly prescription products, has

become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states, and parallel trade, i.e., arbitrage between low-priced and high-priced member states, can further reduce prices. 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 products, if approved in those countries.

Compliance with other federal and state laws or requirements; changing legal requirements

If any products that we may develop are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, labeling, packaging, distribution, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws, among other requirements to we may be subject.

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.

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 criminal prosecution, fines or other penalties, injunctions, exclusion from federal healthcare programs, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, relabeling or repackaging, or refusal to allow a firm to enter into supply contracts, including government contracts. Any claim or action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Prohibitions or restrictions on marketing, sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling or packaging; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Other U.S. environmental, health and safety laws and regulations

We may be subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

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In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

Government regulation of drugs outside of the United States

To market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization or identification of an alternate regulatory pathway, manufacturing, commercial sales and distribution of our products. For instance, in the European Economic Area, or the EEA (comprised of the 28 EU Member States plus Iceland, Liechtenstein and Norway), medicinal products must be authorized for marketing by using either the centralized authorization procedure or national authorization procedures.

- *Centralized procedure*—If pursuing marketing authorization of a product candidate for a therapeutic indication under the centralized procedure, following the opining of the EMA's Committee for Medicinal Products for Human Use, or, CHMP, the European Commission issues a single marketing authorization valid across the EEA. The centralized procedure is compulsory for human medicines derived from biotechnology processes or advanced therapy medicinal products (such as gene therapy, somatic cell therapy and tissue engineered products), products that contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune diseases and other immune dysfunctions, viral diseases, and officially designated orphan medicines. For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the medicine concerned contains a new active substance not yet authorized in the EEA, is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health in the EEA. Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of an MAA under the accelerated assessment procedure is 150 days, excluding clock stops.
- *National authorization procedures*—There are also two other possible routes to authorize products for therapeutic indications in several countries, which are available for products that fall outside the scope of the centralized procedure:
    - *Decentralized procedure*—Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EU country of medicinal products that have not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure.
    - *Mutual recognition procedure*—In the mutual recognition procedure, a medicine is first authorized in one EU Member State, in accordance with the national procedures of that country. Following this, additional marketing authorizations can be sought from other EU countries in a procedure whereby the countries concerned recognize the validity of the original, national marketing authorization.

In the EEA, new products for therapeutic indications that are authorized for marketing (i.e., reference products) qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic or biosimilar applicants from relying on the

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preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until ten years have elapsed from the initial authorization of the reference product in the EU. The ten-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

The criteria for designating an “orphan medicinal product” in the EEA are similar in principle to those in the United States. In the EEA a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. During this ten-year orphan market exclusivity period, no marketing authorization application shall be accepted, and no marketing authorization shall be granted for a similar medicinal product for the same indication. An orphan product can also obtain an additional two years of market exclusivity in the EU for pediatric studies. The ten-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if (i) the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior; (ii) the applicant consents to a second orphan medicinal product application; or (iii) the applicant cannot supply enough orphan medicinal product.

Similar to the United States, the various phases of non-clinical and clinical research in the European Union are subject to significant regulatory controls.

The Clinical Trials Directive 2001/20/EC, the Directive 2005/28/EC on GCP and the related national implementing provisions of the individual EU Member States govern the system for the approval of clinical trials in the European Union. Under this system, an applicant must obtain prior approval from the competent national authority of the EU Member States in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial at a specific study site after the competent ethics committee has issued a favorable opinion. The clinical trial application must be accompanied by, among other documents, an investigational medicinal product dossier (the Common Technical Document) with supporting information prescribed by Directive 2001/20/EC, Directive 2005/28/EC, where relevant the implementing national provisions of the individual EU Member States and further detailed in applicable guidance documents.

In April 2014, the new Clinical Trials Regulation, (EU) No 536/2014 (Clinical Trials Regulation) was adopted. The Regulation is anticipated to come into application in 2019. The Clinical Trials Regulation will be directly applicable in all the EU Member States, repealing the current Clinical Trials Directive 2001/20/EC. Conduct of all clinical trials performed in the European Union will continue to be bound by currently applicable provisions until the new Clinical Trials Regulation becomes applicable. The extent to which ongoing clinical trials will be governed by the Clinical Trials Regulation will depend on when the Clinical Trials Regulation becomes applicable and on the duration of the individual clinical trial. If a clinical trial continues for more than three years from the day on which the Clinical Trials Regulation becomes applicable the Clinical Trials Regulation will at that time

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begin to apply to the clinical trial. The new Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the European Union. The main characteristics of the regulation include: a streamlined application procedure via a single-entry point, the "EU portal"; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (Member States concerned). Part II is assessed separately by each Member State concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU Member State. However, overall related timelines will be defined by the Clinical Trials Regulation.

The collection and use of personal health data in the European Union, previously governed by the provisions of the Data Protection Directive, is now governed by the General Data Protection Regulation, or the GDPR, which became effective on May 25, 2018. While the Data Protection Directive did not apply to organizations based outside the EU, the GDPR has expanded its reach to include any business, regardless of its location, that provides goods or services to residents in the EU. This expansion would incorporate any clinical trial activities in EU members states. The GDPR imposes strict requirements on controllers and processors of personal data, including special protections for "sensitive information" which includes health and genetic information of data subjects residing in the EU. GDPR grants individuals the opportunity to object to the processing of their personal information, allows them to request deletion of personal information in certain circumstances, and provides the individual with an express right to seek legal remedies in the event the individual believes his or her rights have been violated. Further, the GDPR imposes strict rules on the transfer of personal data out of the European Union to the United States or other regions that have not been deemed to offer "adequate" privacy protections. Failure to comply with the requirements of the GDPR and the related national data protection laws of the European Union Member States, which may deviate slightly from the GDPR, may result in fines of up to 4% of global revenues, or € 20,000,000, whichever is greater. As a result of the implementation of the GDPR, we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules.

There is significant uncertainty related to the manner in which data protection authorities will seek to enforce compliance with GDPR. For example, it is not clear if the authorities will conduct random audits of companies doing business in the EU, or if the authorities will wait for complaints to be filed by individuals who claim their rights have been violated. Enforcement uncertainty and the costs associated with ensuring GDPR compliance are onerous and may adversely affect our business, financial condition, results of operations and prospects.

Should we utilize third party distributors, compliance with such foreign governmental regulations would generally be the responsibility of such distributors, who may be independent contractors over whom we have limited control.

Employees

As of October 30, 2019, we had 23 full-time employees. Eleven of our employees have Ph.D. degrees. The following table shows the number of full-time employees as of October 30, 2019 engaged in either research and development or administrative functions, broken out by location.

Function	US	Canada
Research and development	16	2
Administrative	7	—
Total	23	2

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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.

Facilities

We lease a facility containing approximately 2,357 square feet of office space for our principal office, which is located at 139 Main Street, Cambridge, MA 02142. The lease expires on April 30, 2022, subject to an option to extend the lease for three additional years. We also lease approximately 1,000 square feet of laboratory space and 500 square feet of office space at 25 Health Sciences Drive, Stony Brook, NY 11790 and our lease for this location expires on December 31, 2019. In addition, we also have a license to use the private and shared laboratory and office facilities at 180 Varick Street, New York, NY 10014. The license expires on February 11, 2020. For our Canadian subsidiary, we have a non-exclusive license to occupy a portion of a building located at 661 University Avenue, Toronto, Ontario M5G 1M1, for the purposes of conducting laboratory research, business planning and related activities. The license expires on April 5, 2020.

We believe that our current facilities are adequate for our current needs and that suitable additional or substitute space at commercially reasonable terms will be available as needed to accommodate any future expansion of our operations.

Legal proceedings

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. As of the date of this prospectus, we were not a party to any material legal matters or claims. In the future, we may become party to legal matters and claims in the ordinary course of business, the resolution of which we do not anticipate would have a material adverse impact on our financial position, results of operations or cash flows.

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Management

The following table sets forth information about our directors, executive officers and other senior management as of October 30, 2019.

Name	Age	Position(s)
Executive Officers and Senior Management		
David M. Epstein, Ph.D.	60	President, Chief Executive Officer and Director
Thomas Leggett	43	Chief Financial Officer
Brent Hatzis-Schoch, Esq.	54	Chief Operating Officer and General Counsel
Christopher D. Roberts, Ph.D.	50	Chief Scientific Officer
Elizabeth Buck, Ph.D.	45	Executive Vice President, Discovery and Translational Services
Karsten Witt, M.D.	62	Senior Vice President, Clinical Development
Non-Employee Directors		
Bradley Bolzon, Ph.D.	60	Director and Chairman of the Board of Directors
Ali Behbahani, M.D.	43	Director
Alexander Mayweg, Ph.D.	44	Director
Garry E. Menzel, Ph.D.	55	Director
Rajeev Shah	42	Director

(1) Member of our audit committee

(2) Member of our compensation, nomination and corporate governance committee

The following is a biographical summary of the experience of our executive officers, other senior management and directors. There are no family relationships among any of our executive officers, other senior management or directors.

Executive officers

David M. Epstein, Ph.D. is our co-founder and has served as President, Chief Executive Officer and a member of our board of directors since September 2016. Since January 2019, Dr. Epstein has served as an Adjunct Associate Professor for the Cancer and Stem Cell Biology Program at Duke-NUS Medical School. From April 2013 to December 2018, Dr. Epstein held positions at Duke-NUS Medical School, Singapore, where he founded and built Duke-NUS's Center for Technology & Development. Dr. Epstein's positions include Vice Dean, Innovation & Entrepreneurship, and Associate Professor in Cancer and Stem Biology. From June 2010 to March 2013, Dr. Epstein was Senior Vice President, Chief Scientific Officer and Site-Head for OSI Pharmaceuticals, Inc., a pharmaceutical company acquired by Astellas Pharma, Inc. From 2006 to 2010, Dr. Epstein served as Senior Vice President and Chief Scientific Officer, Oncology, at OSI Pharmaceuticals, Inc. until it was acquired by Astellas. Before joining OSI, from 2001 to 2006, Dr. Epstein served as Vice President, Biology, and from 2000 to 2003, as co-founder and a member of the board of directors at Archemix Corporation, a biotechnology company. From April 2013 to April 2015, Dr. Epstein served as a member of the board of directors at MetaStat, Inc., a precision medicine biotechnology company. Dr. Epstein earned a B.S. in Chemistry from Lewis & Clark College and a Ph.D. in Biochemistry at Brandeis University. Dr. Epstein completed a joint post-doctoral fellowship, leading a collaboration in protein structure, function and NMR dynamics between the labs of Steven Benkovic (Penn State) and Peter Wright at The Scripps Research Institute in La Jolla, California.

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We believe that Dr. Epstein is qualified to serve on our board of directors because of his considerable qualifications, attributes and skills, including his distinguished scientific background and experience in leadership roles in the biopharmaceutical industry.

Thomas Leggett has served as our Chief Financial Officer since September 2019. Prior to joining us, from January 2017 to August 2019, Mr. Leggett served as Senior Vice President of Finance and Chief Financial Officer at Axcella Health Inc., a biotechnology company. Prior to joining Axcella, Mr. Leggett served as the Treasurer and Head of Business Development Finance at Purdue Pharma L.P., a pharmaceutical company, from May 2016 to December 2017. From November 2009 to April 2016, Mr. Leggett was an Executive Director at UBS Securities LLC, an investment bank, in the Global Healthcare Group with a primary focus in the biopharmaceutical sector. Mr. Leggett holds an M.B.A. in finance from The Wharton School at the University of Pennsylvania and a B.A. in Economics from Columbia University.

Brent Hatzis-Schoch has served as our Chief Operating Officer and General Counsel since May 2019. Prior to joining us, from April 2015 to May 2019, Mr. Hatzis-Schoch was Senior Vice President, General Counsel and Corporate Secretary at Radius Health, Inc., a commercial-stage biopharmaceutical company. Previously, Mr. Hatzis-Schoch served as Senior Vice President and Chief Legal Counsel at Merz Pharma GmbH & Co. KGaA, an international healthcare company, in Frankfurt, Germany from July 2013 to April 2015. Mr. Hatzis-Schoch began his legal career in private practice and later held senior legal positions in the U.S. and internationally, including as General Counsel to two publicly traded development-stage German biopharmaceutical companies, European legal counsel for Baxter International and Associate General Counsel of Pharmacia Corporation (which now operates under Pfizer Inc.). Mr. Hatzis-Schoch received his B.A. from the University of Delaware and his Juris Doctor from George Washington University. Mr. Hatzis-Schoch was a Fulbright Scholar at the University of Cologne in Germany.

Christopher D. Roberts, Ph.D. has served as our Chief Scientific Officer since September 2019. Prior to joining us, from April 2017 to August 2019, Dr. Roberts was Entrepreneur in Residence at S.R. One Limited, the corporate venture capital arm of GlaxoSmithKline plc. Previously, from April 2015 to March 2017, Dr. Roberts served as Vice President of Chemistry and Early Development at Syros Pharmaceuticals, Inc., a publicly-traded biotechnology company, where he built and led various discovery and development functions and helped guide two oncology assets into clinical development. Prior to joining Syros, from January 2009 to March 2015, Dr. Roberts held numerous positions of increasing responsibility at GSK, including Vice President and Head of the Host Defense Discovery Performance Unit. Dr. Roberts graduated with a B.A. in Chemistry from Whitworth University and earned his Ph.D. in Organic Chemistry from the University of California, Riverside, followed by a post-doctoral fellowship at the University of Bern, Switzerland.

Elizabeth Buck, Ph.D. is our co-founder and has served as our Executive Vice President, Discovery & Translational Services since March 2017. From 2015 to 2017, she served as our Chief Scientific Officer. Prior to joining us, from September 2013 to December 2014, Dr. Buck served as Chief Scientific Officer for Therapeutics at MetaStat, Inc., a precision medicine biotechnology company. Previously, from 2005 to 2013, Dr. Buck was Assistant Director of Advanced Preclinical Pharmacology at OSI Pharmaceuticals, Inc., a pharmaceutical company acquired by Astellas Pharma Inc., where she led discovery and translational research to advance a series of oncology programs to clinical development. In this role, Dr. Buck managed multidisciplinary global teams and spearheaded major academic collaborations to progress programs to IND. Her expertise and productivity are evidenced by more than 40 peer reviewed publications and patents. Dr. Buck received her undergraduate degree in Physics from the University of New Hampshire, her Ph.D. in Cellular and Molecular Biology from New York University/Mount Sinai School of Medicine, and completed postdoctoral work with Jim Wells at Sunesis Pharmaceuticals, Inc., a publicly traded biopharmaceutical company.

Karsten Witt, M.D. has served as our Senior Vice President, Clinical Development since May 2019. Since February 2013, Dr. Witt has served as President of KW Biotech Consulting, LLC, a provider of strategic, scientific

and medical consulting services in drug development. From August 2011 to August 2014, Dr. Witt served as Chair of Scientific Subcommittee for TopoTarget A/S, a Copenhagen-based biotechnology company, until its merger with BioAlliance resulting in the formation of Onxeo SA. Previously, from August 2011 to January 2013, Dr. Witt served as Vice President, Clinical Sciences & Drug Safety at Array BioPharma Inc., a biopharmaceutical company. From 2002 until he joined Array, Dr. Witt served as Senior Vice President, Pharmaceutical Operations at OSI Pharmaceuticals, Inc., a pharmaceutical company acquired by Astellas Pharma, Inc., where he was intimately involved in the development of small-molecule targeted oncology therapies. Dr. Witt received his M.D. from the University of Copenhagen in Denmark and practiced medicine at Hvidovre University Hospital in Copenhagen in the internal medicine subspecialties of gastroenterology, infectious disease, and cardiology, before transitioning to the biopharmaceutical industry.

Non-employee directors

Bradley Bolzon, Ph.D. has been our chairman and a member of our board of directors since December 2017. Dr. Bolzon is a Managing Director of Versant Venture Management, LLC, where he has been employed since May 2004. Dr. Bolzon previously served as a member of the board of directors of Flexion Therapeutics, Inc., a pharmaceutical company, from its inception in 2007 to June 2014. From February 2000 to May 2004, Dr. Bolzon served as Executive Vice President, Global Head of Business Development, Licensing & Alliances of F. Hoffman-La Roche AG., a multinational healthcare company. Dr. Bolzon also formerly served as Head of Cardiovascular Research at Eli Lilly and Company, a global pharmaceutical company. Since April 2014, Dr. Bolzon has served as a member of the board of directors of CRISPR Therapeutics AG, a biotech company. Dr. Bolzon received a Ph.D. in Pharmacology and an M.S. in Pharmacology from the University of Toronto. He conducted post-doctoral work at the University of Ottawa Heart Institute.

We believe that Dr. Bolzon is qualified to serve on our board of directors because of his experience, qualifications, attributes and skills, including his global pharmaceutical industry experience and similar tenure as a venture capitalist.

Ali Behbahani, M.D. has been a member of our board of directors since December 2018. Dr. Behbahani joined New Enterprise Associates, Inc., or NEA, in 2007 and is a General Partner on the healthcare team. Dr. Behbahani is currently on the board of directors of Adaptimmune Therapeutics, a biopharmaceutical company, Genocea Biosciences, Inc., a biopharmaceutical company, and CRISPR Therapeutics AG, a biotech company. Prior to joining NEA, Dr. Behbahani served as a consultant in business development at The Medicines Company, a pharmaceutical company. In addition, Dr. Behbahani formerly served as a Venture Associate at Morgan Stanley and as a Healthcare Investment Banking Analyst at Lehman Brothers. Dr. Behbahani received an M.D. from the University of Pennsylvania School of Medicine, an M.B.A. from the Wharton School of the University of Pennsylvania and a B.S. in Biomedical Engineering, Electrical Engineering and Chemistry from Duke University.

We believe that Dr. Behbahani is qualified to serve on our board of directors because of his experience, qualifications, attributes and skills, including his extensive investment experience in the life sciences and his service as a director of other publicly traded companies.

Alexander Mayweg, Ph.D. has served as a member of our board of directors since March 2017 and, from March 2017 to September 2019, served as our interim Chief Scientific Officer. Dr. Mayweg has served as a Partner at Versant Ventures, a healthcare investment firm, since January 2018, and previously served as a Venture Partner at Versant Ventures from January 2017 to December 2017. Additionally, since April 2017, Dr. Mayweg has served as Chief Scientific Officer at Ridgeline Therapeutics, a Versant Ventures Discovery Engine that creates and operates Versant-financed biotechnology companies in Basel, Switzerland. Prior to joining Versant, from 2013 to 2016, Dr. Mayweg served as Vice President and Global Head of Medicinal Chemistry at F. Hoffmann-La Roche AG, a multinational healthcare company, and held various leadership positions at Roche

in pharmaceutical drug discovery and medicinal chemistry across Europe, the U.S. and Asia. Dr. Mayweg graduated with a B.S. in Chemistry from the Imperial College in London and earned a Ph.D. in Organic Chemistry at Oxford University, followed by post-doctorate training at Stanford University.

We believe that Dr. Mayweg is qualified to serve on our board of directors based on his knowledge of the healthcare sector across international markets and his extensive operational experience in the biopharmaceutical industry.

Garry E. Menzel, Ph.D. has been a member of our board of directors since March 2017. Since October 2016, Dr. Menzel has served as President and Chief Executive Officer at TCR² Therapeutics Inc., a publicly traded immunotherapy company, and is currently a member of the board of directors. Previously, Dr. Menzel was Chief Strategy Officer at Axcella Health Inc., a biotechnology company, from July 2015 to September 2016, the Chief Financial Officer at DaVita Inc., a healthcare services company, from 2013 to May 2015, and the Chief Operating Officer at Regulus Therapeutics Inc., a biopharmaceutical company, from 2008 to 2013. Dr. Menzel also had global leadership roles in running the biotechnology practices at Goldman Sachs & Co. LLC and Credit Suisse Group AG, both of which are multinational investment bank and financial services companies, from 1994 to 2004 and from 2004 to 2008, respectively. In addition, he was a consultant with Bain & Company, a global management consulting firm, and was a research assistant at SmithKline Beecham PLC (now GlaxoSmithKline PLC). Dr. Menzel received his B.S. in Biochemistry from Imperial College of Science and Technology in London, his Ph.D. from the University of Cambridge, where he studied the regulation of oncogenes in immune cells, and his M.B.A. from the Stanford University Graduate School of Business.

We believe that Dr. Menzel is qualified to serve as a member of our board of directors because of his scientific background and extensive corporate leadership experience in the life sciences industry.

Rajeev Shah has been a member of our board of directors since December 2018. Since June 2004, Mr. Shah has served as a Managing Director and Portfolio Manager at RA Capital Management, LLC, an investment advisory firm that invests in healthcare companies. Previously, from 2000 to 2004, Mr. Shah was a Senior Project Leader at Altus Pharmaceuticals Inc., a spin-off company of Vertex Pharmaceuticals, where he assessed business processes and implemented system solutions across all areas of science. Mr. Shah served as a member of the board of directors of KalVista Pharmaceuticals, Inc., a biopharmaceutical company, from June 2015 to April 2018, and currently serves on the board of RA Pharmaceuticals, Inc., Solid Biosciences Inc., Eidos Therapeutics, Inc. and Kala Pharmaceuticals, Inc. He is also an active member of the Big Brothers of Massachusetts Bay program. Mr. Shah holds a B.A. in Chemistry from Cornell University.

We believe that Mr. Shah is qualified to serve as a member of our board of directors because of his extensive experience in the biopharmaceutical industry and his experience with venture capital investments.

