As confidentially submitted to the U.S. Securities and Exchange Commission on August 10, 2020.

Registration No. 333-

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

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

BOLT BIOTHERAPEUTICS, INC.
(Exact name of Registrant as specified in its charter)

Delaware	2834	47-2804636
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

900 Chesapeake Drive
Redwood City, California 94063
(650) 665-9295
(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

Randall C. Schatzman, Ph.D.
Chief Executive Officer
Bolt Biotherapeutics, Inc.
900 Chesapeake Drive
Redwood City, California 94063
(650) 665-9295
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Sonya F. Erickson John T. McKenna Cooley LLP 1700 Seventh Avenue Seattle, Washington 98101 (206) 452-8753	Alan F. Denenberg Stephen Salmon Davis Polk & Wardwell LLP 1600 El Camino Real Menlo Park, California 94025 (650) 752-2000

Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement is declared effective.

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

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, 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 7(a)(2)(B) of the Securities Act. ☒

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities being Registered	Proposed Maximum Aggregate Offering Price(1)(2)	Amount of Registration Fee
Common stock, par value $0.00001 per share	$	$

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

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

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

PROSPECTUS (Subject To Completion)
Issued , 2020

Shares

COMMON STOCK

Bolt Biotherapeutics, Inc. is offering shares of its common stock. This is our initial public offering and no public market currently exists for our shares of common stock. We anticipate 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 "BOLT."

We are an "emerging growth company" as defined under the federal securities laws. Investing in our common stock involves risks. See "Risk Factors" beginning on page 11.

PRICE $ A SHARE

	Per Share	***Total***
Initial public offering price	*$*	*$*
Underwriting discounts and commissions(1)	*$*	*$*
Proceeds, before expenses, to us	*$*	*$*

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

We have granted the underwriters an option to purchase up to an additional shares of common stock at the initial public offering price less underwriting discounts and commissions to cover over-allotments.

The Securities and Exchange Commission and state securities regulators have not approved or disapproved of these securities, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares of common stock to purchasers on , 2020.

MORGAN STANLEY *SVB LEERINK* *STIFEL* *GUGGENHEIM SECURITIES*

, 2020

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

We and the underwriters have not authorized anyone to provide you with any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses we have prepared. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus or in any applicable free writing prospectus is accurate only as of the date of this prospectus or any such free writing prospectus, as applicable, regardless of its time of delivery or of any sale of our common stock. Our business, financial condition, results of operations and future growth prospects may have changed since that date.

For investors outside the United States: Neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of our common stock and the distribution of this prospectus outside of the United States.

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, including "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and our financial statements and the related notes included elsewhere in this prospectus, before making an investment decision. Unless the context otherwise requires, all references in this prospectus to "Bolt Biotherapeutics," "we," "us," "our" and "our company" refer to Bolt Biotherapeutics, Inc.

Overview

We are a clinical-stage immuno-oncology company developing tumor-targeted therapies that leverage the power of the innate and adaptive immune systems. Our proprietary Boltbody Immune-Stimulating Antibody Conjugate, or ISAC, approach uses immunostimulants to engage and activate myeloid cells, including macrophages and dendritic cells, that directly kill tumor cells via phagocytosis and expose tumor neoantigens to the adaptive immune system. This leads to recruitment of cytotoxic T cells and additional tumor-killing myeloid cells thereby converting immunologically "cold" tumors to "hot" tumors. We believe that this process leads to the development of systemic immunological memory with epitope spreading to neoantigens that is critical to achieving a long-term anti-tumor response. Our lead product candidate BDC-1001 is a human epidermal growth factor receptor 2, or HER2, Boltbody ISAC comprised of a HER2-targeting biosimilar of trastuzumab conjugated to one of our proprietary TLR7/8 agonists, for the treatment of patients with HER2-expressing solid tumors, including those with HER2-low tumors. In our preclinical studies we have observed complete regression and durable anti-tumor effects as well as a favorable safety profile that are encouraging for the therapeutic potential of BDC-1001. We initiated a Phase 1/2 trial of BDC-1001 in the first quarter of 2020 for the treatment of patients with HER2-expressing solid tumors. We are currently in the dose escalation portion of the trial and expect to move into Phase 2 dose expansions in key solid tumor indications with unmet medical need in 2021. We anticipate that our Phase 1/2 data will provide us with clinical proof of concept for our HER2 Boltbody ISAC approach. We are also advancing additional Boltbody ISAC product candidates targeting carcinoembryonic antigen, or CEA, and PD-L1, both of which are currently in preclinical development. We anticipate advancing our CEA Boltbody ISAC into the clinic in 2022.

Our Boltbody ISAC approach is pioneering a new category of immunotherapies that combines the precision of antibody targeting with the strength of the innate and adaptive immune systems by activating and recruiting myeloid cells, thereby re-programming the tumor microenvironment to invoke an adaptive immune response. Our Boltbody ISACs are delivered systemically but act locally through a highly targeted approach that triggers a profound localized anti-tumor immune cascade through the following "Three-Factor Authentication" process designed to optimize safety and avoid systemic immune stimulation.

1. **Tumor antigen recognition:** Our selective and specific tumor-targeting Boltbody ISACs recognize and bind specifically to the target antigen-expressing tumors.
2. **FcR-dependent phagocytosis:** Engagement of optimized Fc domains triggers myeloid-mediated phagocytosis of the Boltbody ISAC-bound tumor cell. This process directly kills antigen-expressing tumor cells and delivers tumor neoantigens to myeloid cells.
3. **TLR-mediated activation:** Our proprietary TLR agonist conjugates activate myeloid cells and enable the presentation of tumor-associated neoantigens to cytotoxic T cells, thereby initiating the body's adaptive anti-tumor immune response and converting immunologically "cold" tumors to "hot" tumors. Furthermore, these activated myeloid cells also encourage additional myeloid cell-mediated phagocytosis to amplify the innate and adaptive immune responses.

During this "Three-Factor Authentication," tumor-associated myeloid cells engulf the Boltbody ISAC-bound tumor cells, become armed with tumor neoantigens, and migrate to the lymph nodes where they mediate the activation and rapid expansion of tumor-reactive T cells to eliminate tumor cells, including those without the initial target antigen. We believe that this represents the development of systemic immunological memory with epitope spreading to neoantigens that will result in long-term anti-tumor responses. With the Boltbody ISAC mechanism of action, the patient's immune system determines the relevant neoantigen-specific T cells to mobilize for tumor destruction and subsequent immunosurveillance, providing a compelling example of how an off-the-shelf targeted immunotherapeutic such as BDC-1001 can deliver a personalized therapeutic outcome.

Unlike immuno-oncology approaches that solely seek to relieve immune suppression, Boltbody ISACs act by engaging the immune system at multiple points in the cancer immunity cycle. Boltbody ISACs activate tumor-associated myeloid cells, leading to tumor phagocytosis and the presentation of tumor neoantigens to T cells that enable a productive anti-cancer response. The following key features provide us with the opportunity to develop robust applications across various solid tumors designed to deliver effective and safe therapeutics that provide durable responses.

- *Ability to address difficult-to-treat solid tumors including those refractory to current treatments*: We have observed profound *in vivo* anti-tumor effects in large, well-established tumors as well as in tumors refractory to current therapies;
- *Engaging the body's innate and adaptive immune responses*: Targeted activation of myeloid APCs for antigen presentation encourages the patient's own adaptive immune system to reveal relevant tumor neoantigens;
- *Generation of immunological memory with epitope spreading to provide long-term anti-tumor responses and protect against recurrence*: Our preclinical experiments indicate that Boltbody ISACs generate immunological memory and epitope spreading to tumor antigens that are distinct from the Boltbody ISAC target. This process may prevent tumor recurrence and kill related tumors that do not express the original Boltbody ISAC target antigen;
- *Ability to target tumor antigens with less dense cell surface expression*: We have observed in preclinical studies that Boltbody ISACs demonstrated promising anti-tumor effects even at low levels of target antigen expression;
- *Capability to modulate myeloid cell activity via TLR potency and selectivity and Fc engineering*: Our medicinal chemistry and monoclonal antibody, or mAb, engineering expertise allow us to modulate potency, selectivity and specificity of our TLR agonists as well as enhance the stability, PK/PD profile and safety of our Boltbody ISACs;
- *Favorable safety and tolerability profile by avoiding unintended systemic immune stimulation*: Our "Three-Factor Authentication" system provides additional layers of safety for an initially localized immune effect that may avoid unintended systemic immune activation. This is evidenced by our favorable preclinical safety profile which we believe will potentially enable us to treat patients earlier in the course of their disease. This can be used as monotherapy or as part of a combination therapy strategy; and
- *Potential to benefit patients who have a defective adaptive immune response*: Some patients' tumors may have defects at presenting neoantigens that makes them resistant to T cell-mediated killing. Boltbody ISACs overcome this barrier by activating myeloid cells and enhancing their phagocytic capacity resulting in anti-tumor efficacy.

Our lead product candidate, BDC-1001, is currently in clinical development for the treatment of patients with HER2-expressing solid tumors, including those with HER2-low tumors. We have designed BDC-1001 as a

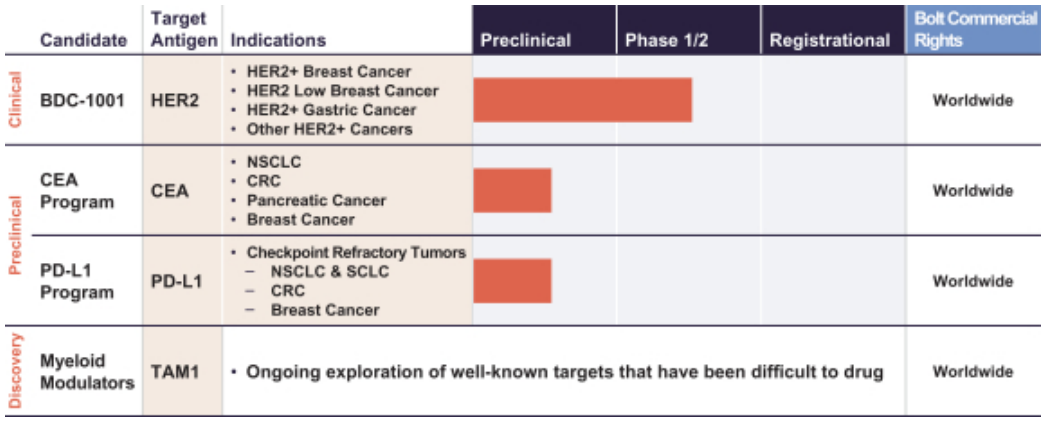
Boltbody ISAC comprised of a HER2-targeting biosimilar trastuzumab conjugated to one of our proprietary TLR7/8 agonists to maximize the potential anti-tumor response. Through our preclinical studies, we have demonstrated that systemic administration of HER2 Boltbody ISACs exhibited localized immune activation that resulted in single agent activity that generated complete tumor regression and immunological memory against cancers with epitope spreading. Furthermore, preclinical data showed compelling anti-tumor efficacy against established tumors resistant to trastuzumab and ado-trastuzumab emtansine, and immunological memory providing protection against tumor cells that no longer express the HER2 antigen. Our observed preclinical anti-tumor response coupled with a favorable safety profile based upon good laboratory practices, or GLP, toxicology studies leads us to believe that BDC-1001 offers the potential for long-term and meaningful response for patients with HER2-expressing cancers, including HER2-low tumors. We initiated a Phase 1/2 trial of BDC-1001 in the first quarter of 2020 for the treatment of patients with HER2-expressing solid tumors. We are currently in the dose escalation portion of the trial and expect to advance into Phase 2 dose expansions in 2021 in four clinically important and commercially compelling indications. We anticipate that our Phase 1/2 data will provide us with clinical proof of concept for our HER2 Boltbody ISAC approach.

Our second program focuses on CEA, a well-known tumor antigen that is overexpressed in various solid tumors with significant unmet medical need including, but not limited to, colorectal cancer, non-small cell lung cancer, pancreatic cancer and breast cancer. CEA is upregulated on the cell surface of these cancers and displays minimal receptor-mediated internalization into the cancer cell. CEA allows us to target these cancers, some of which are immunologically “cold.” In our preclinical studies, we have observed promising *in vivo* and *in vitro* activity with notable anti-tumor activity in xenograft models. We anticipate advancing our CEA Boltbody ISAC into the clinic in 2022.

Our third program, a PD-L1 Boltbody ISAC, focuses on the treatment of patients with tumors that are nonresponsive or become refractory to immune checkpoint blockade. This encompasses more than 15 different tumor types impacting the lives of millions of patients yearly. Our PD-L1 program is a trifunctional therapeutic with the following mechanism: 1) Antibody-dependent cellular phagocytosis of the tumor, 2) Myeloid activation and engagement of an adaptive T cell response, and 3) PD-L1/PD-1 checkpoint inhibition. In our preclinical studies, we have observed superior anti-tumor efficacy compared to checkpoint inhibition alone, and induced immunological memory in syngeneic mice models with our PD-L1 Boltbody ISAC.

Our Pipeline

We are leveraging our myeloid biology expertise to build a robust pipeline of immune-stimulating, myeloid-engaging therapeutics. Our current pipeline is represented in the figure below. In addition to the programs below, we are also exploring various well-known targets that have been traditionally difficult to drug and where our myeloid expertise and the Boltbody ISAC approach may unlock the potential of these promising antigens as viable cancer targets. We hold exclusive worldwide rights to all of the listed programs.



In this graphic, HER2 = human epidermal growth factor receptor 2; CEA = carcinoembryonic antigen; PD-L1 = programmed cell death-ligand 1; TAM1 = tumor-associated macrophage 1 antigen; NSCLC = non-small cell lung cancer; CRC = colorectal cancer; and SCLC = small cell lung cancer.

Our Corporate History and Team

Our company was founded in 2015 to capture the pioneering work of our founder Dr. Edgar G. Engleman, who is Professor of Pathology and Medicine at Stanford University School of Medicine and Co-Director of the Immunology and Immunotherapy Program of the Stanford Cancer Institute. Dr. Engleman's expertise in translating cancer immunotherapeutics from bench to bedside includes the discovery of a dendritic cell-based technology that was the basis for the first active immunotherapy approved by the Food and Drug Administration, or the FDA. It was also at the Engleman Laboratory that the promising new immunotherapy activating dendritic cells in tumors *in situ*, without requiring their removal and activation *in vitro*, was discovered in collaboration with Dr. Yaron Carmi and led to the founding of Bolt Biotherapeutics. Continued research in the Engleman Laboratory led Dr. Michael Alonso, a scientific co-founder, and Dr. Shelley Ackerman to invent the technology that formed the basis of our promising Boltbody ISAC platform.

We have assembled a highly qualified management team with broad experience in myeloid biology, drug discovery and development to execute our mission. Our scientific founders and our management team collectively have extensive experience in immunology, oncology drug development and patient care. We are industry veterans with prior experience at companies such as Alder, Astellas, Gilead, Jazz, Roche / Genentech, Sunesis and others. Together, our team has a proven track record in the discovery, development and commercialization of numerous approved therapeutics such as Alecensa, Cytovene, Evenity, Gazyva, Herceptin, Kadcyla, Polivy, Perjeta, Rituxan, Tecentriq, Valcyte, Venclexta and Vyepti while at other companies. Since our inception through June 30, 2020, we have raised an aggregate of $121.9 million of gross proceeds and our investors include Novo Holdings, Vivo Capital, Pivotal bioVenture Partners, Sofinnova Investments, Nan Fung Life Sciences, RA Capital Management, Surveyor Capital (a Citadel Company), Rock Springs Capital, Pfizer Ventures and Samsara BioCapital.

Strategy

Our goal is to become a leading immuno-oncology company, leveraging our myeloid biology expertise and proprietary Boltbody ISAC approach to discover, develop and commercialize transformative treatments to address key unmet medical needs in cancer. The key components of our strategy are to:

- Leverage our Boltbody ISAC approach and myeloid expertise to develop our pipeline of immune-activating therapies.
- Rapidly advance the development of our lead Boltbody ISAC product candidate, BDC-1001, for the treatment of patients with HER2-expressing cancers.
- Expeditiously advance our pipeline focused on additional promising targets including CEA and PD-L1.
- Continue to invest in our myeloid expertise and Boltbody ISAC approach to explore the full potential of our targeted immunotherapies for the treatment of cancer.
- Selectively enter into collaborations to expand and enhance our proprietary Boltbody ISAC approach and myeloid expertise to increase the impact of our future product candidates.

Risks Associated with Our Business

Our business is subject to numerous risks and uncertainties, including those described in “Risk Factors” and elsewhere in this prospectus. You should carefully consider these risks before making an investment. These risks include, among others, the following:

- We have a limited operating history and have incurred significant losses since inception and we anticipate that we may continue to incur losses for the foreseeable future and may never achieve or maintain profitability. We have not yet generated any product revenue and had an accumulated deficit of $47.7 million as of December 31, 2019.
- We will need substantial funding to pursue our business objectives. If we are unable to raise capital when needed or on terms favorable to us, we could be forced to delay, reduce or terminate our product development, other operations or commercialization efforts.
- We depend primarily on the success of our lead product candidate, BDC-1001, which is in clinical development and which has not completed a pivotal trial. If we do not obtain regulatory approval for and successfully commercialize our lead product candidate in one or more indications or we experience significant delays in doing so, or if we are unable to advance our other product candidates through preclinical and clinical development, obtain regulatory approval for and successfully commercialize our other product candidates in one or more indications, or we experience significant delays in doing so, we may never generate any revenue or become profitable.
- Our approach to the discovery and development of product candidates based on our Boltbody ISAC approach is unproven, and we do not know whether we will be able to develop any products of commercial value, or if competing technological approaches will limit the commercial value of our product candidates or render our platform obsolete.
- We have never commercialized a product candidate and we may lack the necessary expertise, personnel and resources to successfully commercialize any of our products that receive regulatory approval on our own or together with collaborators.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- We do not have our own manufacturing capabilities and will rely on third parties to produce clinical and commercial supplies of BDC-1001 and our other current and future product candidates.

- Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may charge for such product candidates.
- If we are unable to obtain, maintain and protect sufficient patent and other intellectual property rights for our product candidates and technology, we may not be able to compete effectively in our market.
- Our business, operations and clinical development plans and timelines and supply chain could be adversely affected by the effects of health epidemics, including the ongoing COVID-19 pandemic, on the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we conduct business, including our contract manufacturing organizations, or CMOs, clinical research organizations, or CROs, shippers and others.

If we are unable to adequately address these and other risks we face, our business may be harmed.

Implications of Being an Emerging Growth Company

In addition, we are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, and therefore we intend to take advantage of certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved. We may take advantage of these exemptions for up to five years or until we are no longer an "emerging growth company," whichever is earlier. In addition, the JOBS Act provides that an "emerging growth company" can delay adopting new or revised accounting standards until those standards apply to private companies. We have not elected to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not "emerging growth companies."

Corporate Information

We were incorporated under the laws of the state of Delaware in January 2015 under the name Bolt Therapeutics, Inc. and changed our name to Bolt Biotherapeutics, Inc. in July 2015. Our principal executive offices are located at 900 Chesapeake Drive, Redwood City, California 94063. Our telephone number is (650) 665-9295. Our website is www.boltbio.com. Information contained on, or that can be accessed through, our website is not incorporated by reference into this prospectus, and you should not consider information on or accessible through our website to be part of this prospectus.

"Bolt Biotherapeutics," the Bolt Biotherapeutics logo and our other registered or common law trade names, trademarks or service marks appearing in this prospectus are our property. Trade names, trademarks and service marks of other companies appearing in this prospectus are the property of their respective owners.

THE OFFERING

Common stock offered by us	shares
Option to purchase additional shares of common stock from us	shares
Common stock to be outstanding after this offering	shares (or shares if the underwriters exercise their option to purchase additional shares in full)
Use of proceeds	We estimate that the net proceeds from the sale of shares of common stock in this offering will be approximately $ million (or approximately $ million if the underwriters exercise their option to purchase additional shares in full), based upon an assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering to conduct our clinical trials, to fund continued research and development of BDC-1001, to fund other research and development activities, and for working capital and other general corporate purposes. See the section titled "Use of Proceeds" for additional information.
Risk factors	See "Risk Factors" and the other information included in this prospectus for a discussion of risks you should carefully consider before investing in our common stock.
Proposed Nasdaq trading symbol	"BOLT"

The number of shares of common stock that will be outstanding after this offering is based on 83,942,456 shares of common stock (including shares of preferred stock on an as-converted basis) outstanding as of December 31, 2019, and excludes:

- 14,109,134 shares of common stock issuable upon the exercise of outstanding stock options as of December 31, 2019 with a weighted-average exercise price of $0.37 per share;
- 6,233,461 additional shares of common stock reserved for future issuance under our 2015 Equity Incentive Plan as of December 31, 2019, which shares will cease to be available for issuance at the time our 2020 Equity Incentive Plan becomes effective in connection with this offering;
- shares of common stock reserved for future issuance under our 2020 Equity Incentive Plan, which will become effective upon the execution of the underwriting agreement for this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan; and
- shares of common stock reserved for future issuance under our 2020 Employee Stock Purchase Plan, which will become effective upon the execution of the underwriting agreement for this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan.

Subsequent to December 31, 2019, and through June 30, 2020 we issued and sold 36,135,260 shares of our Series C-1 preferred stock at a price of $1.15 per share.

In addition, unless we specifically state otherwise, all information in this prospectus assumes:

- that our amended and restated certificate of incorporation, which we will file in connection with the closing of this offering, and our amended and restated bylaws adopted in connection with this offering are effective;
- the conversion of all 70,490,863 shares of preferred stock outstanding as of December 31, 2019, into an equal number of shares of common stock upon the closing of this offering;
- the issuance of shares of common stock upon the automatic net exercise of warrants, with an exercise price of $0.01 per share, immediately prior to the closing of 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;
- no exercise of outstanding options; and
- no exercise of the underwriters' option to purchase additional shares of common stock.

SUMMARY FINANCIAL DATA

The following tables summarize our statements of operations and balance sheet data. The summary statements of operations data for the years ended December 31, 2018 and 2019 and our balance sheet data as of December 31, 2019 have been derived from our audited financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected for any other period in the future.

You should read the financial data set forth below in conjunction with our financial statements and the accompanying notes, the information in "Selected Financial Data" and the information in "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained elsewhere in this prospectus. The summary financial data in this section are not intended to replace the financial statements and are qualified in their entirety by the financial statements and related notes included elsewhere in this prospectus.

	Year Ended December 31,	
	2018	2019
	(In thousands, except share and per share amounts)	
Statements of Operations Data:		
Collaboration revenue	$ —	$ 215
Operating expenses:		
Research and development	9,420	26,002
General and administrative	2,209	5,182
Total operating expenses	11,629	31,184
Loss from operations	(11,629)	(30,969)
Other income (expense), net:		
Interest income	193	524
Change in fair value of convertible preferred stock purchase right liability	(153)	(42)
Total other income (expense), net	40	482
Net loss and comprehensive loss	$ (11,589)	$ (30,487)
Net loss per share, basic and diluted	$ (1.00)	$ (2.18)
Weighted-average shares outstanding, basic and diluted	11,555,760	13,954,354
Pro forma net loss per share, basic and diluted(1)		$
Pro forma weighted-average shares outstanding, basic and diluted(1)		

(1) See the statements of operations and comprehensive loss and Note 11 to our audited financial statements included elsewhere in this prospectus for further details on the calculation of net loss per share and the pro forma net loss per share and pro forma weighted-average shares outstanding.

	As of December 31, 2019		
	Actual	Pro Forma(1)	Pro Forma As Adjusted(2)(3)
	(In thousands)		
Balance Sheet Data:			
Cash and cash equivalents	$ 34,826	$	$
Total assets	48,447		
Working capital(4)	27,244		
Total liabilities	16,788		
Convertible preferred stock	77,505		
Accumulated deficit	(47,671)		
Total stockholders' (deficit) equity	(45,846)		

(1) The pro forma balance sheet data gives effect to (i) the conversion of 70,490,863 shares of convertible preferred stock outstanding as of December 31, 2019, into an equal number of shares of common stock immediately upon the closing of this offering, (ii) the issuance of shares of common stock upon the automatic net exercise of outstanding warrants, with an exercise price of $0.01 per share, immediately prior to the closing of 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 (iii) the filing and effectiveness of our amended and restated certificate of incorporation that will be in effect upon the closing of this offering.

(2) The pro forma as adjusted balance sheet data further reflects our receipt of net proceeds from the sale of shares of common stock in this offering at the 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 underwriting discounts and commissions and estimated offering expenses payable by us.

(3) Each $1.00 increase or decrease in the assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease, respectively, the amount of cash and cash equivalents, total assets, working capital and total stockholders' equity by $ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. An increase or decrease of 1,000,000 in the number of shares we are offering would increase or decrease the amount of cash and cash equivalents, total assets, working capital and total stockholders' equity by $ million, assuming the assumed initial public offering price per share, the midpoint of the price range set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions. The pro forma as adjusted information is illustrative only, and will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing.

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

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should consider and read carefully all of the risks and uncertainties described below, as well as other information included in this prospectus, including our financial statements and related notes included elsewhere in this prospectus, before making an investment decision. If any of the following risks actually occur, it could harm our business, financial condition, results of operations and prospects. Unless otherwise indicated, references to our business being harmed in these risk factors will include harm to our business, reputation, financial condition, results of operations, net revenue and future prospects. In such event, the trading price of our common stock could decline and you might lose all or part of your investment.

Risks Related to Our Financial Position and Need for Additional Capital

We have a limited operating history and have incurred significant losses since inception and we anticipate that we may continue to incur losses for the foreseeable future and may never achieve or maintain profitability.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are an immuno-oncology company with a limited operating history upon which you can evaluate our business and prospects. With the exception of our lead product candidate, BDC-1001, all of our development programs are in preclinical development or in the drug discovery stage. We commenced operations in 2015, and to date, we have focused primarily on organizing and staffing our company, business planning, raising capital, developing our proprietary Boltbody ISAC approach, identifying product candidates, establishing our intellectual property portfolio and conducting research, preclinical studies and clinical trials. Our approach to the discovery and development of product candidates based on our Boltbody ISAC approach is unproven, and we do not know whether we will be able to develop any product candidates that succeed in clinical development or products of commercial value. As an organization, we have not yet completed any clinical trials, obtained regulatory approvals, manufactured a commercial-scale product (or arranged for a third party to do so on our behalf), or conducted sales and marketing activities necessary for successful product commercialization. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing biopharmaceutical products.

Since inception in 2015, we have not generated any product revenue and have incurred significant operating losses. Our net losses were $11.6 million and $30.5 million in 2018 and 2019, respectively. As of December 31, 2019, we had an accumulated deficit of $47.7 million. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. Since inception, we have devoted substantially all of our efforts to research and preclinical and clinical development of our product candidates, as well as to building our management team and infrastructure. It could be at least several years, if ever, before we have a commercialized drug. The net losses we incur may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if, and as, we:

- continue to advance our research and preclinical and clinical development of our product candidates;
- expand and initiate further clinical trials for our product candidates;
- seek to identify additional product candidates;
- seek marketing approvals for our product candidates that successfully complete clinical trials, if any;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- maintain, expand, protect and enforce our intellectual property portfolio and obtain licenses to third-party intellectual property;
- attract, hire and retain additional administrative, clinical, regulatory and scientific personnel;

- enter into third party relationships for clinical trials, manufacturing and supply; and
- incur additional legal, accounting and other expenses in operating our business, including the additional costs associated with operating as a public company.

In addition, because of the numerous risks and uncertainties associated with pharmaceutical products and development, we are unable to accurately predict the timing or amount of increased expenses and when, or if, we will be able to achieve profitability. Our expenses could increase and profitability could be further delayed if we decide to or are required by the FDA or other regulatory authorities such as the European Medicines Agency, or EMA, or the U.K. Medicines & Healthcare Products Regulatory Agency, or MHRA, to perform studies or trials in addition to those currently expected, or if there are any delays in the development or completion of any planned or future preclinical studies or clinical trials of our current and future product candidates. Even if we complete the development and regulatory processes described above, we anticipate incurring significant costs associated with launching and commercializing our current and future product candidates.

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

We will need substantial funding to pursue our business objectives. If we are unable to raise capital when needed or on terms favorable to us, we could be forced to delay, reduce or terminate our product development, other operations or commercialization efforts.

Identifying and developing potential product candidates and conducting preclinical studies 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 regulatory approval and begin selling any approved products. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our ongoing and planned preclinical studies, initiate additional clinical trials for our product candidates and seek regulatory approval for our current product candidates and any future product candidates we may develop. Our expenses could increase beyond our current expectations if the FDA requires us to perform clinical trials and other studies in addition to those that we currently anticipate. 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. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or terminate our research and development programs or future commercialization efforts.

As of December 31, 2019, we had cash and cash equivalents of $34.8 million. Our recurring losses from operations and negative cash flows raise substantial doubt about our ability to continue as a going concern. As a result, we have concluded that there is substantial doubt about our ability to continue as a going concern. Similarly, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of, and for the year ended, December 31, 2019, describing the existence of substantial doubt about our ability to continue as a going concern. We believe that the successful completion of this offering will eliminate this doubt and enable us to continue as a going concern; however, if we are unable to raise sufficient capital in this offering, we may need to obtain alternative financing or significantly modify our operational plans for us to continue as a going concern. Based upon our current operating plan and assumptions, we believe that our existing cash and cash equivalents, including the net proceeds from this initial public offering, will be sufficient to fund our operations for at least the next months from the date of this prospectus. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. Changes may occur beyond our control that would cause us to consume

our available capital before that time, including changes in and progress of our development activities and changes in regulation. Our future capital requirements will depend on many factors, including:

- the scope, rate of progress, results and costs of drug discovery, preclinical development, laboratory testing and clinical trials for our product candidates;
- the number and development requirements of product candidates that we may pursue, and other indications for our current product candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- the scope and costs of manufacturing development and commercial manufacturing activities;
- the cost associated with commercializing any approved product candidates;
- the cost and timing of developing our ability to establish sales and marketing capabilities, if any;
- the costs of preparing, filing and prosecuting patent applications, maintaining, enforcing and protecting our intellectual property rights, defending intellectual property-related claims and obtaining licenses to third-party intellectual property;
- the timing and amount of milestone and royalty payments we are required to make under our license agreements;
- 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 and associated intellectual property.

We will require additional capital to complete our planned clinical development programs for our current product candidates to obtain regulatory approval. Any additional capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our current and future product candidates, if approved.

In addition, we cannot guarantee that future financing will be available on a timely basis, in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities by us, whether equity or debt, or the market perception that such issuances are likely to occur, could cause the market price of our common stock to decline. If we are unable to obtain funding on a timely basis on acceptable terms, we may be required to delay, reduce or terminate one or more of our research and development programs or the commercialization of any product candidates that may be approved. This could harm our business and could potentially cause us to cease operations.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish proprietary rights.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic 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 of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances 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 when needed, we may be required to delay, reduce or terminate our product development or future commercialization efforts or grant rights to third parties to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We might not be able to utilize a significant portion of our net operating loss carryforwards.

As of December 31, 2019, we had federal and state net operating loss, or NOL, carryforwards of $46.2 million and $46.3 million, respectively. The federal NOLs include $4.4 million that may be used to offset up to 100% of future taxable income and will begin to expire in 2035, unless previously utilized, and $41.8 million that are not subject to expiration. The net operating loss carryforwards subject to expiration could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Cuts and Jobs Act, or the Tax Act, as modified by the Coronavirus Aid, Relief and Economic Security Act, or CARES Act, federal net operating losses incurred in taxable years beginning after December 31, 2017 and in future taxable years may be carried forward indefinitely, but the deductibility of such federal net operating losses in taxable years beginning after December 31, 2020 is limited. There is variation in how states will respond to the Tax Act and CARES Act. In addition, for state income tax purposes, there may be periods during which the use of NOLs is suspended or otherwise limited, such as recent California legislation limiting the usability of NOLs for tax years beginning in 2020 and before 2023.

Separately, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. The completion of this offering, together with private placements and other transactions that have occurred since our inception, may trigger such an ownership change pursuant to Section 382. We have not completed a Section 382 analysis, and therefore, there can be no assurances that the NOLs are not already limited.

We may experience ownership changes as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

Risks Related to the Development of Our Product Candidates

We depend primarily on the success of our lead product candidate, BDC-1001, which is in clinical development and which has not completed a pivotal trial. If we do not obtain regulatory approval for and successfully commercialize our lead product candidate in one or more indications or we experience significant delays in doing so, or if we are unable to advance our other product candidates through preclinical and clinical development, obtain regulatory approval for and successfully commercialize our other product candidates in one or more indications, or we experience significant delays in doing so, we may never generate any revenue or become profitable.

We do not have any products that have received regulatory approval and may never be able to develop marketable product candidates. We are very early in our development efforts. BDC-1001, our lead product candidate, is still in the early stages of clinical development, and is our only product candidate to have advanced beyond preclinical studies. We have invested substantially all of our efforts in developing our Boltbody ISAC approach, identifying potential product candidates and conducting preclinical studies. We expect that a substantial portion of our efforts and expenses over the next several years will be devoted to the development of BDC-1001 in our ongoing and planned clinical trials in HER2-expressing solid tumors, including subsets of HER2-low tumors. As a result, our business currently depends heavily on the successful development, regulatory approval and, if approved, commercialization of BDC-1001 in one or more of these indications. We

cannot be certain that BDC-1001 will receive regulatory approval or will be successfully commercialized even if it receives regulatory approval. The research, testing, manufacturing, safety, efficacy, labeling, approval, sale, marketing and distribution of BDC-1001 is, and will remain, subject to comprehensive regulation by the FDA and similar foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through preclinical studies and clinical trials that the product candidate is safe and effective for use in each target indication. Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. Failure to obtain regulatory approval for our product candidates will prevent us from commercializing and marketing our product candidates. The success of BDC-1001 and any other product candidates, including our CEA Boltbody ISAC for the treatment of CEA-expressing solid tumors, will depend on several additional factors, including:

- completing clinical trials that demonstrate their safety and efficacy;
- successful initiation of clinical trials;
- successful patient enrollment in, and completion, of clinical trials;
- the ability to successfully develop, in-license or otherwise acquire additional targeting agents for our Boltbody ISACs;
- receiving marketing approvals from applicable regulatory authorities;
- obtaining, maintaining, protecting and enforcing patent, trade secret and other intellectual property rights and regulatory exclusivity for our product candidates;
- completing any post-marketing studies required by applicable regulatory authorities;
- making and maintaining arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our product candidates;
- establishing sales, marketing and distribution capabilities and successfully launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- the prevalence and severity of adverse events experienced with our product candidates;
- acceptance of our product candidates by patients, the medical community and third-party payors;
- a continued acceptable safety profile following approval;
- obtaining and maintaining healthcare coverage and adequate reimbursement for our product candidates;
- competing effectively with other cancer therapies, including with respect to the sales and marketing of our product candidates, if approved; and
- obtaining licenses to any third party intellectual property we deem necessary or desirable.