Board composition

Our board of directors currently consists of six members, each of whom is a member pursuant to the board composition provisions of our current certificate of incorporation and agreements with our stockholders, which agreements are described in the section of this prospectus titled “Certain Relationships and Related Party Transactions.” These board composition provisions will terminate upon the closing of this offering. Upon the termination of these provisions, there will be no further contractual obligations regarding the election of our directors. Our compensation, nomination and corporate governance committee and our board of directors may therefore consider a broad range of factors relating to the qualifications and background of nominees. Our compensation, nomination and corporate governance committee’s and our board of directors’ priority in selecting board members is identification of persons who will further the interests of our stockholders through their established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business, understanding of the competitive landscape,

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professional and personal experiences and expertise relevant to our growth strategy. Our directors hold office until their successors have been elected and qualified or until their earlier resignation or removal. Our amended and restated certificate of incorporation and amended and restated bylaws that will become effective upon the closing of this offering also provide that our directors may be removed only for cause by the affirmative vote of the holders of at least of the votes that all our stockholders would be entitled to cast in an annual election of directors, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

Staggered board

In accordance with the terms of our amended and restated certificate of incorporation and our amended and restated bylaws that will become effective upon the closing of this offering, our board of directors will be divided into three staggered classes of directors and each director will be assigned to one of the three classes. At each annual meeting of the stockholders, one class of directors will be elected for a three-year term to succeed the directors of the same class whose terms are then expiring. The terms of the directors will expire upon the election and qualification of successor directors at the annual meeting of stockholders to be held during the years 2020 for Class I directors, 2021 for Class II directors and 2022 for Class III directors.

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

Our amended and restated certificate of incorporation and amended and restated bylaws that will become effective upon the closing of this offering will provide that the number of our directors shall be fixed from time to time by a resolution of the majority of our board of directors.

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

Director independence

We intend to apply to list our common stock on The Nasdaq Global Market. Under the Nasdaq listing rules, independent directors must comprise a majority of a listed company's board of directors within twelve months from the date of listing. In addition, the Nasdaq listing rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and governance committees be independent within twelve months from the date of listing. Audit committee members must also satisfy additional independence criteria, including those set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and compensation committee members must also satisfy the independence criteria set forth in Rule 10C-1 under the Exchange Act. Under Nasdaq listing rules, 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. In order to be considered independent for purposes of Rule 10A-3 under the Exchange Act, 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: (1) accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries, other than compensation for board service; or (2) be an affiliated person of the listed company or any of its subsidiaries. In order to be considered independent for purposes of Rule 10C-1, the board of directors must consider, for each member of a compensation committee of a listed company, all factors specifically

relevant to determining whether a director has a relationship to such 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, but not limited to: the source of compensation of the director, including any consulting advisory or other compensatory fee paid by such company to the director, and whether the director is affiliated with the company or any of its subsidiaries or affiliates.

In , 2019, our board of directors undertook a review of the composition of our board of directors and its committees and the independence of each director. Based upon information requested from and provided by each director concerning his background, employment and affiliations, including family relationships, our board of directors has determined that all members of our board of directors, except , are independent directors, including for purposes of Nasdaq and the SEC rules. In making that determination, our board of directors considered the relationships that each director has with us and all other facts and circumstances the board of directors deemed relevant in determining independence, including the potential deemed beneficial ownership of our capital stock by each director, including non-employee directors that are affiliated with certain of our major stockholders. Upon the completion of this offering, we expect that the composition and functioning of our board of directors and each of our committees will comply with all applicable requirements of Nasdaq and the rules and regulations of the SEC. There are no family relationships among any of our directors or executive officers.

We intend to adopt a policy, subject to and effective upon the effectiveness of the registration statement of which this prospectus forms a part, that outlines a process for our securityholders to send communications to the board of directors.

Board committees

Our board of directors has established an audit committee and a compensation, nomination and corporate governance committee, each of which will operate pursuant to a charter to be adopted by our board of directors and will be effective upon the effectiveness of the registration statement of which this prospectus forms a part. We believe that the composition and functioning of all of our committees will comply with the applicable requirements of Nasdaq, the Sarbanes-Oxley Act of 2002 and SEC rules and regulations that will be applicable to us. We intend to comply with future requirements to the extent they become applicable to us.

Following the consummation of this offering, the full text of our audit committee charter and compensation, nomination and corporate governance charter will be posted on the investor relations portion of our website at https://www.blackdiamondtherapeutics.com/. We do not incorporate the information contained on, or accessible through, our corporate website into this prospectus, and you should not consider it a part of this prospectus.

Audit committee

Upon the effectiveness of the registration statement of which this prospectus forms a part, our audit committee will consist of and will be chaired by . The functions of the audit committee will include:

- appointing, approving the compensation of, and assessing the independence of our independent registered public accounting firm;
- pre-approving auditing and permissible non-audit services, and the terms of such services, to be provided by our independent registered public accounting firm;
- reviewing the overall audit plan with our independent registered public accounting firm and members of management responsible for preparing our financial statements;

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

All members of our audit committee will meet the requirements for financial literacy under the applicable rules and regulations of the SEC and the Nasdaq listing rules. Our board of directors has determined that qualifies as an "audit committee financial expert" within the meaning of applicable SEC regulations. In making this determination, our board of directors considered the nature and scope of experience that has previously had with public reporting companies, including service as . Our board of directors has determined that all of the directors that will become members of our audit committee upon the effectiveness of the registration statement of which this prospectus forms a part satisfy the relevant independence requirements for service on the audit committee set forth in the rules of the SEC and the Nasdaq listing rules. Both our independent registered public accounting firm and management will periodically meet privately with our audit committee.

Compensation, nomination and corporate governance committee

Upon the effectiveness of the registration statement of which this prospectus forms a part, our compensation, nomination and corporate governance committee will consist of , and will be chaired by . The functions of the compensation, nomination and corporate governance committee upon the completion of this offering will include:

- annually reviewing and recommending to the board of directors the corporate goals and objectives relevant to the compensation of our Chief Executive Officer;
- evaluating the performance of our Chief Executive Officer in light of such corporate goals and objectives and based on such evaluation (i) reviewing and determining the cash compensation of our Chief Executive Officer and (ii) reviewing and approving grants and awards to our Chief Executive Officer under equity-based plans;
- reviewing and approving the compensation of our other executive officers;
- reviewing and establishing our overall management compensation, philosophy and policy;
- overseeing and administering our compensation and similar plans;
- evaluating and assessing potential and current compensation advisors in accordance with the independence standards identified in the applicable Nasdaq listing rules;

- reviewing and approving our policies and procedures for the grant of equity-based awards;
- reviewing and recommending to the board of directors the compensation of our directors;
- preparing our compensation committee report if and when required by SEC rules;
- reviewing and discussing annually with management our “Compensation Discussion and Analysis,” if and when required, to be included in our annual proxy statement;
- reviewing and approving the retention or termination of any consulting firm or outside advisor to assist in the evaluation of compensation matters;
- developing and recommending to the board of directors criteria for board and committee membership;
- establishing procedures for identifying and evaluating board of director candidates, including nominees recommended by stockholders;
- reviewing the composition of the board of directors to ensure that it is composed of members containing the appropriate skills and expertise to advise us;
- identifying individuals qualified to become members of the board of directors;
- recommending to the board of directors the persons to be nominated for election as directors and to each of the board’s committees;
- developing and recommending to the board of directors a code of business conduct and ethics and a set of corporate governance guidelines; and
- overseeing the evaluation of our board of directors and management.

Each member of our compensation, nomination and corporate governance committee will be a non-employee director, as defined in Rule 16b-3 promulgated under the Exchange Act.

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

Compensation, nomination and corporate governance committee interlocks and insider participation

None of the members of our compensation, nomination and corporate governance committee is, or has at any time during the prior three years been, one of our officers or employees. None of our executive officers currently serve, or have in the past fiscal year served, as a member of the board of directors or compensation, nomination and corporate governance committee of any entity that has one or more of its executive officers serving as a member of our board of directors or our compensation, nomination and corporate governance committee.

Code of business conduct and ethics

Our board of directors intends to adopt, subject to and effective upon the effectiveness of the registration statement of which this prospectus forms a part, a Code of Business Conduct and Ethics in connection with this offering. The Code of Business Conduct and Ethics will apply to all of our employees, officers (including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions), agents and representatives, including directors and consultants.

We intend to disclose future amendments to certain provisions of our Code of Business Conduct and Ethics and our Code of Ethics on our website identified below. Upon the completion of this offering, the full text of our

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Code of Business Conduct and Ethics and our Code of Ethics will be posted on our website at http://www. blackdiamondtherapeutics.com. The inclusion of our website address in this prospectus does not include or incorporate by reference the information on our website into this prospectus, and you should not consider that information a part of this prospectus.

Limitations on liability and indemnification agreements

As permitted by Delaware law, provisions in our amended and restated certificate of incorporation and amended and restated bylaws, both of which will become effective upon the closing of this offering, limit or eliminate the personal liability of directors for a breach of their fiduciary duty of care as a director. The duty of care generally requires that, when acting on behalf of the corporation, a director exercise an informed business judgment based on all material information reasonably available to him or her. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for:

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

These limitations of liability do not limit or eliminate our rights or any stockholder's rights to seek non-monetary relief, such as injunctive relief or rescission. These provisions will not alter a director's liability under other laws, such as the federal securities laws or other state or federal laws. Our amended and restated certificate of incorporation that will become effective upon the closing of this offering also authorizes us to indemnify our officers, directors and other agents to the fullest extent permitted under Delaware law.

As permitted by Delaware law, our amended and restated bylaws to be effective upon the consummation of this offering will provide that:

- we will indemnify our directors, officers, employees and other agents to the fullest extent permitted by law;
- we must advance expenses to our directors and officers, and may advance expenses to our employees and other agents, in connection with a legal proceeding to the fullest extent permitted by law; and
- the rights provided in our amended and restated bylaws are not exclusive.

If Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director or officer, then the liability of our directors or officers will be so eliminated or limited to the fullest extent permitted by Delaware law, as so amended. Our amended and restated bylaws will also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in connection with their services to us, regardless of whether our bylaws permit such indemnification. We have obtained such insurance.

In addition to the indemnification that will be provided for in our amended and restated certificate of incorporation and amended and restated bylaws, we plan to enter into separate indemnification agreements with each of our directors and executive officers, which may be broader than the specific indemnification provisions contained in the Delaware General Corporation Law. These indemnification agreements may require us, among other things, to indemnify our directors and executive officers for some expenses, including attorneys' fees, expenses, judgments, fines and settlement amounts incurred by a director or executive officer

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in any action or proceeding arising out of his service as one of our directors or executive officers or any other company or enterprise to which the person provides services at our request. We believe that these provisions and agreements are necessary to attract and retain qualified individuals to serve as directors and executive officers.

This description of the indemnification provisions of our amended and restated certificate of incorporation, our amended and restated bylaws and our indemnification agreements is qualified in its entirety by reference to these documents, each of which is attached as an exhibit to the registration statement of which this prospectus forms a part.

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.

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Executive compensation

Overview

The following discussion contains forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. The actual amount and form of compensation and the compensation policies and practices that we adopt in the future may differ materially from currently planned programs as summarized in this discussion.

As an “emerging growth company,” we have opted to comply with the executive compensation disclosure rules applicable to “smaller reporting companies,” as such term is defined in the rules promulgated under the Securities Act. This section provides an overview of the compensation awarded to, earned by, or paid to each individual who served as our principal executive officer during our fiscal year 2018, and our next two most highly compensated executive officers in respect of their service to our company for fiscal year 2018. We refer to these individuals as our named executive officers. Our named executive officers for fiscal year 2018 are:

- David M. Epstein, Ph.D., our President, Chief Executive Officer;
- Elizabeth Buck, Ph.D., our Executive Vice President, Discovery & Translational Sciences; and
- Alexander Mayweg, Ph.D., our former interim Chief Scientific Officer.

Our executive compensation program is based on a pay for performance philosophy. Compensation for Dr. Epstein, Dr. Buck and our executive officers other than Dr. Mayweg is composed primarily of the following main components: base salary, bonus, and equity incentives in the form of stock options. Compensation for Dr. Mayweg, who is employed by Versant, was derived from a portion of a fee that we pay Ridgeline, a portfolio company of Versant, for Ridgeline’s services to us, including services by Dr. Mayweg. Dr. Mayweg is not individually compensated by us. Dr. Mayweg served as our interim Chief Scientific Officer until September 2019. Like all full-time employees, our executive officers (except for Dr. Mayweg who is not employed by us) are eligible to participate in our health and welfare benefit plans. As we transition from a private company to a publicly traded company, we intend to evaluate our compensation philosophy and compensation plans and arrangements as circumstances require.

2018 Summary Compensation Table

The following table provides information regarding the total compensation, for services rendered in all capacities, that was earned by our named executive officers during fiscal year 2018.

Name and Principal Position	Year	Salary ($)	Option Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)(2)	All other Compensation ($)(3)	Total ($)
David M. Epstein, Ph.D.(4)						
Chief Executive Officer	2018	214,250	—	93,267	8,400	315,917
Elizabeth Buck, Ph.D.						
Executive Vice President, Discovery & Translational Sciences	2018	260,185	6,826	68,288	12,000	347,299
Alexander Mayweg, Ph.D. (5)						
Former Interim Chief Scientific Officer	2018	—	—	—	178,298	178,298

(1) The amount reported represent the aggregate grant date fair value of the stock option awarded to Ms. Buck during fiscal year 2018, calculated in accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 718. Such grant date fair value does not take into account any estimated forfeitures. The assumptions used in calculating the grant date fair value of the stock option reported in this column are set forth in note 9 of our consolidated financial statements included elsewhere in this prospectus. The amount reported in this column reflects the accounting cost for the stock option and does not correspond to the actual economic value that may be received by Ms. Buck upon the exercise of the stock option or any sale of the underlying shares of common stock.

(2) The amounts reported reflect discretionary bonuses paid to Dr. Epstein and Dr. Buck based upon achievement of certain company and individual performance metrics.

(3) The amounts reported represent the amount of contributions made by us to the Simplified Employee Pension Plans of Dr. Epstein and Dr. Buck.

(4) The amount reported for Dr. Epstein represents the total salary Dr. Epstein received for his part-time service to us in fiscal year 2018.

(5) Compensation for Dr. Mayweg, who is employed by Versant, was derived from a portion of a fee that we pay Ridgeline, a portfolio company of Versant, for Ridgeline's services to us, including services by Dr. Mayweg. The amount reported reflects the compensation that Ridgeline provides to Dr. Mayweg for his services to us in the form of Swiss Francs, or CHF, converted to United States Dollars, or USD, based on the applicable published CHF to USD exchange rates by the United States Federal Reserve as of the last day of each quarter of our fiscal year 2018. The amounts reported do not include any amounts paid by Versant or Ridgeline to Dr. Mayweg in connection with his services that are unrelated to us. Dr. Mayweg did not receive any compensation directly from us for services rendered in fiscal year 2018. Dr. Mayweg served as our interim Chief Scientific Officer until September 2019.

Narrative to 2018 Summary Compensation Table

Base Salaries

We use base salaries to recognize the experience, skills, knowledge and responsibilities required of all our employees, including our named executive officers employed by the Company. Base salaries are generally reviewed annually, typically in connection with our annual performance review process, and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and experience. For fiscal year 2018, the annual base salaries for Dr. Epstein and Dr. Buck were $214,250 and $250,000, respectively. Dr. Mayweg's compensation is determined by his employer, Versant, and he does not receive any compensation directly from us.

Annual Bonuses

During fiscal year 2018, Dr. Epstein and Dr. Buck earned bonuses as set forth in the 2018 Summary Compensation Table above based on company and individual performance metrics.

Equity Compensation

Although we do not have a formal policy with respect to the grant of equity incentive awards to our executive officers, we believe that equity grants provide our executives with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and our stockholders. In addition, we believe that equity grants with a time-based vesting feature promote executive retention because this feature incentivizes our executive officers to remain in our employment during the vesting period. Accordingly, our board of directors periodically reviews the equity incentive compensation of our named executive officers and from time to time may grant equity incentive awards to them. During fiscal year 2018, we granted an option to purchase shares of our common stock to Dr. Buck, as described in more detail in the "Outstanding Equity Awards at Fiscal 2018 Year End" table.

Executive Employment Arrangements

Executive Employment Arrangements

Employment Agreements in Place During the Year Ended December 31, 2018 for Named Executive Officers

David M. Epstein, Ph.D.

On March 14, 2017, we entered into an employment agreement with Dr. Epstein for the position of President and Chief Executive Officer. The employment agreement provided for Dr. Epstein's employment and set forth his annual base salary, his discretionary annual bonus, the term of his employment, certain expense reimbursements, and his eligibility to participate in our benefit plans generally. Dr. Epstein is subject to our

standard employment, confidential information, return of property, non-competition, non-solicitation, invention assignment and arbitration agreements, as provided in his employment agreement, as may be amended from time to time.

Elizabeth Buck, Ph.D.

On March 14, 2017, we entered into an employment agreement with Dr. Buck for the position of Executive Vice President, Research. The employment agreement provided for Dr. Buck employment and set forth her annual base salary, her discretionary annual bonus, the term of her employment, certain expense reimbursements, and her eligibility to participate in our benefit plans generally. Dr. Buck is subject to the employment, confidentiality, return of property, non-competition, non-solicitation, intellectual property, invention assignment and arbitration agreements as provided in her employment agreement.

Alexander Mayweg, Ph.D.

Dr. Mayweg served as our interim Chief Scientific Officer from March 2017 until September 2019. We do not have an offer letter or employment agreement in place with Dr. Mayweg since he was not employed by us.

Outstanding Equity Awards at Fiscal 2018 Year-End

The following table sets forth information regarding outstanding equity awards held by our named executive officers as of fiscal year 2018:

		Option Awards (1)				Stock Awards	
Name	Vesting Commencement Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock that Have not Vested (#)	Market Value of Shares or Units of Stock that Have Not Vested ($)(2)
Elizabeth Buck, Ph.D. (3)	9/13/2018	—	50,000	$ 0.24	9/12/2028	—	—
Alexander Mayweg, Ph.D. (4)	3/15/2017	—	—	—	—	20,417	$21,642.02

(1) Each equity award is subject to the terms of our 2017 Employee, Director and Consultant Equity Plan, as amended from time to time, or the 2017 Plan.

(2) The amount represents the number of unvested shares underlying the restricted stock award multiplied by the value per share of our common stock on December 31, 2018, which was $1.06 per share.

(3) 25% of the shares subject to the stock option vest on the first anniversary of the vesting commencement date and the remaining 75% vest in 36 equal monthly installments thereafter, generally subject to the named executive officer's continuous service relationship with the Company through each applicable vesting date.

(4) 33% of the shares subject to the restricted stock award vest on the first anniversary of the vesting commencement date and the remaining shares vest in 24 equal monthly installments thereafter, generally subject to the named executive officer's continuous service relationship with the Company through each applicable vesting date.

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Employee Benefits and Stock Plans

2019 Stock Option and Incentive Plan

Our 2019 Stock Option and Incentive Plan, or 2019 Plan, was adopted by our board of directors in and approved by our stockholders in and will become effective on the day before the date on which the registration statement of which this prospectus is part is declared effective by the SEC. The 2019 Plan will replace the 2017 Plan as our board of directors is expected to determine not to make additional awards under the 2017 Plan following the completion of our initial public offering. However, the 2017 Plan will continue to govern outstanding equity awards granted thereunder. The 2019 Plan will allow the compensation, nomination and corporate governance committee to make equity-based incentive awards to our officers, employees, directors and other key persons, including consultants.

Authorized Shares. We have initially reserved shares of our common stock for the issuance of awards under the 2019 Plan. The 2019 Plan provides that the number of shares reserved and available for issuance under the 2019 Plan will automatically increase each January 1, beginning on January 1, , by % of the outstanding number of shares of our common stock on the immediately preceding December 31 or such lesser number of shares as determined by our compensation, nomination and corporate governance committee. This number will be subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization. The shares we issue under the 2019 Plan will be authorized but unissued shares or shares that we reacquire. The shares of common stock underlying any awards that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without the issuance of stock, expire or are otherwise terminated, other than by exercise, under the 2019 Plan and the 2017 Plan will be added back to the shares of common stock available for issuance under the 2019 Plan. The maximum number of shares of common stock that may be issued as incentive stock options in any one calendar year period may not exceed , cumulatively increased on January 1, and on each January 1 thereafter by the lesser of % of the number of outstanding shares of common stock as of the immediately preceding December 31, or shares.

Non-Employee Director Limit. Our 2019 Plan contains a limitation whereby the value of all awards under our 2019 Plan and all other cash compensation paid by us to any non-employee director may not exceed: (i) $ in the first calendar year an individual becomes a non-employee director and (ii) $ in any other calendar year.

Administration. The 2019 Plan will be administered by our compensation, nomination and corporate governance committee. Our compensation, nomination and corporate governance committee will have full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to make any combination of awards to participants, and to determine the specific terms and conditions of each award, subject to the provisions of the 2019 Plan. The plan administrator is specifically authorized to exercise its discretion to reduce the exercise price of outstanding stock options and stock appreciation rights or effect the repricing of such awards through cancellation and re-grants.

Eligibility. Persons eligible to participate in the 2019 Plan will be those employees, non-employee directors and consultants, as selected from time to time by our compensation, nomination and corporate governance committee in its discretion.

Options. The 2019 Plan permits the granting of both options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code and options that do not so qualify. The option exercise price of each option will be determined by our compensation, nomination and corporate governance committee but may not be less than 100% of the fair market value of our common stock on the date of grant unless the option is granted (i) pursuant to a transaction described in, and in a manner consistent with, Section 424(a) of

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the Code or (ii) to individuals who are not subject to U.S. income tax. The term of each option will be fixed by our compensation, nomination and corporate governance committee and may not exceed 10 years from the date of grant. Our compensation, nomination and corporate governance committee will determine at what time or times each option may be exercised.

Stock Appreciation Rights. Our compensation, nomination and corporate governance committee may award stock appreciation rights subject to such conditions and restrictions as it may determine. Stock appreciation rights entitle the recipient to shares of common stock, or cash, equal to the value of the appreciation in our stock price over the exercise price. The exercise price may not be less than 100% of the fair market value of our common stock on the date of grant. The term of each stock appreciation right will be fixed by our compensation, nomination and corporate governance committee and may not exceed 10 years from the date of grant. Our compensation, nomination and corporate governance committee will determine at what time or times each stock appreciation right may be exercised.