Many of these factors are beyond our control, including the time needed to adequately complete clinical testing, the regulatory submission process, potential threats to our intellectual property rights and changes in the competitive landscape. It is possible that none of our product candidates will ever obtain regulatory approval, even if we expend substantial time and resources seeking such 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 complete clinical trials, obtain regulatory approval or, if approved, commercialize our product candidates, which would materially harm our business, financial condition, results of operations and prospects.

In addition, the clinical trial requirements of the FDA, the EMA, the MHRA and other regulatory agencies and the criteria these regulators may use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates.

Our approach to the discovery and development of product candidates based on our Boltbody ISAC approach is unproven, and we do not know whether we will be able to develop any products of commercial value, or if competing technological approaches will limit the commercial value of our product candidates or render our platform obsolete.

The success of our business depends primarily upon our ability to identify, develop and commercialize products based on our proprietary Boltbody ISAC approach, which leverages a novel and unproven approach. While we have had favorable preclinical study results based on our technology, we have not yet succeeded and may not succeed in demonstrating safety and efficacy for any product candidates in clinical trials or in obtaining marketing approval thereafter. Our lead product candidate, BDC-1001, is in clinical development and we have not yet completed any clinical trials for any product candidate. Our research methodology and novel approach to immunotherapy may be unsuccessful in identifying additional product candidates, and any product candidates based on our technology may be shown to have harmful side effects or may have other characteristics that may necessitate additional clinical testing, or make the product candidates unmarketable or unlikely to receive marketing approval. Further, because all of our product candidates and development programs are based on our technology approach, adverse developments with respect to one of our programs may have a significant adverse impact on the actual or perceived likelihood of success and value of our other programs.

In addition, the biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies. Our future success will depend in part on our ability to maintain a competitive position with our Boltbody ISAC approach. If we fail to stay at the forefront of technological change in utilizing our Boltbody ISAC approach to create and develop product candidates, we may be unable to compete effectively. Our competitors may render our Boltbody ISAC approach obsolete, or limit the commercial value of our product candidates, by advances in existing technological approaches (for example, using different antibody drug conjugate, or ADC, technologies than we use) or the development of new or different approaches, potentially eliminating the advantages in our drug discovery process that we believe we derive from our research approach and proprietary technologies. By contrast, adverse developments with respect to other companies that attempt to use a similar approach to our approach may adversely impact the actual or perceived value of our Boltbody ISAC approach and potential of our product candidates.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations.

Our product candidates are based on a novel technology, which makes it difficult to predict the time and cost of product candidate development.

We have concentrated our product research and development efforts on our novel therapeutic approach, and our future success depends on the successful development of our lead product candidate, BDC-1001, and other product candidates. There can be no assurance that any development problems we experience in the future related to our novel therapy will not cause significant delays or unanticipated costs, or that such development problems can be efficiently solved. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all.

We are currently developing, and in the future may develop, product candidates in combination with other therapies and that may expose us to additional risks.

We are developing BDC-1001 as a combination therapy in addition to a single agent therapy. Also, we may develop future product candidates for use in combination with one or more currently approved cancer therapies. Even if any product candidate we develop was to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar

foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other drugs or for indications other than cancer. This could result in our own products being removed from the market or being less successful commercially.

We may also evaluate BDC-1001 or any other future product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA or similar foreign regulatory authorities. We will not be able to market and sell BDC-1001 or any product candidate we develop in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval.

If the FDA or similar foreign regulatory authorities do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing or supply issues arise with, the drugs we choose to evaluate in combination with BDC-1001 or any product candidate we develop, we may be unable to obtain approval of or market BDC-1001 or any product candidate we develop.

We may seek accelerated approval for some or all of our product candidates from the FDA, however, the FDA may disagree and may require completion of additional clinical trials before considering a BLA for review.

We may seek accelerated approval for BDC-1001 for the treatment of patients with HER2-expressing solid tumors. Under the FDA's accelerated approval program, the FDA may approve a drug or biologic for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that 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. For drugs and biologics granted accelerated approval, confirmatory trials are required to confirm safety and clinical benefit and convert the application to full approval. These confirmatory trials must be completed with due diligence. Moreover, the FDA may withdraw approval of an application approved under the accelerated approval pathway if, for example:

- the trial or trials required to verify the predicted clinical benefit of our product candidates fail to verify such benefit or do not demonstrate sufficient clinical benefit, including as to the duration of their effectiveness, to justify the risks associated with the product;
- other evidence demonstrates that the product is not shown to be safe or effective under the conditions of use;
- we fail to conduct any required post-approval trial with due diligence; or
- we disseminate false or misleading promotional materials relating to the relevant product.

Clinical trials are very expensive, time-consuming and difficult to design and implement, and involve uncertain outcomes. Furthermore, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials.

The risk of failure for our product candidates is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval. To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans for use in each target indication. Clinical testing is expensive and can take many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the clinical trial process.

In addition, the results of preclinical studies and earlier clinical trials may not be predictive of the results of later-stage preclinical studies or clinical trials. The results generated to date in preclinical studies or clinical trials

for our product candidates do not ensure that later preclinical studies or clinical trials will demonstrate similar results. We have limited clinical data for any of our product candidates. Product candidates in later stages of clinical trials, although we have none at this stage as of yet, may fail to show the desired safety and efficacy traits despite having progressed through preclinical and earlier stage clinical trials. For example, the favorable results of our ongoing trial of BDC-1001 in patients with HER2-expressing solid tumors may not be predictive of similar results in subsequent trials. In later-stage clinical trials, we will likely be subject to more rigorous statistical analyses than in completed earlier stage clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in later-stage clinical trials due to adverse safety profiles or lack of efficacy, notwithstanding promising results in earlier trials, and we cannot be certain that we will not face similar setbacks. 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 products.

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 clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the dosing regimen and other clinical trial protocols, and the rate of dropout among clinical trial participants. If we fail to produce positive results in our planned preclinical studies or clinical trials of any of our product candidates, the development timeline and regulatory approval and commercialization prospects for our product candidates, and, correspondingly, our business and financial prospects, would be materially and adversely affected.

We may encounter substantial delays in our clinical trials or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidate for its intended indications. Clinical trials are expensive, time-consuming and uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include:

- delays in reaching a consensus with regulatory authorities on trial design;
- delays in reaching agreement or failing to agree on acceptable terms with prospective CROs and clinical trial sites;
- delays in opening sites and recruiting suitable patients to participate in our clinical trials;
- delays in enrollment due to travel or quarantine policies, or other factors, related to COVID-19, other pandemics or other events outside our control;
- imposition of a clinical hold by regulatory authorities as a result of a serious adverse event, concerns with a class of product candidates or after an inspection of our clinical trial operations or trial sites;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits; or
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

For instance, the ongoing COVID-19 pandemic and the measures taken by the governmental authorities could disrupt the supply chain and the manufacture or shipment of drug substances and finished drug products for our product candidates for use in our research and clinical trials, delay, limit or prevent our employees and CROs from continuing research and development activities, impede the ability of patients to enroll or continue in

clinical trials, or impede testing, monitoring, data collection and analysis or other related activities, any of which could delay our clinical trials and increase our development costs, and have a material adverse effect on our business, financial condition and results of operations.

Any inability to timely and successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to achieve regulatory and commercialization milestones. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional testing to bridge our modified product candidate to earlier versions. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates, if approved, or allow our competitors to bring comparable drugs to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business, financial condition, results of operations and prospects.

Additionally, if the results of our clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with our product candidates, we may:

- be delayed in obtaining marketing approval, if at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw, or suspend, their approval of the drug or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy, or REMS;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- experience damage to our reputation.

Our drug development costs will also increase if we experience delays in testing or obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, need to be restructured or be completed on schedule, if at all.

Further, we, the FDA or an institutional review board may suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements, including the FDA's current Good Clinical Practice, or GCP, regulations, that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our Investigational New Drug Applications, or INDs, or the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be negatively impacted, and our ability to generate revenues from our product candidates may be delayed or eliminated entirely.

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 focus on research programs that we identify for 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 therapies or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate 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 product candidate.

If any of our product candidates receives marketing approval and we, or others, later discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability to market the drug could be compromised.

Clinical trials of our product candidates are conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If one or more of our product candidates receives regulatory approval, and we, or others, later discover that they are less effective than previously believed, or cause undesirable side effects, a number of potentially significant negative consequences could result, including:

- withdrawal or limitation by regulatory authorities of approvals of such product;
- seizure of the product by regulatory authorities;
- recall of the product;
- restrictions on the marketing of the product or the manufacturing process for any component thereof;
- requirement by regulatory authorities of additional warnings on the label, such as a “black box” warning or contraindication;
- requirement that we implement a REMS or create a medication guide outlining the risks of such side effects for distribution to patients;
- commitment to expensive additional safety studies prior to approval or post-marketing studies required by regulatory authorities of such product;
- the product may become less competitive;
- initiation of regulatory investigations and government enforcement actions;
- initiation of legal action against us to hold us liable for harm caused to patients; and
- harm to our reputation and resulting harm to physician or patient acceptance of our products.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, financial condition, results of operations and prospects.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;

- the size and health of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before 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 trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial site. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies rather than enroll patients in any future clinical trial.

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

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

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. We currently have no products that have been approved for commercial sale. However, the current and future use of product candidates by us in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients who use the product, healthcare providers, pharmaceutical companies or others selling such products. In addition, we have agreed to indemnify the licensors of the intellectual property related to our product candidates against certain intellectual property infringement, misappropriation and other claims. Any claims against us, or with respect to which we are obligated to provide indemnification, regardless of their merit, could be difficult and costly to defend or settle, and could compromise the market acceptance of our product candidates or any prospects for commercialization of our product candidates, if approved. For more information regarding the risks associated with intellectual property-related litigation, see "Risk Factors—Risks Related to Our Intellectual Property."

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates.

Although we maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage each time we commence a clinical

trial and if we successfully commercialize any product candidate. As the expense of insurance coverage is increasing, we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Risks Related to Commercialization of Our Product Candidates

We have never commercialized a product candidate and we may lack the necessary expertise, personnel and resources to successfully commercialize any of our products that receive regulatory approval on our own or together with collaborators.

We have never commercialized a product candidate. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, acquiring the rights to our product candidates and undertaking preclinical studies and clinical trials of our product candidates. We currently have no sales force, marketing, manufacturing or distribution capabilities. To achieve commercial success of our product candidates, if any are approved, we will have to develop our own sales, marketing and manufacturing capabilities or outsource these activities to a third party.

Factors that may affect our ability to commercialize our product candidates on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, persuading adequate numbers of physicians to prescribe our product candidates and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization requires significant investment, is time-consuming and could delay the launch of our product candidates. We may not be able to build an effective sales and marketing organization in the United States, the European Union or other key global markets. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may have difficulties generating revenue from them.

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

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical, specialty pharmaceutical and biotechnology companies among others. We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop immunotherapies for the treatment of cancer. There are other companies working to develop immunotherapies for the treatment of cancer including divisions of large pharmaceutical and biotechnology companies of various sizes. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

We are developing our initial product candidates for the treatment of cancer and currently none of these therapies are approved. There are already a variety of available drug therapies marketed for cancer and some of the currently approved drug therapies are branded and subject to patent protection, and others are available on a generic basis. Many of these approved drugs are well established therapies and are widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may also encourage the use of generic products. We expect that if our product candidates are approved, they will be priced at a significant premium over competitive generic products. This may make it difficult for us to achieve our business strategy of using our product candidates in combination with existing therapies or replacing existing therapies with our product candidates.

Competition may further increase as a result of advances in the commercial applicability of technologies for drug discovery and development and greater availability of capital for investment in cancer therapies. We are aware that Novartis and Silverback are developing HER2-targeting ISACs, and other companies may develop ISACs and toll-like receptor, or TLR, agonists that may have utility for the treatment of HER2-expressing cancers and other indications we are targeting. With respect to BDC-1001, there are numerous companies developing and marketing therapies focused on HER2-expressing cancers that utilize a range of other technologies and scientific approaches including ADCs, vaccines, bispecific antibodies and receptor tyrosine kinases inhibitors. Several of these companies have approved therapies, including Seattle Genetics, Daiichi Sankyo, Roche, Novartis and AstraZeneca, and many others have therapies in clinical development, including Zymeworks, MacroGenics, Merus and Ambrx. Our current product and future product candidates will also compete more generally with companies developing alternative innate and adaptive immune system approaches for the treatment of cancer.

Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, products that are more effective or less costly than any product candidate that we may develop. In addition, most of these companies have substantially greater sales, marketing and other experience and reserves than we do.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, discovering, developing, receiving FDA approval for or commercializing drugs before we do, which would have an adverse impact on our business and results of operations.

The availability of our competitors' products could limit the demand and the price we are able to charge for any product candidate we commercialize, if any. The inability to compete with existing or subsequently introduced drugs would harm our business, financial condition, results of operations and prospects.

Even if any of our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If BDC-1001 and our other current and future product candidates receive marketing approval, whether as a single agent or in combination with other therapies, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current approved immunotherapies, and other cancer treatments like chemotherapy and radiation therapy, are well established in the medical community, and doctors may continue to rely on these therapies. If any of our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may never become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- the ability to offer our products, if approved, for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- sufficient third-party coverage or reimbursement, including of combination therapies;

- the willingness of patients to pay all, or a portion of, out-of-pocket costs associated with our products in the absence of sufficient third-party coverage and adequate reimbursement;
- adoption of a companion diagnostic or complementary diagnostic; and
- the prevalence and severity of any side effects.

The successful commercialization of certain of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels and pricing policies. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford products such as our product candidates, if approved. Our ability to achieve acceptable levels of coverage and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize our product candidates and attract additional collaboration partners to invest in the development of our product candidates. Coverage under certain government programs, such as Medicare, Medicaid, the 340B drug pricing program and TRICARE, may not be available for certain of our product candidates. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the European Union or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug, biosimilar or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates and other therapies as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing drugs may limit the amount we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates, and may not be able to obtain a satisfactory financial return on products that we may develop.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse health care providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Obtaining and maintaining reimbursement status is time-consuming and costly. No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement 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 will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and

adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. 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, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care services to contain or reduce costs of health care may adversely affect:

- the demand for any products for which we may 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 revenues and achieve or maintain profitability; and
- the level of taxes that we are required to pay.

Even if we receive marketing approval for any of our product candidates, we may not achieve market acceptance, which would limit the revenue that we can generate from sales of any of our approved product candidates.

Even if the FDA approves the marketing of any product candidates that we develop, physicians, patients, third-party payors or the medical community may not accept or use them. Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. Market acceptance of BDC-1001 and our other product candidates, if any are approved, will depend on a number of factors, including, among others:

- the ability of BDC-1001 and our other product candidates to treat cancer, as compared with other available drugs, treatments or therapies;
- the prevalence and severity of any adverse side effects associated with BDC-1001 and our other product candidates;
- limitations or warnings contained in the labeling approved for BDC-1001 or our other product candidates by the FDA;
- availability of alternative treatments;
- the size of the target patient population, and the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity for our product candidates and competing products and treatments;
- pricing and cost effectiveness;
- the effectiveness of our sales and marketing strategies;
- our ability to increase awareness of our product candidates through marketing efforts;

- our ability to obtain sufficient third-party coverage and adequate reimbursement; and
- the likelihood that the FDA may impose additional requirements that limit the promotion, advertising, distribution or sales of our product candidates.

The market acceptance of our product candidates also will depend in part on the market acceptance of other immunotherapies for the treatment of cancer. While a number of other cancer immunotherapies have received regulatory approval and are being commercialized, our approach to harnessing ISACs is novel. Adverse events in clinical trials for our product candidates or in clinical trials of others developing similar products and the resulting publicity, as well as any other adverse events in the field of immuno-oncology that may occur in the future, could result in a decrease in demand for BDC-1001 or any other product candidate that we may develop. If public perception is influenced by claims that the use of cancer immunotherapies is unsafe, whether related to our therapies or those of our competitors, our products may not be accepted by the general public or the medical community. Future adverse events in immuno-oncology or the biopharmaceutical industry generally could also result in greater governmental regulation and stricter labeling requirements.

If any one of our product candidates is approved but does not achieve an adequate level of acceptance by patients, physicians and third-party payors, we may not generate sufficient revenue to become or remain profitable and our business may be harmed.

Even if we obtain regulatory approval for our product candidates, they will remain subject to ongoing regulatory oversight.

Even if we obtain regulatory approval for any of our product candidates, they will be subject to extensive and ongoing regulatory requirements for manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, sampling and record-keeping. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practices, or cGMP, regulations and GCPs, for any clinical trials that we conduct post-approval, all of which may result in significant expense and limit our ability to commercialize such products. In addition, any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS as a condition of approval of our product candidates, which could include 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.

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. Moreover, if there are changes in the application of legislation or regulatory policies, or if problems are discovered with a product or our manufacture of a product, or if we or one of our distributors, licensees or co-marketers fails to comply with regulatory requirements, the regulators could take various actions. These include:

- issuing warning or untitled letters;
- seeking an injunction or imposing civil or criminal penalties or monetary fines;
- suspension or imposition of restrictions on operations, including product manufacturing;

- seizure or detention of products, refusal to permit the import or export of products or request that we initiate a product recall;
- suspension or withdrawal of our marketing authorizations;
- suspension of any ongoing clinical trials;
- refusal to approve pending applications or supplements to applications submitted by us; or
- requiring us to conduct additional clinical trials, change our product labeling or submit additional applications for marketing authorization.

If any of these events occurs, our ability to sell such product may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could harm our business, financial condition, results of operations and prospects.

If any of our product candidates are approved for marketing and commercialization and we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates, we will be unable to successfully commercialize our product candidates if and when they are approved.

We have no sales, marketing or distribution capabilities or experience. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization, which would be expensive and time consuming, or outsource these functions to other third parties. In the future, we may choose to build a focused sales and marketing infrastructure to sell, or participate in sales activities with our collaborators for, some of our product candidates if and when they are approved.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future product candidates;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues to us are likely to be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. In entering into third-party marketing or distribution arrangements, any revenue we receive will depend upon the efforts of the third parties and we cannot assure you that such third parties will establish adequate sales and distribution capabilities or devote the necessary resources and attention to sell and market our product candidates effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

Risks Related to Our Dependence on Third Parties

We do not have our own manufacturing capabilities and will rely on third parties to produce clinical and commercial supplies of BDC-1001 and our other current and future product candidates.

We have limited experience in drug formulation and manufacturing and do not own or operate, and we do not expect to own or operate, facilities for drug manufacturing, storage, distribution or testing. We have entered into supply agreements with Piramal Healthcare UK Ltd, or Piramal, to manufacture drug substance and drug product and EirGenix, Inc., pursuant to which we agreed to purchase monoclonal antibodies, including a biosimilar of trastuzumab, for our Boltbody ISAC. Our current third-party CMOs may be unable or unwilling to supply us with sufficient clinical and commercial grade quantities of our clinical materials due to production shortages or other supply interruptions resulting from the ongoing COVID-19 pandemic or otherwise, because they are purchased by one of our competitors or another company that decides not to continue supplying us with these materials, or for other reasons. If one or more of these events occur and we are unable to timely establish an alternate supply from one or more third-party CMOs, we could experience delays in our development efforts as we locate and qualify new manufacturers. Under such circumstances, we may be required to receive drug substance for use on a purchase order basis, and as such, there can be no assurance that we actually receive sufficient quantities. See also the risk factor titled "—Our business, operations and clinical development plans and timelines and supply chain could be adversely affected by the effects of health epidemics, including the ongoing COVID-19 pandemic, on the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we conduct business, including our CMOs, CROs, shippers and others."

Further, our reliance on third-party manufacturers exposes us to risks beyond our control, including the risk of:

- inability to meet our product specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and quality issues, including related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for additional scale-up;
- failure of the manufacturer to comply with cGMP and similar foreign standards;
- inability to negotiate manufacturing agreements with third parties on commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on a limited number of sources, and in some cases, single sources for components, such that if we are unable to secure a sufficient supply of these drug components, we will be unable to manufacture and sell BDC-1001 or other product candidates in a timely fashion, in sufficient quantities or under acceptable terms;
- lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier or the issuance of a FDA Form 483 notice or warning letter;
- carrier disruptions or increased costs that are beyond our control; and
- failure to deliver our products under specified storage conditions and in a timely manner.

Some of these events could be the basis for FDA action, including injunction, recall, seizure or total or partial suspension of production. In addition, our third-party manufacturers and suppliers are subject to FDA inspection from time to time. Failure by our third-party manufacturers and suppliers to pass such inspections and otherwise satisfactorily complete the FDA approval regimen with respect to our product candidate may result in regulatory actions such as the issuance of FDA Form 483 notices of observations, warning letters or injunctions or the loss of operating licenses. In addition, our third-party manufacturers and suppliers are subject to numerous

environmental, health and safety laws and regulations, including those governing the handling, use, storage, treatment and disposal of waste products, and failure to comply with such laws and regulations could result in significant costs associated with civil or criminal fines and penalties for such third parties. Based on the severity of the regulatory action, our clinical or commercial supply of drug and packaging and other services could be interrupted or limited, which could harm our business.

In addition, our CMOs are or may be engaged with other companies to supply and manufacture materials or products for such companies, which also exposes our suppliers and manufacturers to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may also affect the regulatory clearance of a contract supplier's or manufacturer's facility. If the FDA or a comparable foreign regulatory agency does not approve these facilities for the supply or manufacture of our product candidates, or if it withdraws its approval in the future, we may need to find alternative supply or manufacturing facilities, which would negatively impact our ability to develop, obtain regulatory approval of or market our product candidates, if approved.

As we prepare for later-stage clinical trials and potential commercialization, we will need to take steps to increase the scale of production of our product candidates, which may include transferring production to new third-party suppliers or manufacturers. In order to conduct larger or late-stage scale clinical trials for our product candidates and supply sufficient commercial quantities of the resulting drug product and its components, if that product candidate is approved for sale, our CMOs and suppliers will need to produce our product candidates in larger quantities, more cost effectively and, in certain cases, at higher yields than they currently achieve. These third-party contractors may not be able to successfully increase the manufacturing capacity for any such product candidates in a timely or cost-effective manner or at all. Significant scale up of manufacturing may require additional processes, technologies and validation studies, which are costly, may not be successful and which the FDA and foreign regulatory authorities must review and approve. In addition, quality issues may arise during those scale-up activities because of the inherent properties of a product candidate itself or of a product candidate in combination with other components added during the manufacturing and packaging process, or during shipping and storage of the active pharmaceutical ingredients or the finished product. If our third-party CMOs are unable to successfully scale up the manufacture of any of our product candidates in sufficient quality and quantity and at commercially reasonable prices, and we are unable to find one or more replacement suppliers or manufacturers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality, and we are unable to successfully transfer the processes on a timely basis, the development of that product candidate and regulatory approval or commercial launch for any resulting products may be delayed, or there may be a shortage in supply, either of which could significantly harm our business, financial condition, results of operations and prospects.

Any of these events could lead to clinical trial delays, failure to obtain regulatory approval or impact our ability to successfully commercialize any potential future product candidates.

We rely on third parties to conduct our preclinical studies and clinical trials and if these third parties perform in an unsatisfactory manner, our business could be substantially harmed.

We intend to conduct our future clinical trials using our own clinical resources while also leveraging expertise and assistance from CROs as appropriate. We do not currently have the ability to independently conduct large-scale clinical trials, such as a Phase 3 clinical trial, without outside assistance.

We have relied upon and plan to continue to rely upon medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct or assist us in conducting GCP-compliant clinical trials on our product candidates properly and on time, and may not currently have all of the necessary contractual relationships in place to do so. Once we have established contractual relationships with such third-party CROs, we will have only limited control over their actual performance of these activities.

We and our CROs and other vendors are required to comply with cGMP, GCP and GLP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Union and any comparable foreign regulatory authorities for all of our product candidates in preclinical and clinical development. Regulatory authorities enforce these regulations through periodic inspections of trial sponsors, principal investigators, clinical trial sites and other contractors. Although we rely on CROs to conduct any current or planned GLP-compliant preclinical studies and GCP-compliant clinical trials and have limited influence over their actual performance, we remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities. If we or any of our CROs or vendors fail to comply with applicable regulations, the data generated in our preclinical studies and clinical trials may be deemed unreliable and the FDA, EMA, MHRA or any comparable foreign regulatory agency may require us to perform additional preclinical studies and clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory agency, such regulatory agency will determine that all of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with products produced under cGMP requirements. Our failure to comply with these requirements may require us to repeat clinical trials, which would delay the regulatory approval process.

While we will have agreements governing their activities, our CROs will not be our employees, and we will not be able to control whether or not they devote sufficient time and resources to our future preclinical and clinical programs. These CROs 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 harm our business. We face the risk of potential unauthorized disclosure, infringement, misappropriation or other violation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors, and other third parties, to access and exploit our proprietary technology. CROs also may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property-related proceedings that could jeopardize or invalidate our proprietary information and intellectual property. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines 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 any other reason, our clinical trials may be extended, delayed or terminated, the clinical data generated in our clinical trials may be deemed unreliable, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

If our relationships with these CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus, and could delay development and commercialization of our product candidates. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can negatively impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a negative impact on our business and financial condition.

If we are not able to maintain our current collaborations and establish further collaborations, we may have to alter some of our future development and commercialization plans.

Our product development programs and the potential commercialization of our product candidates will require substantial additional capital to fund expenses. We entered into a joint development and license agreement, or the Toray Development Agreement with Toray Industries, Inc., or Toray, to collaborate with Toray to develop and commercialize a cancer therapy medicine product containing Toray's proprietary antibody or a related antibody, and our proprietary Boltbody ISAC approach. We may enter into other collaboration agreements with pharmaceutical and biotechnology companies for the future development and potential

commercialization of our product candidates. We will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of any product candidates we may seek to develop with them. We cannot predict the success of any collaboration that we have entered into or will enter into.

We face significant competition in seeking appropriate collaborators, and a number of more established companies may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial 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. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, EMA, MHRA or similar foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under future license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate further collaborations on a timely basis, on acceptable terms, or at all. Even if we are able to obtain a license to intellectual property of interest, we may not be able to secure exclusive rights, in which case others could use the same rights and compete with us. Our existing collaboration partners may not prioritize our product candidates or otherwise not effectively pursue the development of our product candidates which may delay, reduce or terminate the development of such product candidate, reduce or delay its development program or delay its potential commercialization. Further if we are unable to successfully obtain rights to required third-party intellectual property rights or maintain and protect the existing intellectual property rights we have, we may have to delay, reduce or terminate the development of such product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. Doing so will likely harm our ability to execute our business plans. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Risks Related to Regulatory Compliance

Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may charge for such product candidates.

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, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act, was enacted, which includes measures that have significantly changed the way health care is financed by both governmental and private insurers. Some of the provisions of the Affordable Care Act have yet to be implemented, and there have been judicial and congressional challenges to certain aspects of the Affordable Care Act. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. In addition, 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. Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the Affordable Care Act-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. On December 14, 2018, a 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 Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. It is unclear how this decision, future decisions, subsequent appeals and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act and our business. We continue to evaluate the effect that the Affordable Care Act and its possible repeal and replacement has on our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, then-President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction, which triggered the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2029 unless Congress takes additional action. Recently, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. congressional inquiries and 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. Further, 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 Department of Health and Human Services has solicited feedback on some of these measures and has implemented others under its existing authority. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control costs pharmaceutical and biological products.

We expect that the healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

Our business operations and current and future relationships with investigators, health care professionals, consultants, third-party payors and customers will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Although we do not currently have any products on the market, our operations may be, directly or indirectly through our prescribers, customers and third-party payors, subject to various U.S. federal and state healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute, the U.S. federal civil and criminal false claims laws and the Physician Payments Sunshine Act and regulations. Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. These laws may impact, among other things, our current business operations, including our clinical research activities, and proposed sales, marketing and education programs and constrain the business of financial arrangements and relationships with healthcare providers, physicians and other parties through which we may market, sell and distribute our products for which we obtain marketing approval. In addition, we may be subject to patient data privacy and security regulation by both the U.S. federal government and the states in which we conduct our business. Finally, we may be subject to additional healthcare, statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. The laws that may affect our ability to operate include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal false claims, including the False Claims Act, which can be enforced through whistleblower actions, and civil monetary penalties laws, which, among other things, impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, and as amended again by the Modifications to the HIPAA Privacy, Security, Enforcement and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules, commonly referred to as the Final HIPAA Omnibus Rule, published in January 2013, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by

covered entities subject to the Final HIPAA Omnibus Rule, i.e. health plans, healthcare clearinghouses and certain healthcare providers, as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information;

- the U.S. Federal Food, Drug and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. federal legislation commonly referred to as Physician Payments Sunshine Act, enacted as part of the Affordable Care Act, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the delay, reduction, termination or restructuring of our operations. Further, defending against any such actions can be costly and time-consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

Failure to comply with current or future federal, state and foreign laws and regulations and industry standards relating to privacy and data protection laws could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.

We and our collaborators and third-party providers may be subject to federal, state and foreign data privacy and security laws and regulations. In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators and third-party providers.

In many jurisdictions, enforcement actions and consequences for noncompliance are rising. In the United States, these include enforcement actions in response to rules and regulations promulgated under the authority of federal agencies and state attorneys general and legislatures and consumer protection agencies. In addition, privacy advocates and industry groups have regularly proposed, and may propose in the future, self-regulatory standards that may legally or contractually apply to us. If we fail to follow these security standards, even if no customer information is compromised, we may incur significant fines or experience a significant increase in costs. Many state legislatures have adopted legislation that regulates how businesses operate online, including measures relating to privacy, data security and data breaches. Laws in all 50 states require businesses to provide notice to customers whose personally identifiable information has been disclosed as a result of a data breach. The laws are not consistent, and compliance in the event of a widespread data breach is costly. States are also constantly amending existing laws, requiring attention to frequently changing regulatory requirements. Furthermore, California recently enacted the California Consumer Privacy Act, or the CCPA, which became effective on January 1, 2020. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. At this time, we do not collect personal data on residents of California but should we begin to do so, the CCPA will impose new and burdensome privacy compliance obligations on our business and will raise new risks for potential fines and class actions.

Foreign data protection laws, including EU General Data Protection Regulation, or the GDPR, may also apply to health-related and other personal information obtained outside of the United States. The GDPR, which came into effect on May 25, 2018, introduced new data protection requirements in the European Union, as well as potential fines for noncompliant companies of up to the greater of €20 million or 4% of annual global revenue. The regulation imposes numerous new requirements for the collection, use and disclosure of personal information, including more stringent requirements relating to consent and the information that must be shared with data subjects about how their personal information is used, the obligation to notify regulators and affected individuals of personal data breaches, extensive new internal privacy governance obligations and obligations to honor expanded rights of individuals in relation to their personal information (e.g., the right to access, correct and delete their data). Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EU and the United States remains uncertain. For example, in 2016, the EU and United States agreed to a transfer framework for data transferred from the EU to the United States, called the Privacy Shield, but the Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union. At this time, we do not believe we are subject to the GDPR, but should this change, the GDPR will increase our responsibility and potential liability in relation to personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the new EU data protection rules.

Compliance with U.S. and foreign 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 by us or our collaborators and third-party providers to comply with U.S. and foreign data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. 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, could result in adverse publicity and could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Our Intellectual Property

If we are unable to obtain, maintain and protect sufficient patent and other intellectual property rights for our product candidates and technology, or if the scope of patent and other intellectual property rights obtained is not sufficiently broad, we may not be able to compete effectively in our market.

Our success depends in significant part on our ability and the ability of our licensors and collaborators to obtain, maintain, enforce and defend patents and other intellectual property rights with respect to our product candidates and technology and to operate our business without infringing, misappropriating or otherwise violating the intellectual property rights of others. We have licensed two patent estates from The Board of Trustees of the Leland Stanford Junior University, or Stanford. For more information, see "Business—License and Collaboration Agreements." In addition, we have filed patent applications that are solely owned by us or co-owned by us with Stanford and for which Stanford has granted us an exclusive license to its rights. As of June 30, 2020, we only have one issued patent. Our only issued patent is a U.S. patent that is co-owned with, and exclusively licensed to us by, Stanford. Many of our patent applications that we own, co-own with Stanford, or have licensed from Stanford are U.S. provisional patent applications. U.S. provisional patent applications are not eligible to become issued patents until, among other things, we file a non-provisional patent application within 12 months of filing of one or more of our related provisional patent applications. With regard to such U.S. provisional patent applications, if we or our licensors do not timely file any 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 patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage.

The patent prosecution process is expensive and time-consuming. We and our current or future licensors, licensees or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our licensors will fail to identify patentable aspects of our research and development output in time to obtain patent protection or fail to file patent applications covering inventions made in the course of development and commercialization activities before a competitor or another third party files a patent application covering, or publishes information disclosing, a similar, independently-developed invention. Such competitor's or other third party's patent application may pose obstacles to our ability to obtain patent protection or limit the scope of the patent protection we may obtain. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or were the first to file for patent protection of such inventions.

The patent position of biotechnology and pharmaceutical companies generally is uncertain, involves complex legal and factual questions and is the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors' patent rights are uncertain. Our and our licensors' pending and future patent applications may not result in patents being issued that protect our technology or product candidates, in whole or in part, or which effectively exclude others from commercializing competitive technologies and product candidates. The patent examination process may require us or our licensors to narrow the scope of the claims of our pending and future patent applications, and therefore, even if such patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Our and our licensors' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover such technology. Any patents that we hold or in-license may be challenged, narrowed, circumvented 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 patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

The patent protection we obtain for our product candidates and technology may be challenged or not sufficient enough to provide us with any competitive advantage.

Even if our owned or licensed patent applications issue as patents, the issuance of any such patents is not conclusive as to their inventorship, scope, validity or enforceability, and such patents may be challenged, invalidated, narrowed or held to be unenforceable, including in the courts or patent offices in the United States and abroad, or circumvented. We may be subject to a third-party preissuance submission of prior art to the United States Patent and Trademark Office, or USPTO, or equivalent foreign bodies, or become involved in opposition, derivation, revocation, re-examination, post-grant and *inter partes* review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation 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. Moreover, we, or one of our licensors, may have to participate in interference or derivation proceedings declared by the USPTO to determine priority or ownership of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge priority of invention or other features of patentability. Such proceedings and any other patent challenges may result in loss of patent rights, loss of exclusivity, loss of priority 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 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. Moreover, there could be public announcements of the results of hearings, motions or other developments related to any of the foregoing proceedings. If securities analysts or investors perceive those results to be negative, it could cause the price of shares of our common stock to decline. Any of the foregoing could harm our business, financial condition, results of operations and prospects.