Restricted Stock and Restricted Stock Units. Our compensation, nomination and corporate governance committee may award restricted shares of common stock and restricted stock units to participants subject to such conditions and restrictions as it may determine. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment with us through a specified vesting period.

Unrestricted Stock Awards. Our compensation, nomination and corporate governance committee may grant shares of common stock that are free from any restrictions under the 2019 Plan. Unrestricted stock may be granted to participants in recognition of past services or for other valid consideration and may be issued in lieu of cash compensation due to such participant.

Dividend Equivalent Rights. Our compensation, nomination and corporate governance committee may grant dividend equivalent rights to participants that entitle the recipient to receive credits for dividends that would be paid if the recipient had held a specified number of shares of common stock.

Cash-Based Awards. Our compensation, nomination and corporate governance committee may grant cash bonuses under the 2019 Plan to participants, subject to the achievement of certain performance goals.

Sale Event. The 2019 Plan provides that upon the effectiveness of a “sale event,” as defined in the 2019 Plan, an acquirer or successor entity may assume, continue or substitute for the outstanding awards under the 2019 Plan. To the extent that awards granted under the 2019 Plan are not assumed or continued or substituted by the successor entity, all unvested awards granted under the 2019 Plan shall terminate. In such case, except as may be otherwise provided in the relevant award agreement, all options and stock appreciation rights with time-based vesting, conditions or restrictions that are not exercisable immediately prior to the sale event will become fully exercisable as of the sale event, all other awards with time-based vesting, conditions or restrictions will become fully vested and nonforfeitable as of the sale event, and all awards with conditions and restrictions relating to the attainment of performance goals may become vested and nonforfeitable in connection with the sale event in the plan administrator’s discretion or to the extent specified in the relevant award agreement. In the event of such termination, individuals holding options and stock appreciation rights will be permitted to exercise such options and stock appreciation rights (to the extent exercisable) prior to the sale event. In addition, in connection with the termination of the 2019 Plan upon a sale event, we may make or provide for a cash payment to participants holding vested and exercisable options and stock appreciation rights equal to the difference between the per share cash consideration payable to stockholders in the sale event and the exercise price of the options or stock appreciation rights.

Amendment. Our board of directors may amend or discontinue the 2019 Plan and our compensation, nomination and corporate governance committee can amend or cancel outstanding awards for purposes of

satisfying changes in law or any other lawful purpose, but no such action may adversely affect rights under an award without the holder's consent. Certain amendments to the 2019 Plan will require the approval of our stockholders.

No awards may be granted under the 2019 Plan after the date that is 10 years from the date of stockholder approval of the 2019 Plan. No awards under the 2019 Plan have been made prior to the date hereof.

2017 Employee, Director and Consultant Equity Plan

Our 2017 Plan was approved by our board of directors and our stockholders in March 2017 and most recently amended by our board of directors in July 2019. As of December 31, 2018 and September 30, 2019, we reserved an aggregate of 5,413,708 shares of our common stock for the grant or issuance of options and other equity awards under the 2017 Plan. This number is subject to adjustment in the event of a stock split, stock dividend, or other change in our capitalization. As of December 31, 2018 and September 30, 2019, options to purchase 143,970 and 4,850,721 shares, respectively, of our common stock at a weighted average exercise price of $0.22 and $2.22 per share, respectively, and 400,039 and 378,503 shares, respectively, of unvested restricted stock were outstanding under the 2017 Plan, and 4,714,278 and 1,460,392 shares, respectively, remained available for future grant or issuance under the 2017 Plan. Following this offering, we will not grant or issue any further awards under our 2017 Plan, but all outstanding awards under the 2017 Plan will continue to be governed by their existing terms.

Authorized Shares. The shares we have issued under the 2017 Plan were authorized but unissued shares or shares we reacquired. The shares of common stock underlying any awards that are forfeited, canceled, reacquired by us prior to vesting, satisfied without the issuance of stock, or otherwise terminated (other than by exercise) and the shares of common stock that are withheld upon exercise of a stock option or settlement of an award to cover the exercise price or tax withholding, are currently added back to the shares of common stock available for issuance under the 2017 Plan. Following this offering, such shares will be added to the shares of common stock available for issuance under the 2019 Plan.

Administration. The 2017 Plan is currently administered by the compensation committee of the board of directors. The plan administrator has the authority to interpret and administer our 2017 Plan and any agreement thereunder and to determine the terms of awards, including the recipients, the number of shares subject to each award, the exercise price, if any, the vesting schedule applicable to the awards together with any vesting acceleration and the terms of the award agreement for use under our 2017 Plan. The plan administrator is specifically authorized to exercise its discretion to reduce or increase the exercise price of outstanding stock options or effect the repricing of stock options through cancellation and re-grants.

Eligibility. The 2017 Plan permits us to make grants of incentive stock options to our employees and any of our subsidiary corporations' employees, and grants of non-qualified stock options, restricted stock awards and unrestricted stock awards to the officers, employees, directors, and consultants of the Company and our subsidiary corporations.

Options. The 2017 Plan permits the granting of (i) stock options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Internal Revenue Code and (ii) stock options that do not so qualify. The option exercise price per share of our common stock underlying each stock option was determined by our board or directors or a committee appointed by the board of directors, and must have been at least equal to 100% of the fair market value of a share of our common stock on the date of grant. In the case of an incentive stock option granted to a participant who, at the time of grant of such stock option, owned stock representing more than 10% of the voting power of stock of the Company, or a 10% owner, the exercise price per share of our common stock underlying each such stock option must have been at least equal to 110% of the fair market value of a share of our common stock on the date of grant. The term of each stock option may not have exceeded 10 years from the date of grant (or five years for a 10% owner). The plan administrator will

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determine the methods of payment of the exercise price of a stock option, which may include cash, a net exercise arrangement for non-qualified stock options, a promissory note (if permitted by the board of directors) and if permitted by the board of directors or a committee appointed by the board of directors and an initial public offering of the Company has occurred, through either the delivery of shares of our common stock owned by the participant or a broker-assisted arrangement. After a participant's termination of service (other than a termination for cause), the participant generally may exercise his or her stock options, to the extent vested as of such date of termination, for thirty days after termination or such longer period of time as specified in the applicable stock option agreement; provided, that if the termination is due to death or disability, the stock option generally will remain exercisable, to the extent vested as of such date of termination, until six months following such termination. However, in no event may a stock option be exercised later than the expiration of its term.

Restricted Stock. The 2017 Plan permits the granting of shares of restricted stock. Restricted stock awards are grants of shares of our common stock that are subject to various restrictions, including restrictions on transferability and forfeitures provisions. Shares of restricted stock will vest, and the restrictions on such shares will lapse, in accordance with terms and conditions established by the administrator.

Unrestricted Stock. The 2017 Plan permits the granting of shares of unrestricted stock. Unrestricted stock awards may be granted to participants in recognition of past services or for other valid consideration and may be issued in lieu of cash compensation due to such participant.

Transferability or Assignability of Awards. The 2017 Plan generally does not allow for the transfer or assignment of awards, other than, at the discretion of the plan administrator, by will or the laws of descent and distribution, by gift to an immediate family member, or by instrument to an inter vivos or testamentary trust in which the award is passed to beneficiaries upon the death of the participant.

Corporate Transaction. The 2017 Plan provides that upon the occurrence of a "Corporate Transaction" as defined in the 2017 Plan, awards may be assumed, substituted for new awards of a successor entity, or otherwise continued or terminated at the effective time of such Corporate Transaction. In the case of the termination of outstanding stock options, such holder of stock options, to the extent such stock options would have been exercisable or as otherwise determined by the administrator, must be provided written notice and a period of time at which such stock options may be exercised prior to the consummation of the Corporate Transaction. We may also make or provide for a cash payment to holders of vested and exercisable stock options, in exchange for the cancellation thereof, equal to, for each share of our common stock underlying such stock option, the difference between the per share cash consideration in the Corporate Transaction and the per share exercise price. We may make or provide for a cash payment to holders of restricted stock awards, in exchange for the cancellation thereof, in an amount equal to the product of the per share cash consideration in the Corporate Transaction and the number of shares subject to each such award, to the extent such restricted stock award is no longer subject to any forfeiture or repurchase rights then in effect or as otherwise determined by the administrator.

Amendment. Our board of directors may amend, suspend, or terminate the 2017 Plan at any time, subject to stockholder approval where such approval is required by applicable law. The board of directors may also amend, modify, or terminate any outstanding award, including the exercise price of such award, provided that no amendment to an award may adversely affect any of the rights of a participant under any awards previously granted without his or her consent. We will not make any further grants under the 2017 Plan following this initial public offering.

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2019 Employee Stock Purchase Plan

In , 2019, our board of directors adopted, and our shareholders approved, our 2019 Employee Stock Purchase Plan, or the ESPP. The ESPP will become effective immediately prior to the time that the registration statement of which this prospectus forms a part is declared effective by the SEC. The ESPP will initially reserve and authorize the issuance of up to a total of shares of common stock to participating employees. The ESPP will provide that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2020, by the lesser of shares of our common stock, 1% of the outstanding number of shares of our common stock on the immediately preceding December 31, or such lesser number of shares as determined by our compensation, nomination and corporate governance committee. This number will be subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization.

All employees whose customary employment is for more than 20 hours per week or are otherwise required to participate by applicable local law are eligible to participate in the ESPP. Any employee who owns 5% or more of the total combined voting power or value of stock will not be eligible to purchase shares under the ESPP.

We will make one or more offerings, consisting of one or more purchase periods, each year to our employees to purchase shares under the ESPP. The first offering will begin on the effective date of the registration statement of which this prospectus is part and, unless otherwise determined by the administrator of the ESPP, will end on the date that is approximately months following such date. Each eligible employee as of the effective date of the registration statement for the offering will be deemed to be a participant in the ESPP at that time and must authorize payroll deductions or other contributions by submitting an enrollment form by the deadline specified by the plan administrator. Subsequent offerings will usually begin every six months and will continue for six-month periods, referred to as offering periods. Each eligible employee may elect to participate in any subsequent offering by submitting an enrollment form at least 15 days before the relevant offering date.

Each employee who is a participant in the ESPP may purchase shares by authorizing contributions of up to % of his or her compensation during an offering period. Unless the participating employee has previously withdrawn from the offering, his or her accumulated contributions will be used to purchase shares on the last business day of the purchase period at a price equal to 85% of the fair market value of the shares on the first business day of the offering period or the last business day of the purchase period, whichever is lower, provided that no more than shares of common stock (or a lesser number as established by the plan administrator in advance of the purchase period) may be purchased by any one employee during each purchase period. Under applicable tax rules, an employee may purchase no more than $25,000 worth of shares of common stock, valued at the start of the offering period, under the ESPP for each calendar year in which a purchase right is outstanding.

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

The ESPP may be terminated or amended by our board of directors at any time but shall automatically terminate on the 10 year anniversary of this offering. An amendment that increases the number of shares of common stock that are authorized under the ESPP and certain other amendments will require the approval of our stockholders. The plan administrator may adopt subplans under the ESPP for employees of our non U.S. subsidiaries who may participate in the ESPP and may permit such employees to participate in the ESPP on different terms, to the extent permitted by applicable law.

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Senior Executive Cash Incentive Bonus Plan

In 2019, our board of directors adopted the Senior Executive Cash Incentive Bonus Plan, or the Bonus Plan. The Bonus Plan will become effective on the day before the date on which the registration statement of which this prospectus is part is declared effective by the SEC. The Bonus Plan provides for cash bonus payments based upon the attainment of performance targets established by our compensation, nomination and corporate governance committee. The payment targets will be related to financial and operational measures or objectives with respect to our company, or corporate performance goals, as well as individual performance objectives.

Our compensation, nomination and corporate governance committee may select corporate performance goals from among the following: changes in the market price of our common stock; economic value-added; acquisitions or strategic transactions, including licenses, collaborations, joint ventures or promotion arrangements; operating income (loss); return on capital, assets, equity, or investment; total stockholder returns; progress with our research and development programs; expense efficiency; margins; operating efficiency; working capital; earnings (loss) per share of our common stock; any of which may be (A) measured in absolute terms or compared to any incremental increase, (B) measured in terms of growth, (C) compared to another company or companies or to results of a peer group, (D) measured against the market as a whole and/or as compared to applicable market indices and/or (E) measured on a pre-tax or post-tax basis (if applicable).

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

Simplified Employee Pension Plans

The Company maintains simplified employee pension plans for its full-time employees, which are intended to satisfy the requirements under Section 408 of the Internal Revenue Code of 1986, as amended. Under the terms of this plans, we may, but are not required, to make discretionary contributions to each participant's individual retirement account. Contributions to the plans are generally deductible by us when made, and are not taxable to participants until distributed. Pursuant to the plans, participants may direct the trustees to invest their individual retirement accounts.

Non-Employee director compensation

We did not pay any compensation or make any equity awards or non-equity awards to any of our non-employee directors during the fiscal year ended December 31, 2018, or fiscal year 2018, and as of December 31, 2018, our non-employee directors did not hold any outstanding equity awards. Directors may be reimbursed for travel and other expenses directly related to their activities as directors.

Directors who also serve as executive officers receive no additional compensation for their service as directors. During our fiscal year 2018, David M. Epstein, Ph.D., our President and Chief Executive Officer and Alexander

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Mayweg, Ph.D., our former interim Chief Scientific Officer served as members of our board of directors, as well as an employee or independent contractor, respectively, and received no additional compensation for their services as members of our board of directors. See the section titled “Executive Compensation” for more information about Dr. Epstein’s and Dr. Mayweg’s compensation for our fiscal year 2018.

Prior to the effectiveness of the registration statement of which this prospectus forms a part, we did not have a formal policy to compensate our non-employee directors. As of the effectiveness of the registration statement of which this prospectus forms a part, we intend to implement a formal policy pursuant to which our non-employee directors will be eligible to receive the following cash retainers and equity awards:

Annual Retainer for Board Membership	
Annual service on the board of directors	$
Additional Annual Retainer for Committee Membership	
Annual service as member of the audit committee (other than chair)	$
Annual service as chair of the audit committee	$
Annual service as member of the compensation, nomination and corporate governance committee (other than chair)	$
Annual service as chair of the compensation, nomination and corporate governance committee	$

Our policy will provide that, upon initial election to our board of directors following the completion of this offering, each non-employee director will be granted (“Initial Grant”). Furthermore, on the date of each of our annual meeting of stockholders following the completion of this offering, each non-employee director who will continue as a non-employee director following such meeting will be granted (“Annual Grant”). The Annual Grant will vest , subject to continued service as a director through the applicable vesting date. The Initial Grant will vest , subject to continued service as a director through the applicable vesting date. Such awards are subject to full accelerated vesting upon the sale of the Company.

Employee directors will receive no additional compensation for their service as a director.

We will reimburse all reasonable out-of-pocket expenses incurred by directors for their attendance at meetings of our board of directors or any committee thereof.

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Certain relationships and related person transactions

The following is a description of transactions or series of transactions since our inception on September 20, 2016, to which we were or will be a party, in which:

- the amount involved in the transaction exceeds, or will exceed, $120,000; and
- in which any of our executive officers, directors or holder of five percent or more of any class of our capital stock, including their immediate family members or affiliated entities, had or will have a direct or indirect material interest.

Compensation arrangements for our named executive officers and our directors are described elsewhere in this prospectus under “Director Compensation” and “Executive Compensation.”

Private placements of securities

Common Stock Financing

In March 2017, we sold an aggregate of 1,000,000 shares of our common stock at a purchase price of $0.10 per share for an aggregate amount of $100,000. The following table summarizes purchases of our common stock by related persons:

Stockholder	Shares of common stock	Total purchase price
Entities affiliated with Versant Venture Capital(1)	1,000,000	$ 100,000.00

(1) Represents 100,000 shares of common stock purchased by Versant Venture Capital VI, L.P. Each of Bradley Bolzon and Alexander Mayweg serves as a director of the Company and is an affiliate of Versant Venture Capital, of which Versant Venture Capital VI, L.P. is an affiliated fund. Entities affiliated with Versant Venture Capital collectively hold more than 5% of our voting securities.

Series A Preferred Stock Financing

In March 2017, with subsequent closings in December 2017, August 2018 and November 2018, we sold an aggregate of 22,501,503 shares of our Series A preferred stock at a purchase price of $1.00 per share for an aggregate amount of $20 million. In connection with the issuance of our Series A preferred stock, all of our outstanding convertible promissory notes issued in 2014, 2015 and 2016 were automatically converted into 2,501,503 shares of our Series A preferred stock. Certain investors holding convertible notes issued in 2014, 2015 and 2016 used such notes to purchase our Series A preferred stock. All outstanding convertible notes were cancelled in connection with the purchase of such Series A preferred stock. The following table summarizes purchases of our Series A preferred stock by related persons:

Stockholder	Shares of Series A preferred stock	Total purchase price
Entities affiliated with Versant Venture Capital(1)	20,000,000	$ 20,000,000.00

(1) Represents 15,000,000 shares of Series A preferred stock purchased by Versant Venture Capital VI, L.P., 3,728,392 shares of Series A preferred stock purchased by Versant Voyageurs I, L.P., and 1,271,608 shares of Series A preferred stock purchased by Versant Voyageurs I Parallel, L.P. Each of Bradley Bolzon and Alexander Mayweg serves as a director of the Company and is an affiliate of Versant Venture Capital, , of which Versant Venture Capital VI, L.P., Versant Voyageurs I, L.P., and Versant Voyageurs I Parallel, L.P. are affiliated funds. Entities affiliated with Versant Venture Capital collectively hold more than 5% of our voting securities.

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Series B preferred stocking financing

In December 2018, with subsequent closings in July 2019 and August 2019, we sold an aggregate of 22,917,726 shares of our Series B preferred stock at a purchase price of $3.806 per share for an aggregate amount of $87.2 million. The following table summarizes purchases of our Series B preferred stock by related persons:

Stockholder	Shares of Series B preferred stock		Total purchase price
Entities affiliated with Versant Venture Capital(1)	3,941,142	$	15,000,000.00
Entities affiliated with New Enterprise Associates(2)	6,568,574	$	25,000,000.00
Entities affiliated with RA Capital Management(3)	3,941,142	$	15,000,000.00
Nextech V Oncology SCS, SICAV-SIF(4)	2,627,430	$	10,000,000.00
Artal International SCA(5)	2,627,430	$	10,000,000.00
David M. Epstein(6)	13,136	$	50,000.00

(1) Represents 1,970,572 shares of Series B preferred stock purchased by Versant Venture Capital VI, L.P., 1,469,412 shares of Series B preferred stock purchased by Versant Voyageurs I, L.P., and 501,158 shares of Series B preferred stock purchased by Versant Voyageurs I Parallel, L.P. Each of Bradley Bolzon and Alexander Mayweg serves as a director of the Company and is an affiliate of Versant Venture Capital, of which Versant Venture Capital VI, L.P., Versant Voyageurs I, L.P., and Versant Voyageurs I Parallel, L.P. are affiliated funds. Entities affiliated with Versant Venture Capital collectively hold more than 5% of our voting securities.

(2) Represents 6,565,290 shares of Series B preferred stock purchased by New Enterprise Associates 16, L.P. and 3,284 shares of Series B preferred stock purchased by NEA Ventures 2018, Limited Partnership. Ali Behbahani serves as a director of the Company and is an affiliate of New Enterprise Associates, of which New Enterprise Associates 16, L.P. and NEA Ventures 2018, Limited Partnership are affiliated funds. Entities affiliated with New Enterprise Associates collectively hold more than 5% of our voting securities.

(3) Represents 2,885,295 shares of Series B preferred stock purchased by RA Capital Healthcare Fund, LP, 492,643 shares of Series B preferred stock purchased by RA Capital Nexus Fund, L.P. and 563,204 shares of Series B preferred stock purchased by Blackwell Partners LLC—Series A. Rajeev Shah serves as a director of the Company and is an affiliate of RA Capital Management, of which RA Capital Healthcare Fund, LP, RA Capital Nexus Fund, L.P. and Blackwell Partners LLC—Series A are affiliated funds. Entities affiliated with RA Capital Management collectively hold more than 5% of our voting securities.

(4) Nextech V Oncology SCS, SICAV-SIF holds more than 5% of our voting securities.

(5) Artal International SCA holds more than 5% of our voting securities.

(6) David M. Epstein is a founder of the Company and currently serves as our Chief Executive Officer and President. Dr. Epstein holds more than 5% of our voting securities.

Agreement with Ridgeline Therapeutics

We entered into a services agreement with Ridgeline Therapeutics GmbH, or Ridgeline, in March 2017, amended in November 2017 and December 2018. Ridgeline is a discovery engine owned by Versant Ventures Capital. Pursuant to the services agreement, Ridgeline provides us with certain services, including research and development and management and administration. Ridgeline also provides us with the services of a team of scientists. In connection with the services provided, we pay Ridgeline $950,000 a month, which is reconciled on a quarterly basis with the actual expenses incurred by Ridgeline on our behalf and a corresponding reconciling payment is made by us to (or received by us from) Ridgeline each quarter. We paid Ridgeline $1.4 million and $2.7 million in the years ended December 31, 2017 and 2018 and $7.6 million in the nine months ended September 30, 2019.

Each of Bradley Bolzon and Alexander Mayweg serves as a director of the Company and is an affiliate of Versant Venture Capital, of which Versant Venture Capital VI, L.P., Versant Voyageurs I, L.P., and Versant Voyageurs I Parallel, L.P. are affiliated funds. Entities affiliated with Versant Venture Capital collectively hold more than 5% of our voting securities. See “Business—Our Collaboration with Ridgeline Therapeutics.”

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Agreements with stockholders

In connection with our Series A preferred stock financings and our Series B preferred stock financings, we entered into investors' rights, voting and right of first refusal and co-sale agreements containing registration rights, information rights, voting rights and rights of first refusal, among other things, with certain holders of our preferred stock and certain holders of our common stock. These stockholder agreements will terminate upon the closing of this offering, except for the registration rights granted under our investors' rights agreement, as more fully described in "Description of Capital Stock—Registration Rights."

Stock option grants to executive officers

We have granted stock options to our named executive officers as more fully described in the section entitled "Executive Compensation."

Indemnification agreements

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

Policies for approval of related party transactions

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

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

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Principal stockholders

The following table sets forth, as of October 30, 2019, information regarding the beneficial ownership of our common stock by:

- each person, or group of affiliated persons, who is known by us to be the beneficial owner of five percent or more of our outstanding common stock (on an as-converted to common stock basis);
- each of our directors;
- each of our named executive officers; and
- all of our current directors and executive officers as a group.

The information in the following table is calculated based on shares of common stock deemed to be outstanding before this offering and shares of common stock outstanding after this offering, assuming no exercise by the underwriters of their option to purchase additional shares of common stock. The number of shares outstanding is based on the number of shares of common stock outstanding as of , 2019 as adjusted to give effect to:

- the automatic conversion of all outstanding shares of our convertible preferred stock into shares of common stock upon the completion of this offering; and
- the sale of shares of common stock in this offering (assuming no exercise of the underwriters' option to purchase additional shares).

Each individual or entity shown on the table has furnished information with respect to beneficial ownership. Except as otherwise indicated below, the address of each officer, director and five percent stockholder listed below is c/o Black Diamond Therapeutics, Inc., 139 Main Street, Cambridge, MA 02142.

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We have determined beneficial ownership in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities as well as any shares of common stock that the person has the right to acquire within 60 days of October 30, 2019 through the exercise of stock options or other rights. These shares are deemed to be outstanding and beneficially owned by the person holding those options for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them.

	Shares of common stock beneficially owned	Percentage of shares outstanding	
		Before offering	After offering
5% or Greater Stockholders			
Entities affiliated with Versant Venture Capital		%	%
Entities affiliated New Enterprise Associates		%	%
Entities affiliated RA Capital Management		%	%
Nextech V Oncology SCS, SICAV-SIF		%	%
Artal International SCA		%	%
Directors, Named Executive Officers and Other Executive Officers			
David M. Epstein		%	%
Brent Hatzis-Schoch		%	%
Thomas Leggett		%	%
Christopher D. Roberts		%	%
Ali Behbahani		%	%
Bradley Bolzon		%	%
Alexander Mayweg		%	%
Garry E. Menzel		%	%
Rajeev Shah		%	%
All executive officers and directors as a group (9 persons)		%	%

* Less than one percent.

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Description of capital stock

The following descriptions are summaries of the material terms of our amended and restated certificate of incorporation and amended and restated bylaws, which will be effective immediately upon the closing of this offering. The descriptions of the common stock and preferred stock give effect to changes to our capital structure that will occur immediately upon the closing of this offering. We refer in this section to our amended and restated certificate of incorporation as our certificate of incorporation, and we refer to our amended and restated bylaws as our bylaws.

General

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

As of September 30, 2019, 6,695,460 shares of our common stock (of which 695,460 shares are subject to a right of repurchase by us pursuant to a stock restriction agreement between us and the holders of such shares) were outstanding and held of record by 12 stockholders, and 22,501,503 shares of Series A preferred stock and 22,917,726 shares of Series B preferred stock were outstanding and held of record by 24 stockholders. This amount does not take into account the conversion of all outstanding shares of our preferred stock into common stock upon the closing of this offering.

Common stock

The holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights. Holders of our common stock are entitled to receive ratably any dividends declared by our board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions.

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock. The shares to be issued by us in this offering will be, when issued and paid for, validly issued, fully paid and non-assessable.

Preferred stock

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

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Options

As of September 30, 2019, options to purchase 4,850,721 shares of common stock at a weighted-average exercise price of $2.22 per share were outstanding under our 2017 Plan.

Warrants

As of September 30, 2019, warrants to purchase shares of common stock at an exercise price of $ per share were outstanding, which warrants were not granted pursuant to a benefits plan.

Registration rights

Upon the completion of this offering, the holders of shares of our common stock, including those issuable upon the conversion of preferred stock, will be entitled to rights with respect to the registration of these securities under the Securities Act. These rights are provided under the terms of an amended and restated investors' rights agreement between us, certain holders of our common stock and holders of our preferred stock. The amended and restated investors' rights agreement includes demand registration rights, short-form registration rights and piggyback registration rights. All fees, costs and expenses of underwritten registrations under this agreement will be borne by us and all selling expenses, including underwriting discounts and selling commissions, will be borne by the holders of the shares being registered.

Demand registration rights

Beginning 180 days after the effective date of this registration statement, the holders of shares of our common stock, including those issuable upon the conversion of shares of our preferred stock upon closing of this offering, are entitled to demand registration rights. Under the terms of the investors' rights agreement, we will be required, upon the written request of holders of at least a majority of the securities eligible for registration then outstanding, to file a registration statement with respect to at least forty percent of the securities eligible for registration then outstanding, we will be required to file a registration statement covering all securities eligible for registration that our stockholders request to be included in such registration. We are required to effect only two registrations pursuant to this provision of the investors' rights agreement in any twelve-month period.

Short-form registration rights

Pursuant to the amended and restated investors' rights agreement, if we are eligible to file a registration statement on Form S-3, upon the written request of stockholders holding at least a majority of the securities eligible for registration then outstanding we will be required to file a Form S-3 registration restatement with respect to outstanding securities of such stockholders having an anticipated aggregate offering, net of related fees and expenses, of at least $5 million. We are required to effect only two registrations in any twelve month period pursuant to this provision of the amended and restated investors' rights agreement. The right to have such shares registered on Form S-3 is further subject to other specified conditions and limitations.

Piggyback registration rights

Pursuant to the amended and restated investors' rights agreement, if we register any of our securities either for our own account or for the account of other security holders, the holders of our common stock, including those issuable upon the conversion of our preferred stock, are entitled to include their shares in the registration. Subject to certain exceptions contained in the amended and restated investors' rights agreement,

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we and the underwriters may limit the number of shares included in the underwritten offering to the number of shares which we and the underwriters determine in our sole discretion will not jeopardize the success of the offering.

Indemnification

Our amended and restated investors' rights agreement contains customary cross-indemnification provisions, under which we are obligated to indemnify holders of registrable securities in the event of material misstatements or omissions in the registration statement attributable to us, and they are obligated to indemnify us for material misstatements or omissions attributable to them.

Expiration of registration rights

The demand registration rights and short form registration rights granted under the amended and restated investors' rights agreement will terminate on the fifth anniversary of the completion of this offering or at such time after this offering when the holders' shares may be sold without restriction pursuant to Rule 144 within a three month period.

Expenses

Ordinarily, other than underwriting discounts and commissions, we are generally required to pay all expenses incurred by us related to any registration effected pursuant to the exercise of these registration rights. These expenses may include all registration and filing fees, printing expenses, fees and disbursements of our counsel, reasonable fees and disbursements of a counsel for the selling security holders and blue-sky fees and expenses.

Anti-takeover effects of Delaware law and certain provisions of our certificate of incorporation and amended and restated bylaws

Our certificate of incorporation and bylaws include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Board composition and filling vacancies

Our certificate of incorporation provides for the division of our board of directors into three classes serving staggered three-year terms, with one class being elected each year. Our certificate of incorporation also provides that directors may be removed only for cause and then only by the affirmative vote of the holders of or more of the shares then entitled to vote at an election of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum. The classification of directors, together with the limitations on removal of directors and treatment of vacancies, has the effect of making it more difficult for stockholders to change the composition of our board of directors.

No written consent of stockholders

Our certificate of incorporation provides that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent

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in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our bylaws or removal of directors by our stockholders without holding a meeting of stockholders.

Meetings of stockholders

Our certificate of incorporation and bylaws provide that only a majority of the members of our board of directors then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance notice requirements

Our bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our bylaws specify the requirements as to form and content of all stockholders' notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

Amendment to certificate of incorporation and bylaws

Any amendment of our certificate of incorporation must first be approved by a majority of our board of directors, and if required by law or our certificate of incorporation, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to stockholder action, board composition, limitation of liability and the amendment of our bylaws and certificate of incorporation must be approved by not less than of the outstanding shares entitled to vote on the amendment, and not less than of the outstanding shares of each class entitled to vote thereon as a class. Our bylaws may be amended by the affirmative vote of a majority of the directors then in office, subject to any limitations set forth in the bylaws; and may also be amended by the affirmative vote of at least of the outstanding shares entitled to vote on the amendment, or, if our board of directors recommends that the stockholders approve the amendment, by the affirmative vote of the majority of the outstanding shares entitled to vote on the amendment, in each case voting together as a single class.

Undesignated preferred stock

Our certificate of incorporation provides for authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our certificate of incorporation grants our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock

could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Delaware anti-takeover statute

Upon completion of this offering, we will be subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or
- at or after the time the stockholder became interested, the business combination was approved by our board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, lease, pledge, exchange, mortgage or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Choice of forum

Our amended and restated bylaws that will become effective upon the completion of this offering provide that the Court of Chancery of the State of Delaware will be the exclusive forum for state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a breach of fiduciary duty by one or more of our directors, officers or employees, (iii) any action asserting a claim against us arising pursuant to the Delaware General Corporation Law or (iv) any action asserting a claim against us that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein (the "Delaware Forum Provision"); provided, however, that this forum provision will not apply to any causes of action arising under the Exchange Act or the Securities

Act. In addition, our amended and restated bylaws will provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the Delaware Forum Provision. We recognize that the Delaware Forum Provision in our bylaws may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware. Additionally, the Delaware Forum Provision may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees. The Court of Chancery of the State of Delaware may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

Stock exchange listing

We intend to apply to list our common stock on The Nasdaq Global Market under the proposed trading symbol "BDTX."

Transfer agent and registrar

The Transfer Agent and Registrar for our common stock will be .

Shares eligible for future sale

Prior to this offering, there has been no public market for our shares. Future sales of our common stock in the public market, or the availability of such shares for sale in the public market, could adversely affect market prices prevailing from time to time. As described below, only a limited number of shares will be available for sale shortly after this offering due to contractual and legal restrictions on resale. Nevertheless, sales of shares of our common stock in the public market after such restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price at such time and our ability to raise equity capital in the future.

Based on the number of shares outstanding as of September 30, 2019, upon the completion of this offering, shares of our common stock will be outstanding, assuming the issuance of shares offered by us in this offering, no exercise of the underwriters' option to purchase additional shares and no exercise of outstanding options or warrants. Of the outstanding shares, all of the shares sold in this offering will be freely tradable, except that any shares held by our affiliates, as that term is defined in Rule 144 under the Securities Act, may only be sold in compliance with the limitations described below, and restricted shares of common stock are subject to time-based vesting terms. All remaining shares of common stock held by existing stockholders immediately prior to the completion of this offering will be "restricted securities" as such term is defined in Rule 144 under the Securities Act. These restricted securities were issued and sold by us in private transactions and are eligible for public sale only if registered under the Securities Act or if they qualify for an exemption from registration under the Securities Act, including the exemptions provided by Rule 144 or Rule 701, summarized below.

Rule 144

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

sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of either of the following:

- 1% of the number of shares then outstanding, which will equal approximately shares immediately after this offering, assuming no exercise of the underwriters' option to purchase additional shares, based on the number of shares outstanding as of September 30, 2019; or
- the average weekly trading volume of our common stock on The Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale;

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

Rule 701

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

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

Lock-up agreements

We, all of our directors and officers and substantially all of our stockholders have agreed not to sell or otherwise transfer or dispose of any of our securities for a period of 180 days from the date of this prospectus, subject to certain exceptions. J.P. Morgan Securities LLC, Jefferies LLC and Cowen and Company LLC may, in their sole discretion, permit early release of shares subject to the lock-up agreements. See the section entitled "Underwriting," appearing elsewhere in this prospectus for more information.

Registration rights

Upon completion of this offering, certain holders of our securities will be entitled to various rights with respect to registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration. See the section entitled "Description of Capital Stock—Registration Rights" appearing elsewhere in this prospectus for more information.

Equity incentive plans

We intend to file one or more registration statements on Form S-8 under the Securities Act to register our shares issued or reserved for issuance under our equity incentive plans. The first such registration statement is expected to be filed soon after the date of this prospectus and will automatically become effective upon filing with the SEC. Accordingly, shares registered under such registration statement will be available for sale in the open market, unless such shares are subject to vesting restrictions with us or the lock-up restrictions described above. As of the date of this prospectus, we estimate that such registration statement on Form S-8 will cover approximately shares.

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

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

- a nonresident alien individual;
- a corporation or other organization taxable as a corporation for U.S. federal income tax purposes that is created or organized in or under laws other than the laws of the United States, any state thereof, or the District of Columbia;
- an estate the income of which is not subject to U.S. federal income tax on a net income basis; or
- a trust the income of which is not subject to U.S. federal income tax on a net income basis and that (1) is not subject to the primary supervision of a court within the United States or over which no U.S. persons have authority to control all substantial decisions and (2) has not made an election to be treated as a U.S. person.

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

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

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

- insurance companies;
- tax-exempt or governmental organizations;
- financial institutions;
- brokers or dealers in securities;
- regulated investment companies;

- pension plans;
- “controlled foreign corporations,” “passive foreign investment companies,” and corporations that accumulate earnings to avoid U.S. federal income tax;
- “qualified foreign pension funds,” or entities wholly owned by a “qualified foreign pension fund”;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment; and
- certain U.S. expatriates.

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

Distributions on our common stock

Distributions, if any, on our common stock will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder’s investment, up to such holder’s tax basis in the common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in “Gain on Sale or Other Taxable Disposition of Our Common Stock.” Any such distributions will also be subject to the discussions below under the sections titled “Backup Withholding and Information Reporting” and “Withholding and Information Reporting Requirements—FATCA.”

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

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

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

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Gain on sale or other taxable disposition of our common stock

Subject to the discussions below under “Backup Withholding and Information Reporting” and “Withholding and Information Reporting Requirements—FATCA,” a non-U.S. holder generally will not be subject to any U.S. federal income or withholding tax on any gain realized upon such holder’s sale or other taxable disposition of shares of our common stock unless:

- the gain is effectively connected with the non-U.S. holder’s conduct of a U.S. trade or business and, if an applicable income tax treaty so provides, is attributable to a permanent establishment or a fixed-base maintained by such non-U.S. holder in the United States, in which case the non-U.S. holder generally will be taxed on a net income basis at the graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code) and, if the non-U.S. holder is a foreign corporation, the branch profits tax described above in “Distributions on Our Common Stock” also may apply;
- the non-U.S. holder is a nonresident alien individual who is present in the United States for 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder’s country of residence) on the net gain derived from the disposition, which may be offset by certain U.S. source capital losses of the non-U.S. holder, if any (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses; or
- we are, or have been, at any time during the five-year period preceding such sale of other taxable disposition (or the non-U.S. holder’s holding period, if shorter) a “U.S. real property holding corporation,” as described below, unless our common stock is regularly traded on an established securities market and the non-U.S. holder holds no more than 5% of our outstanding common stock, directly or indirectly, actually or constructively, during the shorter of the 5-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. Generally, a corporation is a U.S. real property holding corporation if the fair market value of its U.S. real property interests, as defined in the Code and applicable Treasury regulations, equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we do not believe that we are, or have been, a U.S. real property holding corporation, or that we are likely to become one in the future. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above.

Backup withholding and information reporting

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

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

a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker.

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

Withholding and information reporting requirements—FATCA

Provisions of the Code commonly referred to as the Foreign Account Tax Compliance Act (FATCA), generally impose a U.S. federal withholding tax at a rate of 30% on payments of dividends on, or, subject to the discussion of certain proposed U.S. Treasury regulations below, gross proceeds from the sale or other disposition of, our common stock paid to a foreign entity unless (i) if the foreign entity is a "foreign financial institution," such foreign entity undertakes certain due diligence, reporting, withholding, and certification obligations, (ii) if the foreign entity is not a "foreign financial institution," such foreign entity identifies certain of its U.S. investors, if any, or (iii) the foreign entity is otherwise exempt under FATCA. However, the U.S. Treasury recently released proposed regulations which, if finalized in their present form, would eliminate the federal withholding tax of 30% applicable to the gross proceeds of a sale or other disposition of our common stock. In the preamble to such proposed regulations, the U.S. Treasury stated that taxpayers may generally rely on the proposed regulations until final regulations are issued. Under certain circumstances, a non-U.S. holder may be eligible for refunds or credits of this withholding tax. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph. Non-U.S. holders should consult their tax advisors regarding the possible implications of this legislation on their investment in our common stock and the entities through which they hold our common stock, including, without limitation, the process and deadlines for meeting the applicable requirements to prevent the imposition of the 30% withholding tax under FATCA.

Federal estate tax

Individual Non-U.S. Holders and entities the property of which is potentially includible in such an individual's gross estate for U.S. federal estate tax purposes (for example, a trust funded by such an individual and with respect to which the individual has retained certain interests or powers), should note that, absent an applicable treaty exemption, our common stock will be treated as U.S.-situs property subject to U.S. federal estate tax.

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Underwriting

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

Name	Number of shares
J.P. Morgan Securities LLC	
Jefferies LLC	
Cowen and Company, LLC	
Canaccord Genuity LLC	
Total	

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

The underwriters propose to offer the common shares directly to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of $ per share. Any such dealers may resell shares to certain other brokers or dealers at a discount of up to $ per share from the initial public offering price. After the initial offering of the shares to the public, if all of the common shares are not sold at the initial public offering price, the underwriters may change the offering price and the other selling terms.

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

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

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

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We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discounts and commissions, will be approximately $. We have agreed to reimburse the underwriters for expense relating to clearance of this offering with the Financial Industry Regulatory Authority, Inc. of up to $.

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

We have agreed that we will not (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, or submit to, or file with the Securities and Exchange Commission a registration statement under the Securities Act relating to, any shares of our common stock or securities convertible into or exchangeable or exercisable for any shares of our common stock, or publicly disclose the intention to make any offer, sale, pledge, disposition or filing, or (ii) enter into any swap or other arrangement that transfers all or a portion of the economic consequences associated with the ownership of any shares of common stock or any such other securities (regardless of whether any of these transactions are to be settled by the delivery of shares of common stock or such other securities, in cash or otherwise), in each case without the prior written consent of J.P. Morgan Securities LLC, Jefferies LLC and Cowen and Company, LLC for a period of 180 days after the date of this prospectus, other than the shares of our common stock to be sold hereunder and any shares of our common stock issued upon the exercise of options granted under our existing stock-based compensation plans.

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

a) the sale of shares of common stock, to be sold by our directors, executive officers, and certain of our shareholders pursuant to the underwriting agreement;

b) sales or transfers of shares of our common stock acquired in this offering or in open market transactions after the consummation of this offering;

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

d) if the holder is an individual, transfers of shares of our common stock or any security directly or indirectly convertible into our common stock to any trust for the direct or indirect benefit of the holder or the immediate family of the holder, or limited partnerships the partners of which are the holder and/or the immediate family members of the holder, in each case for estate planning purposes;

e) if the holder is a trust, distributions of shares of our common stock or any security directly or indirectly convertible into shares of our common stock to its beneficiaries in a transaction not involving a disposition for value;

f) if the holder is a corporation, limited liability company, partnership (whether general, limited or otherwise), or other entity, distribution of shares of our common stock or any security directly or indirectly convertible into our common stock to current or former members, stockholders, limited partners, general partners, subsidiaries, or affiliates (as defined in Rule 405 promulgated under the Securities Act) of the holder or to any investment fund or other entity that controls or manages the holder (including, for the avoidance of doubt, a fund managed by the same manager or managing member or general partner or management company or by an entity controlling, controlled by, or under common control with such manager or managing member or general partner or management company as the holder or who shares a common investment advisor with the holder) in a transaction not involving a disposition for value;

g) transfers in connection with the exercise of options, warrants or other rights to acquire our common stock or any security convertible into or exercisable for our common stock by way of net exercise and/or to cover withholding tax obligations in connection with such exercise pursuant to an employee benefit plan, option, warrant or other right disclosed in this prospectus, *provided* that any such shares issued upon exercise of such option, warrant or other right shall be subject to the restrictions set forth in the lock-up agreement; and

h) transfers of shares of our common stock pursuant to a bona fide third-party tender offer, merger, consolidation or other similar transaction made to all holders of our common stock involving a change of control after the completion of this offering; *provided*, that in the event that the tender offer, merger, consolidation or other such transaction is not completed, the shares of common stock owned by such stockholders shall remain subject to the terms of the lock-up agreement;

provided that in the case of any transfer or distribution pursuant to clause (c), (d), (e), (f) or (g) each done, transferee, heir, beneficiary or distributee shall execute and deliver to J.P. Morgan Securities LLC, Jefferies LLC and Cowen and Company, LLC a lock-up letter in the form of this paragraph; and *provided*, *further*, *that* in the case of any transfer or distribution pursuant to clause (b), (c), (d), (e), (f) or (g), no filing by any party (donor, donee, transferor or transferee) under the Exchange Act, or other public announcement shall be required or shall be made voluntarily in connection with such transfer or distribution (other than a filing on a Form 5 made after the expiration of the Restricted Period and any required Schedule 13G (or 13G/A) or 13F filing), and, in the case of any transfer pursuant to clause (g), any filing required under the Exchange Act so long as such filing indicates, by footnote disclosure or otherwise, the nature of the transfer).

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

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We will apply to have our common stock approved for listing/quotation on the Nasdaq Global Market under the symbol “BDTX”.

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

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

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

Prior to this offering, there has been no public market for our common stock. The initial public offering price will be determined by negotiations between us and the representatives of the underwriters. In determining the initial public offering price, we and the representatives of the underwriters expect to consider a number of factors including:

- the information set forth in this prospectus and otherwise available to the representatives;
- our prospects and the history and prospects for the industry in which we compete;
- an assessment of our management;
- our prospects for future earnings;
- the general condition of the securities markets at the time of this offering;
- the recent market prices of, and demand for, publicly traded common stock of generally comparable companies; and
- other factors deemed relevant by the underwriters and us.