Moreover, some of our owned or in-licensed patents and patent applications are, and may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, who could market competing products and technology. In addition, we may need the cooperation of any such co-owners in order to enforce such patents against third parties, and such cooperation may not be provided to us.

In addition, our owned and in-licensed patents may be subject to a reservation of rights by one or more third parties. For example, our licenses to certain intellectual property owned by Stanford are subject to certain rights

Stanford retained for itself and for other non-profit research institutions. In addition, the technology claimed by the patents that we licensed from Stanford was developed using U.S. government funding. As a result, the U.S. government has certain rights to such patent rights and technology, including march-in rights and a non-exclusive license authorizing the government to use the invention for noncommercial purposes. These rights may permit the government to disclose our confidential information to third parties or allow third parties to use our licensed technology. The government can also exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, or to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

We are heavily dependent on licensed intellectual property. If we were to lose our rights to licensed intellectual property, we may not be able to continue developing or commercializing our product candidates, if approved. If we breach any of the agreements under which we license the use, development and commercialization rights to our product candidates or technology from third parties or, in certain cases, we fail to meet certain development deadlines, we could lose license rights that are important to our business.

We are heavily reliant upon licenses to certain patent rights and other intellectual property from third parties that are important or necessary to the development of our product candidates, including BDC-1001. For example, in May 2015 and June 2018 we entered into license agreements with Stanford under which we are granted rights to intellectual property that are necessary to the development and commercialization of BDC-1001 or are otherwise important to our business. We may also need to obtain additional licenses to advance the development and commercialization of our current product candidates and other product candidates we may develop. It is possible that we may be unable to obtain any additional licenses at a reasonable cost or on reasonable terms, or at all, or such licenses may be non-exclusive. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly.

Our existing license agreements with Stanford and Toray impose, and we expect that future license agreements will impose, upon us various development, regulatory and/or commercial diligence obligations, obligations to make milestone or royalty payments or to share revenues and other obligations. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy-related event, the licensor may have the right to terminate the license, and if they exercise that right we would not be able to develop, market or otherwise commercialize our technology and product candidates covered by the license, which in the case of our 2015 license agreement with Stanford includes BDC-1001. Our business could suffer, for example, if any current or future licenses terminate, if the licensors fail to abide by the terms of the license, if the licensed patents or other rights are found to be invalid or unenforceable or if we are unable to enter into necessary licenses on acceptable terms.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues, and certain provisions in intellectual property license agreements may be susceptible to multiple interpretations. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property of the licensor that is not subject to the license agreement;
- our right to sublicense patent and other rights to third parties;

- 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 inventorship or ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners;
- the priority of invention of patented technology;
- our right to transfer or assign the license; and
- the effects of termination.

The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could harm our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We may enter into additional licenses to third-party intellectual property that are necessary or useful to our business. Under some license agreements, such as under the Toray Development Agreement, we may not control the preparation, filing, prosecution or maintenance of the licensed intellectual property, or may not have the first right to enforce the intellectual property. In those cases, we may not be able to adequately influence patent prosecution or enforcement, or prevent inadvertent lapses of coverage due to failure to pay maintenance fees and we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business and that does not compromise the patent rights. If we fail to comply with any of our obligations under a current or future license agreement, the licensor may allege that we have breached our license agreement, and may accordingly seek to terminate our license. Termination of any of our current or future licenses could result in our loss of the right to use the licensed intellectual property, which could materially adversely affect our ability to develop and commercialize a product candidate or product, if approved, as well as harm our competitive business position and our business prospects. Under some license agreements, termination may also result in the transfer or granting of rights under certain of our intellectual property and information related to the product candidate being developed under the license, such as regulatory information. If these licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, third parties, including our competitors, would have the freedom to seek regulatory approval of, and to market, products identical to ours. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties, including our competitors, to receive licenses to a portion of the intellectual property that is subject to our existing licenses. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

In addition, if our licensors fail to abide by the terms of the license, if the licensors fail to prevent infringement, misappropriation or violation of the licensed intellectual property by third parties, if the licensed intellectual property or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms, our business, competitive position, financial condition, results of operations and prospects could be materially harmed.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to develop and manufacture our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into

confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite these contractual agreements with third parties, sharing trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may harm our business.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful, and issued patents covering our technology and product candidates could be found invalid or unenforceable if challenged.

Competitors and other third parties may infringe, misappropriate or otherwise violate our issued patents or other intellectual property or the patents or other intellectual property of our licensors. In addition, our patents or the patents of our licensors may become involved in inventorship or priority disputes. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. To counter infringement or other unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents or that our patents are invalid or unenforceable. In a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology. An adverse result in any litigation proceeding could put one or more of our owned or licensed patents at risk of being invalidated, held unenforceable or interpreted narrowly. We may find it impractical or undesirable to enforce our intellectual property against some third parties.

In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or insufficient written description. 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 the USPTO or an equivalent foreign body, even outside the context of litigation. Potential proceedings include re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (*e.g.*, opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our technology or any product candidates that we may develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on the applicable product candidates or technology covered by the patent rendered invalid or unenforceable. Such a loss of patent protection would materially harm our business, financial condition, results of operations and prospects.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the ownership or priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. 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. In addition, if we or our licensors are unsuccessful in any inventorship disputes to which we or they are subject, we may lose valuable intellectual property rights, such as exclusive ownership of, or the exclusive right to use, our owned or in-licensed patents. The loss of exclusivity or the narrowing of our owned and licensed patent claims could limit our ability to stop others from using or commercializing similar or identical technology and products. Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations or prospects. Even if we are successful in any of the foregoing disputes, it could result in substantial costs and be a distraction to management and other employees. 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 or proceeding.

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. Most of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating or otherwise violating our intellectual property. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims could result in substantial costs and diversion of management resources, which could harm our business. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs or in-license needed technology or other product candidates. There could also be public announcements of the results of the hearing, motions or other interim proceedings or developments. If securities analysts or investors perceive those results to be negative, it could cause the price of shares of our common stock to decline. Any of the foregoing events could harm our business, financial condition, results of operations and prospects.

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

Filing, prosecuting, maintaining, defending and enforcing patents and other intellectual property rights on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as 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 or other intellectual property rights to develop their own products and may export otherwise infringing, misappropriating or violating products to territories where we have patent or other intellectual property protection, but enforcement rights are not as strong as those in the United States. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries do not favor the enforcement of patents and other intellectual property rights, which could make it difficult for us to stop the infringement, misappropriation or other violation of our intellectual property rights generally. Proceedings to enforce our intellectual property

rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

Many countries, including European Union countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. 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, which could adversely affect our business, financial condition, results of operations and prospects.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent which might adversely affect our ability to develop and market our product candidates.

We cannot guarantee that any of our or our licensors' patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending patent application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. For example, U.S. patent applications filed before November 29, 2000 and certain U.S. patent applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our product candidates could have been filed by third parties without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. We may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates.

If we fail to identify and correctly interpret relevant patents or if we are unable to obtain licenses to relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, which may be significant, we may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing. We might, if possible, also be forced to redesign product candidates so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business and could adversely affect our business, financial condition, results of operations and prospects.

If we are unable to obtain licenses from third parties on commercially reasonable terms or fail to comply with our obligations under such agreements, our business could be harmed.

It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. If we are unable to license such technology, or if we are forced to license such technology, on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business, and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us.

If we fail to comply with our obligations under our license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market, or may be forced to cease developing, manufacturing or marketing, any product that is covered by these agreements or may face other penalties under such agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, or impede, delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements. For more information on risks related to our licensing of intellectual property, see “Risk Factors—Risks Related to Our Intellectual Property—We are heavily dependent on licensed intellectual property. If we were to lose our rights to licensed intellectual property, we may not be able to continue developing or commercializing our product candidates, if approved. If we breach any of the agreements under which we license the use, development and commercialization rights to our product candidates or technology from third parties or, in certain cases, we fail to meet certain development deadlines, we could lose license rights that are important to our business.”

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

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours.

Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and one or more of our foreign patents may be eligible for patent term extension under similar legislation, for example, in the European Union. In the United States, the Hatch-Waxman Amendments permit a patent term

extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, there are no assurances that the FDA or any comparable foreign regulatory authority or national patent office will grant such extensions, in whole or in part. For example, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval, and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened, and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case, and our competitive position, business, financial condition, results of operations and prospects could be materially harmed.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

Obtaining and enforcing patents in the pharmaceutical industry is inherently uncertain, due in part to ongoing changes in the patent laws. Depending on decisions by Congress, the federal courts, and the USPTO and equivalent institutions in other jurisdictions, the laws and regulations governing patents, and interpretation thereof, could change in unpredictable ways that could weaken our and our licensors' or collaborators' ability to obtain new patents or to enforce existing or future patents. For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Therefore, there is increased uncertainty with regard to our and our licensors' or collaborators' ability to obtain patents in the future, as well as uncertainty with respect to the value of patents once obtained.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and our licensors' or collaborators' patent applications and the enforcement or defense of our or our licensors' or collaborators' issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the Leahy-Smith Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications are prosecuted and may also affect patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, particularly the first inventor-to-file provisions. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents, all of which could harm our business, financial condition, results of operations and prospects.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on any issued patents and applications are required to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of a patent. In certain circumstances, we rely on our licensors to pay these fees. The USPTO and various foreign patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar requirements during the patent application and prosecution process. Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official communications within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in irrevocable abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we or our licensors or collaborators fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market with similar or identical products or technology, which would harm our business, financial condition, results of operations and prospects.

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 negatively impact the success of our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or be threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates and technology, including re-examination, interference, post-grant review, inter partes review or derivation proceedings before the USPTO or an equivalent foreign body. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing our product candidates. For example, we are aware of certain third-party patents, including those of our competitors, that may be construed to cover the use of our Boltbody ISACs for the treatment of cancer and of pending patent applications that, if issued with their current claim scope, may be construed to cover our Boltbody ISAC approach and product candidates more generally. In the event that any of these patents were asserted against us, we believe that we would have defenses against any such action, including that such patents are not valid or that we would be able to replace such technology with alternative, non-infringing technology. However, if any such patents were to be asserted against us and our defenses to such assertion were unsuccessful and such alternative technology was not available or technologically or commercially practical, unless we obtain a license to such patents, we could be liable for damages, which could be significant and include treble damages and attorneys' fees if we are found to willfully infringe such patents, and we could be precluded from commercializing any product candidates that were ultimately held to infringe such patents. Any potential future legal proceedings relating to these patents could cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. If we are unsuccessful in our challenges to these patents and become subject to litigation or are unable to obtain a license on commercially reasonable terms with respect to these patents, it could harm our business, financial condition, results of operations and prospects.

Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction could hold that third-party patents asserted against us

are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize any product candidates we may develop and any other product candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If we are found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, and we are unsuccessful in demonstrating that such rights are invalid or unenforceable, we could be required to obtain a license from such a third party in order to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease commercializing the infringing technology or product candidates. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations. 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, pay royalties and other fees, redesign our infringing drug or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. Any of the foregoing events would harm our business, financial condition, results of operations and prospects.

We may be subject to claims by third parties asserting that we or our employees have infringed upon, misappropriated or otherwise violated their intellectual property rights, or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at other biotechnology or pharmaceutical companies. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer. Litigation may be necessary to defend against these claims.

In addition, we or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents or other intellectual property as an inventor or co-inventor. While it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact conceives, develops or reduces to practice intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs, delay development of our product candidates and be a distraction to management. Any of the foregoing events would harm our business, financial condition, results of operations and prospects.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions

or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace, including compromising our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development collaborations that would help us commercialize our product candidates, if approved. Any of the foregoing events would harm our business, financial condition, 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.

We rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology and other proprietary information and to maintain our competitive position. With respect to our Boltbody ISAC approach and development programs, we consider trade secrets and know-how to be one of our important sources of intellectual property, including our extensive knowledge of certain drug delivery techniques and antibody conjugation. Trade secrets and know-how can be difficult to protect. We seek to protect these trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. 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. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

We may not be able to protect and enforce our trademarks and trade names, or build name recognition in our markets of interest thereby harming our competitive position.

We intend to rely on both registered and common law rights for our trademarks. We have not yet registered certain of our trademarks in all of our potential markets, including our “Boltbody” and “Bolt Biotherapeutics” trademarks. We are currently applying to register these trademarks with the USPTO and may in the future seek to register additional trademarks in the United States and other countries. Our current and future trademark applications may not be allowed for registration in a timely fashion or at all, and our registered trademarks may not be maintained or enforced. In addition, the registered or unregistered trademarks or trade names that we own may be challenged, infringed, circumvented, declared generic, lapsed or determined to be infringing on or dilutive of other marks. We may not be able to protect our rights in 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. In addition, third parties have filed, and may in the future file, for registration of trademarks similar or identical to our trademarks, thereby impeding our ability to build brand identity and possibly leading to market confusion. If they succeed in registering or developing common law rights in such trademarks, and if we are not successful in challenging such rights, we may not be able to use these trademarks to develop brand

recognition of our technologies, products or services. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names.

During the trademark registration process, we may receive Office Actions from the USPTO or from comparable agencies in foreign jurisdictions 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 in the future be filed against our trademark applications or registrations, and our trademark applications or registrations may not survive such proceedings. In addition, third parties may file first for our trademarks in certain countries. If they succeed in registering such trademarks, and if we are not successful in challenging such third party rights, we may not be able to use these trademarks to market our products in those countries. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily address all potential threats.

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

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

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

Risks Related to Our Business Operations, Employee Matters and Managing Growth

Our business, operations and clinical development plans and timelines and supply chain could be adversely affected by the effects of health epidemics, including the ongoing COVID-19 pandemic, on the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we conduct business, including our CMOs, CROs, shippers and others.

Our business could be adversely affected by health epidemics wherever we have clinical trial sites or other business operations. In addition, health epidemics could cause significant disruption in the operations of CMOs, CROs and other third parties upon whom we rely. For example, the COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting employees, patients, communities and business operations, as well as the U.S. economy and financial markets. Many geographic regions have imposed, or in the future may impose, "shelter-in-place" orders, quarantines or similar orders or restrictions to control the spread of COVID-19. Our headquarters are located in the San Francisco Bay Area and our CMOs are located in the United States and in the United Kingdom. At present, we have implemented work-from-home policies for all employees. The effects of the executive order and our work-from-home policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

We are dependent on a worldwide supply chain for products to be used in our clinical trials and, if approved by the regulatory authorities, for commercialization. Quarantines, shelter-in-place and similar government orders, or the expectation that such orders, shutdowns or other restrictions could occur, whether related to COVID-19 or other infectious diseases, could impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials or supplies, which could disrupt our supply chain or our ability to enroll patients in or perform testing for our clinical trials. For example, any manufacturing supply interruption of BDC-1001, which is currently manufactured at facilities in the United Kingdom and the United States, or any future product candidates, could adversely affect our ability to conduct ongoing and future clinical trials of BDC-1001 and any future product candidates. In addition, closures of transportation carriers and modal hubs could materially impact our clinical development and any future commercialization timelines.

If our relationships with our suppliers or other vendors are terminated or scaled back as a result of the COVID-19 pandemic or other health epidemics, we may not be able to enter into arrangements with alternative suppliers or vendors or do so on commercially reasonable terms or in a timely manner. Switching or adding additional suppliers or vendors involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new supplier or vendor commences work. As a result, delays generally occur, which could adversely impact our ability to meet our desired clinical development and any future commercialization timelines. Although we carefully manage our relationships with our suppliers and vendors, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition and prospects. See "Risk Factors—Risks Related to Our Dependence on Third Parties."

In addition, our clinical trials have been and may continue to be affected by the COVID-19 pandemic. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic or concerns among patients about participating in clinical trials during a pandemic and public health measures imposed by the respective national governments of countries in which the clinical sites are located. Some patients may have difficulty following certain aspects of clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our inability to successfully recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 or experience additional restrictions by their institutions, city or state governments could adversely impact our clinical trial operations. We continue to evaluate the impact of the COVID-19 pandemic on

our clinical development timelines. We will provide an update on our clinical development timelines once we have more information about how the COVID-19 pandemic progressed.

The spread of COVID-19 has also led to disruption and volatility in the global capital markets, which increases the cost of, and adversely impacts access to, capital and increases economic uncertainty. The trading prices for the common stock of other biopharmaceutical companies have, at times, been highly volatile as a result of COVID-19. To the extent the COVID-19 pandemic adversely affects our business, financial results and value of our common stock, it may also affect our ability to access capital, which could in the future negatively affect our liquidity.

The global pandemic of COVID-19 continues to evolve rapidly. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the COVID-19 situation closely.

Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified personnel.

We are highly dependent on the management, research and development, clinical, financial and business development expertise of our executive officers, as well as the other members of our scientific and clinical teams. Although we have employment offer letters with each of our executive officers, each of them may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or employees.

Recruiting and retaining qualified scientific and clinical personnel and, if we are successful in obtaining marketing approval for our product candidates, sales and marketing personnel, is critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval for and commercialize our product candidates. Competition to hire qualified personnel in our industry is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. Furthermore, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited, and could harm our business, financial condition, results of operations and prospects.

We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of June 30, 2020, we had 53 employees. As our clinical development progresses, we expect to experience growth in the number of our employees and the scope of our operations, particularly in the areas of research, clinical operations, regulatory affairs, general and administrative and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we

must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

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

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or unauthorized activities that violates (1) the laws and regulations of the FDA, the EMA, the MHRA and other similar regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities, (2) manufacturing standards, (3) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad and (4) laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of product candidates, which could result in regulatory sanctions and serious harm to our reputation.

We intend to adopt a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm and the delay, reduction, termination or restructuring of our operations.

Our international operations may expose us to business, regulatory, political, operational, financial, pricing and reimbursement risks associated with doing business outside of the United States.

Our business is subject to risks associated with conducting business internationally. Some of our suppliers, industry partners and clinical study centers are located outside of the United States. Furthermore, our business strategy incorporates potential international expansion as we seek to obtain regulatory approval for, and commercialize, our product candidates in patient populations outside the United States. If approved, we may hire sales representatives and conduct physician and patient association outreach activities outside of the United States. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;

- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- rejection or qualification of foreign clinical trial data by the competent authorities of other countries;
- delays or interruptions in the supply of clinical trial materials resulting from any events affecting raw material supply or manufacturing capabilities abroad, including those that may result from the ongoing COVID-19 pandemic;
- additional potentially relevant third-party patent and other intellectual property rights;
- complexities and difficulties in obtaining, maintaining, protecting and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our product candidates and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, including COVID-19 and related shelter-in-place orders, travel, social distancing and quarantine policies, boycotts, curtailment of trade and other business restrictions;
- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to anti-corruption compliance and record-keeping that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its accounting provisions or its anti-bribery provisions or provisions of anti-corruption or anti-bribery laws in other countries.

Any of these factors could harm our future international expansion and operations and, consequently, our results of operations.

Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or experience security breaches or other unauthorized or improper access.

Despite the implementation of security measures, our internal computer systems, and those of our CROs and other third parties on which we rely, are vulnerable to privacy and information security incidents, such as data breaches, damage from computer viruses and unauthorized access, malware, natural disasters, fire, terrorism, war and telecommunication, electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. While we have not experienced any such material system failure or security breach to our knowledge to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business.

Unauthorized disclosure of sensitive or confidential data, including personally identifiable information, whether through a breach of computer systems, systems failure, employee negligence, fraud or misappropriation,

or otherwise, or unauthorized access to or through our information systems and networks, whether by our employees or third parties, could result in negative publicity, legal liability and damage to our reputation. Unauthorized disclosure of personally identifiable information could also expose us to sanctions for violations of data privacy laws and regulations around the world. To the extent that any disruption or security breach resulted 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 of our product candidates could be delayed.

As we become more dependent on information technologies to conduct our operations, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, may increase in frequency and sophistication. These threats pose a risk to the security of our systems and networks, the confidentiality and the availability and integrity of our data and these risks apply both to us, and to third parties on whose systems we rely for the conduct of our business. Because the techniques used to obtain unauthorized access, disable or degrade service or sabotage systems change frequently and often are not recognized until launched against a target, we and our partners may be unable to anticipate these techniques or to implement adequate preventative measures. Further, we do not have any control over the operations of the facilities or technology of our cloud and service providers, including any third party vendors that collect, process and store personal data on our behalf. Our systems, servers and platforms and those of our service providers may be vulnerable to computer viruses or physical or electronic break-ins that our or their security measures may not detect. Individuals able to circumvent such security measures may misappropriate our confidential or proprietary information, disrupt our operations, damage our computers or otherwise impair our reputation and business. We may need to expend significant resources and make significant capital investment to protect against security breaches or to mitigate the impact of any such breaches. There can be no assurance that we or our third party providers will be successful in preventing cyber attacks or successfully mitigating their effects. 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 future product candidates could be delayed.

Risks Related to This Offering and Our Common Stock

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

Prior to the completion of this offering, we have been a private company with limited accounting personnel to adequately execute our accounting processes and limited supervisory resources with which to address our internal control over financial reporting. In connection with the audit of our financial statements as of and for the years ended December 31, 2018 and 2019, we identified a material weakness in our internal control over financial reporting. 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 the annual or interim financial statements will not be prevented or detected on a timely basis.

We did not design and have not maintained an effective control environment as required under the rules and regulations of the U.S. Securities and Exchange Commission, or the SEC. Specifically, we lack a sufficient number of professionals with an appropriate level of accounting knowledge, training and experience to appropriately analyze, record and disclose accounting matters timely and accurately while maintaining appropriate segregation of duties. Without such professionals, we did not design and currently do not maintain formal accounting policies, procedures and controls to achieve complete, accurate and timely financial accounting, reporting and disclosures, including controls over the preparation and review of account reconciliations and journal entries.

The above material weakness did not result in a misstatement, however, it could result in a misstatement of our account balances or disclosures that would result in a material misstatement of our annual or interim financial statements that would not be prevented or detected.

To address the material weakness, we have begun adding personnel, such as a Chief Financial Officer, and have implemented new financial processes. We intend to continue to take steps to remediate the material weakness through the hiring of additional experienced accounting and financial reporting personnel, formalizing documentation of policies and procedures and further evolving the accounting processes, including implementing appropriate segregation of duties.

We cannot assure you that the measures we have taken to date, and are continuing to implement, will be sufficient to remediate the material weakness we have identified or avoid potential future material weaknesses. If the steps we take do not correct the material weakness in a timely manner, we will be unable to conclude that we maintain effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected on a timely basis.

If we fail to remediate our existing material weakness or identify new material weaknesses in our internal controls over financial reporting, if we are unable to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, if we are unable to conclude that our internal controls over financial reporting are effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal controls over financial reporting when we are no longer an emerging growth company, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be negatively affected. As a result of such failures, we could also become subject to investigations by the Nasdaq Global Market, the SEC or other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation and financial condition or divert financial and management resources from our regular business activities.

An active trading market for our common stock may not develop and you may not be able to resell your shares of our common stock at or above the initial offering price, if at all.

Prior to this offering, there has been no public market for our common stock. We cannot predict the extent to which an active market for our common stock will develop or be sustained after this offering, or how the development of such a market might affect the market price for our common stock. The initial public offering price for our common stock will be determined through negotiations with the underwriters and may not be indicative of the price at which our common stock will trade after the closing of this offering. 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. If an active market for our common stock does not develop or is not sustained, it may be difficult for you to sell shares you purchased in this offering at an attractive price or at all.

The trading price of the shares of our common stock may be volatile, and purchasers of our common stock could incur substantial losses.

Our stock price may be volatile. The stock market in general and the market for pharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

- adverse regulatory decisions;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority’s review of such

filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;

- the impact of the COVID-19 pandemic;
- the commencement, enrollment or results of any future clinical trials we may conduct, or changes in the development status of our product candidates;
- adverse results from, delays in or termination of clinical trials;
- unanticipated serious safety concerns related to the use of our product candidates;
- lower than expected market acceptance of our product candidates following approval for commercialization;
- changes in financial estimates by us or by any securities analysts who might cover our stock;
- conditions or trends in our industry;
- changes in the market valuations of similar companies;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the pharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- investors' general perception of our company and our business;
- recruitment or departure of key personnel;
- overall performance of the equity markets;
- trading volume of our common stock;
- disputes or other developments relating to intellectual property rights, including patents, litigation matters and our ability to obtain, maintain, defend, protect and enforce patent and other intellectual property rights for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- proposed changes to healthcare laws in the United States or foreign jurisdictions, or speculation regarding such changes;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. We do not currently have and may never obtain research coverage by equity research analysts. Equity research analysts may elect not to provide research coverage of our common stock after this offering, and such lack of research coverage may adversely affect the market price of our

common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

If you purchase shares of our common stock in this offering, you will suffer immediate dilution of your investment.

The assumed initial public offering price of our common stock is substantially higher than the pro forma as adjusted net tangible book value per share of our common stock. Therefore, if you purchase shares of our common stock in this offering, you will pay a price per share that substantially exceeds our pro forma as adjusted net tangible book value per share after this offering. Based on an assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, you will experience immediate dilution of $ per share, representing the difference between our pro forma as adjusted net tangible book value per share after this offering and the assumed initial public offering price. In addition, to the extent outstanding stock options are exercised, there will be further dilution to investors in this offering. In addition, if the underwriters exercise their over-allotment option or if we issued additional equity securities, you will experience additional dilution. See “Dilution” for a more detailed description of the dilution to investors in the offering.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time, subject to the restrictions and limitations described below. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market following this offering, the market price of our common stock could decline significantly.

Upon the closing of this offering, we will have outstanding shares of common stock, after giving effect to the conversion of 70,490,863 outstanding shares of convertible preferred stock as of December 31, 2019 into an equal number of shares of common stock and the issuance of shares of common stock upon the automatic net exercise of warrants, assuming no exercise of the underwriters’ over-allotment option and no exercise of outstanding options. Of these shares, the shares sold in this offering will be freely tradable and the remaining shares of common stock will be available for sale in the public market beginning after the end of the 180th day after the date of this prospectus following the expiration of lock-up agreements between our stockholders and certain of the underwriters for this offering, subject, in the case of our affiliates, to the conditions of Rule 144 under the Securities Act of 1933, as amended, or the Securities Act. Morgan Stanley & Co. LLC and SVB Leerink LLC on behalf of the underwriters may release these stockholders from their lock-up agreements at any time and without notice, which would allow for earlier sales of shares in the public market subject to the conditions of Rule 144 under the Securities Act.

In addition, promptly following the closing of this offering, we intend to file one or more registration statements on Form S-8 registering the issuance of approximately million shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under these registration statements on Form S-8 will be available for sale in the public market subject to vesting arrangements and exercise of options, the lock-up agreements described above and, in the case of our affiliates, the restrictions of Rule 144.

Additionally, after this offering, the holders of an aggregate of shares of our common stock, or their transferees, will have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves

or other stockholders. If we were to register the resale of these shares, they could be freely sold in the public market without limitation. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of our company more difficult, limit attempts by our stockholders to replace or remove our current management and limit the market price of our common stock.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may have the effect of delaying or preventing a change of control or changes in our management. Our amended and restated certificate of incorporation and amended and restated bylaws include provisions that:

- provide for a classified board of directors whose members serve staggered terms;
- authorize our board of directors to issue, without further action by the stockholders, shares of undesignated preferred stock with terms, rights and preferences determined by our board of directors that may be senior to our common stock;
- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders can be called only by our board of directors, the chairperson of our board of directors or our chief executive officer;
- establish an advance notice procedure for stockholder proposals to be brought before an annual meeting, including proposed nominations of persons for election to our board of directors;
- prohibit cumulative voting in the election of directors;
- provide that our directors may be removed for cause only upon the vote of the holders of at least 66 2/3% of our outstanding shares of common stock;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum; and
- require the approval of our board of directors or the holders of at least 66 2/3% of our outstanding shares of common stock to amend our bylaws and certain provisions of our certificate of incorporation.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally, subject to certain exceptions, prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any "interested" stockholder for a period of three years following the date on which the stockholder became an "interested" stockholder. Any delay or prevention of a change of control transaction or changes in our management could cause the market price of our common stock to decline.

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

Based upon our common stock outstanding as of December 31, 2019 and including the shares to be sold in this offering, upon the closing of this offering, our executive officers, directors and current beneficial owners of 5% or more of our common stock will, in the aggregate, beneficially own approximately % of our outstanding common stock. These stockholders, acting together, will be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors and any merger or other significant corporate transactions. The interests of this group of stockholders may not coincide with the interests of other stockholders.

Some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the price at which shares are being sold in this offering and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders.

We will incur costs and demands upon our management as a result of complying with the laws and regulations affecting public companies in the United States, which may harm our business.

As a public company listed in the United States, we will incur significant additional legal, accounting and other expenses. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and the Nasdaq Global Market may increase legal and financial compliance costs and make some activities more time consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from regular business activities to compliance activities. If, notwithstanding our efforts, we fail to comply with new laws, regulations and standards, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Failure to comply with these rules might also make it more difficult for us to obtain certain types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.

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

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an "emerging growth company," we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As an "emerging growth company," we are required to report only two years of financial results and selected financial data compared to three and five years, respectively, for comparable data reported by other public companies. We may take advantage of these exemptions until we are no longer an "emerging growth company." We could be an "emerging growth company" for up to five years, although circumstances could cause us to lose that status earlier, including if the aggregate market value of our common stock held by non-affiliates exceeds $700 million as of any June 30 (the end of our second quarter) before that time, in which case we would no longer be an "emerging growth company" as of the following December 31 (our year-end). 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 the price of our common stock may be more volatile.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

After the closing of this offering, we will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of the Nasdaq Global Market. Section 302 of the Sarbanes-Oxley Act requires, among other things, that we report on the effectiveness of our disclosure controls and procedures in our quarterly and annual reports and, beginning with our annual report for the year ending 2021, Section 404 of the Sarbanes-Oxley Act requires that we perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting in our Form 10-K filing for that year. This will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. Prior to this offering, we have never been required to test our internal control within a specified period, and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner. In addition, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting in our first annual report required to be filed with the SEC following the date we are no longer an emerging growth company or a smaller reporting company.

As a public company, we will be required to maintain internal control over financial reporting and to report any material weaknesses in those internal controls. We identified a material weakness in our internal control over financial reporting as of and for the years ended December 31, 2018 and 2019, related to a lack of an effective control environment as required under SEC rules and regulations. During 2020, we have added personnel, including a Chief Financial Officer, as well as implemented new financial processes. Our remediation efforts are ongoing. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the Nasdaq Global Market, the SEC or other regulatory authorities. In addition, our common stock may not be able to remain listed on the Nasdaq Global Market or any other securities exchange.

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

Our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. We intend to use the net proceeds from this offering to conduct our clinical trials, to fund continued research and development of BDC-1001 in several applications, to fund other research and development activities, and for working capital and other general corporate purposes. The failure by our management to apply these funds effectively could result in financial losses that could have an adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gains and you may never receive a return on your investment.

You should not rely on an investment in our common stock to provide dividend income. We have not declared or paid cash dividends on our common stock to date. We currently intend to retain our future earnings,

if any, to fund the development and growth of our business. In addition, the terms of any existing or future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Investors seeking cash dividends should not purchase our common stock.

Our amended and restated certificate of incorporation that will be in effect upon the closing of this offering will provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us arising under the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could harm our business.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations, financial condition, business strategy and plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” or “would,” or the negative of these words or other similar terms or expressions.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of risks, uncertainties, factors and assumptions described in “Risk Factors” and elsewhere in this prospectus, regarding, among other things:

- the success, cost and timing of our product development activities and clinical trials;
- our expectations about the timing of achieving regulatory approval and the cost of our development programs;
- our ability to obtain funding for our operations, including funding necessary to complete further development and commercialization of our product candidates;
- the impact of the COVID-19 pandemic on our operations;
- the commercialization of our product candidates, if approved;
- our plans to research, develop and commercialize our product candidates;
- our ability to obtain, maintain, expand, protect and enforce our intellectual property rights;
- our ability to operate our business without infringing, misappropriating or otherwise violating the intellectual property rights of third parties;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- future agreements with third parties in connection with the commercialization of our product candidates;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- the rate and degree of market acceptance of our product candidates;
- regulatory developments in the United States and foreign countries;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific or management personnel;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act and as a smaller reporting company under the federal securities laws;
- our use of the proceeds from this offering; and
- our ability to maintain proper and effective internal controls.

These risks are not exhaustive. Other sections of this prospectus may include additional factors that could harm our business and financial performance. New risk factors may emerge from time to time and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements.

You should not rely on forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this prospectus primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition and operating results. We undertake no obligation to update any forward-looking statements made in this prospectus to reflect events or circumstances after the date of this prospectus or to reflect new information or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments.

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

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

INDUSTRY AND MARKET DATA

This prospectus contains estimates, projections and other information concerning our industry and our business, including estimated market size, projected growth rates and the incidence of certain medical conditions. Unless otherwise expressly stated, we obtained this industry, business, market, medical and other information from reports, research surveys, studies and similar data prepared by third parties, industry, medical and general publications, government data and similar sources. In some cases, we do not expressly refer to the sources from which this information is derived. In that regard, when we refer to one or more sources of this type of information in any paragraph, you should assume that other information of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires.

This industry, business, market, medical and other information involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. We have not independently verified any third-party information and cannot assure you of its accuracy or completeness. Although we are responsible for all of the disclosure contained in this prospectus and we believe the market position, market opportunity, market size and medical information included in this prospectus is reliable, such information is inherently imprecise. In addition, projections, assumptions and estimates of our future performance and the future performance of the industry in which we operate is necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section titled “Risk Factors” and elsewhere in this prospectus. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of shares of common stock in this offering will be approximately $ million 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 underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their over-allotment option in full, we estimate that the net proceeds to us will be approximately $ million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

Each $1.00 increase or decrease in the assumed initial public offering price of $ per share would increase or decrease, respectively, our net proceeds by $ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. An increase or decrease of 1,000,000 in the number of shares we are offering would increase or decrease, respectively, the net proceeds from this offering, after deducting underwriting discounts and commissions by $ million, assuming the assumed initial public offering price stays the same.

We currently expect to use our net proceeds from this offering as follows:

- approximately $ million to fund the clinical development of BDC-1001 for the treatment of four distinct groups of patients with HER2-expressing cancers through completion of our existing Phase 1/2 clinical trial;
- approximately $ million to fund completion of IND-enabling studies, chemistry, manufacturing and control, or CMC, activities and the clinical development of our CEA Boltbody ISAC program; and
- the remaining proceeds for PD-L1 Boltbody ISAC program, research and development activities, as well as working capital and general corporate purposes.