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Neither we nor the underwriters can assure investors that an active trading market will develop for our common stock, or that the shares will trade in the public market at or above the initial public offering price.

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

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

Notice to prospective investors in the European Economic Area

In relation to each Member State of the European Economic Area (each, a “Member State”), no offer of shares have been offered or will be offered to the public in that Member State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Member State or, where appropriate, approved in another Member State and notified to the competent authority in accordance with the Prospectus Regulation), except that offers of shares may be made to the public in that Member State at any time under the following exemptions under the Prospectus Regulation:

A. to any legal entity which is a qualified investor as defined under the Prospectus Regulation;

B. to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Regulation), subject to obtaining the prior consent of the underwriters for any such offer; or

C. in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of Shares shall require the Issuer or any Manager 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 Member 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.

Notice to prospective investors in the United Kingdom

In the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are “qualified investors” (as defined in the Prospectus

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

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

Notice to prospective investors in Canada

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

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

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

Notice to prospective investors in Switzerland

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

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

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Notice to prospective investors in the United Arab Emirates

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

Notice to prospective investors in Australia

This Prospectus:

- does not constitute a product disclosure document or a prospectus under Chapter 6D.2 of the Corporations Act 2001 (Cth) (the "Corporations Act");
- has not been, and will not be, lodged with the Australian Securities and Investments Commission ("ASIC"), as a disclosure document for the purposes of the Corporations Act and does not purport to include the information required of a disclosure document under Chapter 6D.2 of the Corporations Act;
- does not constitute or involve a recommendation to acquire, an offer or invitation for issue or sale, an offer or invitation to arrange the issue or sale, or an issue or sale, of interests to a "retail client" (as defined in section 761G of the Corporations Act and applicable regulations) in Australia; and
- may only be provided in Australia to select investors who are able to demonstrate that they fall within one or more of the categories of investors, or Exempt Investors, available under section 708 of the Corporations Act.

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

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

Notice to prospective investors in Japan

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

with, the Financial Instruments and Exchange Act and any other applicable laws, regulations and ministerial guidelines of Japan in effect at the relevant time.

Notice to prospective investors in Hong Kong

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

Notice to prospective investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA"), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

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

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

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

- to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- where no consideration is or will be given for the transfer;
- where the transfer is by operation of law;
- as specified in Section 276(7) of the SFA; or
- as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

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Singapore SFA Product Classification—Solely for the purposes of its obligations pursuant to sections 309B(1)(a) and 309B(1)(c) of the SFA, the Company has determined, and hereby notifies all relevant persons (as defined in Section 309A of the SFA) that the shares are "prescribed capital markets products" (as defined in the Securities and Futures (Capital Markets Products) Regulations 2018) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).

Notice to prospective investors in Bermuda

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

Notice to prospective investors in Saudi Arabia

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

Notice to prospective investors in China

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

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

Notice to prospective investors in South Korea

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

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Notice to prospective investors in Malaysia

No prospectus or other offering material or document in connection with the offer and sale of the shares has been or will be registered with the Securities Commission of Malaysia ("Commission") for the Commission's approval pursuant to the Capital Markets and Services Act 2007. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Malaysia other than (i) a closed end fund approved by the Commission; (ii) a holder of a Capital Markets Services Licence; (iii) a person who acquires the shares, as principal, if the offer is on terms that the shares may only be acquired at a consideration of not less than RM250,000 (or its equivalent in foreign currencies) for each transaction; (iv) an individual whose total net personal assets or total net joint assets with his or her spouse exceeds RM3 million (or its equivalent in foreign currencies), excluding the value of the primary residence of the individual; (v) an individual who has a gross annual income exceeding RM300,000 (or its equivalent in foreign currencies) per annum in the preceding twelve months; (vi) an individual who, jointly with his or her spouse, has a gross annual income of RM400,000 (or its equivalent in foreign currencies), per annum in the preceding twelve months; (vii) a corporation with total net assets exceeding RM10 million (or its equivalent in a foreign currencies) based on the last audited accounts; (viii) a partnership with total net assets exceeding RM10 million (or its equivalent in foreign currencies); (ix) a bank licensee or insurance licensee as defined in the Labuan Financial Services and Securities Act 2010; (x) an Islamic bank licensee or takaful licensee as defined in the Labuan Financial Services and Securities Act 2010; and (xi) any other person as may be specified by the Commission; provided that, in the each of the preceding categories (i) to (xi), the distribution of the shares is made by a holder of a Capital Markets Services Licence who carries on the business of dealing in securities. The distribution in Malaysia of this prospectus is subject to Malaysian laws. This prospectus does not constitute and may not be used for the purpose of public offering or an issue, offer for subscription or purchase, invitation to subscribe for or purchase any securities requiring the registration of a prospectus with the Commission under the Capital Markets and Services Act 2007.

Notice to prospective investors in Taiwan

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

Notice to prospective investors in South Africa

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

i the offer, transfer, sale, renunciation or delivery is to:

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

(b) the South African Public Investment Corporation;

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

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(d) authorised financial service providers under South African law;

(e) financial institutions recognised as such under South African law;

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

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

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

No "offer to the public" (as such term is defined in the South African Companies Act, No. 71 of 2008 (as amended or re-enacted) (the "South African Companies Act")) in South Africa is being made in connection with the issue of the shares. Accordingly, this document does not, nor is it intended to, constitute a "registered prospectus" (as that term is defined in the South African Companies Act) prepared and registered under the South African Companies Act and has not been approved by, and/or filed with, the South African Companies and Intellectual Property Commission or any other regulatory authority in South Africa. Any issue or offering of the shares in South Africa constitutes an offer of the shares in South Africa for subscription or sale in South Africa only to persons who fall within the exemption from "offers to the public" set out in section 96(1)(a) of the South African Companies Act. Accordingly, this document must not be acted on or relied on by persons in South Africa who do not fall within section 96(1)(a) of the South African Companies Act (such persons being referred to as "SA Relevant Persons"). Any investment or investment activity to which this document relates is available in South Africa only to SA Relevant Persons and will be engaged in South Africa only with SA relevant persons.

Notice to prospective investors in Israel

In the State of Israel this prospectus shall not be regarded as an offer to the public to purchase shares of common stock under the Israeli Securities Law, 5728 – 1968, which requires a prospectus to be published and authorized by the Israel Securities Authority, if it complies with certain provisions of Section 15 of the Israeli Securities Law, 5728–1968, including, inter alia, if: (i) the offer is made, distributed or directed to not more than 35 investors, subject to certain conditions (the "Addressed Investors"); or (ii) the offer is made, distributed or directed to certain qualified investors defined in the First Addendum of the Israeli Securities Law, 5728 - 1968, subject to certain conditions (the "Qualified Investors"). The Qualified Investors shall not be taken into account in the count of the Addressed Investors and may be offered to purchase securities in addition to the 35 Addressed Investors. The Company has not and will not take any action that would require it to publish a prospectus in accordance with and subject to the Israeli Securities Law, 5728 – 1968. We have not and will not distribute this prospectus or make, distribute or direct an offer to subscribe for our common stock to any person within the State of Israel, other than to Qualified Investors and up to 35 Addressed Investors.

Qualified Investors may have to submit written evidence that they meet the definitions set out in of the First Addendum to the Israeli Securities Law, 5728 – 1968. In particular, we may request, as a condition to be offered common stock, that Qualified Investors will each represent, warrant and certify to us and/or to anyone acting on our behalf: (i) that it is an investor falling within one of the categories listed in the First Addendum to the Israeli Securities Law, 5728 – 1968; (ii) which of the categories listed in the First Addendum to the Israeli Securities Law, 5728 – 1968 regarding Qualified Investors is applicable to it; (iii) that it will abide by all provisions set forth in the Israeli Securities Law, 5728 – 1968 and the regulations promulgated thereunder in connection with the offer to be issued common stock; (iv) that the shares of common stock that it will be issued are, subject to exemptions available under the Israeli Securities Law, 5728 – 1968: (a) for its own account;

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(b) for investment purposes only; and (c) not issued with a view to resale within the State of Israel, other than in accordance with the provisions of the Israeli Securities Law, 5728 - 1968; and (v) that it is willing to provide further evidence of its Qualified Investor status. Addressed Investors may have to submit written evidence in respect of their identity and may have to sign and submit a declaration containing, inter alia, the Addressed Investor's name, address and passport number or Israeli identification number.

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Legal matters

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

Experts

The financial statements as of December 31, 2018 and 2017 and for the years then ended included in this prospectus have been so included in reliance on the report (which contains an explanatory paragraph relating to the Company's ability to continue as a going concern as described in Note 1 to the consolidated financial statements) of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

Change in our independent public accounting firm

On May 9, 2019, our board of directors approved the decision to change independent registered public accounting firms and we dismissed Adeptus LLC, or Adeptus, as our independent registered public accounting firm. On July 11, 2019 we retained PricewaterhouseCoopers LLP as our new independent registered public accounting firm to audit our consolidated financial statements as of and for the fiscal year ended December 31, 2018 and to reaudit our financial statements as of and for the fiscal year ended December 31, 2017, which had previously been audited by Adeptus. Our previously issued 2017 financial statements were subsequently restated. See "Risk factors—We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business."

The report of Adeptus on our financial statements as of and for the fiscal year ended December 31, 2017 did not contain any adverse opinion or disclaimer of opinion and was not qualified or modified as to uncertainty, audit scope or accounting principles. During the two most recent fiscal years preceding our dismissal of Adeptus and the subsequent interim period through May 9, 2019, we had no "disagreements" (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions thereto) with Adeptus on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of Adeptus, would have caused Adeptus to make reference in connection with its report to the subject matter of the disagreement during its audit of our financial statements for the fiscal year ended December 31, 2017. During the two most recent fiscal years preceding our discharge of Adeptus and the subsequent interim period through May 9, 2019, there were no "reportable events" (as defined in Item 304(a)(1)(v) of Regulation S-K and the related instructions thereto).

During the two fiscal years ended December 31, 2018 and through the period ended July 11, 2019, we did not consult with PricewaterhouseCoopers LLP with respect to (i) the application of accounting principles to a specified transaction, either completed or proposed, the type of audit opinion that might be rendered on our financial statements, and neither a written report nor oral advice was provided to us that PricewaterhouseCoopers LLP concluded was an important factor considered by us in reaching a decision as to any accounting, auditing or financial reporting issue, or (ii) any other matter that was the subject of a disagreement or a reportable event (each as defined above).

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We have provided Adeptus with a copy of the foregoing disclosure and requested that Adeptus furnish us with a letter addressed to the SEC stating whether or not Adeptus agrees with the above statements and, if not, stating the respects in which it does not agree. A copy of the letter, dated , furnished by Adeptus in response to that request, is filed as Exhibit 16 to the registration statement of which this prospectus is a part.

Where you can find more information

We have filed with the SEC a registration statement on Form S-1 (File Number 333-) under the Securities Act with respect to the common stock we are offering by this prospectus. This prospectus, which constitutes part of the registration statement, does not contain all of the information included in the registration statement. For further information pertaining to us and our common stock, you should refer to the registration statement and to its exhibits. Whenever we make reference in this prospectus to any of our contracts, agreements or other documents, the references are not necessarily complete, and you should refer to the exhibits attached to the registration statement for copies of the actual contract, agreement or other document.

Upon the completion of the offering, we will be subject to the informational requirements of the Exchange Act and will file annual, quarterly and current reports, proxy statements and other information with the SEC. You can read our SEC filings, including the registration statement, at the SEC's website at www.sec.gov. We also maintain a website at www.blackdiamondtherapeutics.com and upon completion of the offering, you may access, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to those reports, as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not part of, and is not incorporated into, this prospectus.

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of
Black Diamond Therapeutics, Inc.

Opinion on the financial statements

We have audited the accompanying consolidated balance sheets of Black Diamond Therapeutics, Inc. and its subsidiary (the "Company") as of December 31, 2018 and 2017, and the related consolidated statements of operations, of convertible preferred stock and stockholders' deficit and of cash flows for the years then ended, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Substantial doubt about the company's ability to continue as a going concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred recurring losses from operations and negative cash flows from operating activities since inception, has an accumulated deficit and will require additional financing to fund future operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated 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 of these consolidated financial statements 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 consolidated 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 consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
August 22, 2019

We have served as the Company's auditor since 2019.

FOIA CONFIDENTIAL TREATMENT REQUESTED

Black Diamond Therapeutics, Inc.
Consolidated balance sheets
(In thousands, except share and per share amounts)

	December 31, 2017	December 31, 2018	September 30, 2019 (unaudited)	Pro forma September 30, 2019 (unaudited)
Assets				
Current assets:				
Cash and cash equivalents	$ 7,878	$51,660	$ 78,659	$ 78,659
Prepaid expenses and other current assets	36	24	294	294
Total current assets	7,914	51,684	78,953	78,953
Equipment, net	102	134	116	116
Restricted cash	—	—	55	55
Deferred offering costs	—	—	1,577	1,577
Other assets	5	8	33	33
Total assets	$ 8,021	$51,826	$ 80,734	$ 80,734
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)				
Current liabilities:				
Accounts payable	$ 152	$ 416	$ 1,411	$ 1,411
Amounts due to related party	1,920	1,707	1,254	1,254
Accrued expenses and other current liabilities	158	452	1,982	1,982
Total current liabilities	2,230	2,575	4,647	4,647
Derivative liabilities	8	4,023	39	—
Total liabilities	2,238	6,598	4,686	4,647
Commitments and contingencies (Note 12)				
Convertible preferred stock (series A and B); $0.0001 par value; 12,501,503 shares authorized at December 31, 2017, 44,867,103 shares authorized at December 31, 2018 and 45,451,685 shares authorized at September 30, 2019 (unaudited); 12,501,503 shares issued and outstanding at December 31, 2017, 33,668,075 shares issued and outstanding at December 31, 2018 and 45,419,229 shares issued and outstanding at September 30, 2019 (unaudited); aggregate liquidation preference of $12,502 at December 31, 2017, $65,002 at December 31, 2018 and $109,727 at September 30, 2019 (unaudited); no shares issued or outstanding, pro forma as of September 30, 2019 (unaudited)	12,458	60,770	115,840	—

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	December 31, 2017	December 31, 2018	September 30, 2019	Pro forma September 30, 2019
			(unaudited)	
Stockholders' equity (deficit)				
Common stock; $0.0001 par value; 19,533,945 shares authorized at December 31, 2017, 57,803,522 shares authorized at December 31, 2018 and 58,803,522 shares authorized at September 30, 2019 (unaudited); 6,276,500 shares issued and outstanding at December 31, 2017, 6,555,460 shares issued and outstanding at December 31, 2018 and 6,695,460 shares issued and outstanding at September 30, 2019 (unaudited); 52,114,689 shares issued and outstanding, pro forma as of September 30, 2019 (unaudited)	1	1	1	5
Additional paid-in capital	105	169	1,302	117,177
Accumulated deficit	(6,781)	(15,712)	(41,095)	(41,095)
Total stockholders' equity (deficit)	(6,675)	(15,542)	(39,792)	76,087
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 8,021	$ 51,826	$ 80,734	$ 80,734

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

FOIA CONFIDENTIAL TREATMENT REQUESTED

Black Diamond Therapeutics, Inc.
Consolidated statements of operations
(In thousands, except share and per share amounts)

	Year ended December 31,		Nine months ended September 30,	
	2017	2018	2018	2019
			(unaudited)	
Operating expenses				
Research and development (inclusive of $1,348 and $2,403, respectively, and $1,595 and $8,497 (unaudited), respectively, with a related party)	$ 3,453	$ 6,950	$ 4,571	$ 14,293
General and administrative (inclusive of $42 and $325, respectively, and $238 and $357 (unaudited), respectively, with a related party)	666	1,954	1,287	4,695
Total operating expenses	4,119	8,904	5,858	18,988
Loss from operations	(4,119)	(8,904)	(5,858)	(18,988)
Other income (expense)				
Interest expense	(65)	—	—	—
Interest income	—	4	2	21
Loss on extinguishment of convertible promissory notes	(282)	—	—	—
Change in fair value of derivative liabilities	(130)	(15)	—	(6,416)
Other income (expense)	(6)	(16)	(9)	—
Total other income (expense), net	(483)	(27)	(7)	(6,395)
Net loss	(4,602)	(8,931)	(5,865)	(25,383)
Net loss attributable to common stockholders	$ (4,602)	$ (8,931)	$ (5,865)	$ (25,383)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.79)	$ (1.47)	$ (0.97)	$ (4.10)
Weighted average common shares outstanding, basic and diluted	5,802,740	6,089,819	6,069,399	6,194,913
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)		$ (0.41)		$ (0.37)
Pro forma weighted average common shares outstanding, basic and diluted (unaudited)		21,701,364		51,614,142

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

FOIA CONFIDENTIAL TREATMENT REQUESTED

Black Diamond Therapeutics, Inc.
Consolidated statements of convertible preferred stock and stockholders' deficit

(In thousands, except share amounts)

	Convertible preferred stock		Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2016	**—**	**$ —**	**5,000,000**	**$ 1**	**$ —**	**$ (2,179)**	**$ (2,178)**
Issuance of common stock	—	—	1,000,000	—	100	—	100
Grant of restricted common stock awards	—	—	276,500	—	—	—	—
Issuance of series A convertible preferred stock, net	10,000,000	9,964	—	—	—	—	—
Conversion of convertible promissory notes and accrued interest into series A convertible preferred stock	2,501,503	2,494	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	5	—	5
Net loss	—	—	—	—	—	(4,602)	(4,602)
Balance at December 31, 2017	**12,501,503**	**12,458**	**6,276,500**	**1**	**105**	**(6,781)**	**(6,675)**
Grant of restricted common stock awards	—	—	278,960	—	—	—	—
Issuance of series A convertible preferred stock, net	10,000,000	9,899	—	—	—	—	—
Issuance of series B convertible preferred stock, net	11,166,572	38,413	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	64	—	64
Net loss	—	—	—	—	—	(8,931)	(8,931)
Balance at December 31, 2018	**33,668,075**	**$ 60,770**	**6,555,460**	**$ 1**	**$ 169**	**$ (15,712)**	**$ (15,542)**

For the nine months ended September 30, 2018 (unaudited)	Convertible preferred stock		Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2017	**12,501,503**	**$ 12,458**	**6,276,500**	**$ 1**	**$ 105**	**$ (6,781)**	**$ (6,675)**
Issuance of series A convertible preferred stock, net	5,000,000	4,899	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	24	—	24
Net loss	—	—	—	—	—	(5,865)	(5,865)
Balance at September 30, 2018 (unaudited)	**17,501,503**	**$ 17,357**	**6,276,500**	**$ 1**	**$ 129**	**$ (12,646)**	**$ (12,516)**

For the nine months ended September 30, 2019 (unaudited)	Convertible preferred stock		Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2018	**33,668,075**	**$ 60,770**	**6,555,460**	**$ 1**	**$ 169**	**$ (15,712)**	**$ (15,542)**
Grant of restricted common stock awards	—	—	140,000	—	—	—	—
Issuance of series B convertible preferred stock, net	11,751,154	55,070	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	1,133	—	1,133
Net loss	—	—	—	—	—	(25,383)	(25,383)
Balance at September 30, 2019 (unaudited)	**45,419,229**	**$115,840**	**6,695,460**	**$ 1**	**$ 1,302**	**$ (41,095)**	**$ (39,792)**

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

FOIA CONFIDENTIAL TREATMENT REQUESTED

Black Diamond Therapeutics, Inc.
Consolidated statements of cash flows
(In thousands)

	Year ended December 31,		Nine months ended September 30,	
	2017	2018	2018	2019
			(unaudited)	
Cash flows from operating activities				
Net loss	$(4,602)	$ (8,931)	$ (5,865)	$ (25,383)
Adjustments to reconcile net loss to net cash used in operating activities:				
Stock-based compensation expense	5	64	24	1,133
Non-cash interest expense	66	—	—	—
Change in fair value of derivative liabilities	130	15	—	6,416
Loss on extinguishment of convertible promissory notes	282	—	—	—
Depreciation expense	24	44	32	38
Changes in operating assets and liabilities				
Prepaid expenses and other current assets	(21)	12	15	(270)
Other assets	(5)	(3)	(2)	—
Accounts payable	(59)	264	337	496
Amounts due to related party	1,920	(213)	(1,311)	(453)
Accrued expenses and other current liabilities	(91)	294	700	860
Net cash used in operating activities:	(2,351)	(8,454)	(6,070)	(17,163)
Cash flows from investing activities				
Purchases of equipment	(77)	(76)	(71)	(19)
Changes in other assets	—	—	—	(25)
Net cash used in investing activities	(77)	(76)	(71)	(44)
Cash flows from financing activities				
Proceeds from issuance of common stock	100	—	—	—
Repayment of convertible promissory notes	(50)	—	—	—
Proceeds from issuance of convertible preferred stock, net	9,924	52,312	4,987	44,669
Payment of deferred offering costs	—	—	—	(408)
Net cash provided by financing activities	9,974	52,312	4,987	44,261
Net increase (decrease) in cash and restricted cash	7,546	43,782	(1,154)	27,054
Cash, cash equivalents and restricted cash at beginning of period	332	7,878	7,878	51,660
Cash, cash equivalents and restricted cash at end of period	$ 7,878	$51,660	$ 6,724	$ 78,714
Supplemental disclosures of non-cash investing and financing activities:				
Issuance of shares of series A convertible preferred stock, net in connection with conversion of convertible promissory notes	$ 2,494	$ —	$ —	$ —
Exercise of series A convertible preferred stock tranche right	$ 40	$ —	$ —	$ —
Issuance of series B convertible preferred stock tranche right	$ —	$ 4,000	$ —	$ —
Deferred offering costs included in accounts payable and accrued expenses and other current liabilities	$ —	$ —	$ —	$ 1,169
Exercise of series B convertible preferred stock tranche right	$ —	$ —	$ —	$ 6,400

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

FOIA CONFIDENTIAL TREATMENT REQUESTED

Black Diamond Therapeutics, Inc.
Notes to consolidated financial statements
(Amounts in thousands, except share and per share amounts)

1. Nature of the business and basis of presentation

Black Diamond Therapeutics, Inc. (the "Company") is a precision oncology medicine company pioneering the discovery and development of small molecule, tumor-agnostic therapies. The Company was originally organized as a limited liability company in December 2014 under the name ASET Therapeutics LLC. In September 2016 the Company was converted to a corporation under the laws of the State of Delaware under the name ASET Therapeutics, Inc. The Company changed its name to Black Diamond Therapeutics, Inc. in January 2018. Since its inception, the Company has devoted substantially all of its efforts to raising capital, obtaining financing, and incurring research and development costs related to the development of its mutation, allostery, and pharmacology computational and discovery platform.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's technology will be obtained, that any products developed will obtain necessary government regulatory approval or that any products, if approved, will be commercially viable. The Company operates in an environment of rapid technological innovation and substantial competition from pharmaceutical and biotechnological companies. In addition, the Company is dependent upon the services of its employees, consultants and service providers including a related party Ridgeline Therapeutics GmbH ("Ridgeline"). Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

Going concern

In accordance with Accounting Standards Update ("ASU") 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40)*, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued.