However, due to the uncertainties inherent in the product development process, it is difficult to estimate with certainty the exact amounts of the net proceeds from this offering that may be used for the above purposes. Our management will have broad discretion over the use of the net proceeds from this offering. The amounts and timing of our expenditures will depend upon numerous factors including the results of our research and development efforts, the timing and success of preclinical studies and any ongoing clinical trials or clinical trials we may commence in the future, the timing of regulatory submissions and the amount of cash obtained through future collaborations, if any. Following this offering, we will require additional funding in order to complete clinical development and commercialize our lead product candidate, BDC-1001, and complete the clinical development of any additional product candidates.

We believe opportunities may exist from time to time to expand our current business through acquisitions or in-licenses of complementary companies, medicines or technologies. While we have no current agreements, commitments or understandings for any specific acquisitions or in-licenses at this time, we may use a portion of the net proceeds for these purposes.

Pending the use of the proceeds from this offering as described above, we intend to invest the net proceeds in interest-bearing investment-grade securities or government securities.

DIVIDEND POLICY

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and future earnings, if any, to fund the development and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination regarding the declaration and payment of dividends will be at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

CAPITALIZATION

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

- an actual basis;
- a pro forma basis to give effect to (1) the conversion of 70,490,863 shares of convertible preferred stock outstanding as of December 31, 2019, into an equal number of shares of common stock upon the closing of this offering; (2) the issuance of shares of common stock upon the automatic net exercise of outstanding warrants, with an exercise price of $0.01 per share, immediately prior to the closing of 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 (3) the filing and effectiveness of our amended and restated certificate of incorporation; and
- a pro forma as adjusted basis to give further effect to the issuance and sale of shares of common stock in this offering at the 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 underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this information in conjunction with our financial statements and the related notes included elsewhere in this prospectus, the information set forth in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and other financial information contained elsewhere in this prospectus.

	As of December 31, 2019		
	Actual	Pro Forma	Pro Forma As Adjusted(1)
	(In thousands, except share and per share data)		
Cash and cash equivalents	$ 34,826	$	$
Convertible preferred stock, $0.00001 par value—83,541,150 shares authorized, 70,490,863 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	$ 77,505	$	$
Stockholders' equity (deficit):			
Preferred stock, $0.00001 par value—no shares authorized, issued or outstanding, actual; shares authorized, no shares issued or outstanding, pro forma and pro forma as adjusted	—		
Common stock, $0.00001 par value—126,000,000 shares authorized, 13,451,593 shares issued and outstanding, actual; shares authorized, shares issued and outstanding, pro forma; shares authorized, shares issued and outstanding, pro forma as adjusted	—		
Additional paid-in capital	1,825		
Accumulated deficit	(47,671)		
Total stockholders' equity (deficit)	(45,846)		
Total capitalization	$ 31,659	$	$

(1) Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share of common stock, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) each of cash and cash equivalents, additional paid-in capital, total stockholders' equity and total capitalization by $ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions and

estimated offering expenses payable by us. Similarly, an increase (decrease) of 1,000,000 shares of common stock offered by us would increase (decrease) each of cash and cash equivalents, additional paid-in capital, total stockholders' equity and total capitalization by $ million, assuming the assumed initial public offering price of $ per share of common stock, the midpoint of the price range set forth on the cover page of this prospectus, remains the same, after deducting underwriting discounts and commissions. The pro forma as adjusted information is illustrative only, and will depend on the actual initial public offering price, number of shares offered and other terms of this offering determined at pricing.

The outstanding share information in the table above is based on 83,942,456 shares of common stock (including shares of preferred stock on an as-converted basis) outstanding as of December 31, 2019, and excludes:

- 14,109,134 shares of common stock issuable upon the exercise of outstanding stock options as of December 31, 2019 with a weighted-average exercise price of $0.37 per share;
- 6,233,461 additional shares of common stock reserved for future issuance under our 2015 Equity Incentive Plan as of December 31, 2019, which shares will cease to be available for issuance at the time our 2020 Equity Incentive Plan becomes effective in connection with this offering;
- shares of common stock reserved for future issuance under our 2020 Equity Incentive Plan, which will become effective upon the execution of the underwriting agreement for this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan; and
- shares of common stock reserved for future issuance under our 2020 Employee Stock Purchase Plan, which will become effective upon the execution of the underwriting agreement for this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan.

Subsequent to December 31, 2019, and through June 30, 2020 we issued and sold 36,135,260 shares of our Series C-1 preferred stock at a price of $1.15 per share.

DILUTION

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

As of December 31, 2019, our pro forma net tangible book value was $ million, or $ per share of common stock. Pro forma net tangible book value per share represents our total tangible assets less our total liabilities, divided by the number of shares of common stock outstanding as of December 31, 2019, after giving effect to (i) the conversion of all outstanding shares of convertible preferred stock into an equal number of shares of common stock upon the closing of this offering, and (ii) the issuance of shares of common stock upon the automatic net exercise of outstanding warrants, with an exercise price of $0.01 per share, immediately prior to the closing of 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.

After giving further effect to the receipt of the net proceeds from our sale of shares of 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 underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2019, was $ million, or $ per share of common stock. This represents an immediate increase in pro forma net tangible book value of $ per share to our existing stockholders and immediate dilution of $ per share to investors purchasing common stock in this offering.

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

Assumed initial public offering price per share		$
Pro forma net tangible book value per share as of December 31, 2019	$	
Increase in pro forma net tangible book value per share attributed to investors purchasing shares in this offering		
Pro forma as adjusted net tangible book value per share after this offering		
Dilution in pro forma net tangible book value per share to investors in this offering		$

Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted net tangible book value per share after this offering by $ and dilution to investors in this offering by $, assuming that the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions. An increase of 1,000,000 shares in the number of shares of common stock offered by us would increase the pro forma as adjusted net tangible book value by $ per share and the dilution to investors in this offering would decrease by $ per share, assuming the assumed initial public offering price remains the same and after deducting underwriting discounts and commissions. A decrease of 1,000,000 shares in the number of shares of common stock offered by us would decrease the pro forma as adjusted net tangible book value by $ per share and the dilution to investors in this offering would increase by $ per share, assuming the assumed initial public offering price remains the same and after deducting underwriting discounts and commissions.

If the underwriters exercise their option to purchase additional shares in full, the pro forma as adjusted net tangible book value after the offering would be $ per share, the increase in pro forma net tangible book value per share to existing stockholders would be $ per share and the dilution per share to investors in this offering would be $ per share, in each case assuming an initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus.

The dilution information above is for illustration purposes only. Our pro forma as adjusted net tangible book value following the closing of this offering will depend on the actual initial public offering price and other terms of this offering determined at pricing.

The following table summarizes, as of December 31, 2019:

- the total number of shares of common stock purchased from us by our existing stockholders and by investors purchasing shares in this offering;
- the total consideration paid to us by our existing stockholders and by investors purchasing shares in this offering, assuming an initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, before deducting underwriting discounts and commissions and estimated offering expenses payable by us in connection with this offering; and
- the average price per share paid by existing stockholders for shares issued prior to this offering and by investors purchasing shares in this offering.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders			$		$
New investors					
Total		100%	$	100%	

Each $1.00 increase or decrease in the assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease, respectively, the total consideration paid by investors in this offering by $ million and increase or decrease, respectively, the total consideration paid by investors in this offering by %, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and before deducting underwriting discounts and commissions.

Except as otherwise indicated, the above discussion and tables assume no exercise of the underwriters' option to purchase additional shares. If the underwriters exercise their option to purchase an additional shares in full, our existing stockholders would own % and investors in this offering would own % of the total number of shares of common stock outstanding upon the closing of this offering.

The outstanding share information in the table above is based on 83,942,456 shares of common stock (including shares of preferred stock on an as-converted basis), outstanding as of December 31, 2019, and excludes:

- 14,109,134 shares of common stock issuable upon the exercise of outstanding stock options as of December 31, 2019 with a weighted-average exercise price of $0.37 per share;
- 6,233,461 additional shares of common stock reserved for future issuance under our 2015 Equity Incentive Plan as of December 31, 2019, which shares will cease to be available for issuance at the time our 2020 Equity Incentive Plan becomes effective in connection with this offering;
- shares of common stock reserved for future issuance under our 2020 Equity Incentive Plan, which will become effective upon the execution of the underwriting agreement for this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan; and
- shares of common stock reserved for future issuance under our 2020 Employee Stock Purchase Plan, which will become effective upon the execution of the underwriting agreement for this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan.

Subsequent to December 31, 2019, and through June 30, 2020 we issued and sold 36,135,260 shares of our Series C-1 preferred stock at a price of $1.15 per share.

To the extent any outstanding options are exercised, there will be further dilution to investors purchasing in this offering.

SELECTED FINANCIAL DATA

The statements of operations data for the years ended December 31, 2018 and 2019 and balance sheet data as of December 31, 2018 and 2019 have been derived from our audited financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected for any other period in the future.

You should read the selected financial data set forth below in conjunction with our financial statements and the accompanying notes and the information in "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained elsewhere in this prospectus. The selected financial data included in this section are not intended to replace the financial statements and are qualified in their entirety by the financial statements and related notes included elsewhere in this prospectus.

	Year Ended December 31,	
	2018	2019
	(In thousands, except share and per share amounts)	
Statements of Operations Data:		
Collaboration revenue	$ —	$ 215
Operating expenses:		
Research and development	9,420	26,002
General and administrative	2,209	5,182
Total operating expenses	11,629	31,184
Loss from operations	(11,629)	(30,969)
Other income (expense), net:		
Interest income	193	524
Change in fair value of convertible preferred stock purchase right liability	(153)	(42)
Total other income (expense), net	40	482
Net and comprehensive loss	$ (11,589)	$ (30,487)
Net loss per share, basic and diluted	$ (1.00)	$ (2.18)
Weighted-average shares outstanding, basic and diluted	11,555,760	13,954,354
Pro forma net loss per share, basic and diluted(1)		$
Pro forma weighted-average shares outstanding, basic and diluted(1)		

(1) See the statements of operations and comprehensive loss and Note 11 to our financial statements included elsewhere in this prospectus for further details on the calculation of pro forma net loss per share and pro forma weighted-average shares outstanding.

	As of December 31,	
	2018	2019
	(In thousands)	
Balance Sheet Data:		
Cash and cash equivalents	$ 13,634	$ 34,826
Total assets	15,975	48,447
Working capital(1)	11,345	27,244
Total liabilities	3,551	16,788
Convertible preferred stock	28,367	77,505
Accumulated deficit	(17,184)	(47,671)
Total stockholders' deficit	(15,943)	(45,846)

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

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes included elsewhere in this prospectus. Some of the information contained in this discussion and analysis are set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, and includes forward looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the section of this prospectus titled "Risk Factors," 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 clinical-stage immuno-oncology company developing tumor-targeted therapies that leverage the power of the innate and adaptive immune systems. Our proprietary Boltbody ISAC approach uses immunostimulants to engage and activate myeloid cells, including macrophages and dendritic cells, that directly kill tumor cells via phagocytosis and expose tumor neoantigens to the adaptive immune system. This leads to recruitment of cytotoxic T cells and additional tumor-killing myeloid cells thereby converting immunologically "cold" tumors to "hot" tumors. We believe that this process leads to the development of systemic immunological memory with epitope spreading to neoantigens that is critical to achieving a long-term anti-tumor response. Our lead product candidate BDC-1001 is a HER2 Boltbody ISAC comprised of a HER2-targeting biosimilar of trastuzumab conjugated to one of our proprietary TLR7/8 agonists, for the treatment of patients with HER2-expressing solid tumors, including those with HER2-low tumors. In our preclinical studies we have observed complete regression and durable anti-tumor effects as well as a favorable safety profile that are encouraging for the therapeutic potential of BDC-1001. We initiated a Phase 1/2 trial of BDC-1001 in the first quarter of 2020 for the treatment of patients with HER2-expressing solid tumors. We are currently in the dose escalation portion of the trial and expect to move into Phase 2 dose expansions in key solid tumor indications with unmet medical need in 2021. We anticipate that our Phase 1/2 data will provide us with clinical proof of concept for our HER2 Boltbody ISAC approach. We are also advancing additional Boltbody ISAC product candidates targeting CEA and PD-L1, both of which are currently in preclinical development. We anticipate advancing our CEA Boltbody ISAC into the clinic in 2022.

Since our inception in January 2015, we have focused primarily on organizing and staffing our company, business planning, licensing and developing intellectual property, raising capital, developing our product candidates and conducting preclinical studies and early clinical trials. We have not recorded any revenue from product sales. Our only revenue has been derived from our collaboration with Toray. In March 2019, we entered into the Toray Development Agreement, to jointly develop and commercialize a Boltbody ISAC utilizing Toray's proprietary antibody. To date, we have funded our operations primarily through private placements of our convertible preferred stock for gross proceeds of $121.9 million, including Toray's purchase of 5,022,601 shares of Series T convertible preferred stock for gross proceeds of $10.0 million.

We have incurred operating losses since our inception. Our net losses were $11.6 million and $30.5 million in 2018 and 2019, respectively. As of December 31, 2019, we had an accumulated deficit of $47.7 million. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future, and we further expect our expenses will increase substantially as we:

- conduct our ongoing and planned clinical trials;
- continue our research and development programs;
- expand our clinical, regulatory, quality and manufacturing capabilities;

- seek regulatory approvals for our product candidates; and
- operate as a public company.

Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending in particular on the timing of our planned clinical trials and preclinical studies, and our expenditures on other research and development activities.

Components of Results of Operations

Revenue

To date our only revenue has been collaboration revenue derived from our collaboration with Toray. We are collaborating with Toray to develop a Boltbody ISAC that incorporates a proprietary Toray antibody against a novel tumor antigen target. We are jointly responsible for early stage development and for providing technical and regulatory support, and Toray will pay for all of the program expenses through the end of Phase 1 development. In conjunction with the collaboration, Toray purchased 5,022,601 shares of our Series T convertible preferred stock for $10.0 million. We evaluated the collaboration together with Toray's purchase of Series T convertible preferred stock, and allocated $1.5 million from the stock purchase proceeds to deferred revenue, which we recognize, together with payments received from Toray for reimbursement based on agreed-upon full-time equivalent rates and out of pocket costs, as collaboration revenue over time as we fulfill our performance obligation to Toray.

We expect that any collaboration revenue we generate from our current collaboration, and from any future collaboration partners, will fluctuate in the future as a result of the timing and results of development activities and the timing and amount of payments, including upfront and milestone payments, and other factors.

We have not generated any revenue from product sales, and we do not expect to generate any revenue from product sales unless and until we obtain regulatory approval of and commercialize one of our product candidates.

Operating Expenses

Research and Development

Research and development expenses have related primarily to early research and discovery activities and to preclinical and clinical development of our product candidates. Research and development expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received.

Research and development expenses include:

- external research and development expenses, including lab materials and supplies and payments to contract research organizations, investigative sites and consultants to conduct our clinical trials and preclinical and non-clinical studies;
- salaries, payroll taxes, employee benefits and stock-based compensation charges for those individuals involved in research and development efforts;
- costs related to manufacturing our product candidates for clinical trials and preclinical studies, including fees paid to third-party manufacturers; and
- facilities and other allocated expenses which include direct and allocated expenses for rent, insurance and other supplies.

Our direct research and development expenses consist principally of external costs, such as fees paid to contract research organizations and consultants in connection with our preclinical and toxicology studies and costs related to manufacturing materials for our preclinical studies. Since our inception and through December 31, 2019, the vast majority of our third-party expenses related to the research and development of BDC-1001. With the exception of our collaboration with Toray, we do not allocate employee costs and costs associated with our discovery efforts, laboratory supplies and facilities, including other indirect costs, to specific product candidates because these costs are deployed across multiple programs and, as such, are not separately classified. We use internal resources primarily to conduct our research as well as for managing our preclinical development, process development, manufacturing and clinical development activities. We deploy our personnel across all of our research and development activities and, as our employees work across multiple programs, we do not currently track our costs by product candidate.

We plan to substantially increase our research and development expenses for the foreseeable future as we continue the development of our product candidates, particularly as product candidates in later stages of development generally have higher development costs than those in earlier stages of development. We cannot determine with certainty the timing of initiation, the duration or the completion costs of future clinical trials and preclinical studies of our product candidates due to the inherently unpredictable nature of clinical and preclinical development. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations.

We anticipate that we will make determinations as to which product candidates and development programs to pursue and how much funding to direct to each product candidate or program on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments and our ongoing assessments as to each product candidate's commercial potential. We will need to raise substantial additional capital in the future. In addition, we cannot forecast which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

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

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

General and Administrative

General and administrative expenses consist primarily of salaries and employee-related costs, including stock-based compensation, for personnel in executive, finance and other administrative functions. Other significant costs include legal fees relating to intellectual property and corporate matters, professional fees for accounting and consulting services and facility-related costs.

We expect our general and administrative expenses will increase for the foreseeable future to support our increased research and development activities and increased costs of operating as a public company. These increased costs will likely include higher expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with Nasdaq and SEC requirements, director and officer insurance premiums and investor relations costs associated with operating as a public company.

Other Income (Expense), Net

Interest Income, Net

Interest income consists of interest on our cash and cash equivalents.

Change in Fair Value of Preferred Stock Purchase Right Liability

In connection with the issuance of our Series A-1 convertible preferred stock in September 2016, and our Series B convertible preferred stock in July 2018, the investors agreed to buy, and we agreed to sell, additional shares of such preferred convertible stock at the original issue price upon the achievement of pre-defined milestones. These contractual obligations were required to be accounted for as liabilities and remeasured to fair value at each reporting date, with any change in the fair value reported as a component of other income (expense). In February 2018 and July 2019, we issued such additional shares of Series A-1 convertible preferred stock and Series B convertible preferred stock, respectively, and accordingly these contractual obligations were settled and the preferred stock purchase right liabilities were remeasured to fair value on the purchase date and reclassified to permanent equity.

Results of Operations

Comparison of the Years Ended December 31, 2018 and 2019

	Years Ended December 31,		
	2018	2019	Change
		(In thousands)	
Collaboration revenue	$ —	$ 215	$ 215
Operating expenses:			
Research and development	9,420	26,002	16,582
General and administrative	2,209	5,182	2,973
Total operating expenses	11,629	31,184	19,555
Loss from operations	(11,629)	(30,969)	(19,340)
Other income (expense), net	40	482	442
Net loss and comprehensive loss	$(11,589)	$ (30,487)	$(18,898)

Collaboration Revenue

Revenue increased $0.2 million from 2018 to 2019. The increase in revenue was a result of the execution of the Toray Development Agreement in March 2019 and the recognition of the transaction price proportional to the hours incurred and the total estimated hours to be incurred to perform the services over the period using an input method based on project hours.

Research and Development Expenses

Research and development expenses increased by $16.6 million from $9.4 million in 2018 to $26.0 million in 2019. The increase was due primarily to $12.2 million of higher expenses related to BDC-1001 and our other preclinical programs as we completed our GLP toxicology program and submitted our IND application for BDC-1001, as well as $2.9 million in higher personnel-related expenses due to increased headcount and $1.2 million in higher facilities-related expenses.

General and Administrative Expenses

General and administrative expenses increased by $3.0 million from $2.2 million in 2018 to $5.2 million in 2019. The increase was due primarily to $1.2 million in higher professional services expenses related to accounting services, legal fees and other professional services and $1.5 million in higher personnel-related expenses due to increased headcount.

Other Income (Expense), Net

Net other income was approximately $0.1 million and $0.5 million in 2018 and 2019, respectively. The increase is primarily due to higher interest income as a result of higher cash and cash equivalent balances resulting from the net proceeds of $48.6 million from our sale of our convertible preferred stock in July 2019 and the receipt of $10.0 million from the sale of our convertible preferred stock and the execution of the Toray Development Agreement in March 2019.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred net losses and negative cash flows from operations since our inception and anticipate we will continue to incur net losses for the foreseeable future. As of December 31, 2019, we had an accumulated deficit of $47.7 million. Our net loss was $11.6 million and $30.5 million for December 31, 2018 and 2019, respectively, and we expect to incur additional losses in the future. We evaluated our current cash position, historical results, forecasted cashflows and plans in regards to liquidity. Considering all of these factors, we believe, absent this offering, that there is substantial doubt about our ability to continue as a going concern for the next 12 months.

To date, we have funded our operations primarily through the private placement of our convertible preferred stock and have received gross proceeds of $121.9 million from such sales. As of December 31, 2019, we had cash and cash equivalents of $34.8 million. In June 2020, we received aggregate net proceeds of $41.3 million from the sale of 36,135,260 shares of Series C-1 convertible preferred stock at $1.15 per share. Upon the achievement of a specified milestone, the purchasers have agreed to purchase, and we have agreed to sell, an additional 39,277,459 shares of Series C-2 convertible preferred stock at $1.3225 per share for potential additional gross proceeds of $51.9 million.

The following table sets forth a summary of our cash flows for each of the periods indicated:

	Years Ended December 31,	
	2018	2019
	(In thousands)	
Net cash provided by (used in)		
Operating activities	$ (9,872)	$(26,343)
Investing activities	(290)	(508)
Financing activities	19,094	48,627
Net increase in cash, cash equivalents and restricted cash	$ 8,932	$ 21,776

Operating Activities

Net cash used in operating activities was $9.9 million and $26.3 million for 2018 and 2019, respectively. Net cash used in operating activities for 2018 was primarily due to our net loss of $11.6 million, adjusted for $0.6 million of noncash charges and a $1.1 million change in operating assets and liabilities. The change in net operating assets was primarily due to increases in our accounts payable and accrued expenses related to an increase in research and development expenses and the timing of vendor payments. Net cash used in operating activities for 2019 was primarily due to our net loss of $30.5 million, adjusted for $1.9 million of noncash charges and a $2.3 million change in operating assets and liabilities. The change in net operating assets was primarily due to increases in our accounts payable and accrued expenses related to an increase in research and development expenses and the timing of vendor payments, as well as an increase in our deferred revenue related to the unsatisfied performance obligation under the Toray Development Agreement entered into during 2019, partially offset by an increase in our operating lease liabilities.

Investing Activities

Net cash used in investing activities was due to purchases of other assets and property and equipment in all periods presented.

Financing Activities

Net cash provided by financing activities was $19.1 million for 2018 was due to net proceeds of $19.1 million from the issuance of convertible preferred stock in July 2018. Net cash provided by financing activities was $48.6 million for 2019 was due to net proceeds of $48.6 million from the issuance of 39,913,673 shares of our convertible preferred stock.

Funding Requirements

Without giving effect to the anticipated net proceeds from this offering, we do not believe our existing cash and cash equivalents will be sufficient to fund our operations through the next 12 months. As a result, we have concluded that there is substantial doubt about our ability to continue as a going concern. See Note 1 to our financial statements included elsewhere in this prospectus for additional information on our assessment. Similarly, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of and for the year ended December 31, 2019, describing the existence of substantial doubt about our ability to continue as a going concern.

Based upon our current operating plans, we believe that the estimated net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our operations for at least the next months from the date of this prospectus. In particular, we expect the net proceeds from this offering will allow us to conduct our clinical trials, fund continued research and development of BDC-1001 in several applications, and fund other research and development activities. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. Additionally, the process of testing product candidates in clinical trials is costly, and the timing of progress and expenses in these trials is uncertain.

Our future capital requirements will depend on many factors, including:

- the type, number, scope, progress, expansions, results, costs and timing of our clinical trials;
- preclinical studies for our product candidates or other potential product candidates or indications which we are pursuing or may choose to pursue in the future;

- the outcome, timing and costs of regulatory review of our product candidates;
- the costs and timing of manufacturing for our product candidates, including commercial manufacturing;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting;
- the costs associated with hiring additional personnel and consultants as our preclinical and clinical activities increase;
- the costs and timing of establishing or securing sales and marketing capabilities if any product candidate is approved;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third party payors and adequate market share and revenue for any approved products;
- patients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements;
- the costs of obtaining, maintaining, defending and enforcing our patent and other intellectual property rights; and
- costs associated with any product candidates, products or technologies that we may in-license or acquire.

Until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our cash needs through public or private equity or debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, or other similar arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams or research programs or may have to grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations and commitments at December 31, 2019:

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
	(In thousands)				
Operating lease obligations(1)	$11,863	$3,644	$4,051	$3,198	$ 970
Total	$11,863	$3,644	$4,051	$3,198	$ 970

(1) Our operating lease obligations relate to our two facilities in Redwood City, California. We lease 9,400 square feet of office space under an operating lease that expires in January 2023 and 25,956 square feet of

office and laboratory space under an operating lease that expires in July 2025. Subsequent to December 31, 2019, we entered into a lease agreement for 45,690 square feet of office and laboratory space adjacent to our headquarters facility in Redwood City, California, which is anticipated to expire in May 2031. The new lease agreement also provides a lease for our existing 25,956 square foot facility making it coterminous with the new facility. Our contractual obligations for the term of the new lease agreement are approximately $33.8 million for the new facility and approximately $11.8 million for the extension of our existing facility.

We enter into contracts in the normal course of business with clinical trial sites and clinical supply manufacturers and with vendors for preclinical studies and other services and products for operating purposes. These contracts generally provide for termination after a notice period, and, therefore, are cancelable contracts and not included in the table above.

We have not included in the table above potential contingent payment obligations pursuant to the supply agreement and license agreements discussed below, as the timing and likelihood of such payments is not known. These payments generally become due and payable only upon achievement of certain development, regulatory or commercial milestones.

Contract Supply Agreement

In March 2019, we entered into a supply agreement with EirGenix, Inc., pursuant to which EirGenix agreed to supply us, on a non-exclusive basis, bulk drug substance of EG12014, its monoclonal antibody being developed as a biosimilar of trastuzumab, which we use in the manufacture of our BDC-1001 HER2 Boltbody ISAC. Under this agreement, we are required to make milestone payments to EirGenix up to an aggregate of $2.0 million based on achievement of certain regulatory milestones by our HER2 Boltbody ISAC. For more information regarding our supply agreement with EirGenix, please see “Business—Manufacturing.”

License and Collaboration Agreements

In May 2015 and June 2018, we entered into license agreements with Stanford, pursuant to which Stanford granted us worldwide exclusive licenses under certain patents related to our proprietary Boltbody ISAC technology and myeloid modulation for cancer immunotherapy, respectively. Under these agreements, we are obligated to pay annual license maintenance fees, which are nominal and will be creditable against any royalties payable to Stanford under such agreement in the applicable year. We are required in each agreement to make milestone payments up to an aggregate of $0.4 million for the first licensed product under such agreement that meets certain patent issuance, clinical and regulatory milestones, and an additional milestone payment of $0.2 million for each additional regulatory approval. We also agreed in each agreement to pay Stanford tiered royalties on our and our sublicensees’ net sales of licensed products, at low single-digit percentage rates, subject to certain customary reductions. Our royalty obligations continue for the term of each agreement and we are required to pay royalties on any licensed products made, used, imported or offered for sale during the term of such agreement but sold after the term of the agreement. In addition, we are obligated in each agreement to pay Stanford a percentage, based on the date of sublicensing, of certain consideration we receive as a result of granting sublicenses to the licensed patents. Pursuant to each agreement, we will reimburse Stanford’s patent expenses, including reasonable costs incurred in assisting us with prosecuting and maintaining licensed patents. For more information regarding our license agreement with Stanford, please see “Business—License and Collaboration Agreements.”

Off-Balance Sheet Arrangements

During 2018 and 2019 we did not have any off-balance sheet arrangements as defined under the rules and regulations of the SEC.

Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

As of December 31, 2019, our cash and cash equivalents consists of cash in readily available checking accounts and money market accounts. We do not hold any short-term investments. As a result, the fair value of our portfolio is relatively insensitive to interest rate changes.

Foreign Currency Risk

We are exposed to market risk related to changes in foreign currency exchange rates. We contract with vendors that are located outside the United States and certain invoices are denominated in foreign currencies. We are subject to fluctuations in foreign currency rates in connection with the arrangements. We do not currently hedge our foreign currency exchange risk. As of December 31, 2019, we had liabilities of $0.4 million denominated in foreign currencies. Due to the nature of our cash and cash equivalents, an immediate hypothetical 10% change in interest rates would not have a material effect on the fair value of our cash and cash equivalents.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our financial statements and accompanying notes. We base our estimates on historical experience, known trends and events and various other factors that are believed to be 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. 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 financial statements included elsewhere in this prospectus, we believe the following accounting policies and estimates to be most critical to the preparation of our financial statements.

Revenue Recognition

Effective January 1, 2018, we adopted the provisions of ASC Topic 606, *Revenue from Contracts with Customers*, or ASC 606, using a modified retrospective method of transition. Under ASC 606, we recognize revenue as research and development activities are performed in an amount that reflects the consideration we expect to receive in exchange for those goods and services.

For all periods presented, we recognized revenue in accordance with the provisions of ASC 606. In accordance with ASC 606, we perform the following five steps in determining the appropriate amount of revenue to be recognized as we fulfill our obligations under each of these agreements:

- identification of the promised goods and services in the contract;
- determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract;
- measurement of the transaction price, including any constraint on variable consideration;
- allocation of the transaction price to the performance obligations; and
- recognition of revenue when, or as, we satisfy each performance obligation.

If an agreement includes a license to our intellectual property and that license is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues allocated to the

license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

With respect to our assessment of the Toray Development Agreement, we identified multiple promises to deliver goods and services, which include at inception of the agreement: (i) a license to technology and patents, information and know-how; and (ii) development services, including research services, technical and regulatory support provided by us. We have identified one performance obligation for all the deliverables under the agreement since the delivered elements are either not capable of being distinct or are not distinct within the context of the contract. Accordingly, we will recognize revenue for the fixed or determinable collaboration in an amount proportional to the hours incurred and the total estimated hours to be incurred over the period over which it expects to deliver its performance obligations. We periodically review and update the estimated hours, when appropriate, which adjusts the percentage of revenue that is recognized for the period. While such changes to our estimates have no impact on our reported cash flows, the amount of revenue recorded in the period could be materially impacted.

Amounts received prior to satisfying the above revenue recognition criteria were recognized as deferred revenue until all applicable revenue recognition criteria were met. Deferred revenue represented the portion of payments received that have not been earned.

Accrued Research and Development Expenses

We are required to estimate our expenses resulting from our obligations under contracts with vendors, consultants and CROs, in connection with conducting research and development activities. The financial terms of these contracts vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. We reflect research and development expenses in our financial statements by matching those expenses with the period in which services and efforts are expended.

We account for these expenses according to the progress of the preclinical study as measured by the timing of various aspects of the study or related activities. We determine accrual estimates through review of the underlying contracts along with discussions with our third-party services providers and our personnel as to the progress of studies, or other services being conducted. During the course of a study, we adjust our rate of expense recognition if actual results differ from its estimates.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

Preferred Stock Purchase Right Liabilities

We have entered into convertible preferred stock financings where, in addition to the initial closing, investors agree to buy, and we agree to sell, additional shares of that convertible preferred stock at a fixed price in the event that certain agreed-upon milestones are achieved. We evaluate this purchase right and assesses whether it meets the definition of a freestanding instrument and, if it does, determine the fair value of the purchase right liability and record it on the balance sheet with the remainder of the proceeds raised being allocated to convertible preferred stock. The preferred stock purchase right liability is revalued at each reporting period with changes in the fair value of the liability recorded as a component of other income (expense), net in

the statements of operations and comprehensive loss. The preferred stock purchase right liability is revalued at settlement and the resultant fair value is then reclassified to convertible preferred stock at that time. The estimated fair value of the preferred stock purchase right liability is determined using valuation models that consider the probability of achieving the requisite milestones, our cost of capital, the estimated time period the preferred stock right would be outstanding, consideration received for the convertible preferred stock, the number of shares to be issued to satisfy the preferred stock purchase right and at what price, and probability of the consummation of an initial public offering, as applicable.

There are significant judgments and estimates inherent in the determination of the fair value of our preferred stock purchase right liability. If we had made different assumptions, the carrying value of our preferred stock, net loss and net loss per common share could have been significantly different.

Stock-Based Compensation Expense

Stock-based compensation expense represents the cost of the grant date fair value of equity awards recognized over the requisite service period of the awards (usually the vesting period) on a straight-line basis. We estimate the fair value of stock option awards using the Black-Scholes option pricing model and recognize forfeitures as they occur.

For restricted stock awards, the fair value of the award is the estimated fair value of our common stock on the grant date, as determined by our board of directors.

The Black-Scholes option pricing model requires the use of subjective assumptions, including the risk-free interest rate, the expected stock price volatility, the expected term of stock options, the expected dividend yield and the fair value of the underlying common stock on the date of grant. Changes in the assumptions can materially affect the fair value and ultimately how much stock-based compensation expense is recognized. These inputs are subjective and generally require significant analysis and judgment to develop. See Note 10 to our financial statements included elsewhere in this prospectus for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options granted in 2018 and 2019.

As of December 31, 2019, the unrecognized stock-based compensation expense related to stock options was $2.6 million and is expected to be recognized as expense over a weighted-average period of approximately 3.3 years.

Common Stock Valuations

We are required to estimate the fair value of the common stock underlying our equity awards when performing fair value calculations. The fair value of the common stock underlying our equity awards was determined on each grant date by our board of directors, taking into account input from management and independent third-party valuation analyses. All options to purchase shares of our common stock are intended to be granted with an exercise price per share no less than the fair value per share of our common stock underlying those options on the date of grant, based on the information known to us on the date of grant. In the absence of a public trading market for our common stock, on each grant date we develop an estimate of the fair value of our common stock in order to determine an exercise price for the option grants. Our determinations of the fair value of our common stock were made using methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants Accounting and Valuation Guide: *Valuation of Privately Held Company Equity Securities Issued as Compensation*, or the Practice Aid.

Our board of directors considered various objective and subjective factors, along with input from management, to determine the fair value of our common stock, including:

- our stage of development and business strategy, including the status of research and development efforts of our product candidates and the material risks related to our business and industry;

- our results of operations and financial position, including our levels of available capital resources;
- the valuation of publicly traded companies in the life sciences and biotechnology sectors, as well as recently completed mergers and acquisitions of peer companies;
- the lack of marketability of our common stock as a private company;
- the prices of our convertible preferred stock sold to investors in arm's length transactions and the rights, preferences and privileges of our convertible preferred stock relative to those of our common stock;
- the likelihood of achieving a liquidity event for the holders of our common stock, such as an initial public offering or a sale of our company, given prevailing market conditions;
- trends and developments in our industry; and
- external market conditions affecting the life sciences and biotechnology industry sectors.

The Practice Aid prescribes several valuation approaches for setting the value of an enterprise, such as the cost, income and market approaches and various methodologies for allocating the value of an enterprise to its common stock. The cost approach establishes the value of an enterprise based on the cost of reproducing or replacing the property less depreciation and functional or economic obsolescence, if present. The income approach establishes the value of an enterprise based on the present value of future cash flows that are reasonably reflective of our future operations, discounting to the present value with an appropriate risk adjusted discount rate or capitalization rate. The market approach is based on the assumption that the value of an asset is equal to the value of a substitute asset with the same characteristics. Each valuation methodology was considered in our valuations.