From its inception through September 30, 2019, the Company has funded its operations primarily with proceeds from the sale of convertible preferred and common stock and borrowings under convertible promissory notes. The Company has incurred recurring losses since its inception, including net losses of $4,602 and $8,931 for the years ended December 31, 2017 and 2018, respectively, and $5,865 and $25,383 for the nine months ended September 30, 2018 and 2019 (unaudited), respectively. In addition, as of December 31, 2018 and September 30, 2019 (unaudited), the Company had an accumulated deficit of $15,712 and $41,095, respectively. The Company expects to continue to generate operating losses for the foreseeable future.

As of August 22, 2019, the issuance date of the consolidated financial statements for the year ended December 31, 2018, the Company expected that its cash balance at December 31, 2018 and funding from the issuances of series B preferred stock on July 8, 2019 and August 9, 2019 (see Note 15) would enable it to fund its operating expense and capital requirements through the third quarter of 2020. As of October 30, 2019, the issuance date of the interim consolidated financial statements for the nine months ended September 30, 2019 (unaudited), the Company expects that its cash balance will enable it to fund its operating expenses and capital requirements through the third quarter of 2020. The future viability of the Company is largely dependent on its ability to generate cash from operating activities and to raise additional capital to finance its operations. The

Company's failure to raise capital as and when needed will have a negative impact on its financial condition and its ability to continue to pursue its business strategies.

The Company is seeking to complete an initial public offering ("IPO") of its common stock. Upon the closing of a qualified public offering, on specified terms, the Company's outstanding convertible preferred stock will automatically convert into common stock (see Note 7). In the event the Company does not complete an IPO, the Company expects to seek additional funding through private equity financings, debt financings, or other capital sources, which may include collaborations with other companies, government funding arrangements or other strategic transactions. The Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into collaborations or other arrangements. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders.

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

Based on its recurring losses from operations incurred since inception, expectation of continuing losses for the foreseeable future and need to raise additional capital to finance its future operations, as of August 22, 2019, the issuance date of the consolidated financial statements for the year ended December 31, 2018, and as of October 30, 2019, the issuance date of the interim consolidated financial statements for the nine months ended September 30, 2019 (unaudited), the Company has concluded that there is substantial doubt about its ability to continue as a going concern.

The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Accordingly, the consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

2. Summary of significant accounting policies

Principles of consolidation

The accompanying consolidated financial statements have been prepared in accordance with GAAP and include the accounts of the Company and its wholly owned subsidiary, Black Diamond Therapeutics (Canada), Inc., after elimination of all significant intercompany accounts and transactions.

Use of estimates

The preparation of the Company's consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the accrual of research and development expenses, the valuation of common stock, the valuation of stock-based awards and the valuation of derivative liabilities. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results may differ from those estimates or assumptions.

FOIA CONFIDENTIAL TREATMENT REQUESTED

Unaudited interim financial information

The accompanying consolidated balance sheet as of September 30, 2019, the consolidated statements of operations, of convertible preferred stock and stockholders' deficit and of cash flows for the nine months ended September 30, 2018 and 2019 are unaudited. The unaudited interim consolidated financial statements have been prepared on the same basis as the audited annual consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of September 30, 2019 and the results of its operations and its cash flows for the nine months ended September 30, 2018 and 2019. The financial data and other information disclosed in these notes related to the nine months ended September 30, 2018 and 2019 are also unaudited. The results for the nine months ended September 30, 2019 are not necessarily indicative of results to be expected for the year ending December 31, 2019, any other interim periods, or any future year or period.

Unaudited pro forma information

The accompanying unaudited pro forma consolidated balance sheet as of September 30, 2019 has been prepared to give effect, upon the completion of the proposed offering, to (i) the conversion of all outstanding shares of convertible preferred stock into 45,419,229 shares of common stock and (ii) the settlement of the derivative liabilities, as if the proposed offering had occurred on September 30, 2019.

In the accompanying consolidated statements of operations, the unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2018 and nine months ended September 30, 2019 have been prepared to give effect, upon the completion of the proposed offering, to (i) the conversion of all outstanding shares of convertible preferred stock into shares of common stock and (ii) the settlement of the derivative liabilities, as if the proposed offering had occurred on the later of January 1, 2018 or the issuance date of the convertible preferred stock or the warrants (see Note 11). The derivative liabilities will be settled upon the closing of this offering due to all outstanding warrants to purchase shares of convertible preferred stock becoming warrants to purchase shares of common stock.

Foreign currency and currency translation

The functional currency for the Company's wholly owned foreign subsidiary, Black Diamond Therapeutics (Canada), Inc. is the United States dollar. Adjustments that arise from exchange rate changes on transactions denominated in a currency other than the local currency are included in other income (expense), net in the consolidated statements of operations, as incurred.

Cash and cash equivalents

The Company classifies deposits in banks, money market funds and cash invested temporarily in various instruments with maturities of three months or less at the time of purchase as cash and cash equivalents. At December 31, 2017 and 2018, cash consisted of cash on deposit at commercial banks. At September 30, 2019, cash and cash equivalents includes cash on deposit at commercial banks and a money market fund that invests in U.S. Government securities.

Restricted cash

In connection with its operating lease commitments, the Company maintains certain balances for security deposits that are classified as restricted cash on the consolidated balance sheets. At December 31, 2017 and 2018, the Company had no restricted cash. As of September 30, 2019 (unaudited), the Company had $55 of restricted cash, which has been classified as a non-current asset on the consolidated balance sheet.

FOIA CONFIDENTIAL TREATMENT REQUESTED

Concentrations of credit risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash. The Company generally maintains balances in various operating accounts at financial institutions in amounts that may exceed federally insured limits. The Company has not experienced any losses related to its cash and does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

Equipment

Equipment is recorded at cost less accumulated depreciation. Depreciation expense is recognized using the straight-line method over the estimated useful life of each asset as follows:

	Estimated useful life
Laboratory equipment	5 years
Furniture and fixtures	5 years
Computer and office equipment	3 years

When assets are retired or otherwise disposed of, the cost of assets disposed of and the related accumulated depreciation is removed from the accounts and any resulting gain or loss is included in the consolidated statements of operations in the period of disposal. Expenditures for repairs and maintenance are charged to expense as incurred.

Impairment of long-lived assets

Long-lived assets consist of equipment. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset group for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset group to its carrying value. An impairment loss would be recognized in loss from operations when estimated undiscounted future cash flows expected to result from the use of an asset group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value, determined based on discounted cash flows. The Company did not record any impairment losses on long-lived assets during the years ended December 31, 2017 or 2018 or during the nine months ended September 30, 2019 (unaudited).

Deferred offering costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process preferred stock or common stock financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded as a reduction to the carrying value of convertible preferred stock or in stockholders' equity (deficit) as a reduction of additional paid-in capital generated as a result of the offering. Should a planned equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statements of operations. The Company had no deferred offering costs as of December 31, 2017 and 2018. As of September 30, 2019 (unaudited), the Company recorded deferred offering costs of $1,577.

Fair value measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most

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advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

Level 1 — Quoted prices in active markets for identical assets or liabilities.

Level 2 — Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

Level 3 — Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The carrying values of the Company's prepaid expenses and other current assets, and accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities.

Derivative liabilities

In connection with certain convertible promissory notes and preferred stock financings, the Company has identified certain embedded and freestanding derivatives, which are recorded as liabilities on the consolidated balance sheets and are remeasured to fair value at each reporting date until the derivative is settled. Changes in the fair value of the derivative liabilities are recognized in the consolidated statements of operations.

Classification of convertible preferred stock

The Company's convertible preferred stock is classified outside of stockholders' deficit because the holders of such shares have liquidation rights in the event of a deemed liquidation that, in certain situations, are not solely within the control of the Company.

Segment information

The Company manages its operations as a single operating segment for the purposes of assessing performance and making operating decisions. The Company's singular focus is the development of selective medicines for patients with genetically defined cancers driven by oncogenes activated by allosteric mutations.

Research and development costs

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred to discover, research and develop drug candidates, including personnel expenses, stock-based compensation expense, allocated facility-related and depreciation expenses, third-party license fees and external costs of outside vendors engaged to conduct preclinical development activities. Non-refundable prepayments for goods or services that will be used or rendered for future research and development activities are recorded as prepaid expenses. Such amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered, or the services rendered.

Research contract costs and accruals

The Company has entered into various research and development-related contracts with companies both inside and outside of the United States. The related costs are recorded as research and development expenses as

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incurred. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ materially from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Patent costs

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

Stock-based compensation

The Company measures all stock-based awards granted to employees and directors based on the fair value on the date of grant and recognizes compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. Forfeitures are accounted for as they occur. Generally, the Company issues awards with only service-based vesting conditions and records the expense for these awards using the straight-line method.

For stock-based awards granted to consultants and non-employees, compensation expense is recognized over the vesting period of the awards, which is generally the period during which services are rendered by such consultants and non-employees until completed. At the end of each financial reporting period prior to completion of the service, the fair value of these awards is remeasured using the then-current fair value of the Company's common shares and updated assumption inputs in the Black-Scholes option-pricing model.

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

The fair value of each restricted common stock award is estimated on the date of grant based on the fair value of the Company's common stock on that same date. The fair value of each option grant is estimated on the date of grant using the single option award approach, which requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the award, the risk-free interest rate, and expected dividends (see Note 9). The Company historically has been a private company and lacks company-specific historical and implied volatility information for its stock. Therefore, it estimates its expected stock price volatility based on the historical volatility of publicly traded peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future.

Income taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized

in the consolidated financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined 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. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties. To date, the Company has not taken any uncertain tax positions or recorded any reserves, interest or penalties.

Net income (loss) per share

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

Basic net income (loss) per share attributable to common stockholders is computed by dividing the net income (loss) attributable to common stockholders by the weighted average number of common shares outstanding for the period. Diluted net income (loss) attributable to common stockholders is computed by adjusting net income (loss) attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net income (loss) per share attributable to common stockholders is computed by dividing the diluted net income (loss) attributable to common stockholders by the weighted average number of common shares outstanding for the period, including potential dilutive common stock. For purpose of this calculation, outstanding options, unvested restricted common stock and convertible preferred stock are considered potential dilutive common stock and are excluded from the computation of net income (loss) per share as their effect is anti-dilutive.

The Company's convertible preferred stock contractually entitles the holders of such shares to participate in dividends but does not contractually require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss, such losses are not allocated to such participating securities. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to be outstanding if their effect is anti-dilutive. The Company reported a net loss attributable to common stockholders for the years ended December 31, 2017 and 2018 and for the nine months ended September 30, 2018 and 2019 (unaudited).

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Recently adopted accounting pronouncements

In May 2017, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2017-09, *Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting* ("ASU 2017-09"), which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. ASU 2017-09 is effective for annual periods beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted. The Company adopted ASU 2017-09 as of the required effective date of January 1, 2018. The adoption of ASU 2017-09 will have an impact on the modification of share-based awards, if any, after the date of adoption.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-09"). ASU 2016-09 addresses several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, an option to recognize gross share compensation expense with actual forfeitures recognized as they occur, and classification on the statement of cash flows. Certain of these changes are required to be applied retrospectively, while other changes are required to be applied prospectively. The Company adopted ASU 2016-09 effective as of January 1, 2018 and elected prospectively to account for forfeitures as they occur rather than apply an estimated forfeiture rate to share-based compensation expense. The adoption of ASU 2016-09 did not have a material impact on the Company's financial position, results of operations or cash flows.

In November 2014, the FASB issued ASU No. 2014-16, *Determining Whether the Host Contract in a Hybrid Financial Instrument Issued in the Form of a Share Is More Akin to Debt or to Equity* ("ASU 2014-16"). The guidance requires an entity to determine the nature of the host contract by considering all stated and implied substantive terms and features of the hybrid financial instrument, weighing each term and feature on the basis of the relevant facts and circumstances (commonly referred to as the whole-instrument approach). The Company adopted ASU 2014-16 effective as of January 1, 2017, which did not have a material impact on the Company's financial position, results of operations or cash flows.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements—Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* ("ASU 2014-15"). The amendments in this update explicitly require a company's management to assess if there is substantial doubt about an entity's ability to continue as a going concern within one year of the date of issuance of the entity's financial statements and to provide related footnote disclosures in certain circumstances. The Company adopted ASU 2014-15 effective as of January 1, 2017. This guidance relates to footnote disclosure only and its adoption had no impact on the Company's financial position, results of operations or cash flows.

Recently issued accounting pronouncements

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement.* The ASU modifies, and in certain cases eliminates, the disclosure requirements on fair value measurements in Topic 820. The amendments in ASU No. 2018-13 are effective for the Company on January 1, 2020. Early adoption is permitted. An entity is permitted to early adopt any removed or modified disclosures upon issuance of ASU No. 2018-13 and delay adoption of the additional disclosures until their effective date. The Company is currently assessing the impact that adopting this new accounting standard will have on its consolidated financial statements and footnote disclosures.

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In July 2017, the FASB issued ASU No. 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815) I. Accounting for Certain Financial Instruments with Down Round Features II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception ("ASU 2017-11").* Part I applies to entities that issue financial instruments such as warrants, convertible debt or convertible preferred stock that contain down-round features. Part II replaces the indefinite deferral for certain mandatorily redeemable noncontrolling interests and mandatorily redeemable financial instruments of nonpublic entities contained within ASC Topic 480 with a scope exception and does not impact the accounting for these mandatorily redeemable instruments. ASU 2017-11 is required to be adopted for annual periods beginning after December 15, 2019. This standard is effective for the Company on January 1, 2020. The Company is still assessing the impact of adopting this standard.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"). This guidance addresses diversity in practice in how certain cash receipts and cash payments are presented in the statement of cash flows. The standard is effective for fiscal years beginning after December 15, 2018, and early adoption is permitted. The adoption of ASU 2016-15 is required to be applied retrospectively. The Company adopted ASU 2017-09 as of January 1, 2019, and the adoption did not have an impact on the Company's consolidated statement of cash flows.

In February 2016, the FASB issued ASU No. 2016-02*, Leases (Topic 842)* ("ASU 2016-02"), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less will be accounted for substantially similar to existing guidance for operating leases today. The guidance is effective for the Company on January 1, 2020, and early adoption is permitted.

In July 2018, the FASB subsequently issued ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements* ("ASU 2018-11"), which includes certain amendments to ASU 2016-02 intended to provide relief in implementing the new standard. Among these amendments is the option to not restate comparative periods presented in the financial statements. The Company is assessing the impact of adopting the new standard.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* (Topic 606) ("ASU 2014-09"), which supersedes existing revenue recognition guidance under GAAP. The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The standard defines a five-step process to achieve this principle and will require companies to use more judgment and make more estimates than under the current guidance. The Company expects that these judgments and estimates will include identifying performance obligations in the customer contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts. In August 2015, the FASB issued ASU No. 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, which delays the effective date of ASU 2014-09 such that the standard is effective for annual periods beginning after December 15, 2018. The FASB subsequently issued amendments to ASU 2014-09 that have the same effective date and transition date. The Company adopted ASU 2014-09 as of January 1, 2019

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and the adoption did not have an impact on the Company's consolidated financial statements as the Company does not currently have any revenue-generating arrangements.

3. Fair value of financial assets and liabilities

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy used to determine such fair values:

	Fair value measurements as of December 31, 2017 using:			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets				
	$ —	$ —	$ —	$ —
Liabilities				
Derivative liabilities	$ —	$ —	$ 8	$ 8
	$ —	$ —	$ 8	$ 8

	Fair value measurements as of December 31, 2018 using:			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets				
	$ —	$ —	$ —	$ —
Liabilities				
Derivative liabilities	$ —	$ —	$ 4,023	$4,023
	$ —	$ —	$ 4,023	$4,023

	Fair value measurements as of September 30, 2019 using:			
	Level 1	**Level 2**	**Level 3**	**Total**
				(unaudited)
Assets				
Money market funds	$73,781	$ —	$ —	$73,781
	$73,781	$ —	$ —	$73,781
Liabilities				
Derivative liabilities	$ —	$ —	$ 39	$ 39
	$ —	$ —	$ 39	$ 39

The Company did not hold any cash equivalents as of December 31, 2017 or 2018. Money market funds were valued by the Company based on quoted market prices, which represent a Level 1 measurement within the fair value hierarchy. During the years ended December 31, 2017 and 2018 and the nine months ended September 30, 2019 (unaudited), there were no transfers between Level 1, Level 2 and Level 3.

Valuation of derivative liabilities

The fair value of the derivative liabilities (see Notes 6 and 7) is based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy.

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Conversion feature

The Company's outstanding convertible promissory notes (see Note 6) contained a conversion feature, which met the definition of a derivative instrument as it was not considered clearly and closely related to the economic characteristics and risks of the convertible promissory notes because the conversion feature provided for the accelerated repayment of the convertible promissory notes at a substantial premium upon the occurrence of specified events. The Company classified the instrument as a derivative liability, which was initially recorded at fair value upon issuance of the convertible promissory notes and was subsequently remeasured to fair value at each reporting date, with the Company recognizing changes in the fair value of the derivative liabilities in the consolidated statement of operations.

The fair value was determined using a with and without analysis within a probability-weighted expected return method ("PWERM"), which considered as inputs the type, timing and probability of occurrence of a future equity financing; the potential amount of the payment under each of these potential settlement scenarios (with and without the conversion feature); and the discount rate reflecting the expected risk profile for each of the potential settlement scenarios.

In March 2017, in connection with the Company's issuance and sale of series A convertible preferred stock, all of the outstanding principal and accrued interest under the convertible promissory notes was automatically converted into shares of series A convertible preferred stock and the derivative liability was extinguished (see Notes 6 and 7).

Tranche rights

The Company's issuance of series A and series B convertible preferred stock (see Note 7) provided investors the right to participate in subsequent offerings of series A and series B convertible preferred stock, respectively, in the event specified developmental and regulatory milestones were achieved. The Company classifies the tranche rights as derivative liabilities on its consolidated balance sheet as it was determined that the tranche rights met the definition of a freestanding financial instrument since they are legally detachable. It was also determined that such instruments represent forward sale contracts on redeemable shares and, accordingly, the instruments should be accounted for as a liability separate from the convertible preferred stock. The Company remeasures the derivative liabilities associated with tranche rights to fair value at each reporting date, and recognizes changes in the fair value of the derivative liabilities in the consolidated statements of operations.

The fair value of the derivative liabilities was determined using a back solve approach based on the price paid for the underlying series A and B convertible preferred stock and the derivative liability. The derivative liabilities were valued as forward contracts which considered inputs including, but not limited to, the probability of attaining milestones, market-based assumptions for expected term and the risk free rate.

Series A tranche right

The fair value of the tranche right related to the Company's series A convertible preferred stock (see Note 7) upon issuance in March 2017 was $500. In December 2017, the Company executed a waiver of the developmental milestone whereby the tranche right was executed and an additional 5,000,000 series A preferred shares were issued, resulting in the extinguishment of the related derivative liability.

Series B tranche right

The fair value of the tranche right related to the Company's series B convertible preferred stock (see Note 7) upon issuance in December 2018 was $4,000. The change in fair value between the issuance date of

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December 21, 2018 and December 31, 2018 was *de minimis*. In July 2019, the Company executed a waiver of the developmental milestone whereby the tranche right was executed and an additional 11,294,902 series B preferred shares were issued, resulting in the extinguishment of the related derivative liability. The change in the fair value of the tranche right between December 31, 2018 and the date of extinguishment was $6,400.

Warrants to purchase series A convertible preferred stock

In March 2017, the Company issued warrants to purchase 32,442 shares of series A convertible preferred stock. The Company accounts for the warrants to purchase series A convertible preferred stock as a liability as these warrants are freestanding financial instruments that may require the Company to transfer assets upon exercise. Such liability is *de minimis* to the consolidated financial statements, and is included in derivative liabilities.