Through December 31, 2019, we estimated the enterprise value of our business and underlying stock option grants using the income approach and the Option Pricing Method, or OPM, to allocate enterprise value to the various share classes. The present value of future cash flows was utilized to estimate our current equity value. Under the OPM, shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The values of the preferred and common stock are inferred by analyzing these options. We believed the OPM was the most appropriate method at that time given the uncertainty of various potential liquidity outcomes and the difficulty of selecting and supporting specific outcomes given our early stage of development. In 2020, we changed to a hybrid of the OPM and Probability-Weighted Expected Return Method, or PWERM. The PWERM is a scenario-based analysis that estimates the value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to us, as well as the economic and control rights of each share class. Under this hybrid method, we considered the expected initial public offering liquidity scenario, but also used the OPM to capture all other scenarios in the event a near-term initial public offering does not occur. The IPO liquidity scenario equity value was estimated based on recent IPO valuations in the life sciences and biotechnology sectors, discounted to present value based on anticipated IPO timing. The OPM scenario equity value was determined based on the terms of a recent arm's-length convertible preferred stock financing, which implies an equity value by taking into account our capital structure and the rights and preferences of each class of our stock.

We further adjusted the fair value of our common stock to recognize the lack of liquidity associated with shares of our common stock due to the fact that our stockholders do not have access to public trading markets similar to those enjoyed by stockholders of public companies. Accordingly, we applied discounts to reflect this lack of marketability of our common stock based on the weighted-average expected time to liquidity.

There are significant judgments and estimates inherent in the determination of the fair value of our common stock. These judgments and estimates include assumptions regarding our future operating performance, the time to complete an initial public offering or other liquidity event and the determination of the appropriate valuation methods. If we had made different assumptions, our stock-based compensation expense, net loss and net loss per

common share could have been significantly different. Following the closing of this offering, the fair value of our common stock will be based on the closing price of our common stock as reported by the Nasdaq Global Market.

Based on the assumed public offering price of $ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, the intrinsic value of all outstanding stock options as of December 31, 2019 was $ million, of which $ million related to vested options and $ million related to unvested options.

Emerging Growth Company and Smaller Reporting Company Status

In April 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" may take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Therefore, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards, and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. We intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act.

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 as of the last business day of the second fiscal quarter 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 as of the last business day of the second fiscal quarter. 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.

Net Operating Loss and Research and Development Carryforwards and Other Income Tax Information

As of December 31, 2019, we had federal and state NOL carryforwards of $46.2 million and $46.3 million, respectively. The federal NOLs include $4.4 million that may be used to offset up to 100% of future taxable income and will begin to expire in 2035 unless previously utilized and $41.8 million that are not subject to expiration. The net operating loss carryforwards subject to expiration could expire unused and be unavailable to offset future income tax liabilities. The federal NOLs not subject to expiration are available to offset up to 80% of taxable income each year indefinitely. The state NOL carryforwards will begin to expire in 2035, unless previously utilized. As of December 31, 2019, we also had federal and state research credit carryforwards of $1.5 million and $1.3 million, respectively. The federal research and development tax credit carryforwards expire beginning in 2038 unless previously utilized, and the state research and development tax credit carryforwards do not expire. We have established valuation allowances against our NOLs and research and development credits due to the uncertainty surrounding the realization of these assets.

We have not completed a Section 382 study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our formation due to the complexity and cost associated with such a study and the fact that there may be additional such ownership changes in the future. Pursuant to Sections 382 and 383 of the Internal Revenue Code, annual use of our NOL and research and development tax credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period.

Recently Issued Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board issued Accounting Standards Update, or ASU, No. 2016-02, *Leases (Topic 842)*. ASU 2016-02 provides new comprehensive lease accounting guidance that supersedes existing lease guidance. The new standard establishes a right-of-use, or ROU, model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The guidance is effective for all public business entities and certain not-for-profit entities in fiscal years beginning after December 15, 2018, and for all other entities in fiscal years beginning after December 15, 2021. We adopted Topic 842 on January 1, 2019 using the modified retrospective method and did not restate comparative periods. We elected to apply the "practical expedient package," which permits us to not reassess previous conclusions around lease identification, lease classification and initial direct costs. Further, we made an accounting policy election to exclude leases with terms of 12 months or less from the recognition requirements. We did not elect the use of the hindsight practical expedient. As a result of the adoption of the standard on January 1, 2019, we recognized lease liabilities based on the present value of the total fixed payments for our leases in the amount of $1.9 million and ROU assets in the amount of $2.0 million on our balance sheet. The adoption of the new standard did not have a material impact on our statements of operations and comprehensive loss or cash flows.

In August 2017, the FASB issued ASU No. 2017-12, *Derivatives and Hedging (Topic 815), Targeted Improvements to Accounting for Hedging Activities*. The new guidance better aligns an entity's risk management activities and financial reporting for hedging relationships through changes to both the designation and measurement guidance for qualifying hedging relationships and the presentation of hedge results. The new guidance also makes certain targeted improvements to simplify the application of hedge accounting guidance and ease the administrative burden of hedge documentation requirements and assessing hedge effectiveness. The standard is effective for fiscal years beginning after December 15, 2018, and early adoption is permitted. We elected to early adopt the standard on January 1, 2018. The adoption of the new standard did not have a material impact on our financial statements and related disclosures.

New Accounting Pronouncements Not Yet Adopted

In August 2018, the FASB issued ASU No. 2018-13, *Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*. The primary focus of the standard is to improve the effectiveness of the disclosure requirements for fair value measurements. The standard is effective for fiscal years and interim periods beginning after December 15, 2019. We are currently evaluating the impact of adopting this standard.

BUSINESS

Overview

We are a clinical-stage immuno-oncology company developing tumor-targeted therapies that leverage the power of the innate and adaptive immune systems. Our proprietary Boltbody ISAC approach uses immunostimulants to engage and activate myeloid cells, including macrophages and dendritic cells, that directly kill tumor cells via phagocytosis and expose tumor neoantigens to the adaptive immune system. This leads to recruitment of cytotoxic T cells and additional tumor-killing myeloid cells thereby converting immunologically "cold" tumors to "hot" tumors. We believe that this process leads to the development of systemic immunological memory with epitope spreading to neoantigens that is critical to achieving a long-term anti-tumor response. Our lead product candidate BDC-1001 is a HER2 Boltbody ISAC comprised of a HER2-targeting biosimilar of trastuzumab conjugated to one of our proprietary TLR7/8 agonists, for the treatment of patients with HER2-expressing solid tumors, including those with HER2-low tumors. In our preclinical studies we have observed complete regression and durable anti-tumor effects as well as a favorable safety profile that are encouraging for the therapeutic potential of BDC-1001. We initiated a Phase 1/2 trial of BDC-1001 in the first quarter of 2020 for the treatment of patients with HER2-expressing solid tumors. We are currently in the dose escalation portion of the trial and expect to move into Phase 2 dose expansions in key solid tumor indications with unmet medical need in 2021. We anticipate that our Phase 1/2 data will provide us with clinical proof of concept for our HER2 Boltbody ISAC approach. We are also advancing additional Boltbody ISAC product candidates targeting CEA and PD-L1, both of which are currently in preclinical development. We anticipate advancing our CEA Boltbody ISAC into the clinic in 2022.

Our Boltbody ISAC approach is pioneering a new category of immunotherapies that combines the precision of antibody targeting with the strength of the innate and adaptive immune systems by activating and recruiting myeloid cells, thereby re-programming the tumor microenvironment to invoke an adaptive immune response. Our Boltbody ISACs are delivered systemically but act locally through a highly targeted approach that triggers a profound localized anti-tumor immune cascade through the following "Three-Factor Authentication" process designed to optimize safety and avoid systemic immune stimulation.

1. **Tumor antigen recognition:** Our selective and specific tumor-targeting Boltbody ISACs recognize and bind specifically to the target antigen-expressing tumors.
2. **FcR-dependent phagocytosis:** Engagement of optimized Fc domains triggers myeloid-mediated phagocytosis of the Boltbody ISAC-bound tumor cell. This process directly kills antigen-expressing tumor cells and delivers tumor neoantigens to myeloid cells.
3. **TLR-mediated activation:** Our proprietary TLR agonist conjugates activate myeloid cells and enable the presentation of tumor-associated neoantigens to cytotoxic T cells, thereby initiating the body's adaptive anti-tumor immune response and converting immunologically "cold" tumors to "hot" tumors. Furthermore, these activated myeloid cells also encourage additional myeloid cell-mediated phagocytosis to amplify the innate and adaptive immune responses.

During this "Three-Factor Authentication," tumor-associated myeloid cells engulf the Boltbody ISAC-bound tumor cells, become armed with tumor neoantigens, and migrate to the lymph nodes where they mediate the activation and rapid expansion of tumor-reactive T cells to eliminate tumor cells, including those without the initial target antigen. As a result, the patient's immune system determines which neoantigens are most important to eliminate the target tumors. We believe that this represents the development of systemic immunological memory with epitope spreading to neoantigens that will result in long-term anti-tumor responses.

Unlike immuno-oncology approaches that solely seek to relieve immune suppression, Boltbody ISACs act by engaging the immune system at multiple points in the cancer immunity cycle. Boltbody ISACs activate tumor-associated myeloid cells, leading to tumor phagocytosis and the presentation of tumor neoantigens to T cells that enable a productive anti-cancer response. The following key features provide us with the opportunity

to develop robust applications across various solid tumors designed to deliver effective and safe therapeutics that provide durable responses.

- *Ability to address difficult-to-treat solid tumors including those refractory to current treatments*;
- *Engaging the body's innate and adaptive immune responses;*
- *Generation of immunological memory with epitope spreading to provide long-term anti-tumor responses and protect against recurrence;*
- *Ability to target tumor antigens with less dense cell surface expression;*
- *Capability to modulate myeloid cell activity via TLR potency and selectivity and Fc engineering;*
- *Favorable safety and tolerability profile by avoiding unintended systemic immune stimulation*; *and*
- *Potential to benefit patients who have a defective adaptive immune response.*

Our lead product candidate, BDC-1001, is currently in clinical development for the treatment of patients with HER2-expressing solid tumors, including those with HER2-low tumors. We have designed BDC-1001 as a Boltbody ISAC comprised of a HER2-targeting biosimilar trastuzumab conjugated to one of our proprietary TLR7/8 agonists to maximize the potential anti-tumor response. Through our preclinical studies, we have demonstrated that systemic administration of HER2 Boltbody ISACs exhibited localized immune activation that resulted in single agent activity that generated complete tumor regression and immunological memory against cancers with epitope spreading. Furthermore, preclinical data showed compelling anti-tumor efficacy against established tumors resistant to trastuzumab and ado-trastuzumab emtansine, and immunological memory providing protection against tumor cells that no longer express the HER2 antigen. Our observed preclinical anti-tumor response coupled with a favorable safety profile based upon GLP toxicology studies leads us to believe that BDC-1001 offers the potential for long-term and meaningful response for patients with HER2-expressing cancers, including HER2-low tumors. We initiated a Phase 1/2 trial of BDC-1001 in the first quarter of 2020 for the treatment of patients with HER2-expressing solid tumors. We are currently in the dose escalation portion of the trial and expect to advance into Phase 2 dose expansions in 2021 in four clinically important and commercially compelling indications. We anticipate that our Phase 1/2 data will provide us with clinical proof of concept for our HER2 Boltbody ISAC approach.

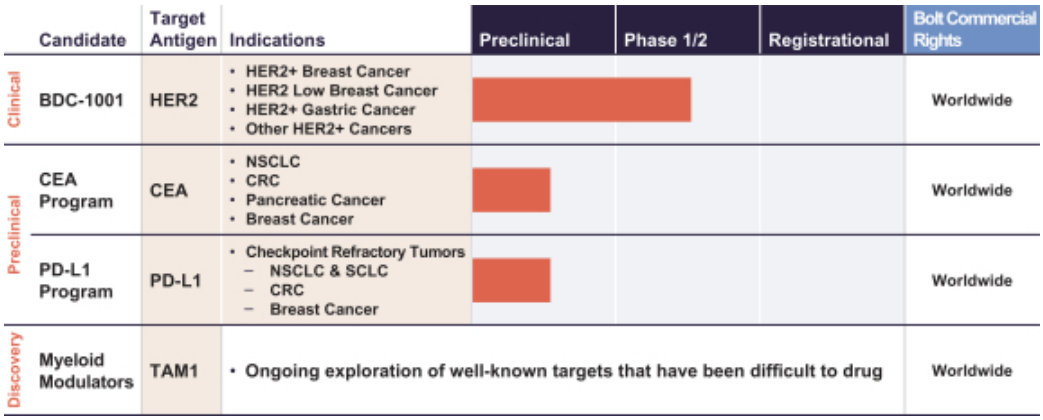
Our second program focuses on CEA, a well-known tumor antigen that is overexpressed in various solid tumors with significant unmet medical need including, but not limited to, colorectal cancer, non-small cell lung cancer, pancreatic cancer and breast cancer. CEA is upregulated on the cell surface of these cancers and displays minimal receptor-mediated internalization into the cancer cell. CEA allows us to target these cancers, some of which are immunologically "cold." In our preclinical studies, we have observed promising *in vivo* and *in vitro* activity with notable anti-tumor activity in xenograft models. We anticipate advancing our CEA Boltbody ISAC into the clinic in 2022.

Our third program, a PD-L1 Boltbody ISAC, focuses on the treatment of patients with tumors that are nonresponsive or become refractory to immune checkpoint blockade. This encompasses more than 15 different tumor types impacting the lives of millions of patients yearly. Our PD-L1 program is a trifunctional therapeutic with the following mechanism: 1) Antibody-dependent cellular phagocytosis of the tumor, 2) Myeloid activation and engagement of an adaptive T cell response, and 3) PD-L1/PD-1 checkpoint inhibition. In our preclinical studies, we have observed superior anti-tumor efficacy compared to checkpoint inhibition alone, and induced immunological memory in syngeneic mice models with our PD-L1 Boltbody ISAC.

Our Pipeline

We are leveraging our myeloid biology expertise to build a robust pipeline of immune-stimulating, myeloid-engaging therapeutics. Our current pipeline is represented in the figure below. In addition to the programs below,

we are also exploring various well-known targets that have been traditionally difficult to drug and where our myeloid expertise and the Boltbody ISAC approach may unlock the potential of these promising antigens as viable cancer targets. We hold exclusive worldwide rights to all of the listed programs.



In this graphic, HER2 = human epidermal growth factor receptor 2; CEA = carcinoembryonic antigen; PD-L1 = programmed cell death-ligand 1; TAM1 = tumor-associated macrophage 1 antigen; NSCLC = non-small cell lung cancer; CRC = colorectal cancer; and SCLC = small cell lung cancer.

Our Corporate History and Team

Our company was founded in 2015 to capture the pioneering work of our founder Dr. Edgar G. Engleman, who is Professor of Pathology and Medicine at Stanford University School of Medicine and Co-Director of the Immunology and Immunotherapy Program of the Stanford Cancer Institute. Dr. Engleman's expertise in translating cancer immunotherapeutics from bench to bedside includes the discovery of a dendritic cell-based technology that was the basis for the first active immunotherapy approved by the FDA. It was also at the Engleman Laboratory that the promising new immunotherapy activating dendritic cells in tumors *in situ*, without requiring their removal and activation *in vitro*, was discovered in collaboration with Dr. Yaron Carmi and led to the founding of Bolt Biotherapeutics. Continued research in the Engleman Laboratory led Dr. Michael Alonso, a scientific co-founder, and Dr. Shelley Ackerman to invent the technology that formed the basis of our promising Boltbody ISAC platform.

We have assembled a highly qualified management team with broad experience in myeloid biology, drug discovery and development to execute our mission. Our scientific founders and our management team collectively have extensive experience in immunology, oncology drug development and patient care. We are industry veterans with prior experience at companies such as Alder, Astellas, Gilead, Jazz, Roche / Genentech, Sunesis and others. Together, our team has a proven track record in the discovery, development and commercialization of numerous approved therapeutics such as Alecensa, Cytovene, Evenity, Gazyva, Herceptin, Kadcyla, Polivy, Perjeta, Rituxan, Tecentriq, Valcyte, Venclexta and Vyepti while at other companies. Since our inception through June 30, 2020, we have raised an aggregate of $122 million of gross proceeds and our investors include Novo Holdings, Vivo Capital, Pivotal bioVenture Partners, Sofinnova Investments, Nan Fung Life Sciences, RA Capital Management, Surveyor Capital (a Citadel Company), Rock Springs Capital, Pfizer Ventures and Samsara BioCapital.

Strategy

Our goal is to become a leading immuno-oncology company, leveraging our myeloid biology expertise and proprietary Boltbody ISAC approach to discover, develop and commercialize transformative treatments to address key unmet medical needs in cancer. The key components of our strategy are to:

- **Leverage our Boltbody ISAC approach and myeloid expertise to develop our pipeline of immune-activating therapies.** Our expertise in myeloid biology and immuno-oncology has led us to research various tumor antigens across solid tumors where significant unmet medical needs remain. Our expertise in medicinal chemistry and mAb engineering and our ability to modulate TLR linker-payloads allow us to optimize the therapeutic profile of our product candidates for any particular tumor antigen as part of our research and discovery efforts to produce durable anti-tumor responses. We believe that our approach is applicable to a broad spectrum of tumor-associated antigens expressed on cancers, including those that are refractory to existing therapies.
- **Rapidly advance the development of our lead Boltbody ISAC product candidate, BDC-1001, for the treatment of patients with HER2-expressing cancers.** BDC-1001 is currently in an ongoing Phase 1/2 clinical trial for the treatment of patients with HER2-expressing solid tumors. Based on our promising preclinical activity, BDC-1001 has the potential to be effective both as a monotherapy and in combination with existing therapies for patients with HER2-expressing solid tumors. While currently approved HER2-targeting agents are important and effective treatment options for some patients with HER2-expressing solid tumors, a large percentage of patients do not respond to these therapies, develop tumor progression after initial response or are not indicated for current HER2-targeting therapies. These sizable patient populations do not have adequate treatment options available to them. Therefore, we intend to rapidly advance development of BDC-1001 across multiple HER2-expressing cancers, including in both HER2-expressing and certain HER2-low cancers.
- **Expeditiously advance our pipeline focused on additional promising targets including CEA and PD-L1.** Our robust pipeline includes a CEA Boltbody program and a PD-L1 Boltbody program for which we have observed promising preclinical activity. These programs represent additional opportunities to differentiate our Boltbody ISAC approach from traditional immuno-oncology therapies that seek to inhibit key oncology pathways. By contrast, our Boltbody ISACs utilize target tumor antigens to bring nearby myeloid cells to the targeted tumor microenvironment to initiate robust innate and adaptive immune responses. We believe that this differentiated approach could improve the lives of patients by producing durable anti-tumor responses.
- **Continue to invest in our myeloid expertise and Boltbody ISAC approach to explore the full potential of our targeted immunotherapies for the treatment of cancer.** Our expertise, rigor and unbiased data-driven approach may lead to additional research and discovery programs that are complementary or independent of our Boltbody ISAC approach and our growing library of innate immune stimulators. Our research and discovery efforts are exploring additional immune agonists for the Boltbody ISAC approach as well as identifying novel targets in tumor-associated myeloid cells that can be targeted for profound anti-tumor outcomes. We believe such agents have the potential to reprogram tumor-supportive macrophages into tumor-destructive macrophages to elicit a productive anti-tumor immune response. This approach could potentially provide an avenue to further develop precision medicine with an immune modulator.
- **Selectively enter into collaborations to expand and enhance our proprietary Boltbody ISAC approach and myeloid expertise to increase the impact of our future product candidates.** In order to advance treatment options for patients, we may selectively collaborate with other companies with complementary technology or resources that could maximize the value of our product candidates and also expand our pipeline. Such collaborations may provide us with novel technologies, targets, agents or approaches that complement our myeloid expertise and innovative Boltbody ISAC approach to improve the lives of patients with cancer.

Background of Myeloid Cell Biology

Overview of Myeloid Cell Biology in Cancer

Myeloid cells are a group of immune cells that belong to the innate immune system, consisting of cell types known as monocytes, macrophages, dendritic cells and granulocytes. These cells serve various essential roles in the body's immune system. In particular, myeloid antigen presenting cells, or myeloid APCs, which include monocytes, macrophages and dendritic cells, are critically involved in the regulation of T cell responses and thereby bridge our body's innate and adaptive immune systems. Due to various immunosuppressive factors produced in the tumor microenvironment, the normal function of these cells can be inhibited and limited in their ability to create a productive anti-tumor immune response. The source of these immunosuppressive factors can be from cancer cells, cancer-associated fibroblasts, tumor-associated neutrophils, T regulatory cells, tumor-associated macrophages or myeloid-derived suppressor cells. When functioning properly, myeloid APCs can stimulate profound anti-tumor effects in the body, including direct tumor cell killing by phagocytosis and subsequent activation of T cells to effect long lasting tumor cell killing. This type of T cell response, which is critical for durable anti-tumor immunity, begins when the Boltbody ISAC targets the antigen-expressing tumor cells for phagocytosis by myeloid APCs such as dendritic cells. When appropriately activated by a Boltbody ISAC or other stimuli, these myeloid cells transform into effective antigen-presenting cells that can migrate to the lymph nodes to activate tumor antigen-specific T cells that are critical to direct tumor cell killing. These activated myeloid APCs also secrete pro-inflammatory chemokines and cytokines that help convert immunologically "cold" tumors into "hot" tumors. As such, tumor-supportive myeloid cells are converted to tumor-destructive myeloid cells, further amplifying the innate and adaptive immune responses and thereby leading to a productive and durable anti-tumor immune response.

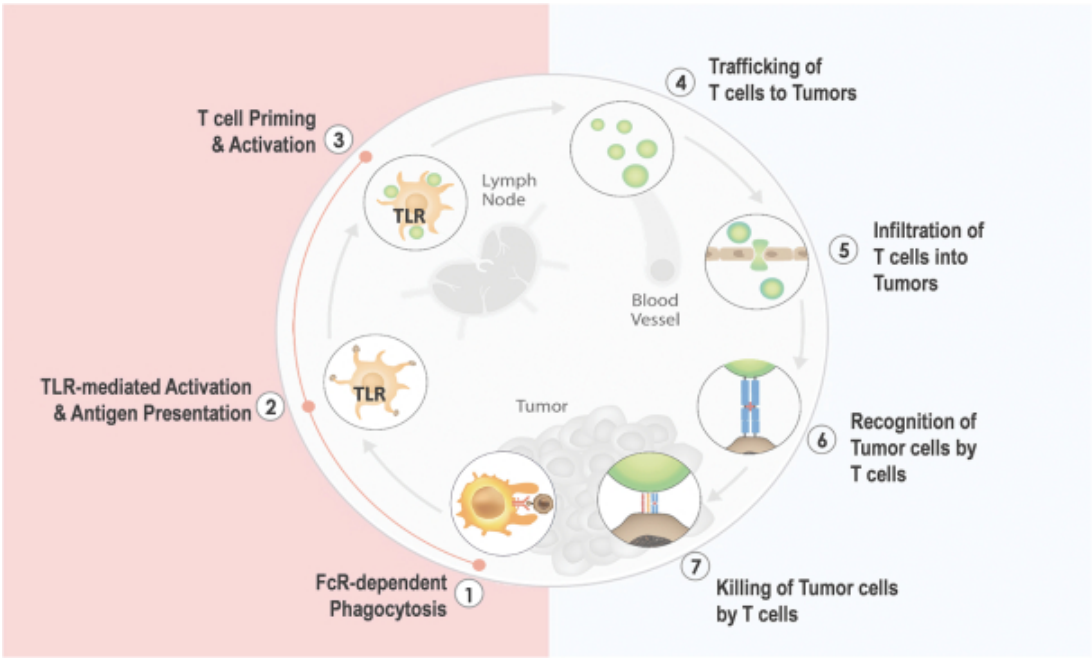
Overview of Toll-Like Receptors and Their Use in Cancer

Toll-like receptors, or TLRs, are a class of pattern recognition receptors that bind to molecules present on bacteria, viruses and other microorganisms. They are highly expressed by myeloid APCs and other innate immune cells and play a key role in the activation of the immune system in response to microbial invasion. Stimulation of the TLRs by their natural ligands or synthetic agonists induces the secretion of pro-inflammatory cytokines as well as the upregulation of molecules involved in antigen processing and presentation. As part of TLR activation, certain pathogens may be phagocytosed and digested and their antigens presented to T cells that further enhance the innate immune response. These events culminate in the bridging of the innate and adaptive immune responses leading to the induction of a robust T cell response by TLR-activated myeloid APCs, which is critical for the development of durable immunity against foreign pathogens and cancerous cells.

TLR7 and TLR8 are often described together in scientific literature due to their high degree of homology and shared function. They are both intracellular TLRs that detect virus-associated single-stranded RNA (ssRNA) and are expressed at varying levels by myeloid APCs, including monocytes, macrophages and dendritic cells. TLR8 is unique in that its expression is restricted to myeloid APCs, whereas TLR7 is expressed by myeloid APCs, B cells and plasmacytoid dendritic cells. Importantly, both TLR7 and TLR8 agonists can strongly activate myeloid APCs and elicit protective T cell responses. Targeting both TLR7 and TLR8 thus activates a broader set of immune cells that contribute to a productive anti-tumor immune response.

TLR agonists have been tested to activate the innate immune response to generate anti-tumor activity. If administered systemically, TLR agonists by themselves pose a risk of systemic immune activation that can lead to cytokine release syndrome. As such, they have been administered via intratumoral injection. Examples of intratumoral TLR approaches include CMP-001, SD-101 and NKTR-262. While TLR agonists may have anti-tumor efficacy as a monotherapy, our publication in *Nature* indicates that anti-tumor responses can be greatly augmented if immune stimulants are co-administered with tumor-targeting antibody as the combination enables myeloid cells to more effectively uptake (phagocytosis) and present tumor neoantigens to T cells. Furthermore, our preclinical data demonstrate that conjugation of TLR agonists to tumor-targeting antibodies greatly enhances anti-tumor efficacy beyond co-administration of unconjugated TLR agonists and tumor-targeting antibodies.

Boltbody ISACs Initiate a New Innate Anti-tumor Immune Response which Leads to Adaptive Immunity with Subsequent Immunological Memory



While the majority of the current immunotherapy approaches are focused largely on the adaptive immune response, the right-hand side of the above cancer immunity cycle, there remains limited approaches to successfully engage the innate immune response that is depicted on the left-hand (shaded) side of the cancer immunity cycle. Our ISACs are designed to elicit an all-encompassing immune response by engaging the innate immune system to trigger a new adaptive immune response using a single therapeutic agent.

Current immunotherapies seek to address the immune suppression aspects of tumor survival. While these approaches have had a tremendous impact on the lives of patients, they also have several shortcomings and limitations:

- **T cell exhaustion:** Due to chronic antigen stimulation, activated T cells become less effective over time, losing much of their function due to sustained expression of inhibitory receptors
- **Complexities and costs of "personalized" T cell approaches:** Personalized approaches have significant costs which limit their utilization and complexities with manufacturing and administration further restricts access to primarily academic centers
- **Re-treatment in the event of relapse:** Lack of engagement with adaptive immunity reduces likelihood of a long-term anti-tumor response as tumor survival mechanisms often evolve to shed the initial antigen and lead to relapse/recurrence of tumor
- **Inability to target "undruggable" tumor targets:** Limited number of accessible antigen targets reduce the ability of therapies to fully engage the immune system
- **Systemic overstimulation of the immune system:** Limited ability to directly target the tumor can lead to cytokine release syndrome and life-threatening toxicity, narrowing a treatment's therapeutic window

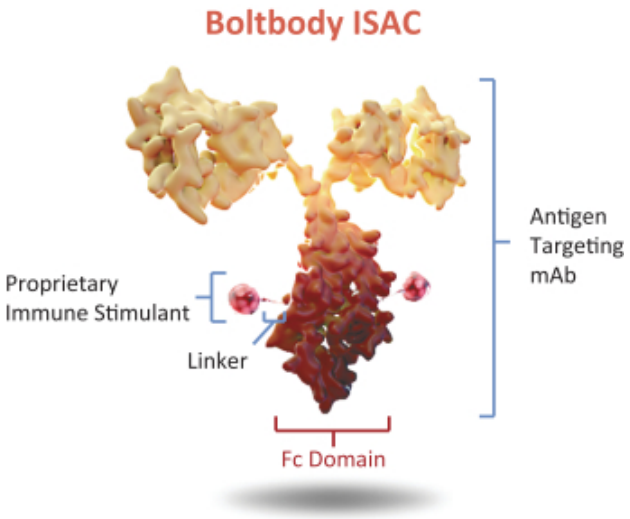
We address each of these pitfalls by engaging an entirely new immune response via our tumor-targeted Boltbody ISACs, which have the potential to safely stimulate the TLRs within the myeloid cells ultimately leading to a T cell-driven anti-tumor response.

Our Boltbody ISAC Approach

Our Boltbody ISAC approach is pioneering a new category of targeted immunotherapies engineered for systemic administration such that circulating Boltbody ISACs reprogram the tumor microenvironment. In the tumor microenvironment, the Boltbody ISACs initiate anti-tumor activity through a "Three-Factor Authentication" process that involves the following:

1. **Tumor antigen recognition:** Our selective and specific tumor-targeting Boltbody ISACs recognize and bind specifically to the target antigen-expressing tumors.
2. **FcR-dependent phagocytosis:** Engagement of optimized Fc domains triggers myeloid-mediated phagocytosis of the Boltbody ISAC-bound tumor cell. This process directly kills antigen-expressing tumor cells and delivers tumor neoantigens to myeloid cells.
3. **TLR-mediated activation:** Our proprietary TLR agonist conjugates activate myeloid cells and enable the presentation of tumor-associated neoantigens to cytotoxic T cells, thereby initiating the body's adaptive anti-tumor immune response and converting immunologically "cold" tumors to "hot" tumors. Furthermore, these activated myeloid cells also encourage additional myeloid cell-mediated phagocytosis to amplify the innate and adaptive immune responses.

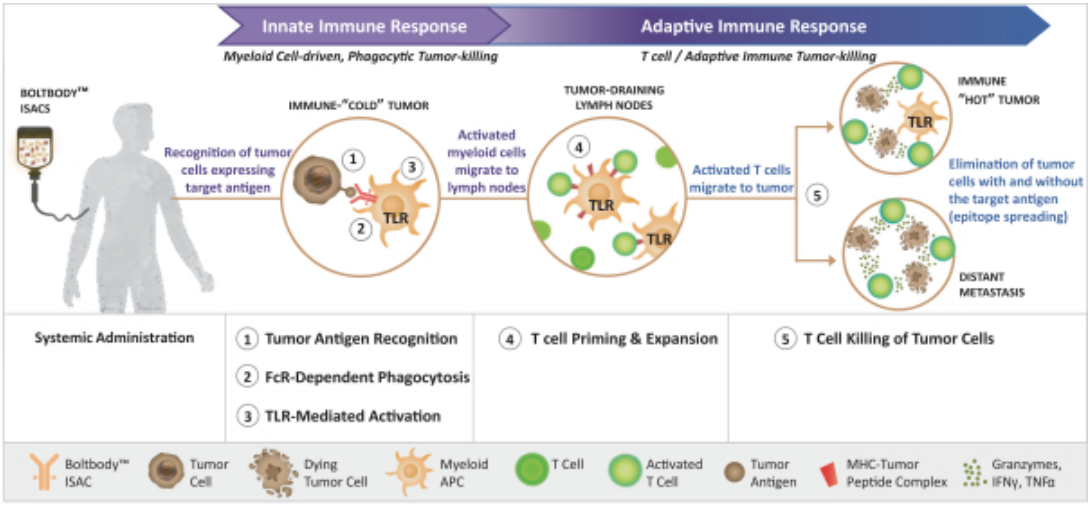
The "Three-Factor Authentication" process provides an added safety benefit to ensure that the immune system is selectively targeted and only fully activated when all three steps have been met. This ensures an initially localized immune effect. During the "Three-Factor Authentication," tumor-associated myeloid APCs engulf the Boltbody ISAC-bound tumors, become armed with tumor neoantigens, and migrate to the lymph nodes where they mediate the activation and rapid expansion of tumor-reactive T cells to eliminate tumor cells, including those without the initial target antigen. This process enables the body's own immune system to determine which neoantigens are most important to eliminate the target tumors. We believe that this represents the development of systemic immunological memory with epitope spreading to neoantigens that will result in long-term anti-tumor responses in patients.



The Boltbody Immune-Stimulating Antibody Conjugate

We designed our Boltbody ISACs with three primary components: a tumor antigen-targeting antibody, a linker that can be designed either as cleavable or non-cleavable and a proprietary immune stimulant to activate the patient's innate and adaptive immune systems. Together these components allow our Boltbody ISACs to overcome the limitations of existing immunotherapies by triggering both the body's innate and adaptive immune systems through different stages of the cancer immunity cycle to produce long-term anti-tumor efficacy.

The figure below depicts the mechanism of action of our Boltbody ISACs starting with systemic administration followed by 1) tumor antigen recognition, 2) FcR-dependent phagocytosis and 3) TLR-mediated activation, to target tumors locally and activate the body's innate and adaptive immune systems, leading to systemic immunological memory with epitope spreading to neoantigens.



Key Features of Our Boltbody ISAC Approach

We believe the following key features are critical to the successful engineering of Boltbody ISACs and set our approach apart from traditional immunotherapies. These advantages provide us with the opportunity for robust applications across various solid tumors designed to deliver effective and safe therapeutics to provide durable anti-tumor responses.

- *Ability to address difficult-to-treat solid tumors including those refractory to current treatments:* We have observed profound *in vivo* anti-tumor effects in large, well-established tumors as well as in tumors refractory to current therapies;
- *Engaging the body's innate and adaptive immune responses:* Targeted activation of myeloid APCs for antigen presentation encourages the patient's own adaptive immune system to reveal relevant tumor neoantigens;
- *Generation of immunological memory with epitope spreading to provide long-term anti-tumor responses and protect against recurrence:* Our preclinical experiments indicate that Boltbody ISACs generate immunological memory and epitope spreading to tumor antigens that are distinct from the Boltbody ISAC target. This process may prevent tumor recurrence and kill related tumors that do not express the original Boltbody ISAC target antigen;
- *Ability to target tumor antigens with less dense cell surface expression:* We have observed in preclinical studies that Boltbody ISACs demonstrated promising anti-tumor effects even at low levels of target antigen expression;

- *Capability to modulate myeloid cell activity via TLR potency and selectivity and Fc engineering:* Our medicinal chemistry and mAb engineering expertise allow us to modulate potency, selectivity and specificity of our TLR agonists as well as enhance the stability, PK/PD profile and safety of our Boltbody ISACs;
- *Favorable safety and tolerability profile by avoiding unintended systemic immune stimulation:* Our "Three-Factor Authentication" system provides additional layers of safety for an initially localized immune effect that may avoid unintended systemic immune activation. This is evidenced by our favorable preclinical safety profile which we believe will potentially enable us to treat patients earlier in the course of their disease. This can be used as monotherapy or as part of a combination therapy strategy; and
- *Potential to benefit patients who have a defective adaptive immune response:* Some patients' tumors may have defects at presenting neoantigens that makes them resistant to T cell-mediated killing. Boltbody ISACs overcome this barrier by activating myeloid cells and enhancing their phagocytic capacity resulting in anti-tumor efficacy.