The following table presents the key inputs of the tranche rights derivative liabilities:

	Fiscal year ended December 31,		Nine months ended September 30,	
	2017	2018	2018	2019
				(unaudited)
Risk-free interest rate	1.8%	2.6%	—	1.6%
Expected term (in years)	2.0	2.0	—	2.0
Expected volatility	65.0%	65.0%	—	65.0%
Expected dividend yield	0.0%	0.0%	—	0.0%

	Derivative liabilities
Balance at December 31, 2016	$ 410
Extinguishment of convertible promissory notes conversion feature	(500)
Issuance of series A preferred stock tranche right	500
Exercise of series A preferred stock tranche right	(540)
Issuance of warrants to purchase series A convertible preferred stock	8
Change in fair value	130
Balance at December 31, 2017	8
Issuance of series B preferred stock tranche right	4,000
Change in fair value	15
Balance at December 31, 2018	$ 4,023
Change in fair value	6,416
Exercise of series B preferred stock tranche right	(10,400)
Balance at September 30, 2019 (unaudited)	$ 39

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4. Equipment, net

Equipment, net consisted of the following (in thousands):

	December 31,		September 30,
	2017	2018	2019
			(unaudited)
Laboratory equipment	$ 154	$ 220	$ 221
Furniture and fixtures	—	—	12
Computer and office equipment	4	14	21
	158	234	254
Less: Accumulated depreciation	(56)	(100)	(138)
Total equipment, net	$ 102	$ 134	$ 116

Depreciation expense for the years ended December 31, 2017 and 2018 and for the nine months ended September 30, 2018 and 2019 (unaudited) was $24, $44, $32 and $38, respectively.

5. Accrued expenses

Accrued expenses consisted of the following (in thousands):

	December 31,		September 30,
	2017	2018	2019
			(unaudited)
Contracted research services	$ 19	$ —	$ —
Payroll and related expenses	124	357	693
Professional and consulting fees	15	95	647
Legal fees	—	—	642
	$ 158	$ 452	$ 1,982

6. Convertible promissory notes

From July 2014 to September 2016, the Company issued convertible promissory notes to various parties and stockholders totaling $1,350 (the “Original Notes”). In October 2016, the Company issued a series of convertible promissory notes (the “Restated Notes”) which amended and restated in their entirety the Original Notes in favor of the Original Notes holders at the original stated principal amount with interest accruing from the original issue date. In September 2016, the Company also issued a new convertible promissory note to a party in the amount of $500 (the “New Note” and together with the Restated Notes, the “Notes”). The Notes bore interest at 8% per annum. All unpaid principal, together with the then accrued interest, for each of the Notes outstanding was due and payable on September 21, 2018.

The outstanding Notes, and accrued interest thereon, were (1) automatically convertible upon the closing of a qualifying equity financing, as defined in the agreement, into the class and series of shares to be issued to investors participating in the financing at a conversion price per share equal to the price per share paid by the investors multiplied by 80%, (2) convertible at the option of each holder upon written election, whereby all outstanding principal and accrued interest thereon, are converted to shares of common stock at the price per share obtained by dividing $4,500,000 by the Company’s fully-diluted capitalization assuming exercise or conversion of all convertible securities of the Company and excluding any shares issuable upon conversion of the notes, (3) due and payable in cash upon a change in control, as defined in the agreement, in an amount

equal to 300% of such principal and accrued interest, (4) due and payable in cash upon an event of default, as defined in the agreement and (5) prepayable at any time without penalty. There were no financial or negative covenants associated with the Notes.

The Company concluded that the conversion feature in the event of a qualified financing met the definition of an embedded derivative that was required to be bifurcated for as a separate instrument because it was not clearly and closely related to the economic characteristics and risks of the Notes since the conversion feature provided for the accelerated repayment of the Notes at a substantial premium upon the occurrence of specified events. The Company recorded the issuance-date fair value of the derivative liability of $370 as a debt discount and as a derivative liability in the Company's consolidated balance sheet.

In January 2017, $50 of the Notes were repaid. In March 2017, the Company completed a qualified financing and all of the outstanding Notes and the accrued interest thereon, aggregating $1,800 and $201, respectively, were converted into 2,501,503 shares of series A convertible preferred stock. The Company accounted for the conversion of the Notes as a debt extinguishment and recognized a loss on extinguishment of convertible promissory notes of $282 in the accompanying statements of operations. The loss on extinguishment was calculated as the difference between (i) the fair value of the 2,501,503 shares of series A convertible preferred stock issued of $2,502 (inclusive of the $8 warrant liability recorded upon issuance) and (ii) the carrying value of the Notes, net of the unamortized debt discount, of $1,519, plus the then-current fair value of derivative liability associated with the Notes at the time of the extinguishment of $500 and the accrued interest of $201.

7. Convertible preferred stock

As of December 31, 2018, the Company's Certificate of Incorporation, as amended and restated (the "Amended Certificate of Incorporation"), designated 44,867,103 authorized shares to be issued as convertible preferred stock with a par value of $0.0001 per share, of which 22,533,945 shares have been further designated as series A convertible preferred stock (the "series A preferred stock") and 22,333,158 shares have been further designated as series B convertible preferred stock (the "series B preferred stock"). As of September 30, 2019, the Company's Amended Certificate of Incorporation designated 45,451,685 authorized shares to be issued as convertible preferred stock with a par value of $0.0001 per share, of which 22,533,945 shares have been further designated as series A preferred stock, and 22,917,740 shares have been further designated as series B preferred stock. The holders of preferred stock have liquidation rights in the event of a deemed liquidation that, in certain situations, are not solely within the control of the Company. Therefore, the series A and series B preferred stock (collectively, the "preferred stock") are classified outside of stockholders' deficit.

Series A preferred stock financing

In March 2017, the Company issued and sold 5,000,000 shares of series A preferred stock at a price of $1.00 per share for proceeds of $4,924, net of issuance costs of $76. The sale of series A preferred shares met the definition of a qualified equity financing, which triggered the automatic conversion of the Company's outstanding notes payable plus unpaid interest into 2,501,503 series A preferred shares (see Note 6).

The series A preferred stock financing included a provision for the issuance of an additional 5,000,000 series A preferred shares at a price of $1.00 in exchange for gross proceeds of $5,000 in the event the Company achieved certain developmental milestones. The Company classified this tranche right as a derivative liability on its consolidated balance sheet on the date of issuance, and the fair value of the tranche right on the date of issuance of $500 was recorded as both a derivative liability and as a reduction to the carrying value of the series A preferred stock. In December 2017, the Company executed a waiver of the developmental milestones whereby the tranche right was executed and an additional 5,000,000 series A preferred shares were issued.

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In August 2018, the Company issued and sold an additional 5,000,000 series A preferred shares at a price of $1.00 per share for proceeds of $4,899, net of issuance costs of $101. The issuance of series A preferred shares included a provision for the issuance of an additional 5,000,000 series A preferred shares at a price of $1.00 in exchange for gross proceeds of $5,000, provided the purchase occurred before December 15, 2018. In November 2018, the additional series A preferred shares were issued.

Series B preferred stock financing

In December 2018, the Company issued 11,166,572 series B preferred shares at a price of $3.81 for proceeds of $42,414, net of issuance costs of $86.

The series B preferred stock financing included a provision for the issuance of an additional 11,166,572 series B preferred shares at a price of $3.81 in exchange for gross proceeds of $42,500 in the event the Company achieved a regulatory milestone. Consistent with the accounting considerations for the series A tranche right, the Company classified this tranche right as a derivative liability on its consolidated balance sheet on the date of issuance, and the fair value of the tranche right on the date of issuance of $4,000 was recorded as both a derivative liability and as a reduction to the carrying value of the series B preferred shares.

In July 2019, the Company issued and sold an additional 456,252 shares of its series B preferred stock at a price of $3.81 per share for gross proceeds of $1,736 and increased the series B tranche right provision for the issuance of an additional 128,330 series B preferred shares at a price of $3.81. In August 2019, the Company waived the clinical milestone requirement and exercised the tranche right for the second tranche of its series B preferred stock and issued an additional 11,294,902 shares of its series B preferred stock.

As of each balance sheet date, the preferred stock consisted of the following:

As of December 31, 2017	Shares authorized	Shares issued and outstanding	Carrying value	Liquidation preference	Conversion price per share
Series A convertible preferred stock	12,501,503	12,501,503	$ 12,458	$ 12,502	$ 1.00

As of December 31, 2018	Shares authorized	Shares issued and outstanding	Carrying value	Liquidation preference	Conversion price per share
Series A convertible preferred stock	22,533,945	22,501,503	$ 22,357	$ 22,502	$ 1.00
Series B convertible preferred stock	22,333,158	11,166,572	38,413	42,500	3.81
	44,867,103	33,668,075	$ 60,770	$ 65,002	

As of September 30, 2019 (unaudited)	Shares authorized	Shares issued and outstanding	Carrying value	Liquidation preference	Conversion price per share
Series A convertible preferred stock	22,533,945	22,501,503	$ 22,357	$ 22,502	$ 1.00
Series B convertible preferred stock	22,917,740	22,917,726	93,483	87,225	3.81
	45,451,685	45,419,229	$115,840	$ 109,727	

The holders of the preferred stock have the following rights and preferences:

Voting

The holders of preferred stock are entitled to vote, together with the holders of common stock, on all matters submitted to stockholders for a vote. Each holder of outstanding shares of preferred stock shall be entitled to

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cast the number of votes equal to the number of whole shares of common stock into which the shares of preferred stock held by such holder are convertible as of the record date for determining stockholders entitled to vote on such matter. Except as provided by law or by the other provisions of the Amended Certificate of Incorporation, holders of preferred stock vote together with the holders of common stock as a single class.

The holders of record of the shares of series B preferred stock, exclusively and as a separate class, are entitled to elect two directors of the Company (the “series B directors”); the holders of record of the shares of series A preferred stock, exclusively and as a separate class, are entitled to elect two directors of the Company (the “series A directors” and together with the series B directors, the “preferred directors”).

Conversion

Each share of preferred stock shall be convertible, at the option of the holder, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and non-assessable shares of common stock as is determined by dividing the original issue price by the conversion price (as defined below) in effect at the time of conversion.

The series A original issue price and series A conversion price were equal to $1.00 as of December 31, 2017 and 2018 and September 30, 2019 (unaudited). The series B original issue price and series B conversion price were equal to $3.81 as of December 31, 2018 and September 30, 2019 (unaudited). Such series A and series B original issue prices and series A and series B conversion prices, the rate at which each series of preferred stock may be converted into common stock, are subject to adjustment from time to time to reflect future stock dividends, splits, combinations, recapitalizations and similar events. The series A and series B conversion prices are also subject to adjustments based on weighted-average anti-dilution provisions set forth in the Amended Certificate of Incorporation in the event that additional securities are issued at a purchase price less than the series A conversion price and/or the series B conversion price then in effect. As of December 31, 2017 and 2018 and September 30, 2019 (unaudited), each share of series A preferred stock was convertible into one share of common stock. As of December 31, 2018 and September 30, 2019 (unaudited), each share of series B preferred stock was convertible into one share of common stock.

Upon either (a) the closing of the sale of shares of common stock to the public at a price per share of at least $7.00, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the common stock in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least $75,000 of gross proceeds to the Company, a qualified IPO, or (b) the date and time, or the occurrence of an event, specified by vote or written consent of the requisite preferred holders, then (i) all outstanding shares of preferred stock shall automatically be converted into shares of common stock, at the then effective conversion rate and (ii) such stock may not be reissued by the Company.

Dividends

The holders of the preferred stock are entitled to receive noncumulative dividends when and if declared by Company’s board of directors. The Company may not declare, pay or set aside any dividends on any other class or series of stock of the Company, other than dividends on common stock payable in common stock, unless the holders of the preferred stock first receive, or simultaneously receive, a dividend on each outstanding preferred stock equal to (a) in the case of a dividend on any class of common stock or any class or series that is convertible into common stock, that dividend per preferred stock as would equal the product of (i) the dividend payable on each share of such class or series determined, if applicable, as if all shares of such class or series had been converted into common stock and (ii) the number of common stock issuable upon conversion of a

stock the applicable series of preferred stock, or (b) in the case of a dividend on any class or series that is not convertible into common stock, at a rate per preferred stock determined by (i) dividing the amount of the dividend payable on each share of such class or series of stock by the original issue price of such class or series (subject to appropriate adjustment in the event of any bonus stock, stock dividend, stock split, combination of or other similar recapitalization with respect to such class or series) and (ii) multiplying such fraction by an amount equal to the applicable series A or series B original issue price. No cash dividends were declared or paid during the years ended December 31, 2017 or 2018 or the nine months ended September 30, 2019 (unaudited).

Liquidation preference

In the event of any liquidation, dissolution or winding up of the Company, the holders of shares of series B preferred stock and series A preferred stock then outstanding, on a pro rata, as converted and *pari passu* basis, shall be entitled to be paid out of the assets of the Company available for distribution to its stockholders, an amount per share equal to the applicable original issue price for such class or series of preferred stock, plus any dividends declared but unpaid thereon.

If upon any such liquidation, dissolution or winding up of the Company or deemed liquidation event, the assets of the Company available for distribution to its stockholders shall be insufficient to pay the holders of shares of preferred stock the full amount to which they shall be entitled, the holders of shares of series preferred stock shall stock ratably, on a *pari passu* basis, in any distribution of the assets available for distribution in proportion to the respective amounts which would otherwise be payable in respect of the stock held by them upon such distribution if all amounts payable on or with respect to such stock were paid in full.

Unless a majority of the holders of the then outstanding preferred stock, on an as-if-converted to common stock basis, elect otherwise, a deemed liquidation event shall include a merger or consolidation (other than one in which stockholders of the Company own a majority by voting power of the outstanding shares of the surviving or acquiring company or corporation) or a sale, lease, transfer, exclusive license or other disposition of all or substantially all of the assets of the Company.

Redemption

The Amended Certificate of Incorporation do not provide redemption rights to the holders of preferred stock.

The holders of shares of convertible preferred stock have liquidation rights in the event of a deemed liquidation that, in certain situations, are not solely within the control of the Company. Therefore, the preferred stock is classified outside of stockholders' deficit.

Upon issuance of each class of preferred stock, the Company assessed the embedded conversion and liquidation features of the securities. The Company determined that each class of preferred stock did not require the Company to separately account for the liquidation features. The Company also concluded that no beneficial conversion feature existed upon the issuance date of the series A preferred stock or series B preferred stock as of December 31, 2017 or 2018 or September 30, 2019 (unaudited).

8. Common stock

As of December 31, 2017, the Amended Certificate of Incorporation authorized the Company to issue 19,533,945 shares of common stock with a par value of $0.0001. As of December 31, 2018, the Amended Certificate of Incorporation authorized the Company to issue 57,803,522 shares of common stock with a par value of $0.0001. As of September 30, 2019, the Amended Certificate of Incorporation authorized the Company to issue 58,803,522 shares of common stock with a par value of $0.0001. The voting, dividend and liquidation rights of

the holders of the Company's common stock are subject to and qualified by the rights, powers and preferences of the holders of the preferred stock as set forth above.

The Company had reserved 13,257,445 shares and 38,558,765 shares as of December 31, 2017 and 2018, respectively, and 51,762,784 shares as of September 30, 2019 (unaudited), of common stock for the conversion of outstanding shares of preferred stock (see Note 7), the exercise of outstanding stock options, the number of shares remaining available for grant under the Company's 2017 Equity Incentive Plan (see Note 9) and the exercise of the outstanding warrants to purchase shares of series A preferred stock (see Note 6), assuming all warrants to purchase shares of series A preferred stock became warrants to purchase shares of common stock at the applicable conversion ratio.

On March 13, 2017, the Company effected a 2.45818-for-1 stock split of its issued and outstanding and authorized shares of common stock. Accordingly, all share and per share amounts for all periods presented in the accompanying consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this stock split.

Voting

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders.

Dividends

Common stockholders are entitled to receive dividends, as may be declared by the board of directors. These dividends are subject to the preferential dividend rights of the holders of the Company's preferred stock. When dividends are declared on shares of common stock, the Company must declare at the same time a dividend payable to the holders of preferred stock equivalent to the dividend amount they would receive if each preferred share were converted into common stock. The Company may not pay dividends to common stockholders until all dividends declared but unpaid on the preferred stock have been paid in full. No cash dividends were declared or paid during the years ended December 31, 2017 or 2018 or the nine months ended September 30, 2019 (unaudited).

9. Stock-based compensation

2017 Equity Incentive Plan

The Company's 2017 Employee, Director and Consultant Equity Incentive Plan, as amended (the "2017 Plan"), provides for the Company to grant qualified incentive options, nonqualified options, stock grants and other stock-based awards to employees and non-employees to purchase the Company's common stock. The 2017 Plan is administered by the board of directors, or at the discretion of the board of directors, by a committee of the board of directors.

The total number of shares of common stock that may be issued under the 2017 Plan was 1,000,000 shares as of December 31, 2017. The total number of shares of common stock that may be issued under the 2017 Plan was 5,413,708 as of December 31, 2018 and 7,006,573 as of September 30, 2019 (unaudited), of which 4,714,278 and 1,460,392 shares remained available for future grant as of December 31, 2018 and September 30, 2019 (unaudited), respectively.

The exercise price for incentive options is determined at the discretion of the board of directors. All incentive options granted to any person possessing less than 10% of the total combined voting power of all classes of

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stock may not have an exercise price of less than 100% of the fair market value of the common stock on the grant date. All incentive options granted to any person possessing more than 10% of the total combined voting power of all classes of stock may not have an exercise price of less than 110% of the fair market value of the common stock on the grant date. The option term for incentive awards may not be greater than ten years from the date of the grant. Incentive options granted to persons possessing more than 10% of the total combined voting power of all classes of stock may not have an option term of greater than five years from the date of the grant. The vesting period for equity-based awards is determined at the discretion of the board of directors, which is generally four years. For awards granted to employees and non-employees with four-year vesting terms, 25% of the option vests on the first anniversary of the grant date and the remaining stock vest equally each month for three years thereafter.

Shares that are expired, terminated, surrendered or canceled under the 2017 Plan without having been fully exercised will be available for future awards.

During the years ended December 31, 2017 and 2018 and the nine months ended September 30, 2018 and 2019 (unaudited), the Company granted options to purchase 10,000, 73,970, 73,970 and 4,093,851 shares of common stock, respectively, to employees. The Company recorded stock-based compensation expense for options granted to employees of $0, $1, $0 and $234 during the years ended December 31, 2017 and 2018 and the nine months ended September 30, 2018 and 2019 (unaudited), respectively.

During the years ended December 31, 2017 and 2018 and the nine months ended September 30, 2018 and 2019 (unaudited), the Company granted options to purchase 10,000, 50,000, 50,000 and 612,900 shares of common stock, respectively, to non-employees. The Company recorded stock-based compensation expense for options granted to non-employees of $0, $9, $8 and $350 during the years ended December 31, 2017 and 2018 and the nine months ended September 30, 2018 and 2019 (unaudited), respectively.

Option valuation

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

	Year ended December 31,		Nine months ended September 30,	
	2017	2018	2018	2019
				(unaudited)
Risk-free interest rate	2.40%	2.87%	2.87%	1.63%
Expected term (in years)	6.1	6.1	6.1	6.1
Expected volatility	63.4%	58.4%	58.4%	63.4%
Expected dividend yield	0%	0%	0%	0%

The assumptions that the Company used to determine the fair value of options granted to non-employees were as follows, presented on a weighted-average basis:

	Year ended December 31,		Nine months ended September 30,	
	2017	2018	2018	2019
				(unaudited)
Risk-free interest rate	2.40%	2.87%	2.87%	1.58%
Expected term (in years)	9.2	9.7	9.7	5.7
Expected volatility	63.4%	58.4%	58.4%	62.8%
Expected dividend yield	0%	0%	0%	0%

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Options

Through September 30, 2019, all options granted by the Company under the 2017 Plan were for the purchase of shares of common stock. The following table summarizes option activity under the 2017 Plan since December 31, 2016 (in thousands, except share and per share amounts):

	Number of stock options	Weighted average exercise price	Weighted average remaining contractual term (in years)	Aggregate intrinsic value
Balance at December 31, 2016	—	—	—	$ —
Options granted	20,000	$ 0.10		
Balance at December 31, 2017	20,000	$ 0.10	9.2	$ 2
Options granted	123,970	$ 0.24		
Balance at December 31, 2018	143,970	$ 0.22	9.5	$ 121
Options granted	4,706,751	$ 2.28		
Balance at September 30, 2019 (unaudited)	4,850,721	$ 2.22	9.8	$ 6,718
Options vested and expected to vest at December 31, 2018	143,970	$ 0.22	9.5	$ 121
Options vested and expected to vest at September 30, 2019 (unaudited)	4,850,721	$ 2.22	9.8	$ 6,718
Options exercisable at December 31, 2018	58,750	$ 0.22	9.5	$ 49
Options exercisable at September 30, 2019 (unaudited)	277,116	$ 1.74	9.5	$ 515

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

The weighted-average grant-date fair value per share of options granted during the years ended December 31, 2017 and 2018 and the nine months ended September 30, 2019 (unaudited) was $0.06, $0.13 and $1.38, respectively.

The total fair value of options vested during the years ended December 31, 2017 and 2018 and the nine months ended September 30, 2018 and 2019 (unaudited) was $0, $7, $6 and $274, respectively.

Restricted stock

Under terms of the restricted stock agreements covering the common stock, shares of restricted common stock are subject to a vesting schedule. The restricted stock vests over a three-year period during which time all unvested stock will immediately be forfeited to the Company if the relationship between the recipient and the Company ceases. Subject to the continued employment (or other engagement of the recipient by the Company as described in the restricted stock agreements), all shares of restricted common stock become fully vested within three years of the vesting commencement date.

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The following table summarizes restricted stock activity since December 31, 2016:

	Number of shares	Weighted average grant date fair value
Unvested restricted common stock as of December 31, 2016	—	—
Granted	276,500	$ 0.10
Unvested restricted common stock as of December 31, 2017	276,500	$ 0.10
Granted	278,960	$ 0.24
Vested	(155,421)	$ 0.10
Unvested restricted common stock as of December 31, 2018	400,039	$ 0.17
Granted	140,000	$ 1.06
Vested	(161,536)	$ 0.14
Unvested restricted common stock as of September 30, 2019 (unaudited)	378,503	$ 0.54

The aggregate fair value of restricted stock that vested during the years ended December 31, 2017 and 2018 and the nine months ended September 30, 2018 and 2019 (unaudited) was $0, $40, $28 and $444, respectively.

The Company recorded stock-based compensation expense for restricted stock of $6, $53, $16 and $549, during the years ended December 31, 2017 and 2018 and the nine months ended September 30, 2018 and 2019 (unaudited), respectively.

Stock-based compensation expense

The Company recorded stock-based compensation expense in the following expense categories of its consolidated statements of operations (in thousands):

	Fiscal year ended December 31,		Nine months ended September 30,	
	2017	2018	2018	2019
				(unaudited)
Research and development	$ 6	$ 62	$ 24	$ 984
General and administrative	—	1	—	149
Total stock-based compensation expense	$ 6	$ 63	$ 24	$ 1,133

For options granted in June 2019, the board of directors determined that the fair value of the Company's common stock was $1.06 per share as of the grant date. However, the fair value of the Company's common stock at the date of the grant was adjusted to $1.37 per share in connection with a retrospective fair value assessment solely for accounting purposes. Accordingly, stock-based compensation recorded during the nine months ended September 30, 2019 (unaudited) was based on the adjusted fair value for the options granted in June 2019.

As of December 31, 2018 and September 30, 2019 (unaudited), total unrecognized compensation cost related to the unvested stock-based awards was $335 and $7,296, respectively, which is expected to be recognized over a weighted average period of 3.3 and 3.6 years, respectively.

10. Income taxes

For the years ended December 31, 2017 and 2018 and the nine months ended September 30, 2018 and 2019 (unaudited), the Company recorded no income tax benefit for the net operating losses incurred in each year, due to its uncertainty of realizing a benefit from those items.

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A reconciliation of income taxes computed using United States statutory federal tax rate to that reflected in operations as of December 31, 2017 and 2018 are as follows:

	Tax year ended December 31,	
	2017	2018
U.S. federal statutory income tax rate	34.0%	21.0%
State and local taxes, net of federal benefit	3.7%	5.1%
Permanent differences	(4.8)%	0.0%
Nondeductible expenses	0.0%	0.0%
Research and development credits	2.5%	3.7%
Tax rate change and true-up	(12.3)%	0.0%
Change in valuation allowance	(23.4)%	(29.8)%
Effective income tax rate	0.0%	0.0%

The tax effects of temporary differences that gave rise to significant portions of the deferred tax assets were as follows (in thousands):

	Tax year ended December 31,	
	2017	2018
Deferred tax assets:		
Net operating loss carryforwards	$ 668	$ 2,904
Research and development tax credits	124	459
Accrual to cash adjustment	566	657
Net fixed assets	(13)	(10)
Gross deferred tax assets	1,345	4,010
Less: valuation allowance	(1,345)	(4,010)
Net deferred taxes	$ —	$ —

As of December 31, 2018, the Company had federal net operating loss carryforwards of $2,557 that are subject to expire at various dates through 2037, and net operating loss carryforwards of $8,535, which have no expiration date, can be carried forward indefinitely, and are limited to a deduction to 80% of annual taxable income. The Company has state tax net operating loss carryforwards of approximately $11,088, which may be available to offset future income tax liabilities and expire at various dates through 2038. The Company also has net operating loss carryforwards in Canada of $19 that are set to expire in 2038. Additionally, the Company has federal research and development tax credit carryforwards of $459 that expire at various dates through 2038.

In assessing the realizability of the net deferred tax asset, the Company considers all relevant positive and negative evidence in determining whether it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The realization of the gross deferred tax assets is dependent on several factors, including the generation of sufficient taxable income prior to the expiration of the net operating loss carryforwards. Management believes that it is more likely than not that the Company's deferred income tax assets will not be realized. As such, there is a full valuation allowance against the net deferred tax assets as of December 31, 2017 and 2018 and September 30, 2019 (unaudited). The valuation allowance increased by $1,345 during the year ended December 31, 2017 and $2,665 during the year ended December 31, 2018 primarily as a result of net operating losses generated during the periods. The Company reevaluates the positive and negative evidence at each reporting period. The valuation allowance increased by $6,643 during the nine months ended September 30, 2019 (unaudited) primarily as a result of net operating losses generated during the period.

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Utilization of the net operating loss carryforwards and research and development tax credit carryforwards may be subject to an annual limitation under Section 382 of the Internal Revenue Code of 1986, and corresponding provisions of state law, due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50% over a three-year period. The Company has not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382, at any time since inception, utilization of the net operating loss carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before utilization. Further, until a study is completed and any limitation is known, no amounts are being presented as an uncertain tax position.

The Company also has not conducted a study of its research and development credit carryforwards, which may result in an adjustment to research and development credit carryforwards. A full valuation allowance has been provided against the Company's research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the balance sheets or statements of operations if an adjustment were required. Further, until a study is completed and any limitation is known, no amounts are being presented as an uncertain tax position.

The Company applies the accounting guidance in ASC 740 related to accounting for uncertainty in income taxes. The Company's reserves related to taxes are based on a determination of whether, and how much of, a tax benefit taken by the Company in its tax filings or positions is more likely than not to be realized following resolution of any potential contingencies present related to the tax benefit. As of December 31, 2017 and 2018 and September 30, 2019 (unaudited), the Company had no unrecognized tax benefits.

The Company will recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2018 and September 30, 2019 (unaudited), the Company had no accrued interest or penalties related to uncertain tax positions.

In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implementation of the Tax Cuts and Jobs Act (SAB No. 118), which allowed the Company to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. The Company's provisional estimate associated with the reduction in U.S. federal corporate tax rate from 35% to 21% impacted the changes in the valuation allowance and change in tax rate component of the Company's effective tax rate reconciliation as well as its ending deferred tax assets and valuation allowance in the deferred tax footnote disclosure. In the fourth quarter of 2018, the Company completed our analysis to determine the effect of the Tax Act and recorded no adjustments.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending tax examinations. As of December 31, 2018 and 2017, the Company's tax years are still open under statute from 2016 to the present.

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11. Net loss per share and unaudited pro forma net loss per share

Net loss per share

The following table summarizes the computation of basic and diluted net loss per share attributable to common stockholders of the Company (in thousands, except share and per share amounts):

	Year ended December 31,		Nine months ended September 30,	
	2017	2018	2018	2019
				(unaudited)
Net loss attributable to common stockholders	$ (4,602)	$ (8,931)	$ (5,865)	$ (25,383)
Weighted average common shares outstanding—basic and diluted	5,802,740	6,089,819	6,069,399	6,194,913
Net loss per share attributable to common stockholders—basic and diluted	$ (0.79)	$ (1.47)	$ (0.97)	$ (4.10)

The Company's unvested restricted common shares have been excluded from the computation of basic net loss per share attributable to common stockholders.

The Company's potentially dilutive securities, which include options, unvested restricted stock, convertible preferred stock and warrants to purchase convertible preferred stock, have been excluded from the computation of diluted net loss per share attributable to common stockholders as the effect would be to reduce the net loss per share attributable to common stockholders. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Year ended December 31,		Nine months ended September 30,	
	2017	2018	2018	2019
				(unaudited)
Options to purchase common stock	20,000	143,970	143,970	4,850,721
Unvested restricted stock	276,500	400,039	400,039	378,503
Preferred stock (as converted to common stock)	12,501,503	33,668,075	17,501,503	45,419,229
Warrants to purchase shares of series A preferred stock (as converted to common stock)	32,442	32,442	32,442	32,442
	12,830,445	34,244,526	18,077,954	50,680,895

Unaudited pro forma net loss per share attributable to common stockholders

The unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2018 and the nine months ended September 30, 2019 have been prepared to give effect to adjustments arising upon the completion of the proposed offering. The unaudited pro forma net loss attributable to common stockholders used in the calculation of unaudited pro forma basic and diluted net loss per share attributable to common stockholders does not include the effects of the warrant liability because the calculation gives effect, upon the proposed offering, to (i) the conversion of shares of preferred stock into shares of common stock and (ii) the warrants to purchase shares of series A preferred stock becoming warrants

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to purchase shares of common stock as if the proposed offering had occurred on the later of January 1, 2018 or the issuance date of the preferred stock and the warrants to purchase shares of series A preferred stock.

Unaudited pro forma basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share amounts):

	Year ended December 31, 2018	Nine months ended September 30, 2019
Numerator:		
Net loss attributable to common stockholders	$ (8,931)	$ (25,383)
Reversal of the change in fair value of the warrant liability due to the warrants to purchase shares of series A preferred stock becoming warrants to purchase shares of common stock upon completion of the proposed initial public offering	15	6,416
Pro forma net loss attributable to common stockholders	$ (8,916)	$ (18,967)
Denominator:		
Weighted average common shares outstanding—basic and diluted	6,089,819	6,194,913
Pro forma adjustment to reflect assumed conversion of preferred stock to common stock upon completion of the proposed initial public offering	15,611,545	45,419,229
Pro forma weighted average common shares outstanding—basic and diluted	21,701,364	51,614,142
Net loss per share attributable to common stockholders— basic and diluted	$ (0.41)	$ (0.37)

12. Commitments and contingencies

Lease agreements

The Company leases approximately 1,000 square feet of laboratory space and 500 square feet of office space at 25 Health Sciences Drive, Stony Brook, NY 11790 and the lease for this location expires on December 31, 2019. The Company classifies the lease as an operating lease and records rent expense on a straight-line basis over the term of the lease. The Company recorded rent expense of $26 and $36 during the years ended December 31, 2017 and 2018, respectively. As of December 31, 2018, future minimum lease payments under non-cancelable operating lease commitments, which are all due during the year ended December 31, 2019, totaled $51.

Indemnification agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any indemnification arrangements could have a material

effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of December 31, 2017 or 2018.

Legal proceedings

From time to time, the Company may become involved in legal proceedings arising in the ordinary course of business. As of December 31, 2017 and 2018, the Company was not a party to any material legal matters or claims.

13. Benefit plans

In 2018 the Company established a Simplified Employee Pension ("SEP") defined-contribution savings plan. This plan covers substantially all employees who meet minimum age and service requirements. The Company provides contributions of 6% of each participant's salary. Employees are immediately and fully vested in the Company's contribution. During the year ended December 31, 2018 and the nine months ended September 30, 2019 (unaudited), the Company contributed $20 and $13 to the plan, respectively.

14. Related party transactions

The Company is party to a services agreement, which was entered into in March 2017 and amended in November 2017, with Ridgeline, an entity owned by one of its investors, whereby an individual who is a Company director and executive officer and other employees of Ridgeline provide the Company with management, scientific, business development and other operational services. The agreement is effective until either party elects to terminate. Under the services agreement the Company will pay for services based on the costs incurred plus a markup of ten percent (10%) and reimburse for certain pass-through costs. The services agreement was further amended in December 2018. Subsequent to this amendment, in connection with the services provided, the Company pays Ridgeline $950,000 per month, which is reconciled on a quarterly basis with the actual expenses incurred by Ridgeline on its behalf. Total amounts due to related party were $1,920 and $1,707, as of December 31, 2017 and 2018 and $1,254 as of September 30, 2019 (unaudited). Total service fees incurred were $1,390 and $2,728, for the years ended December 31, 2017 and 2018 and $8,854 for the nine months ended September 30, 2019 (unaudited).

15. Subsequent events

For its consolidated financial statements as of December 31, 2018 and for the year then ended, the Company evaluated subsequent events through August 22, 2019, the date on which those financial statements were issued.

Lease agreements

In February 2019, the Company entered into an agreement to lease approximately 2,357 square feet of office space for its principal office, which is located in Cambridge, MA. The lease expires on April 30, 2022, subject to an option to extend the lease for three additional years.

Also in February 2019, the Company entered into a lease agreement to use laboratory and office facilities in New York, NY. The lease expires on February 11, 2020, however, the Company may terminate the lease upon a 30-day notice.

In March 2019, the Company entered into a lease agreement to occupy a portion of a building in Toronto, Ontario for the purposes of conducting laboratory research, business planning and related activities. The lease expires on April 5, 2020.

FOIA CONFIDENTIAL TREATMENT REQUESTED

Future minimum rental payments related to these leases total $239, $268, $231 and $58 for the years ending 2019, 2020, 2021 and 2022, respectively.

Series B preferred stock financing

On July 8, 2019, the Company issued an additional 584,582 shares of its series B preferred stock for gross proceeds of $2,224. In addition, on August 9, 2019, the Company waived the clinical milestone requirement and exercised the tranche right for the second tranche of its series B preferred stock and issued an additional 11,166,572 shares of its series B preferred stock at a price of $3.81 for gross proceeds of $42,500.

Grant of stock options and restricted stock

On March 4, 2019, June 12, 2019, August 8, 2019 and August 14, 2019, the Company granted performance-based options for the purchase of 103,199, 1,271,839, 117,200 and 1,745,870 shares of common stock, respectively, at exercise prices of $1.06, $1.06, $2.13 and $2.13 per share, respectively, to employees and non-employees as compensation for future services to the Company. The options vest over a term of four years. Additionally on March 4, 2019, the Company granted an aggregate of 140,000 shares of restricted common stock, at a purchase price of $1.06 per share, to non-employees. The restricted common stock vests over a term of two years.

16. Subsequent events (unaudited)

For its consolidated financial statements as of September 30, 2019 and for the nine months then ended, the Company evaluated subsequent events through October 30, 2019, the date on which those financial statements were issued, and determined that there are no additional material subsequent events to report.

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shares

Common stock

Prospectus

J.P. Morgan **Jefferies** **Cowen**

Canaccord Genuity

Until , all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

, 2019

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Part II

Information not required in prospectus

Item 13. Other expenses of issuance and distribution

The following table sets forth the costs and expenses, other than underwriting discounts and commissions, to be paid by us in connection with the sale of the shares of common stock being registered hereby. All amounts shown are estimates except for the SEC registration fee, the FINRA filing fee and the Nasdaq Global Market initial listing fee.

SEC registration fee	$	*
FINRA filing fee		*
Nasdaq listing fee		*
Printing and engraving expenses		*
Legal fees and expenses		*
Accounting fees and expenses		*
Blue Sky fees and expenses (including legal fees)		*
Transfer agent and registrar fees and expenses		*
Miscellaneous		*
Total		*****

* To be provided by amendment.

Item 14. Indemnification of directors and officers

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

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

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

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

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In addition, our bylaws provide that:

- we will indemnify our directors, officers and, in the discretion of our board of directors, certain employees to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended; and
- we will advance reasonable expenses, including attorneys' fees, to our directors and, in the discretion of our board of directors, to our officers and certain employees, in connection with legal proceedings relating to their service for or on behalf of us, subject to limited exceptions.

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

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

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

Item 15. Recent sales of unregistered securities

On March 13, 2017, we effected a 2.45818-for-1 stock split (the "Stock Split") of our issued and outstanding and authorized common stock. All per share amounts and number of shares of common stock in this Item 15 reflect the Stock Split. In the three years preceding the filing of this registration statement, we have issued the following securities that were not registered under the Securities Act:

(a) Founder Capital Stock

In September 2016 and February 2017 we issued an aggregate of 5,000,000 shares of our common stock to our founders.

No underwriters were involved in the foregoing sales of securities. The sales of securities described above were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act, including Regulation D and Rule 506 promulgated thereunder, as transactions by an issuer not involving a public offering. All of the purchasers in these transactions represented to us in connection with their purchase that they were acquiring the securities for investment and not distribution, that they could bear the risks of the investment and could hold the securities for an indefinite period of time. Such purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration or an available exemption from such registration. All of the foregoing securities are deemed restricted securities for the purposes of the Securities Act.

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(b) Issuances of Capital Stock

In March 2017 we issued and sold an aggregate of 1,000,000 shares of our common stock at a purchase price of $0.10 per share, for an aggregate purchase price of 100,000 to Versant Venture Capital VI, L.P.

In March 2017, with subsequent offerings in December 2017, August 2018 and November 2018, investors purchased an aggregate of 20,000,000 shares of our Series A preferred stock at $1.00 per share. In connection with the issuance of our Series A preferred stock, all of our outstanding convertible promissory notes issued in 2014, 2015 and 2016 were automatically converted into 2,501,503 shares of our Series A preferred stock.

In December 2018, with subsequent offerings in July 2019 and August 2019, investors purchased an aggregate of 22,917,726 shares of Series B preferred stock at $3.806 per share.

No underwriters were involved in the foregoing sales of securities. The sales of securities described above were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act, including Regulation D and Rule 506 promulgated thereunder, as transactions by an issuer not involving a public offering. All of the purchasers in these transactions represented to us in connection with their purchase that they were acquiring the securities for investment and not distribution, that they could bear the risks of the investment and could hold the securities for an indefinite period of time. Such purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration or an available exemption from such registration. All of the foregoing securities are deemed restricted securities for the purposes of the Securities Act.

(c) Grants and Exercises of Stock Options and Restricted Stock

We have granted stock options to purchase an aggregate of 4,850,721 shares of our common stock, with exercise prices ranging from $0.10 to $3.60 per share, to employees, directors and consultants pursuant to the 2017 Employee, Director and Consultant Equity Incentive Plan, as amended (the 2017 Plan). Through the date of filing, no shares of common stock have been issued upon the exercise of stock options pursuant to the 2017 Plan. Between December 2017 through the filing, we granted an aggregate of 695,460 shares of restricted stock under the 2017 Plan.

The issuances of the securities described above were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act or Rule 701 promulgated under the Securities Act as transactions pursuant to compensatory benefit plans. The shares of common stock issued upon the exercise of options are deemed to be restricted securities for purposes of the Securities Act.

(d) Issuances of Warrants and Non-Plan Stock Options

In September 2016 we granted a warrant to purchase an aggregate of 32,442 shares of our Series A preferred stock, with an exercise price of $1.00 per share, to consultants, which grants were not made pursuant to a benefits plan.

No underwriters were involved in the foregoing sales of securities. The sales of securities described above were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act, including Regulation D and Rule 506 promulgated thereunder, as transactions by an issuer not involving a public offering. All of the purchasers in these transactions represented to us in connection with their purchase that they were acquiring the securities for investment and not distribution, that they could bear the risks of the investment and could hold the securities for an indefinite period of time. Such purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration or an available exemption from such registration. All of the foregoing securities are deemed restricted securities for the purposes of the Securities Act.

FOIA CONFIDENTIAL TREATMENT REQUESTED

Item 16. Exhibits and financial statement schedules

(a) Exhibits.

Exhibit number	Exhibit table
1.1*	Form of Underwriting Agreement
3.1*	Second Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect
3.2*	Certificate of Amendment of Second Amended and Restated Certificate of Incorporation of the Registrant
3.3*	Form of Third Amended and Restated Certificate of Incorporation of the Registrant (to be effective upon the closing of this offering)
3.4**	By-laws of the Registrant, as currently in effect
3.5*	Form of Amended and Restated By-laws (to be effective upon the closing of this offering)
4.1*	Amended and Restated Investors' Rights Agreement among the Registrant and certain of its stockholders, dated December 21, 2018
4.2*	Form of Specimen Common Stock Certificate
4.3*	Form of Common Stock Warrant
5.1*	Opinion of Goodwin Procter LLP
10.1**#	2017 Employee, Director and Consultant Equity Incentive Plan, as amended, and forms of award agreements thereunder
10.2*#	2019 Stock Option and Incentive Plan and forms of award agreements thereunder
10.3*#	Senior Executive Cash Incentive Bonus Plan
10.4*#	2019 Employee Stock Purchase Plan
10.5*#	Form of Officer Indemnification Agreement
10.6*#	Form of Director Indemnification Agreement
10.7*#	Employment Agreement between the Registrant and David M. Epstein, Ph.D., to be in effect upon the closing of this offering
10.8*#	Employment Agreement between the Registrant and Brent Hatzis-Schoch, to be in effect upon the closing of this offering
10.9*#	Employment Agreement between the Registrant and Thomas Leggett, to be in effect upon the closing of this offering
10.10*#	Employment Agreement between the Registrant and Christopher D. Roberts, to be in effect upon the closing of this offering
10.11**	Lease Agreement, dated as of March 27, 2019, by and between MIT 139 Main Street Leasehold LLC and the Registrant
10.12**†	Services Agreement, dated as of March 15, 2017, by and between Ridgeline Therapeutics GmbH and the Registrant, as amended
16.1*	Letter of Adeptus Partners, LLC, Independent Public Accountants
21.1**	Subsidiaries of the Registrant
23.1*	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm
23.2*	Consent of Goodwin Procter LLP (included in Exhibit 5.1)

FOIA CONFIDENTIAL TREATMENT REQUESTED

Exhibit number	Exhibit table
24.1*	Power of Attorney (included on signature page to this registration statement)

* To be filed by amendment.

** Previously filed.

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

† Portions of this exhibit (indicated by asterisks) will be omitted in accordance with the rules of the Securities and Exchange Commission.

(b) Financial Statement Schedules.

None.

Item 17. Undertakings

The undersigned Registrant hereby undertakes to provide to the underwriters at the closing specified in the Underwriting Agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act 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 Registrant 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 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.

FOIA CONFIDENTIAL TREATMENT REQUESTED

Signatures

Pursuant to the requirements of the Securities Act of 1933, as amended, Black Diamond Therapeutics, Inc. has duly caused this registration statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Cambridge, State of Massachusetts, on the day of , 2019.

Black Diamond Therapeutics, Inc.

By: _____
David M. Epstein
President and Chief Executive Officer

Signatures and power of attorney

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints David M. Epstein and Brent Hatzis-Schoch, and each of them, either of whom may act without the joinder of the other, as his true and lawful attorneys-in-fact and agents with full power of substitution and re-substitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement, and to sign any registration statement for the same offering covered by the registration statement that is to be effective upon filing pursuant to Rule 462(b) promulgated under the Securities Act, and all post-effective amendments thereto, and to file the same, with all exhibits thereto and all 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 he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or his or their substitute or substitutes, may lawfully do or cause to be done or 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 indicated on the day of , 2019.

Signature	Title
_____ David M. Epstein	President, Chief Executive Officer and Director (Principal Executive Officer)
_____ Thomas Leggett	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)
_____ Bradley Bolzon	Chairman and Director
_____ Ali Behbahani	Director
_____ Alexander Mayweg	Director
_____ Garry E. Menzel	Director
_____ Rajeev Shah	Director