Our Lead Program: BDC-1001

BDC-1001—*Overview*

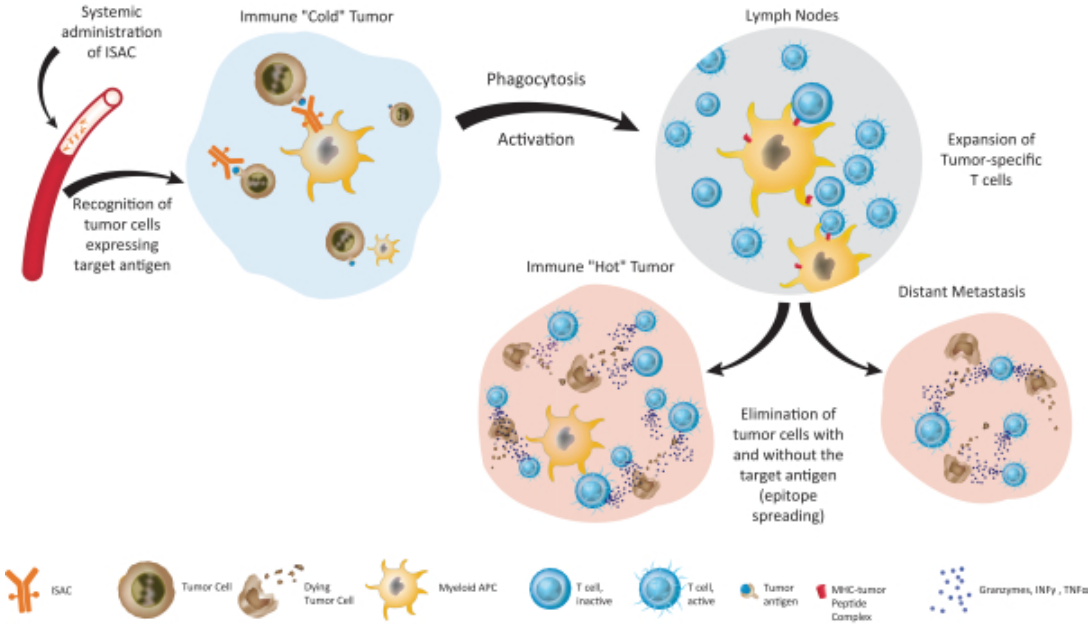
Our lead product candidate, BDC-1001, is currently in clinical development for the treatment of patients with HER2-expressing solid tumors, including those with HER2-low tumors. BDC-1001 provides a compelling example of the potential of Boltbody ISACs to address unmet medical needs in solid tumors. BDC-1001 is delivered systemically and acts locally by targeting HER2-expressing tumors and related metastatic disease, triggering their destruction by the innate and adaptive immune systems. BDC-1001 consists of a biosimilar of the humanized monoclonal antibody trastuzumab that is chemically conjugated to one of our proprietary TLR7/8 agonists via a non-cleavable linker. We have observed through our preclinical studies that BDC-1001 is an activator of human myeloid antigen presenting cells that may kill tumors via three distinct mechanisms: trastuzumab-mediated cell killing, robust immune activation and induction of immunological memory. Our observed preclinical anti-tumor response coupled with a favorable safety profile based upon GLP toxicology studies leads us to believe that BDC-1001 offers the potential for long-term and meaningful response for patients with HER2-expressing cancers, including certain HER2-low tumors. We initiated a Phase 1/2 trial of BDC-1001 in the first quarter of 2020 for the treatment of patients with HER2-expressing solid tumors. We are currently in the dose escalation portion of the trial and expect to move into Phase 2 dose expansions in 2021. We anticipate that our Phase 1/2 data will provide us with clinical proof of concept for our HER2 Boltbody ISAC approach.

BDC-1001—*Mechanism of Action*

BDC-1001 stimulates anti-tumor activity with a three-pronged approach: direct tumor cell killing by trastuzumab-mediated mechanisms, localized phagocytosis and elimination of HER2-expressing tumor cells by activated myeloid APCs and durable immunity manifested by T cells reactive to tumor-associated antigens or neoantigens. These mechanisms are supported by our *in vivo* data demonstrating complete tumor regression and immunological memory when treated with our BDC-1001 surrogates.

The mechanism governing myeloid cell activation is tripartite with BDC-1001 binding to HER2-expressing tumor cells via the antibody variable region, leading to phagocytosis and tumor cell killing by myeloid APCs expressing Fcg receptors, or FcRs, such as macrophages, dendritic cells and monocytes. Once internalized, the TLR7/8 agonist attached to BDC-1001 gains access to the phagolysosome and mediates downstream events associated with TLR7/8 activation, including increased cytotoxicity, cytokine secretion, recruitment of immune effector cells and the processing and presentation of tumor-associated antigens that stimulate T cell-mediated immunity. Taken together, the downstream effects of myeloid APC activation induced by BDC-1001 results in the conversion of immunologically "cold" tumors into "hot" tumors.

Activated myeloid APCs migrate to the draining lymph nodes following BDC-1001 mediated phagocytosis of HER2-expressing tumor cells. Upon arrival to the draining lymph nodes, activated APCs present the full diversity of potential tumor-associated antigens and neoantigens located within the phagocytosed tumor cells on peptide-MHC complexes to naïve and antigen experienced or previously exhausted T cells. This process, in conjunction with elevated co-stimulatory molecule expression following TLR7/8 recognition in myeloid APCs, leads to the polyclonal activation and expansion of T cells. As a result, the patients' own immune system determines which are the relevant T cells to mobilize for tumor destruction and subsequent immunosurveillance, providing a compelling example of how an off-the-shelf targeted immunotherapeutic such as BDC-1001 can deliver a personalized therapeutic outcome.



BDC-1001—*Design / Selection Process*

To demonstrate the promise of our Boltbody ISAC approach, we sought a target that was well-validated and was present in cancer indications that continue to have significant unmet medical need. We selected HER2 as the target for our first Boltbody ISAC as it met these criteria and is expressed at high levels in multiple malignancies and remains expressed at a high level in the majority of patients who unfortunately develop tumor progression while on HER2-targeted therapies. HER2-expressing tumors also tend to be rich in myeloid cells, which BDC-1001 utilizes to initiate the ISAC-mediated anti-tumor cascade that ultimately resulted in complete tumor regression and immunological memory in our various preclinical studies.

We selected a biosimilar of trastuzumab as the antibody backbone for BDC-1001 based on the following parameters: 1) trastuzumab is a well-validated and successful monoclonal antibody that induces meaningful clinical responses in patients with a well understood safety profile, 2) trastuzumab is effective at promoting antibody-dependent cellular phagocytosis, or ADCP, which is a key step in unlocking the full power of our mechanism of action, 3) trastuzumab has low rates of immunogenicity in patients, 4) trastuzumab has been commercialized as a biosimilar, thereby making biosimilars of trastuzumab available for the manufacturing of Boltbody ISACs and 5) our preclinical data demonstrated that trastuzumab-based ISACs outperformed pertuzumab-based ISACs with the same payloads.

The other key design element of a Boltbody ISAC is the linker payload, which is designed to promote immune stimulation. For BDC-1001, the combination of TLR7 and TLR8 was selected as the immune stimulant for the following reasons: 1) targeting of an endosomal TLR was desirable when considering the safety of the ISAC, as FcR-mediated uptake into the myeloid APC is required for access to the TLR, 2) gene expression data demonstrated that TLR7 and TLR8 are largely restricted to expression on cells of myeloid lineage including monocytes, macrophages and dendritic cells, 3) TLR7 is also expressed on B cells and plasmacytoid dendritic cells, which stimulate type I interferon and antibody responses following stimulation, 4) the expression pattern of murine TLR7 recapitulates the combination of TLR7 and TLR8 expression in the human, which enables us to use murine tumor models as an appropriate setting to investigate our ISAC-mediated mechanisms and 5) we generated data in preclinical experiments demonstrating that dual TLR7/8 agonists outperformed TLR7-specific and TLR8-specific agonists for activating myeloid cells. Therefore, we believe that a dual TLR7/8 agonist will enhance the potential for a productive anti-tumor immune response.

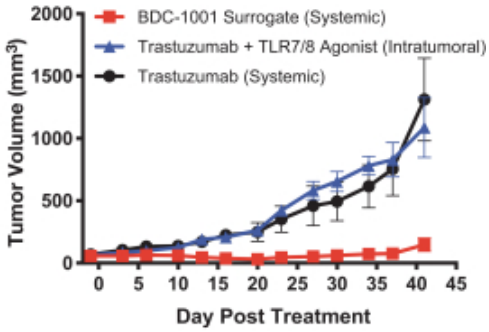
BDC-1001 was designed with safety in mind. The final linker-payload selection was motivated by the goal to demonstrate a favorable safety profile in IND-enabling toxicology studies. Our preclinical data demonstrated that non-cleavable linkers lead to increased myeloid activation and provide a favorable pharmacokinetic and safety profile, as compared to cleavable linkers. In addition, non-cleavable linkers are also less likely to release an active TLR agonist, further reducing the potential for systemic toxicity. We selected both a non-cleavable linker and the TLR7/8 agonist payload because it conferred a favorable immunogenicity profile and pharmacokinetic profile for BDC-1001 in non-human primate studies, and importantly, did not induce cytokine release syndrome. Furthermore, the BDC-1001 linker-payload is cell membrane impermeable which limits off target activity and enables our “Three-Factor Authentication” process for added safety.

BDC-1001—*Validation of the HER2 Boltbody ISAC Approach*

Boltbody ISACs Outperform Equimolar Mixture of Unconjugated TLR7/8 Agonist and Trastuzumab

To demonstrate that our Boltbody ISAC approach is more potent than the mixture of unconjugated TLR7/8 agonist and trastuzumab, we implanted mice with a HER2-expressing tumor cell line and treated mice with our BDC-1001 surrogate, trastuzumab alone or trastuzumab and an unconjugated TLR7/8 agonist. We observed that a single administration of our BDC-1001 surrogate resulted in markedly improved anti-tumor efficacy as compared to an equimolar mixture of the unconjugated TLR7/8 agonist and trastuzumab. Therefore, we believe that covalent attachment of a TLR7/8 agonist to a tumor-targeting antibody such as trastuzumab in the form of a Boltbody ISAC dramatically improves the immunostimulatory outcome and anti-tumor efficacy of otherwise intratumorally administered, unconjugated TLR agonists.

Figure 1: BDC-1001 Surrogate Delivers Superior Anti-Tumor Efficacy vs. Unconjugated TLR7/8 Agonist and Trastuzumab



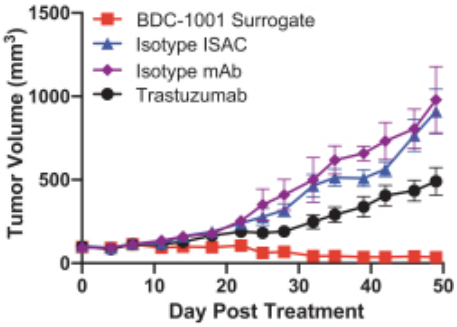
In all figures, data are shown as mean with standard error of the mean.

Myeloid APCs Eliminate Tumors via Phagocytosis Following Boltbody ISAC "Three-Factor Authentication"

To assess that Boltbody ISAC activity is governed by three key factors: tumor-targeting, FcR engagement and TLR agonism, we performed experiments in which each step was perturbed and measured the subsequent anti-tumor effects. In each experiment, mice were implanted with a HER2-expressing tumor cell line and were randomized when the tumor volume reached 50 – 75 mm^3. The figures below demonstrate that our Boltbody ISACs follow a "Three-Factor Authentication" process, in which tumor-targeting, FcR and TLR engagement are essential to initiate myeloid mediated tumor destruction, even in the absence of the adaptive immune system.

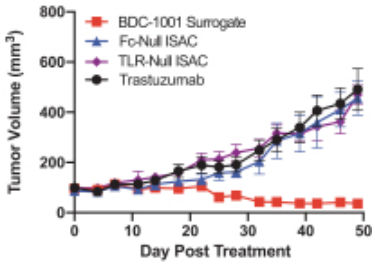
To demonstrate the requirement for tumor targeting, mice were treated systemically with our BDC-1001 surrogate, trastuzumab, isotype mAb or isotype ISAC. We observed that while our BDC-1001 surrogate led to complete tumor regression, an isotype ISAC that does not recognize the HER2 tumor antigen abrogated the observed efficacy.

Figure 2: BDC-1001 Surrogate Activity Requires Tumor-Targeting



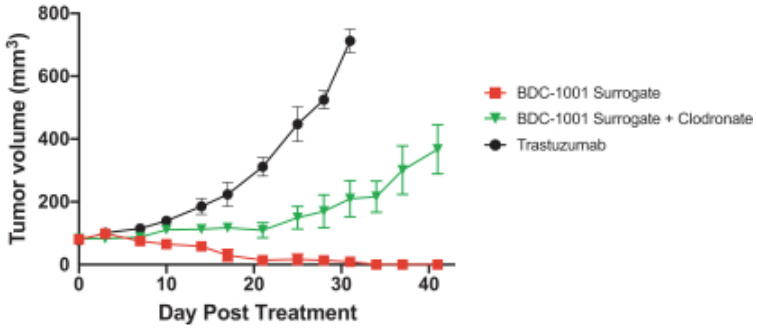
To demonstrate the requirement for Fc-mediated engagement and TLR agonism, we altered the ISAC by inactivating the Fc domain (Fc-Null ISAC) or by inactivating the payload (TLR-Null ISAC). In the figure below, mice were treated systemically with our BDC-1001 surrogate, trastuzumab, Fc-Null ISAC or TLR-Null ISAC. We observed that only the BDC-1001 surrogate mediated complete tumor regression, confirming the requirement for both Fc-mediated engagement and TLR agonism.

Figure 3: BDC-1001 Surrogate Activity Dependent on Both FcR Engagement and TLR Agonism



Lastly, to demonstrate that BDC-1001 activity is dependent on the presence of phagocytes, tumor cells were implanted into mice, and phagocytes were depleted prior to and during BDC-1001 surrogate treatment using clodronate-loaded or control liposomes. The control liposomes had no effect. We observed that depletion of phagocytes, including myeloid APCs, significantly reduced our BDC-1001 surrogate-mediated efficacy.

Figure 4: BDC-1001 Surrogate Activity Dependent on Presence of Phagocytes

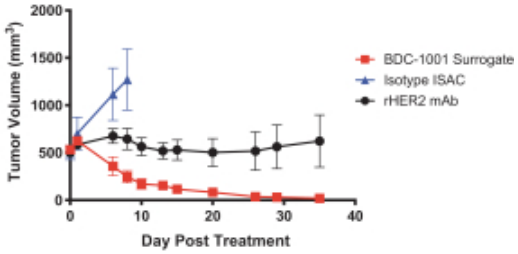


Boltbody ISAC-stimulated CD8⁺ Cytotoxic T cells Infiltrate and Eliminate Large Syngeneic Tumors

To assess the capacity of ISACs to mediate anti-tumor efficacy in the presence of a functional innate and adaptive immune systems, we utilized an immunologically "cold" syngeneic mouse mammary carcinoma, or MMC, tumor model. To minimize cross-species immunogenicity associated with rat HER2, or rHER2, expression in the MMC tumor, transgenic mice that endogenously express rat HER2 were used as the host.

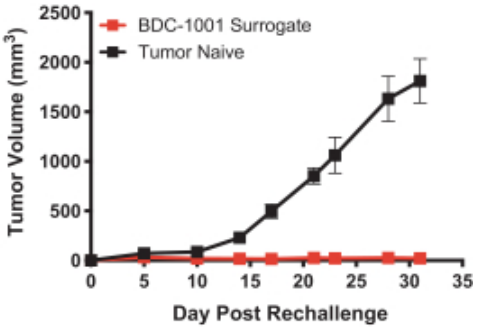
In the figure below, mice were implanted with the MMC tumor cell line and the tumors were allowed to grow until they were very large and well established. Mice were then treated systemically with our BDC-1001 surrogate, rHER2 mAb or isotype ISAC. We observed that systemic administration of the BDC-1001 surrogate was well tolerated and the only agent that led to complete tumor regression.

Figure 5: BDC-1001 Surrogate Mediated Complete Tumor Regression in Very Large Well-Established Tumors



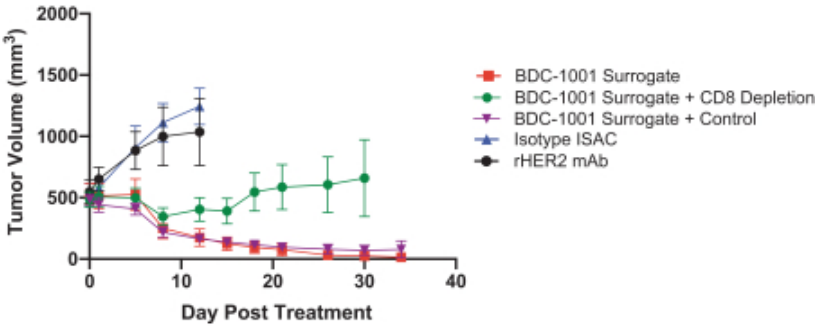
To demonstrate the induction of immunological memory, BDC-1001 surrogate treated mice that experienced complete tumor regression for >60 days after their last treatment were re-challenged with the MMC tumor cell line; tumor naïve mice served as implantation controls. We observed that our BDC-1001 surrogate generated durable immunological memory as the previously treated, tumor-free mice were protected against tumor re-challenge and remained tumor-free without retreatment.

Figure 6: BDC-1001 Surrogate Generated Immunological Memory



To demonstrate that BDC-1001 also results in a T cell-mediated adaptive immune response, mice were implanted with the MMC tumor cell line and then pre-treated with anti-CD8 depleting antibody with rIgG2b serving as the non-depleting control. Mice were then treated with our BDC-1001 surrogate. We observed that BDC-1001 surrogate-driven tumor regression was heavily dependent on CD8 T cell activity, as depletion of CD8 T cells reduced anti-tumor efficacy. Furthermore, significant increases in phagocytes and CD8 T cells were measured in tumors following BDC-1001 surrogate treatment, further supporting a mechanism that bridges the innate and adaptive immune systems.

Figure 7: BDC-1001 Surrogate Activity Dependent on CD8 T Cell Activity



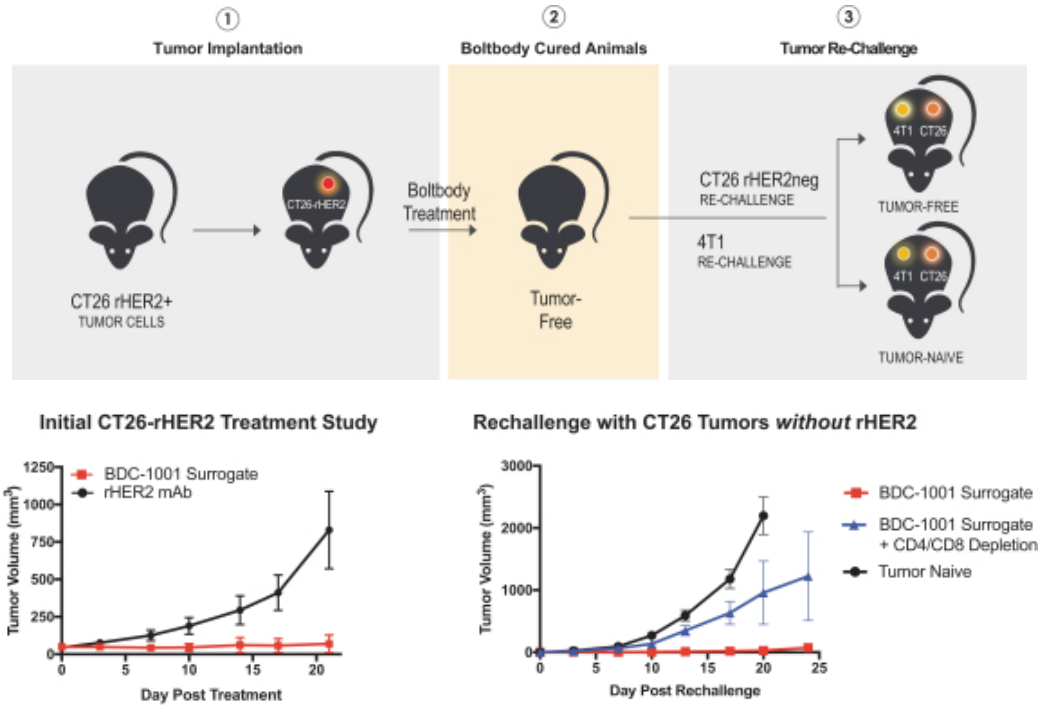
Boltbody ISACs Generate Immunological Memory & Evidence of Epitope Spreading Beyond HER2

To demonstrate that BDC-1001 surrogate-induced T cell response and immunological memory extend beyond HER2-expressing tumor cells, as would be expected if epitope spreading occurred, we developed a CT26 cell line that stably expresses rat HER2 (CT26-rHER2) where approximately 10% of the CT26 cells did not express rHER2 after tumor implantation. We observed that treatment with BDC-1001 surrogate resulted in complete tumor regression in approximately 75% of mice whereas none of the mice treated with the unconjugated antibody achieved complete regression. These data demonstrate that the BDC-1001 surrogate was capable of eliminating tumor cells expressing HER2 as well as those with no HER2 expression, suggesting that BDC-1001 surrogate induced epitope spreading. This is an important observation as human tumors are heterogeneous with regards to cell surface HER2 expression. A tumor determined to be HER2-positive will have tumor cells with varying levels of HER2 expression and BDC-1001 should be capable of eliminating even those tumor cells with low or no HER2 expression.

We performed a re-challenge experiment to further assess the potential for immunological memory with epitope spreading. Mice that experienced complete regression, i.e. were tumor-free, following BDC-1001

surrogate treatment were re-challenged with the parental CT26 cell line that lacked rHER2 expression or a genetically distinct tumor cell line, 4T1, in the presence and absence of CD4/CD8 T cells. We observed that mice were protected from re-challenge with the parental CT26 line and that this protection required the presence of CD4/CD8 T cells. Finally, we observed that the development of immunological memory and potential epitope spreading was specific to CT26 as tumor growth of 4T1 tumors was not impacted.

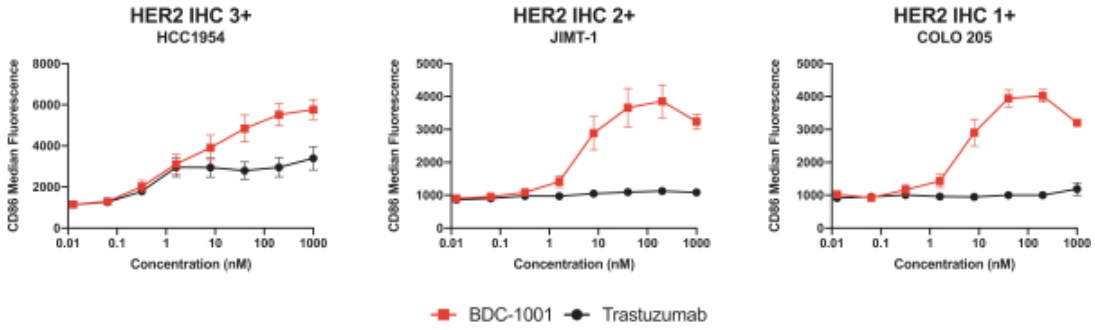
Figure 8: BDC-1001 Surrogate Elicits Tumor Regression with Epitope Spreading and Immunological Memory



BDC-1001 Is an Activator of Human Myeloid APCs at Various Levels of HER2 Expression

BDC-1001 activates human myeloid APCs to a greater extent than trastuzumab following co-culture with variable HER2-expressing cancer cell lines. As demonstrated in the figure below, BDC-1001 stimulation led to increased expression of CD86, a co-stimulatory molecule that is essential for T cell activation. BDC-1001 also led to increased expression of the co-stimulatory molecule CD40 and increased TNFa secretion, each of which is indicative of a robust myeloid activation response. Importantly, BDC-1001 activated myeloid APCs to a similar extent when co-cultured with tumor cell lines expressing high (IHC3+) or lower levels of HER2 (IHC2+ or IHC1+). These data suggest that BDC-1001 can activate myeloid cells even in the presence of low levels of HER2 surface expression on the tumor cells. These data highlight the potential benefit of BDC-1001 in patients with HER2-low tumors, currently a population for which trastuzumab is not approved.

Figure 9: BDC-1001 Activates Human Myeloid APCs in Tumor Co-culture Assays



In a separate set of experiments, we confirmed the requirement for "Three-Factor Authentication," as FcR-mediated internalization was needed to bring the linker-payload inside the cell to drive myeloid activation through TLR7/8 agonism. We also confirmed that BDC-1001 retains native trastuzumab functionality, as determined by HER2 binding and *in vitro* tumor growth inhibition assays.

BDC-1001 Is Well Tolerated in Non-Human Primates

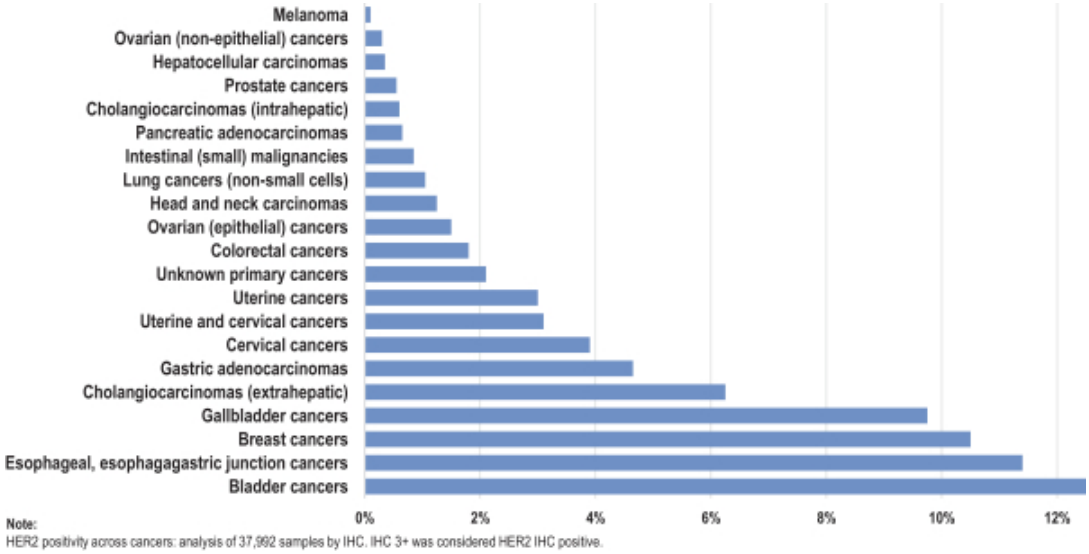
To assess the potential safety and tolerability of BDC-1001, we performed a multi-dose GLP toxicology study where we administered vehicle, 10, 30 or 90 mg/kg of BDC-1001 at weekly intervals for a total of 4 dose administrations. We did not observe any BDC-1001-related clinical signs or changes in any of the in-life observations/examinations (e.g., body weights, respiratory rate, as well as ophthalmological, cardiac and neurological endpoints). Furthermore, we did not observe any BDC-1001-related changes in the serum cytokines evaluated and there were no BDC-1001-related organ weight changes. As a result, it was concluded that BDC-1001 was well-tolerated in non-human primates and that the no observed adverse effect level, or NOAEL, for BDC-1001 was 90 mg/kg, the highest dose tested.

BDC-1001—*Overview of HER2 Indications and Treatment Paradigms*

HER2 is a proto-oncogene that encodes a transmembrane protein involved in signal transduction pathways that promote cell growth and differentiation. HER2 protein overexpression and gene amplification have been documented across multiple cancers. Targeting HER2 with mAbs and small molecule tyrosine kinase inhibitors has had a major impact on patients with HER2-expressing breast and gastric cancer, but there remains a significant unmet medical need on an individual and global patient basis. Our BDC-1001 program seeks to improve therapeutic outcomes for patients with HER2-expressing tumors across three categories: 1) HER2-positive breast and gastric cancer refractory to existing anti-HER2 therapies, 2) tumors with lower expression of HER2 that are not indicated for approved therapies, and 3) other HER2-positive tumors not indicated for approved therapies. In addition, the innovative Boltbody ISAC approach of BDC-1001 seeks to address this critically important unmet medical need not only in patients with the aforementioned advanced tumors, but also to extend that innovation to neoadjuvant and adjuvant settings.

As is widely scientifically accepted and as shown in a 2015 study in the Cancer Metastasis Review, HER2-positivity (IHC 3+ or gene amplification) has been identified in a wide range of malignancies including breast, gastric, bladder, lung, esophageal, colorectal, ovarian, salivary gland, pancreatic, cervical cancers and others. Prevalence of HER2 overexpressing or amplified tumors varies across indications.

Figure 10: Estimated Percentage Prevalence of HER2 Positivity by Protein Expression Across Solid Tumor Indications



Although there is broad prevalence of HER2 expression across tumor types, HER2-targeting agents have only been approved for patients with HER2-positive breast and gastric cancers, with HER2-positivity based on protein overexpression or gene amplification. Only trastuzumab is approved for both indications. Additional approved HER2-targeting agents include the following: pertuzumab, trastuzumab emtansine, trastuzumab-hyaluronidase-oysk, lapatinib, neratinib, and most recently, trastuzumab-deruxtecan and tucatinib.

Trastuzumab-deruxtecan and tucatinib are important and effective agents for the treatment of patients with previously treated advanced HER2-positive breast cancer. While both these agents provide important options for patients with advanced breast cancer, it is important to highlight the large percentage of patients who do not respond to these therapies or develop tumor progression after initial response. There are no approved treatments for either of these patient groups. In addition, margetuximab is an Fc-engineered monoclonal antibody in late stage development that targets the HER2 protein. Margetuximab has a biologics license application, or BLA, under review by the FDA and a published Prescription Drug User Fee Act, as amended, or the PDUFA, date of December 18, 2020.

Despite the availability of these HER2-targeted agents, most patients with advanced disease and many with early disease are not cured and require multiple lines of therapy to achieve disease control, improve quality of life and extend survival. Additionally, there are patients not recognized in the current HER2-positive treatment paradigm such as those with lower HER2-expressing tumors or with HER2-expressing tumor types other than breast and gastric. As a result, there remains a large unmet medical need for a HER2 therapy utilizing our Boltbody ISAC approach to deliver potentially long-term anti-tumor responses through systemic immunological memory.

BDC-1001—*Clinical Development Overview*

We are currently conducting a four-part, Phase 1/2 multiple ascending dose and dose-expansion trial of BDC-1001 administered as a single agent or in combination with an immune checkpoint inhibitor. We initiated the trial in the first quarter of 2020 and plan to enroll up to 390 patients at 20 sites worldwide. This trial will evaluate safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary anti-tumor activity in patients with HER2-positive disease (IHC3+ or HER2 gene amplification) as well as patients whose tumors have lower

HER2 expression (defined as IHC2+). Collectively, we call these groups "HER2-expressing." All patients in our study have metastatic disease and disease progression after prior therapies.

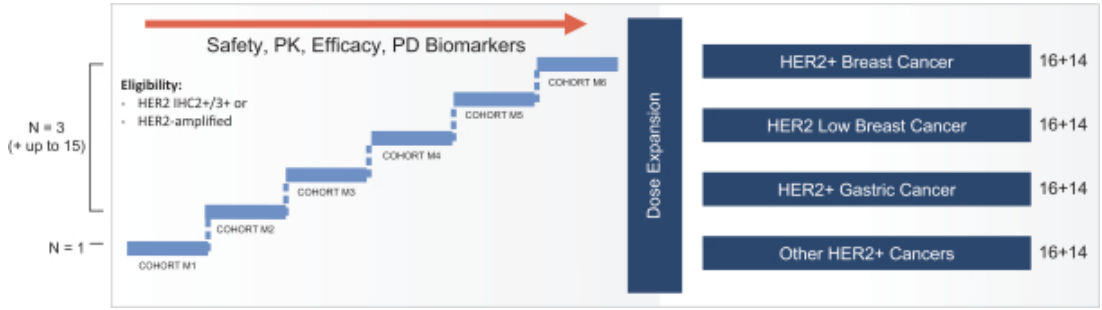
Monotherapy

- Part 1: Monotherapy dose escalation to evaluate safety and determine a maximum tolerated dose, or MTD, or recommended Phase 2 dose, or RP2D.
- Part 3: Monotherapy dose expansion to evaluate safety and preliminary responses in 4 predefined tumor types (HER2-positive breast cancer, HER2 Low breast cancer, HER2-positive gastric cancer and other HER2-positive cancers).

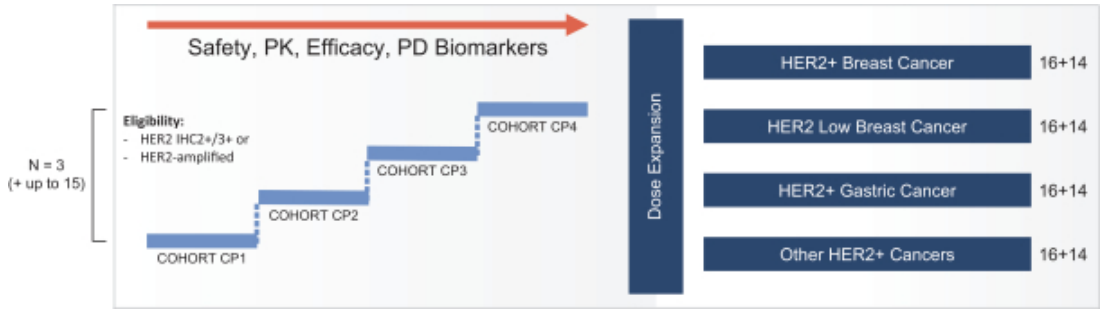
Combination with Checkpoint Inhibitor

- Part 2: Combination with checkpoint inhibitor dose escalation to evaluate safety and determine a MTD or RP2D.
- Part 4: Combination therapy with an immune checkpoint inhibitor to evaluate safety and preliminary responses in 4 predefined tumor types (HER2-positive breast cancer, HER2 Low breast cancer, HER2-positive gastric cancer and other HER2-positive cancers).

Monotherapy—Parts 1 and 3



Combination Therapy with Checkpoint Inhibitor—Parts 2 and 4



Biomarker analyses will be performed and assessed in both tumor tissue and blood. BDC-1001 biological activity will be evaluated by exploring pharmacodynamics or predictive biomarkers that may correlate with activity or help identify patients likely to respond to BDC-1001 as monotherapy or BDC-1001 in combination with specific anti-cancer therapies. Patients may receive study drug up to 24 months after Cycle 1 and may be followed for survival up to 2 years after their last dose. They will remain on treatment until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent or if other reasons to discontinue treatment occur.

We are currently in the Part 1 dose escalation portion of the trial and expect to move into Phase 2 dose expansions in 2021. We anticipate that our Phase 1/2 data will provide clinical proof of concept for our HER2-targeted Boltbody ISAC approach in general and for our BDC-1001 product profile in the HER2 space.

CEA Program

Our second program focuses on CEA, a well-known tumor antigen that is overexpressed in various solid tumors with significant unmet medical need including, but not limited to, colorectal cancer, non-small cell lung cancer, pancreatic cancer and breast cancer. CEA is upregulated on the cell surface of these cancers and displays minimal receptor-mediated internalization into the cancer cell. In our preclinical studies, we have observed promising anti-tumor activity *in vivo* with potent *in vitro* ADCP.

Immune profiling of various solid tumors has revealed that myeloid cells are present in immunologically “hot” and “cold” tumors. Immunologically “cold” tumors include, but are not limited to, colorectal cancer and pancreatic cancer. CEA is overexpressed in these immunologically “cold” cancers. We believe that this, combined with the aforementioned properties, makes CEA-expressing tumors an attractive therapeutic opportunity for our Boltbody ISAC approach. We anticipate advancing our CEA Boltbody ISAC into the clinic in 2022.

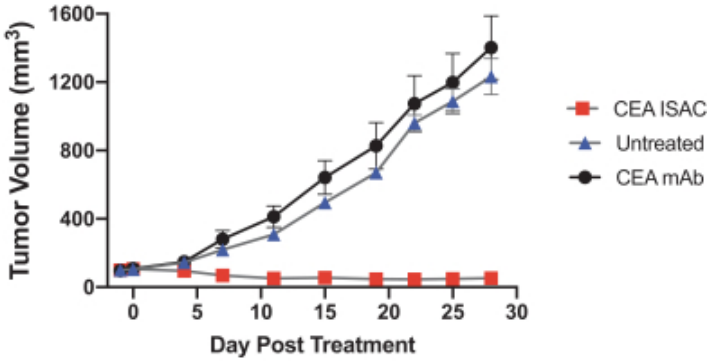
Preclinical Data

In our preclinical experiments we have identified a CEA-targeting mAb that has the desired CEA binding properties as well as selectivity over other key members of the CEACAM family. We believe this selectivity will reduce unwanted off-target effects that could lead to safety complications. The favorable binding properties of this mAb will permit increased residence time on CEA to permit an opportunity for myeloid cells to engage the Fc portion of the CEA mAb through Fc receptors.

We also tested the ability of CEA-targeting mAbs to invoke activity in a cellular-based assay that measures ADCP. We observed that our lead CEA-targeting mAb (CEA mAb) has prominent ADCP activity relative to other mAbs tested. We believe this will serve as a strong foundational mAb for the CEA-ISAC since ADCP is a key part of the ISAC mechanism that leads to a productive anti-tumor immune response.

To assess the potential efficacy of our CEA Boltbody ISAC program targeting CEA-expressing tumors, we conducted *in vivo* xenograft experiments in mice engrafted with the human pancreatic cancer cell line HPAFII. The cell surface expression of CEA on HPAFII tumors is believed to represent the typical CEA expression levels found in human pancreatic cancers. In this study we compared the anti-tumor efficacy of our lead CEA mAb to a CEA Boltbody ISAC prototype (CEA-ISAC). In addition, we also compared both of these groups to mice that did not receive either therapy (Untreated). Measuring tumor volumes throughout the course of the study revealed that the HPAFII model was refractory to naked CEA mAb with no evidence of anti-tumor efficacy compared to the Untreated group of animals. In contrast, CEA Boltbody ISAC displayed profound anti-tumor efficacy and mediated tumor regression in all animals. We believe that these data support continued research and development of a CEA Boltbody ISAC for patients with CEA-expressing cancers.

Figure 11: *In vivo* Efficacy of CEA Boltbody ISAC in HPAFII Human Pancreatic Xenograft Model



PD-L1 Program

Our third program, a PD-L1 Boltbody ISAC, focuses on another area with significant unmet medical need, the treatment of patients with tumors that are nonresponsive or become refractory to immune checkpoint blockade, such as NSCLC, CRC, breast and other cancers. PD-L1 is an immune checkpoint protein that can be expressed on cancer and immune cells. Expression of PD-L1 on the cell surface of these cells engages the PD-1 checkpoint and results in the inhibition of a productive anti-tumor immune response. More specifically, T cell-mediated immune responses are significantly dampened since the expression of PD-L1 on the cancer cells engages with the PD-1 on the cell surface of T cells and acts as a brake on the immune system. Inhibition of the PD-L1/PD-1 axis has shown potent anti-tumor immune responses in numerous types of cancers; however, a substantial number of cancer patients' tumors are non-responsive or become refractory to immune checkpoint blockade. These patients with checkpoint refractory tumors represent a significant unmet medical need. We believe that a PD-L1 Boltbody ISAC has the potential to overcome the limitations of current anti-PD-L1 therapies.

Our PD-L1 Boltbody ISAC is designed to be a trifunctional therapeutic to overcome such limitations. As such, our PD-L1 ISAC is built to elicit: 1) antibody-dependent cellular phagocytosis of the tumor, 2) activation of myeloid cells in the tumor microenvironment to enhance neoantigen presentation and consequential T cell-dependent tumor killing and immunological memory, and 3) inhibition of the PD-L1/PD1 axis that can thwart T cell-dependent responses.

Preclinical Data

In our preclinical experiments, we have identified PD-L1-targeting mAbs that have the desired activity in a cellular-based assay that measures ADCP. Our PD-L1-targeting mAbs have ADCP activity and meet the criteria for the PD-L1 Boltbody ISAC given ADCP is a key part of the ISAC mechanism that leads to a productive anti-tumor immune response.

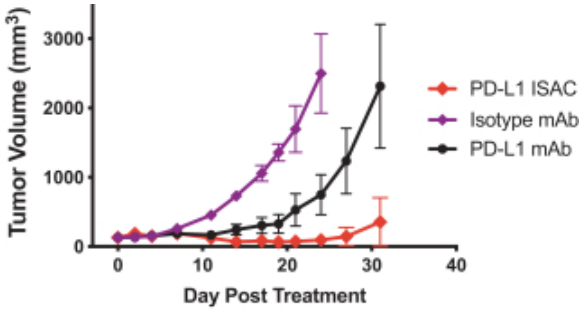
PD-1/PD-L1 blockade is a key property for our desired PD-L1 Boltbody ISAC in order to endow the molecule with a trifunctional mechanism of action. In our preclinical experiments, we observed the ability of our PD-L1-targeting mAbs to disrupt the PD-L1/PD-1 interaction in a cellular-based reporter assay. All three of our top PD-L1-targeting mAbs show robust PD-L1/PD-1 blockade. We believe this property within a PD-L1 Boltbody ISAC would provide a substantial increase in the capacity to elicit a robust anti-tumor immune response.

To further assess and characterize the PD-1/PD-L1 blockade capacity of each of our PD-L1 mAbs, we conducted mixed lymphocyte reaction, or MLR, *in vitro* assays experiments. All three of our top PD-L1-targeting

mAbs demonstrated robust production of IFNg, a cytokine produced as a result of PD-L1/PD-1 blockade. These data, combined with the PD-L1/PD-1 blockade cellular reporter assay, suggest that our PD-L1 mAbs have the desired PD-L1/PD-1 blockade function required for a PD-L1 Boltbody ISAC.

To assess the potential efficacy of our PD-L1 Boltbody ISAC program targeting PD-L1-expressing tumors, we conducted *in vivo* syngeneic experiments in mice engrafted with the murine colorectal cancer cell line, MC38 that expresses human PD-L1. In this preclinical study we compared the anti-tumor efficacy of one of our PD-L1-targeting mAb (PD-L1 mAb) to the same PD-L1-targeting mAb conjugated to a murine TLR7 agonist (PD-L1 ISAC). In addition, we also compared both of these groups to animals that received a non-tumor-targeting mAb (isotype mAb). We observed that MC38-hPD-L1 was partially sensitive to our PD-L1-targeting mAbs relative to the isotype mAb-treated animals; however, no complete responses were observed. In contrast, PD-L1 ISAC displayed marked anti-tumor efficacy with complete responses observed in 75% of animals tested. We believe that these data support continued research and development of a PD-L1 Boltbody ISAC for PD-L1-expressing cancers for the potential treatment of patients with checkpoint refractory tumors.

Figure 12: *In vivo* Efficacy of PD-L1 Boltbody ISAC in MC38-hPD-L1 Colorectal Syngeneic Tumor Model



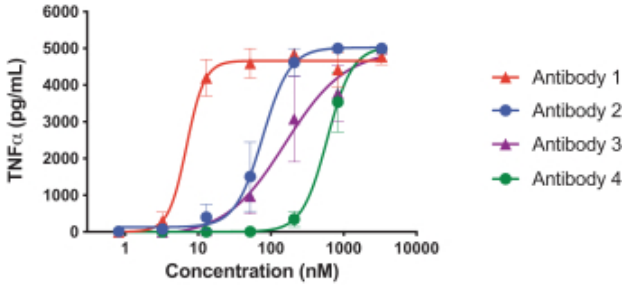
Myeloid Modulators and Future Research

Our expertise in myeloid biology and immuno-oncology has led us to research various tumor antigens across solid tumors where significant unmet medical need remains. In addition, we have expertise in modulating the various properties of a Boltbody ISAC that would further optimize the profile for any particular tumor antigen in our research and discovery programs. Our Boltbody ISAC approach is designed to elicit a robust anti-tumor immune response with a favorable safety profile. We believe this approach has the potential to enable us to develop product candidates to treat patients with a wide variety of tumors.

Our expertise may lead to additional research and discovery programs that are independent, but may complement, our Boltbody ISAC approach and our growing library of innate immune stimulators. Importantly, tumor-associated myeloid cells tend to be tumor-supportive rather than tumor destructive. Additional ways of modulating tumor-associated myeloid cells are warranted given the heterogeneity of human cancers with respect to tumor mutational burden as well as immunological profile. Our research and discovery efforts are exploring additional immune agonists for the Boltbody ISAC approach as well as identifying novel targets in tumor-associated myeloid cells that can be targeted with other therapeutic modalities.

An example from these efforts is shown in the figure below where we have identified mAbs (Antibodies 1-4) in our laboratories that are capable of binding to and agonizing a novel cell surface protein, which we refer to as TAM1, on tumor-supportive macrophages. TAM1 agonism results in the production of pro-inflammatory cytokines more consistent with the characteristics of tumor-destructive myeloid cells. We believe such molecule may have the potential to reprogram tumor-supportive macrophages into tumor-destructive macrophages to elicit a productive anti-tumor immune response. Additionally, KRAS and TP53 mutations may upregulate TAM1 on tumor-associated myeloid cells and could provide an avenue to develop precision medicine with an immune modulator.

Figure 13: Capacity of TAM1 Binding mAbs to Enhance TNFa Secretion from Tumor-Supportive Macrophages



License and Collaboration Agreements

License Agreements with Stanford University

In May 2015, we entered into a license agreement with Stanford, or the 2015 Stanford Agreement, pursuant to which Stanford granted us a worldwide exclusive, sublicenseable license under certain patents related to our proprietary Boltbody ISAC technology, to develop, manufacture and commercialize licensed products incorporating such technology. In consideration for the rights granted to us under the 2015 Stanford Agreement, we paid Stanford a nominal nonrefundable license issue fee and issued Stanford and two co-inventors an aggregate of 366,819 shares of our common stock. Stanford retained the right under the 2015 Stanford Agreement, on behalf of itself and all other non-profit research institutions, to practice the licensed patents for any non-profit purpose, including sponsored research and collaborations, but excluding delivery of paid or reimbursed healthcare. However, Stanford retained the right to practice the licensed patents for the delivery of its own paid or reimbursed healthcare.

In June 2018, we entered into a second license agreement with Stanford, or the 2018 Stanford Agreement, and collectively with the 2015 Stanford Agreement, the Stanford Agreements. Pursuant to the 2018 Stanford Agreement, Stanford granted us a worldwide exclusive license, under certain patents related to myeloid modulation for cancer immunotherapy to develop, manufacture and commercialize products containing such technology. In consideration for the rights granted to us under the 2018 Stanford Agreement, we paid Stanford a nominal nonrefundable license issue fee and reimbursed Stanford for past patent expenses, together totaling less than $0.1 million. Stanford retained the right under the 2018 Stanford Agreement, on behalf of itself, Stanford Health Care, Lucile Packard Children's Hospital at Stanford and all other non-profit research institutions, to practice the licensed patents for any non-profit purpose, including sponsored research and collaborations. The licensed patents are additionally subject to a nonexclusive, worldwide license held by the Howard Hughes Medical Institute to exercise such intellectual property rights for research purposes, with the right to sublicense to non-profit and governmental entities.

The technology claimed by the patents licensed under both Stanford Agreements was developed using U.S. government funding and the licenses are therefore subject to a nonexclusive license held by the U.S. government, certain requirements that licensed products be manufactured in the U.S. (unless waived according to U.S. government process) and U.S. government march-in rights. For more information on risks related to technology developed using government funding see "Risk Factors—Risks Related to Our Intellectual Property."

Under each Stanford Agreement, we are obligated to pay annual license maintenance fees, which are nominal and will be creditable against any royalties payable to Stanford under such agreement in the applicable year. We are required in each Stanford Agreement to make milestone payments up to an aggregate of $0.4 million for the first licensed product under such agreement that meets certain patent issuance, clinical and regulatory milestones, and an additional milestone payment of $0.2 million for each additional regulatory approval. We also agreed in each Stanford Agreement to pay Stanford tiered royalties on our and our

sublicensees' net sales of licensed products, at low single-digit percentage rates, subject to certain customary reductions. Our royalty obligations continue for the term of each Stanford Agreement and we are required to pay royalties on any licensed products made, used, imported or offered for sale during the term of such agreement but sold after the term of the agreement. In addition, we are obligated in each Stanford Agreement to pay Stanford a percentage, based on the date of sublicensing, of certain consideration we receive as a result of granting sublicenses to the licensed patents. Pursuant to each Stanford Agreement, we will reimburse Stanford's patent expenses, including reasonable costs incurred in assisting us with prosecuting and maintaining licensed patents.

Under each Stanford Agreement, we are obligated to use commercially reasonable efforts to develop and commercialize licensed products and we are also required to achieve certain funding, development and/or regulatory milestones by certain dates, which can be extended a limited number of times upon the payment of a nominal fee.

The Stanford Agreements continue until terminated. We may terminate either of the Stanford Agreements at any time for any reason by providing at least 30 days' written notice to Stanford. Stanford may terminate either of the Stanford Agreements if we breach certain provisions of such Stanford Agreement, including the payment and funding, development and/or regulatory milestone obligations, and fail to remedy such breach within 60 days after written notice of such breach by Stanford.

Joint Development and License Agreement with Toray Industries

In March 2019, we entered into the Toray Development Agreement to develop and commercialize collaboration products, each containing a proprietary antibody owned by Toray, or the Toray Antibody, or a related antibody against the same novel tumor antigen target, and our Boltbody technology, for cancer in the United States, Japan and the European Union, or the Territory. In conjunction with the Toray Development Agreement, Toray purchased 5,022,601 shares of our preferred stock at an aggregate purchase price of $10.0 million.

Under the Toray Development Agreement, we granted Toray a co-exclusive (with us) license under certain of our patents and know-how related to our Boltbody technology, and we received from Toray a co-exclusive (with Toray) license under certain of its patents and know-how related to the Toray Antibody. Both co-exclusive licenses are limited to the development, manufacture and commercialization of collaboration products in the Territory for the diagnosis, treatment and prevention of a specified number of cancer indications to be selected by the parties, or the Indications. The parties are obligated to work exclusively on each collaboration product, and neither party is permitted to independently develop or commercialize any collaboration product, or independently use the other party's technology or patents generated during the collaboration that are specific to collaboration products. The terms of the Toray Development Agreement do not restrict our use of our Boltbody technology independent of the Toray Antibody and related antibodies against the same antigen target, nor do they restrict Toray's use of the Toray Antibody and related antibodies independent of our Boltbody technology.

Each party is required to use commercially reasonable efforts to conduct development and regulatory activities assigned to it under a development plan. Toray will be solely responsible for both parties' development costs up to the conclusion of the first Phase I clinical trial and Toray is entitled to reimbursement for 50% of such development costs from our share of revenues collected from the sale or licensing of collaboration products. After the conclusion of the first Phase I clinical trial, the parties will share equally all costs of development activities necessary for obtaining regulatory approval of collaboration products in the Indications in the Territory, unless either party elects to opt out of its co-funding obligations or reduce them by half, which election can be on a region-by-region basis or for the Territory as a whole. Unless a party has made such an election, the parties will share equally all commercialization and outlicense revenues and other consideration received from collaboration activities.

If either party opts out of its co-funding obligation, then the other party will have the exclusive, sublicensable right to develop and commercialize collaboration products in the Indications in the applicable

regions of the Territory. The opting-out party, instead of equally sharing revenues from the sale of collaboration products in the opt-out regions, will receive royalties on other party's net sales of collaboration products in such regions, at rates from a mid-single digit to high teens percentage, subject to certain customary reductions, as well as a portion of any outlicensing revenue.

Unless earlier terminated, the Toray Development Agreement will remain in effect until collaboration products are no longer sold in the Territory. Either party has the right to terminate the Toray Development Agreement for the other party's uncured material breach or insolvency. The parties additionally may terminate the Toray Development Agreement by mutual agreement. The Toray Development Agreement will automatically terminate if the results of preclinical studies or the first Phase I clinical trial of the collaboration product do not meet the success criteria that are specified in the Toray Development Agreement. In the event of termination all licenses granted under the Toray Development Agreement and all development and commercialization obligations under the Toray Development Agreement will terminate. If either party elects to reduce its co-funding obligations by half in any region, then it will receive an adjusted share of revenues from the collaboration in such region to reflect such reduced funding.

Manufacturing

We do not own or operate any manufacturing facilities. We rely on third-party CMOs for production and testing of our clinical material, including the linkers, payloads and antibodies used to make our Boltbody ISACs, and we expect to continue to do so to meet our toxicology, clinical and commercial activities. We believe there are multiple sources for all of the materials required for the manufacture of our product candidates.

Manufacturing Agreement with Piramal

In June 2018, we entered into a master services agreement with Piramal pursuant to which Piramal provides development and cGMP manufacturing services to us on a non-exclusive basis, with initial statements of work covering our BDC-1001 drug substance and drug product. The agreement has an initial term of five years, and will continue for consecutive one-year renewal terms unless terminated by either party upon written notice to the other party prior to the end of the then current term. We may terminate the agreement or any statement of work upon prior written notice to Piramal, and may be required to pay cancellation fees if we cancel scheduled cGMP manufacturing slots without sufficient advance notice prior to the planned start date. In addition, either party may terminate the agreement for the other party's uncured material breach.

Supply Agreement with EirGenix

In March 2019, we entered into a supply agreement with EirGenix, Inc., pursuant to which EirGenix agreed to supply to us, on a non-exclusive basis, bulk drug substance of EG12014, its monoclonal antibody being developed as a biosimilar of trastuzumab, which we use in the manufacture of our BDC-1001 HER2 Boltbody ISAC. In addition, EirGenix provides us access to its regulatory data package to facilitate our development and commercialization efforts and we are required to make milestone payments to EirGenix up to an aggregate of $2.0 million based upon achievement of certain regulatory milestones by our HER2 Boltbody ISAC. The agreement will remain in effect as long as we, or any of our affiliates or licensees, continue to pursue the development or commercialization of any Boltbody ISAC, unless earlier terminated. We may terminate the agreement if EirGenix fails to supply sufficient quantities of EG12014, or if EirGenix does not obtain regulatory approval for EG12014 as a standalone biosimilar product. We may also terminate the EirGenix Agreement upon prior written notice to EirGenix. EirGenix may terminate the agreement if we do not actively develop a HER2 Boltbody ISAC for more than two years. In addition, either party may terminate the agreement for the other party's uncured material breach or insolvency.

Competition

The biotechnology and pharmaceutical industries, including the immuno-oncology subsector, are characterized by rapidly advancing technologies, fierce competition and a strong emphasis on proprietary drugs

and defense of intellectual property. We face potential competition from many sources, including pharmaceutical and biotechnology companies, academic institutions, public and private research institutions and governmental agencies. Any drug candidates that we successfully develop and commercialize will compete with existing treatments and new treatments that are in development and may become available in the future.

Oncology therapeutics on the market and in development range from traditional cancer therapies, including chemotherapy, to new therapies that harness the body's own immune system to fight cancer. A significant part of the immune response to cancer involves myeloid cells, including macrophages, dendritic cells, neutrophils, monocytes and granulocytes, all of which dynamically regulate tumor growth and progression. There are several therapies targeting myeloid cells on the market or in development. We view companies developing ISACs containing TLR agonists as the closest competitors for our lead program, BDC-1001. At least two other TLR agonist-containing ISACs are in development for oncology indications including Novartis' NJH-395 and Silverback's SBT6050. We currently do not consider any company potentially developing unconjugated TLR agonists to be direct competitors given our Boltbody ISAC approach has demonstrated greater effectiveness and differentiating biology compared to an unconjugated TLR agonist and such agents typically are administered intratumorally or have significant toxicities when administered systemically.

We are initially developing BDC-1001 for the treatment of HER2-expressing cancers. HER2 is a well-known and validated oncology target and there are marketed therapies and others in development addressing this target. Marketed therapies include Roche's Herceptin, Perjeta and Kadcyla, Novartis' Tykerb, Seattle Genetics' TUKYSA, as well as Daiichi Sankyo and AstraZeneca's ENHERTU. We are aware of several therapies in development for patients with HER2-expressing tumors including Zymework's zanidatamab and ZW49, MacroGenics' margetuximab, Merus' MCLA-128 and Ambrx's ARX788.

Many of the companies against which we currently are competing or which we may compete with in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical and clinical development, obtaining regulatory approvals and marketing approved drugs than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and enrolling subjects for our clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our success is contingent in part upon the successful development and commercialization of BDC-1001 and our other pipeline candidates from the Boltbody ISAC approach that prove to be more effective or safer than competing products in our target indications. We could see a reduction or elimination of our commercial opportunity if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than BDC-1001 or any other drug that we may develop. Our competitors also may be more successful than us in obtaining FDA or other regulatory approvals for their drugs more rapidly than we may obtain approval for BDC-1001 or our other drugs, which could result in our competitors establishing a strong market position before we are able to enter the market.

Intellectual Property

Our commercial success depends in part on our ability to obtain, maintain and protect intellectual property and other proprietary rights for our current and future product candidates, and our Boltbody ISAC approach through a variety of methods, including seeking and maintaining patents intended to cover our Boltbody ISAC approach, our products and compositions, their methods of use and processes for their manufacture and any other inventions that are commercially important to the development of our business, novel discoveries, product development technologies and know-how, to operate without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of others and to prevent others from infringing, misappropriating or violating our intellectual property and proprietary rights. We also rely on trademarks, trade secrets, know-how, continuing technological innovation and confidential information to develop and maintain our proprietary position.

Regardless of the coverage we seek under our existing patent applications, there is always a risk that an alteration to the product or process may provide sufficient basis for a competitor to avoid infringement claims. In addition, the coverage claimed in a patent application can be significantly reduced before a patent is issued and courts can reinterpret patent scope after issuance. Moreover, many jurisdictions, including the United States, permit third parties to challenge issued patents in administrative proceedings, which may result in further narrowing or even cancellation of patent claims. Moreover, we cannot provide any assurance that any patents will be issued from our pending or any future applications or that any current or future issued patents will adequately protect our intellectual property. For this and other risks related to our proprietary technology, inventions, improvements, Boltbody ISAC approach and product candidates, please see the section entitled "Risk Factors—Risks Related to Our Intellectual Property."

As of June 30, 2020, we have one issued patent in the U.S. which we co-own with Stanford and for which Stanford has exclusively licensed their rights to us. In addition, as of June 30, 2020, we have approximately 58 pending patent applications (20 of which are in the United States) including 26 pending patent applications (16 of which are in the United States and 1 of which is an International (PCT) application that has yet to enter the national phase in the United States) that are owned by us, 19 pending patent applications (1 of which is in the United States and 7 of which are International (PCT) applications that have yet to enter the national phase in the United States) that we co-own with Stanford and 13 pending patent applications (3 of which are in the United States) that are owned solely by Stanford and that we exclusively license from Stanford subject to retained rights described herein. Our issued patent in the U.S. will expire July 7, 2037 and the pending patent applications, including our licensed patent applications, if issued, are expected to expire between 2035 and 2040 excluding any extension of patent term that may be available. For more information regarding our license agreement with Stanford, please see "Business—License and Collaboration Agreements."

The patents and patent applications licensed from Stanford are subject to retained rights by Stanford to allow academic and non-profit research institutions to practice the licensed technology and patents for non-commercial purposes. The patents and patent applications licensed from Stanford Pursuant to the 2018 Stanford Agreement are additionally subject to a non-exclusive, worldwide license held by the Howard Hughes Medical Institute to exercise such intellectual property rights for research purposes, with the right to sublicense to non-profit and governmental entities.

Some of our pending patent applications in the United States are provisional patent applications. Provisional patent applications are not eligible to become issued patents until, among other things, we file a non-provisional patent application within 12 months of filing of one or more of our related provisional patent applications. If we do not timely file any 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 patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage.

The term of individual issued patents extend for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, utility patents issued for applications filed in the United States are granted a term of 20 years from the earliest effective filing date of a non-provisional patent application, assuming the patent has not been terminally disclaimed over a commonly-owned patent or a patent naming a common inventor, or over a patent not commonly owned but that was disqualified as prior art as the result of activities undertaken within the scope of a joint research agreement. The life of a patent, and the protection it affords, is therefore limited and once the patent life of our issued patents have expired, we may face competition, including from other competing technologies. In addition, in certain instances, the term of a U.S. patent can be extended to recapture a portion of the delay by the USPTO in issuing the patent as well as a portion of the term effectively lost as a result of the FDA regulatory review period. However, as to the FDA component, the restoration period cannot be longer than five years, the total patent term including the restoration period must not exceed 14 years following FDA

approval, only one patent applicable to each regulatory review period may be extended and only those claims covering the approved drug or a method for using it may be extended. We may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. There can be no assurance that we will benefit from any patent term extension or favorable adjustment to the term of any of our patents. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective filing date. The actual protection afforded by a patent may vary on a product-by-product basis and from country to country and can depend upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Furthermore, we rely upon trade secrets and know-how, confidential information, unpatented technologies, continuing technological innovation and other proprietary information to develop, protect and maintain our competitive position and aspects of our business that are not amenable to, or that we do not presently consider appropriate for, patent protection and prevent competitors from reverse engineering or copying our technologies. However, the foregoing rights, technologies and information are difficult to protect. We seek to protect them by, in part, using confidentiality agreements with our employees and consultants and any potential commercial partners and collaborators and invention assignment agreements with our employees. We also have implemented or intend to implement confidentiality agreements or invention assignment agreements with our selected consultants and any potential commercial partners. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. These agreements may be breached, and we may not have adequate remedies for any breach. There can be no assurance that these agreements will be self-executing or otherwise provide meaningful protection for our trade secrets or other intellectual property or proprietary information, In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Our commercial success will also depend in part on not infringing, misappropriating or otherwise violating the intellectual or proprietary rights of third parties. The issuance of third-party patents could require us to alter our development or commercial strategies, change our products or processes, obtain licenses to additional third-party patents or other intellectual property or cease certain activities. Our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop or commercialize our future products may have an adverse impact on us. Given that patent applications in the United States and certain other jurisdictions are maintained in secrecy for 18 months or potentially longer, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the patent protection being sought by third parties and/or the priority of inventions covered by such patent applications. Moreover, we may have to participate in interference, revocation, derivation, re-examination, post-grant review, *inter partes* review, or opposition proceedings brought by third parties or declared by the USPTO or an equivalent foreign body. See “Risk Factors—Risks Related to Our Intellectual Property” for additional information regarding these and other risks related to our intellectual property portfolio and their potential effect on us.

Government Regulation

Government authorities in the United States at the federal, state and local level and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and

biological products, such as our investigational medicines and any future investigational medicines. Generally, before a new drug or biologic can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

Regulatory Approval in the United States

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The FDCA, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Biological products used for the prevention, treatment or cure of a disease or condition of a human being are subject to regulation under the FDCA, except the section of the FDCA that governs the approval of new drug applications, NDAs. Biological products, such as our Boltbody ISAC product candidates, are approved for marketing under provisions of the Public Health Service Act. the PHSA, via a BLA. However, the application process and requirements for approval of BLAs are very similar to those for NDAs, and biologics are associated with similar approval risks and costs as drugs. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as clinical hold, FDA refusal to approve pending NDAs or BLAs, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

Our investigational medicines and any future investigational medicines must be approved by the FDA pursuant to a BLA before they may be legally marketed in the United States. The process generally involves the following:

- completion of extensive preclinical laboratory and animal studies in accordance with applicable regulations, including studies conducted in accordance with GLP requirements;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an IRB or independent ethics committee at each clinical trial site before each clinical trial may be commenced;
- performance of adequate and well-controlled human 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 a BLA;
- payment of any user fees for FDA review of the BLA;
- a determination by the FDA within 60 days of its receipt of a BLA to accept the filing for review;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the biologic, or components thereof, will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the biologic’s identity, strength, quality and purity;
- satisfactory completion of any potential FDA audits of the clinical trial sites that generated the data in support of the BLA to assure compliance with GCPs and integrity of the clinical data;
- FDA review and approval of the BLA, including consideration of the views of any FDA advisory committee; and
- compliance with any post-approval requirements, including REMS, where applicable, and post-approval studies required by the FDA as a condition of approval.

The preclinical and clinical 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, or at all.

Preclinical Studies

Before testing any biological product candidates in humans, the product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as *in vitro* and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin. Some long-term preclinical testing may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical Trials

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with GCPs, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors; as well as (iii) under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated in the trial. Each protocol involving testing on U.S. patients and subsequent protocol amendments 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 in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Information about certain clinical trials, including clinical trial results, must be submitted within specific timeframes for publication on the www.clinicaltrials.gov website. Information related to the product, patient population, phase of investigation, clinical trial sites and investigators and other aspects of the clinical trial is then made public as part of the registration. Disclosure of the results of these clinical trials can be delayed in certain circumstances for up to two years after the date of completion of the trial.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of a BLA. The FDA will accept a well-designed and well-conducted foreign clinical trial not conducted under an IND if the clinical trial 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 are generally conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3:

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate.

The primary purpose of these clinical trials is to assess the metabolism, pharmacokinetics, pharmacologic action, side effect tolerability, safety of the product candidate, and, if possible, early evidence of effectiveness.

- Phase 2 clinical trials generally involve studies in disease-affected patients to evaluate proof of concept and/or determine the dosing regimen(s) for subsequent investigations. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, possible adverse effects and safety risks are identified, and a preliminary evaluation of efficacy is conducted.
- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product labeling. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the biologic.

These Phases may overlap or be combined. For example, a Phase 1/2 clinical trial may contain both a dose-escalation stage and a dose-expansion stage, the latter of which may confirm tolerability at the recommended dose for expansion in future clinical trials (as in traditional Phase 1 clinical trials) and provide insight into the anti-tumor effects of the investigational therapy in selected subpopulation(s).

Typically, during the development of oncology therapies, all subjects enrolled in Phase 1 clinical trials are disease-affected patients and, as a result, considerably more information on clinical activity may be collected during such trials than during Phase 1 clinical trials for non-oncology therapies. A single Phase 3 or Phase 2 trial with other confirmatory evidence may be sufficient in rare instances to provide substantial evidence of effectiveness (generally subject to the requirement of additional post-approval studies).

Phase 1, Phase 2, Phase 3 and other types of clinical trials may not be completed successfully within any specified period, if at all. The FDA, the IRB, or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including non-compliance with regulatory requirements or a finding that the patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug or biologic has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated checkpoints based on access to certain data from the trial.

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

FDA Review Process

Following completion of the clinical trials, the results of preclinical studies and clinical trials are submitted to the FDA as part of a BLA, along with proposed labeling, chemistry and manufacturing information to ensure product quality and other relevant data. 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 a BLA must be obtained before a biologic or drug may be marketed in the United States.

The cost of preparing and submitting a BLA is substantial. Under the PDUFA, each BLA must be accompanied by a substantial user fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication. The applicant under an approved BLA is also subject to an annual program fee.

The FDA reviews all submitted BLAs before it accepts them for filing and may request additional information. The FDA must make a decision on accepting a BLA 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 review of the BLA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has 10 months, from the filing date, in which to complete its initial review of an original BLA for a new molecular entity and respond to the applicant, and six months from the filing date of an original BLA designated for priority review. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs, and the review process can be extended by FDA requests for additional information or clarification.

Before approving a BLA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications.

The FDA also may audit data from clinical trials to ensure compliance with GCP requirements and the integrity of the data supporting safety and efficacy. Additionally, the FDA may refer applications for novel products or products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it generally follows such recommendations when making decisions on approval. The FDA likely will reanalyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process.

After the FDA evaluates a BLA, it will issue either an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the biologic with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter generally outlines the deficiencies in the BLA and may require additional clinical data, additional pivotal clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing in order for FDA to reconsider the application. If a Complete Response Letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing. The FDA has committed to reviewing such resubmissions in two or six months, depending on the type of information included. Even if such data and information are submitted, the FDA may decide that the BLA does not satisfy the criteria for approval.

As a condition of BLA approval, the FDA may require a REMS to help ensure that the benefits of the biologic outweigh the potential risks to patients. A REMS can include medication guides, communication plans for healthcare professionals and elements to assure a product’s safe use, or ETASU. An ETASU can include, but is not limited to, special training or certification for prescribing or dispensing the product, dispensing the product only under certain circumstances, special monitoring and the use of patient-specific registries. The requirement for a REMS can materially affect the potential market and profitability of the product. Moreover, the FDA may require substantial post-approval testing and surveillance to monitor the product’s safety or efficacy.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States but for which there is no reasonable expectation that the cost of developing and making the product for this type of disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation on its own does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same product for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety, or providing a major contribution to patient care, or in instances of drug supply issues. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication. In the latter case, because healthcare professionals are free to prescribe products for off-label uses, the competitor's product could be used for the orphan indication despite another product's orphan exclusivity.

FDA's determination of whether two ADCs are the same product for purposes of orphan drug exclusivity is based on a determination of sameness of the monoclonal antibody element and the functional element of the conjugated molecule. Two ADCs are deemed to be the same product if the complementarity determining region sequences of the antibody and the functional element of the conjugated molecule are the same. A difference in either of those two elements can result in a determination that the molecules are different.

Expedited Development and Review Programs

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition.

Fast track designation may be granted for products that are intended to treat a serious or life-threatening disease or condition for which there is no effective treatment and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to both the product and the specific indication for which it is being studied. The sponsor of a new biologic candidate can request the FDA to designate the candidate for a specific indication for fast track status concurrent with, or after, the submission of the IND for the candidate. The FDA must determine if the biologic candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product's BLA before the application is complete. This "rolling review" is available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. Any product submitted to the FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval.

Breakthrough therapy designation may be granted for products that are intended, alone or in combination with one or more other products, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or

more clinically significant endpoints. Under the breakthrough therapy program, the sponsor of a new biologic candidate may request that the FDA designate the candidate for a specific indication as a breakthrough therapy concurrent with, or after, the submission of the IND for the biologic candidate. The FDA must determine if the biological product qualifies for breakthrough therapy designation within 60 days of receipt of the sponsor's request. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process, providing timely advice to the product sponsor regarding development and approval, involving more senior staff in the review process, assigning a cross-disciplinary project lead for the review team and taking other steps to design the clinical studies in an efficient manner.

Priority review may be granted for products that are intended to treat a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of an application designated for priority review in an effort to facilitate the review.

Accelerated approval may be granted for products that are intended to treat a serious or life-threatening condition and that generally provide a meaningful therapeutic advantage to patients over existing treatments. A product eligible for accelerated approval may be approved on the basis of either a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that 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. In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions or survives. The accelerated approval pathway is most often used in settings in which the course of a disease is long, and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of products for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large studies to demonstrate a clinical or survival benefit. The accelerated approval pathway is contingent on a sponsor's agreement to conduct additional post-approval confirmatory studies to verify and describe the product's clinical benefit. These confirmatory trials must be completed with due diligence and, in some cases, the FDA may require that the trial be designed, initiated and/or fully enrolled prior to approval. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

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 standards for approval, but may expedite the development or approval process.

Additional Controls for Biologics

To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the United States and between states.

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the

manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency and effectiveness of biological products. As with drugs, after approval of biologics, manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection after approval.

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, BLAs or supplements to BLAs must contain data to assess the safety and effectiveness of the biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the biological product is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA generally does not apply to any biological product for an indication for which orphan designation has been granted. However, beginning in 2020, PREA will apply to BLAs for orphan-designated biologics if the biologic is a molecularly targeted cancer product intended for the treatment of an adult cancer and is directed at a molecular target that FDA has determined is substantially relevant to the growth or progression of a pediatric cancer.

The Best Pharmaceuticals for Children Act, or the BPCA, provides a six-month extension of any exclusivity—patent or non-patent—for a biologic if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new biologic in the pediatric population may produce health benefits in that population, FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Post-Approval Requirements

Once a BLA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of biologics, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Biologics may be marketed only for the approved indications and in a manner consistent with the provisions of the approved labeling.

Adverse event reporting and submission of periodic safety summary reports is required following FDA approval of a BLA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, biological product manufacture, packaging and labeling procedures must continue to conform to cGMPs after approval. Biologic manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects a biologic product's manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with required regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes or failure to comply with regulatory requirements, may result in

revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical studies to assess new safety risks or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

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

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under 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. Patent term extension, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term extension period is generally one half the time between the effective date of an IND and the submission date of a BLA, plus the time between the submission date of a BLA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for such an extension, only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, we or our licensors may apply for patent term extension for our owned or licensed patents to add patent life beyond their current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA. However, an extension might not be granted because of, for example, our or our licensors' failure to exercise due diligence during the testing phase or regulatory review process, failure to apply within applicable deadlines, failure to apply prior to expiration of relevant patents or any other failure to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than requested. There is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether any extensions should be granted, and if granted, the length of such extensions.

The Biologics Price Competition and Innovation Act of 2009, or the BPCIA, created an abbreviated approval pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed reference biological product. Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies and a clinical trial or trials. Interchangeability requires that a biological product be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product without such alternation or switch.

A reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product and the FDA will not accept an application for a biosimilar or interchangeable product based on the

reference biological product until four years after the date of first licensure of the reference product. “First licensure” typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity or potency.

Regulatory Approval in the European Union

The EMA is a decentralized scientific agency of the European Union. It coordinates the evaluation and monitoring of centrally authorized medicinal products. It is responsible for the scientific evaluation of applications for EU marketing authorizations, as well as the development of technical guidance and the provision of scientific advice to sponsors. The EMA decentralizes its scientific assessment of medicines by working through a network of about 4,500 experts throughout the European Union, nominated by the member states. The EMA draws on resources of over 40 National Competent Authorities of European Union member states.

The process regarding approval of medicinal products in the European Union follows roughly the same lines as in the United States and likewise generally involves satisfactorily completing each of the following:

- preclinical laboratory tests, animal studies and formulation studies all performed in accordance with the applicable EU Good Laboratory Practice regulations;
- submission to the relevant national authorities of a clinical trial application, or CTA, for each trial in humans, which must be approved before the trial may begin in each country where patient enrollment is planned;
- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication;
- submission to the relevant competent authorities of a MAA, which includes the data supporting safety and efficacy as well as detailed information on the manufacture and composition of the product in clinical development and proposed labelling;
- satisfactory completion of an inspection by the relevant national authorities of the manufacturing facility or facilities, including those of third parties, at which the product is produced to assess compliance with strictly enforced cGMP;
- potential audits of the non-clinical and clinical trial sites that generated the data in support of the MAA; and
- review and approval by the relevant competent authority of the MAA before any commercial marketing, sale or shipment of the product.

Preclinical Studies

Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animal studies, in order to assess the quality and potential safety and efficacy of the product. The conduct of the preclinical tests and formulation of the compounds for testing must comply with the relevant international, EU and national legislation, regulations and guidelines. The results of the preclinical tests, together with relevant manufacturing information and analytical data, are submitted as part of the CTA.

Clinical Trials

Pursuant to the Clinical Trials Directive 2001/20/EC, as amended, or the Clinical Trials Directive, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the

member states. Under this system, approval must be obtained from the competent national authority of each European Union member state in which a clinical trial is planned to be conducted. To this end, a CTA is submitted, which must be supported by an investigational medicinal product dossier and further supporting information prescribed by the Clinical Trials Directive and other applicable guidance documents including but not being limited to the clinical trial protocol. Furthermore, a clinical trial may only be started after a competent ethics committee has issued a favorable opinion on the clinical trial application in that country.

Directive 2001/20/EC will be replaced by Regulation (EU) No. 536/2014, which became effective on June 16, 2014. The Regulation introduces an authorization procedure based on a single submission via a single EU portal, an assessment procedure leading to a single decision, as well as transparency requirements (the proactive publication of clinical trial data in the EU database). Since October 2016, based on its Policy 0070, the EMA has been publishing clinical data submitted by pharmaceutical companies to support their MAA for human medicines under this centralized procedure.

Manufacturing and import into the EU of investigational medicinal products is subject to the holding of appropriate authorizations and must be carried out in accordance with cGMP.

Review and Approval

Authorization to market a product in the European Union member states proceeds under one of four procedures: a centralized authorization procedure, a mutual recognition procedure, a decentralized procedure or a national procedure. Since our products by their virtue of being antibody-based biologics fall under the centralized procedure, only this procedure will be described here.

Certain drugs, including medicinal products developed by means of biotechnological processes, must be approved via the centralized authorization procedure for marketing authorization. A successful application under the centralized authorization procedure results in a marketing authorization from the European Commission, which is automatically valid in all European Union member states. The other European Economic Area member states (namely Norway, Iceland and Liechtenstein) are also obligated to recognize the European Commission decision. The EMA and the European Commission administer the centralized authorization procedure.

Under the centralized authorization procedure, the Committee for Medicinal Products for Human Use, or the CHMP, serves as the scientific committee that renders opinions about the safety, efficacy and quality of human products on behalf of the EMA. The CHMP is composed of experts nominated by each member state’s national drug authority, with one of them appointed to act as Rapporteur for the co-ordination of the evaluation with the possible assistance of a further member of the CHMP acting as a Co-Rapporteur. After approval, the Rapporteur(s) continue to monitor the product throughout its life cycle. The CHMP is required to issue an opinion within 210 days of receipt of a valid application, though the clock is stopped if it is necessary to ask the applicant for clarification or further supporting data. The process is complex and involves extensive consultation with the regulatory authorities of member states and a number of experts. Once the procedure is completed, a European Public Assessment Report is produced. If the CHMP concludes that the quality, safety and efficacy of the medicinal product is sufficiently proven, it adopts a positive opinion. The CHMP’s opinion is sent to the European Commission, which uses the opinion as the basis for its decision whether or not to grant a marketing authorization. If the opinion is negative, information is given as to the grounds on which this conclusion was reached.

After a drug has been authorized and launched, it is a condition of maintaining the marketing authorization that all aspects relating to its quality, safety and efficacy must be kept under review. Sanctions may be imposed for failure to adhere to the conditions of the marketing authorization. In extreme cases, the authorization may be revoked, resulting in withdrawal of the product from sale.

Conditional Approval and Accelerated Assessment

As per Article 14(7) of Regulation (EC) 726/2004, a medicine that would fulfill an unmet medical need may, if its immediate availability is in the interest of public health, be granted a conditional marketing authorization on the basis of less complete clinical data than are normally required, subject to specific obligations being imposed on the authorization holder. These specific obligations are to be reviewed annually by the EMA. The list of these obligations shall be made publicly accessible. Such an authorization shall be valid for one year, on a renewable basis.

When an application is submitted for a marketing authorization in respect of a drug for human use which is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation, the applicant may request an accelerated assessment procedure pursuant to Article 14(9) of Regulation (EC) 726/2004. Under the accelerated assessment procedure, the CHMP is required to issue an opinion within 150 days of receipt of a valid application, subject to clock stops. We believe that some of the disease indications in which our product candidates are currently being or may be developed in the future qualify for this provision, and we will take advantage of this provision as appropriate.

Period of Authorization and Renewals

A marketing authorization is initially valid for five years and may then be renewed on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To this end, the marketing authorization holder shall provide the EMA or the competent authority with a version of the file in respect of quality, safety and efficacy, including all variants introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization shall be valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization which is not followed by the actual placing of the drug on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization shall cease to be valid (the so-called “sunset clause”).

Without prejudice to the law on the protection of industrial and commercial property, marketing authorizations for new medicinal products benefit from an 8+2+1 year period of regulatory protection. This regime consists of a regulatory data protection period of eight years plus a concurrent market exclusivity of 10 years plus an additional market exclusivity of one further year if, during the first eight years of those 10 years, the marketing approval holder obtains an approval for one or more new therapeutic indications which, during the scientific evaluation prior to their approval, are determined to bring a significant clinical benefit in comparison with existing therapies. Under the current rules, a third party may reference the preclinical and clinical data of the reference product beginning eight years after first approval, but the third party may market a generic version of the reference product after only 10 (or 11) years have lapsed.

Orphan Drug Designation

Regulation (EC) 141/2000 states that a drug shall be designated as an orphan drug if its sponsor can establish (i) that it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union when the application is made, or that it is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the drug in the European Union would generate sufficient return to justify the necessary investment; and (ii) that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union or, if such method exists, the drug will be of significant benefit to those affected by that condition.

Regulation (EC) 847/2000 sets out criteria for the designation of orphan drugs. An application for designation as an orphan product can be made any time prior to the filing of an application for approval to market

the product. Marketing authorization for an orphan drug leads to a 10-year period of market exclusivity, which means that no similar medicinal product can be authorized in the same indication. This period may, however, 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 drug designation, for example because the product is sufficiently profitable not to justify continued market exclusivity. In addition, derogation from market exclusivity may be granted on an individual basis in very selected cases, such as consent from the marketing authorization holder, inability to supply sufficient quantities of the product or demonstration of "clinically relevant superiority" by a similar medicinal product. Medicinal products designated as orphan drugs pursuant to Regulation (EC) 141/2000 are eligible for incentives made available by the European Union and by the member states to support research into, and the development and availability of, orphan drugs.

If the MAA of a medicinal product designated as an orphan drug pursuant to Regulation (EC) 141/2000 includes the results of all studies conducted in compliance with an agreed PIP, and a corresponding statement is subsequently included in the marketing authorization granted, the 10-year period of market exclusivity will be extended to 12 years.

European Data Collection and Processing

The collection, transfer, processing and other use of personal information, including health data, in the European Union is governed by the GDPR, which came into effect in May 2018. This directive imposes several requirements relating to (i) obtaining, in some situations, the consent of the individuals to whom the personal data relates, (ii) the information provided to the individuals about how their personal information is used, (iii) ensuring the security and confidentiality of the personal data, (iv) the obligation to notify regulatory authorities and affected individuals of personal data breaches, (v) extensive internal privacy governance obligations and (vi) obligations to honor rights of individuals in relation to their personal data (for example, the right to access, correct and delete their data). The GDPR prohibits the transfer of personal data to countries outside the European Economic Area, such as the United States, which are not considered by the European Commission to provide an adequate level of data protection. Switzerland has adopted similar restrictions. Failure to comply with the requirements of the GDPR and the related national data protection laws of the European Union member states may result in fines and other administrative penalties. The GDPR introduces new data protection requirements in the EU and substantial fines for breaches of the data protection rules. The GDPR and related data protection laws may impose additional responsibility and liability in relation to personal data that we collect and process and we may be required to put in place additional mechanisms ensuring compliance with such rules. This may be onerous and adversely affect our business, financial condition, results of operations and prospects.

Marketing

Much like the Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of European Union member states, such as the U.K. Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

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

International Regulation

In addition to regulations in the United States and Europe, a variety of foreign regulations govern clinical trials, commercial sales and distribution of product candidates. The approval process varies from country to country and the time to approval may be longer or shorter than that required for FDA or European Commission approval.

Other Healthcare Laws and Regulations and Legislative Reform

Healthcare and Privacy Laws and Regulations

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our operations, including any arrangements with healthcare providers, physicians, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws that may affect the business or financial arrangements and relationships through which we would market, sell and distribute our products. The healthcare laws that may affect our ability to operate include, but are not limited to:

- The federal Anti-Kickback Statute, which prohibits any person or entity from, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value. The federal Anti-Kickback Statute has also been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection.
- Federal civil and criminal false claims laws, such as the FCA, which can be enforced by private citizens through civil qui tam actions, and civil monetary penalty laws prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment of federal funds, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. For example, pharmaceutical companies have been prosecuted under the FCA in connection with their alleged off-label promotion of drugs, purportedly concealing price concessions in the pricing information submitted to the government for government price reporting purposes, and allegedly providing free product to customers with the expectation that the customers would bill federal healthcare programs for the product. In addition, 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 FCA. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. In addition, 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.
- HIPAA, among other things, imposes criminal liability for executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and creates federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services.

- HIPAA, as amended by HITECH, and their implementing regulations, which impose privacy, security and breach reporting obligations with respect to individually identifiable health information upon entities subject to the law, such as health plans, healthcare clearinghouses and certain healthcare providers, known as covered entities, and their respective business associates that perform services for them that involve individually identifiable health information. 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 U.S. federal courts to enforce HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.
- Federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.
- The federal transparency requirements under the Physician Payments Sunshine Act, created under the Patient Protection and Affordable Care Act, or the Health Care Reform Act, which requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to CMS information related to payments and other transfers of value provided to physicians, as defined by such law, and teaching hospitals and physician ownership and investment interests, including such ownership and investment interests held by a physician's immediate family members.
- State and foreign laws that are analogous to each of the above federal laws, such as anti-kickback and false claims laws, that may impose similar or more prohibitive restrictions, and may apply to items or services reimbursed by non-governmental third-party payors, including private insurers.
- State and foreign laws that require pharmaceutical companies to implement compliance programs, comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or to track and report gifts, compensation and other remuneration provided to physicians and other healthcare providers; state laws that require the reporting of marketing expenditures or drug pricing, including information pertaining to and justifying price increases; state and local laws that require the registration of pharmaceutical sales representatives; state laws that prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals; state laws that require the posting of information relating to clinical trials and their outcomes; and other federal, state and foreign laws that govern the privacy and security of health information or personally identifiable information in certain circumstances, including state health information privacy and data breach notification laws which govern the collection, use, disclosure and protection of health-related and other personal information, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus requiring additional compliance efforts.

If our operations are found to be in violation of any of these laws or any other current or future healthcare laws that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could substantially disrupt our operations. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Legislative Reform

We operate in a highly regulated industry, and new laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, related to healthcare availability, the method of delivery and payment for healthcare products and services could negatively affect our business, financial condition and prospects. There is significant interest in promoting healthcare reforms, and it is likely that federal and state legislatures within the United States and the governments of other countries will continue to consider changes to existing healthcare legislation.

For example, the United States and state governments continue to propose and pass legislation designed to reduce the cost of healthcare. In 2010, the U.S. Congress enacted the Health Care Reform Act, which included changes to the coverage and reimbursement of drug products under government healthcare programs such as:

- increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program;
- established a branded prescription drug fee that pharmaceutical manufacturers of certain branded prescription drugs must pay to the federal government;
- expanded the list of covered entities eligible to participate in the 340B drug pricing program by adding new entities to the program;
- established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% 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;
- extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- created a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, that are inhaled, infused, instilled, implanted or injected;
- established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- established a Center for Medicare and Medicaid Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending; and
- created a licensure framework for follow-on biologic products.

There remain judicial and congressional challenges to certain aspects of the Health Care Reform Act as well as efforts by the current U.S. Presidential Administration to repeal or replace certain aspects of the Health Care Reform Act. For example, in 2017, the U.S. Congress enacted the Tax Act, which eliminated the tax-based shared responsibility payment imposed by the Health Care Reform 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, the U.S. District Court for the Northern District of Texas held that the individual mandate is a critical and inseverable feature of the Health Care Reform Act, and therefore, because it was repealed by the Tax Act, the remaining provisions of the Health Care Reform Act are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit upheld the District Court ruling that the

individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Health Care Reform Act are invalid as well. On March 2, 2020, the Supreme Court of the United States granted the petitions for writ of certiorari to review this case and has allotted one hour for oral arguments, which are expected to occur in the fall. It is unclear how this litigation and other efforts to repeal and replace the Health Care Reform Act will impact the Health Care Reform Act. It is difficult to predict the future legislative landscape in healthcare and the effect on our business, results of operations, financial condition and prospects.

In 2017, the U.S. Congress enacted the Right to Try Act. 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.

In addition, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs. In 2011, the U.S. Congress enacted the Budget Control Act, which included provisions intended to reduce the federal deficit. The Budget Control Act resulted in the imposition of 2% reductions in Medicare payments to providers beginning in 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 absent additional congressional action. The CARES Act suspended the 2% Medicare sequester reductions under the Budget Control Act from May 1, 2020 through December 31, 2020 and extended the sequester by one year, through 2030. In 2012, the U.S. Congress enacted the American Taxpayer Relief Act, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. If government spending is further reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA, to continue to function at current levels, which may impact the ability of relevant agencies to timely review and approve research and development, manufacturing and marketing activities, which may delay our ability to develop, market and sell any product candidates we may develop. In addition, any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented, or any significant taxes or fees that may be imposed on us, as part of any broader deficit reduction effort or legislative replacement to the Budget Control Act, could have an adverse impact on our anticipated product revenues.

Furthermore, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several congressional inquiries and proposed legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drug products. At the federal level, the U.S. Presidential Administration’s budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the current U.S. Presidential Administration sent “principles” for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses and place limits on pharmaceutical price increases. Further, the current U.S. Presidential Administration previously released a “Blueprint” to lower drug prices and reduce out-of-pocket costs of drugs that contained proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out-of-pocket costs of drug products paid by consumers. HHS has solicited feedback on some of these measures and has implemented others under its existing authority. For example, CMS issued a final rule in May 2019 to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS’s policy change that was effective January 1, 2019. While some of these and other

measures may require additional authorization to become effective, Congress and the current U.S. Presidential Administration have each indicated that it will continue to seek new measures to control drug costs. Individual states in the United States have also become increasingly active in passing legislation and implementing 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. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. We expect that additional state and federal healthcare reform measures will be adopted in the future.

Environmental, Health and Safety Laws and Regulations

We and our third-party contractors are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the use, generation, manufacture, distribution, storage, handling, treatment, remediation and disposal of hazardous materials and wastes. Hazardous chemicals, including flammable and biological materials, are involved in certain aspects of our business, and we cannot eliminate the risk of injury or contamination from the use, generation, manufacture, distribution, storage, handling, treatment or disposal of hazardous materials and wastes. In particular, our product candidates use PBDs, which are highly potent cytotoxins that require special handling by our and our contractors' staff. In the event of contamination or injury, or failure to comply with environmental, health and safety laws and regulations, we could be held liable for any resulting damages, fines and penalties associated with such liability could exceed our assets and resources. Environmental, health and safety laws and regulations are becoming increasingly more stringent. We may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations.

Pharmaceutical Coverage, Pricing and Reimbursement

The availability and extent of coverage and adequate reimbursement by governmental and private third-party payors are essential for most patients to be able to afford expensive medical treatments. In both domestic and foreign markets, sales of our product candidates will depend substantially on the extent to which the costs of our product candidates will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. These third-party payors decide which products will be covered and establish reimbursement levels for those products.

Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

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

Obtaining coverage approval and reimbursement for a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to the payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement at a satisfactory level. If coverage and adequate reimbursement of our future products, if any, are unavailable or limited in scope or amount, such as may result where alternative or generic treatments are available, we may be unable to achieve or sustain profitability. Adverse coverage and reimbursement limitations may hinder our ability to recoup our investment in our product candidates, even if such product candidates obtain regulatory approval.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. There is no uniform policy for coverage and reimbursement in the United States and, as a result, coverage and reimbursement can differ significantly from payor to payor. In the United States, the principal decisions about reimbursement for new medicines are typically made by the CMS, which decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors often, but not always, follow the CMS's decisions regarding coverage and reimbursement. It is difficult to predict what third-party payors will decide with respect to coverage and reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these new products. Further, one payor's determination to provide coverage and adequate reimbursement for a product does not assure that other payors will also provide coverage and adequate reimbursement for that product. We may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our product candidates. There can be no assurance that our product candidates will be considered medically necessary or cost-effective. In addition to third-party payors, professional organizations and patient advocacy groups such as the National Comprehensive Cancer Network and the American Society of Clinical Oncology can influence decisions about reimbursement for new medicines by determining standards for care. Therefore, it is possible that any of our product candidates, even if approved, may not be covered by third-party payors or the reimbursement limit may be so restrictive that we cannot commercialize the product candidates profitably.

Reimbursement agencies in Europe may be more restrictive than payors in the United States. For example, a number of cancer products have been approved for reimbursement in the United States but not in certain European countries. In Europe, pricing and reimbursement schemes vary widely from country to country. For example, some countries provide that products may be marketed only after an agreement on reimbursement price has been reached. Such pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Other countries require the completion of additional health technology assessments that compare the cost-effectiveness of a particular product candidate to currently available therapies. In addition, 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, may adopt a system of direct or indirect controls on the profitability of the company placing the product on the market or monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. Furthermore, many countries in the European Union have increased the amount of discounts required on pharmaceutical products, 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, and prescription products in particular, has become increasingly intense. As a result, there are increasingly higher barriers to entry for new products. There can be no assurance that any country that has reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products, if approved in those countries. Accordingly, the reimbursement for any products in Europe may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

Furthermore, the containment of healthcare costs has become a priority of foreign and domestic governments as well as private third-party payors. The prices of drugs have been a focus in this effort. Governments and private third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability to sell our product candidates profitably. We also expect to experience pricing pressures due to the trend towards managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. These and other cost-control initiatives could cause us to decrease the price we might establish for products, which could result in lower-than-anticipated product revenues. In addition, the publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication

and other countries. If pricing is set at unsatisfactory levels or if coverage and adequate reimbursement of our products is unavailable or limited in scope or amount, our revenues and the potential profitability of our product candidates in those countries would be negatively affected.

Employees

As of June 30, 2020, we had 53 full-time employees. 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 and we have not experienced any work stoppages.

Facilities

Our headquarters are located in Redwood City, California, where we lease space in three locations totaling approximately 80,500 square feet of leased space, of which we have subleased approximately 20,500 square feet to third parties. Our leases expire between 2023 and 2031. We believe that our headquarters and other offices are adequate for our current needs.

Legal Proceedings

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. There are currently no claims or actions pending against us, the ultimate disposition of which we believe could have a material adverse effect on our results of operations, financial condition or cash flows.

MANAGEMENT

Executive Officers and Directors

The following table sets forth certain information for our executive officers and directors as of June 30, 2020:

Name	Age	Position(s)
Executive Officers		
Randall C. Schatzman, Ph.D.	65	Chief Executive Officer and Director
William P. Quinn	49	Chief Financial Officer
David Dornan, Ph.D.	43	Senior Vice President of Research and Manufacturing
Edith A. Perez, M.D.	64	Chief Medical Officer
Grant Yonehiro	56	Chief Business Officer
Non-Employee Directors		
Peter Moldt, Ph.D.	61	Chairman of the Board
Edgar G. Engleman, M.D.	74	Director
Ashish Khanna, Ph.D.	49	Director
Richard A. Miller, M.D.	69	Director
Jason Pitts, Ph.D.	34	Director
Mahendra G. Shah, Ph.D.	75	Director

(1) Member of the audit committee
(2) Member of the compensation committee
(3) Member of the nominating and corporate governance committee

Executive Officers

Randall C. Schatzman, Ph.D. has served as our Chief Executive Officer and director since July 2019. From 2004 to March 2018, Dr. Schatzman served as President, Chief Executive Officer and a member of the board of directors of Alder BioPharmaceuticals, Inc. From 1999 to 2004, Dr. Schatzman served as Senior Vice President of Discovery Research at Celltech R&D, Inc., a wholly-owned subsidiary of Celltech Group plc. From 1995 to 1999, Dr. Schatzman served as Director of Gene Discovery at Mercator Genetics Inc. From 1987 to 1995, Dr. Schatzman served as Section Leader at Roche Bioscience, previously Syntex Corp., a subsidiary of Roche Holdings Ltd. Dr. Schatzman holds a Ph.D. in Molecular Pharmacology from Emory University and a B.S. in Biochemistry from Purdue University. We believe that Dr. Schatzman is qualified to serve on our board of directors due to his daily insight into corporate matters as our Chief Executive Officer and his extensive background in the biotechnology industry.

William P. Quinn has served as our Chief Financial Officer since May 2020. From November 2017 to May 2020, Mr. Quinn served as Chief Financial Officer and Senior Vice President, Finance and Corporate Development, of Sunesis Pharmaceuticals, Inc. From 2011 to November 2017, Mr. Quinn served as President and Chief Executive Officer of Bullet Biotechnology, Inc. From 2003 to 2011, Mr. Quinn served in various positions at Jazz Pharmaceuticals, Inc. From 2001 to 2002, Mr. Quinn served as Chief Operating Officer and Chief Financial Officer at Novation Biosciences. From 1999 to 2001, Mr. Quinn served as Associate Partner at Mobius Venture Capital, an early-stage venture capital fund. Since 2011, Mr. Quinn has served on the board of directors of A Foundation Building Strength, a non-profit dedicated to finding treatments for Nemaline Myopathy. Mr. Quinn holds a B.A. and M.A. from Stanford University and an M.B.A. from Stanford Graduate School of Business.

David Dornan, Ph.D. has served as our Senior Vice President of Research and Manufacturing since March 2019. From November 2017 to March 2019, Dr. Dornan served as our Senior Vice President of Research. From 2012 to November 2017, Dr. Dornan held various positions at Gilead Sciences, Inc., including Director and Head of Oncology Research and Senior Research Scientist II, Oncology. From 2002 to 2012, Dr. Dornan held various positions at Genentech, Inc. Dr. Dornan received a B.Sc. in Biochemistry and Molecular Biology from the University of Strathclyde and a Ph.D. in Molecular Oncology/Biochemistry from the University of Dundee.

Edith A. Perez, M.D. has served as our Chief Medical Officer since April 2020. From August 2015 to May 2018, Dr. Perez served as Vice President and Head of the U.S. BioOncology Medical Unit of Genentech, Inc. From 2011 to 2015, Dr. Perez served in multiple senior leadership positions at Alliance for Clinical Trials in Oncology, including Vice President and Group Vice Chair. Since 2001, Dr. Perez has held various positions at the Mayo Clinic, including Supplemental Consultant in the Departments of Hematology/Oncology and Cancer Biology, Director of the Breast Cancer Translational Genomics Program and Professor of Medicine. From 2014 to 2018, Dr. Perez served as a member of the board of directors for the American Association for Cancer Research. Dr. Perez received a B.S. in Biology from the University of Puerto Rico, Rio Piedras and an M.D. from the University of Puerto Rico.

Grant Yonehiro has served as our Chief Business Officer since November 2016. From February 2016 to November 2016, Mr. Yonehiro served as Interim Chief Commercial Officer at Vium, Inc., a private biotechnology company. From 2013 to January 2016, Mr. Yonehiro served as Chief Business Officer at Berkeley Lights, a public biotechnology company. From 2009 to 2013, Mr. Yonehiro served as Chief Executive Officer and President at Perseid Therapeutics LLC. From 2003 to 2009, Mr. Yonehiro served as Chief Business Officer and Senior Vice President at Maxygen, Inc, a public biopharmaceutical company. From 1997 to 2003, Mr. Yonehiro served as Vice President, Drug Development at GenVec, Inc. Mr. Yonehiro received a B.I.S. in Business, Economics and International Relations from the University of Minnesota, Twin Cities and an M.B.A. from the University of California at Berkeley.

Non-Employee Directors

Peter Moldt, Ph.D. has served as chairman of our board of directors since September 2016. Since May 2012, Dr. Moldt has served as a Partner of Novo Ventures (US) Inc., which provides certain consultancy services to Novo Holdings A/S, a Danish limited liability company that manages investments and financial assets. From 2009 to 2012, Dr. Moldt served as Partner of Novo Holdings A/S. From 2004 to 2009, Dr. Moldt served as Chief Executive Officer of Curalogic A/S, a publicly listed Danish pharmaceutical company which Dr. Moldt founded. From 2000 to 2004, Dr. Moldt served as Chief Operating Officer of 7TM Pharma A/S, a private biotechnology company which Dr. Moldt co-founded. From 1989 to 2000, Dr. Moldt held various positions with NeuroSearch A/S, a publicly listed Danish biotechnology company. Dr. Moldt currently serves on the boards of directors of several private biotechnology and biopharmaceutical companies. He received an M.Sc. and a Ph.D. in Pharmacy and Medicinal Chemistry from the Royal Danish School of Pharmacy. Dr. Moldt also holds a Ph.D. in Organic Chemistry from Yale University. We believe that Dr. Moldt is qualified to serve on our board of directors due to his experience in the biotechnology and biopharmaceutical industries and his substantial professional experience.

Edgar G. Engleman, M.D. has been a member of our board of directors since January 2015, when he founded Bolt. Since 1996, Dr. Engleman has held various positions at Vivo Capital, LLC, a global investment firm focused on healthcare that Dr. Engleman co-founded, and currently serves as Partner, Chief Scientific Advisor. Since 1990, Dr. Engleman has served as Professor of Pathology and Medicine at Stanford University School of Medicine, where he established the Stanford Blood Center, mentors a wide range of trainees and co-directs the Tumor Immunology and Immunotherapy Program of the Stanford Cancer Institute. Dr. Engleman has co-founded a number of biopharmaceutical companies, including Cetus Immune Corporation, Genelabs Technologies, Inc., Dendreon Corporation, Medeor Therapeutics and Tranquis Therapeutics. He received a B.A. from Harvard University and an M.D. from Columbia University School of Medicine. We believe that Dr. Engleman is qualified to serve on our board of directors due to his experience as founder of our company and his expertise and experience in the biopharmaceutical industry.

Ashish Khanna, Ph.D. has served as a member of our board of directors since July 2018. Since September 2017, Dr. Khanna has served as a Venture Partner at Pivotal bioVenture Partners. Dr. Khanna also serves on the board of directors of two private biopharmaceutical companies, Evommune, Inc. and Fountain Therapeutics, Inc. From 2013 to August 2017, Dr. Khanna served as Chief Business Officer of Vaxcyte, Inc., a company which he co-founded. Prior to his role at Vaxcyte, Dr. Khanna was a Principal at SV Life Sciences, a healthcare focused venture capital firm, investing in private biotech and diagnostic companies. Dr. Khanna holds a B.S. in Pharmacy from the University of Bombaya, an M.B.A. in Finance from The Wharton School and a Ph.D. in Pharmaceutics from the State University of New York. We believe that Dr. Khanna is qualified to serve on our board of directors due to his expertise and experience in the biopharmaceutical industry and his experience in healthcare investing.

Richard A. Miller, M.D. has served as a member of our board of directors since July 2017. Since 2014, Dr. Miller has served as Chief Executive Officer, President and Chairman of the Board of Directors of Corvus Pharmaceuticals, Inc., a public biotechnology company developing drugs and biologics for cancer and other diseases. From 2012 to 2014, Dr. Miller served as Chairman and Chief Executive Officer of Graphea, Inc., a privately held chemical company that he founded. From 2010 to 2011, Dr. Miller served as Chief Commercialization Officer, Associate Dean and Research Professor in Chemistry at The University of Texas at Austin. From 2009 to 2011, Dr. Miller served as President, Chief Executive Officer and Director of Principia Biopharma Inc., which he founded. From 1991 to 2008, Dr. Miller served as President, Chief Executive Officer and Director of Pharmacyclics, Inc., which he co-founded. Since 1991, Dr. Miller has been an Adjunct Clinical Professor of Medicine (Oncology) at Stanford University Medical Center. Dr. Miller received a B.A. in Chemistry from Franklin & Marshall College and an M.D. from the State University of New York Medical School. He is board certified in both Internal Medicine and Medical Oncology. We believe that Dr. Miller is qualified to serve on our board of directors due to his expertise and experience in the biotechnology industry and his leadership experience as a senior executive at various biotechnology companies.

Jason Pitts, Ph.D. has served as a member of our board of directors since June 2020. Since June 2019, Dr. Pitts has served as a Principal at Sofinnova Investments. From January 2018 to May 2019, Dr. Pitts served as an Associate at Sofinnova Investments. From February 2016 to January 2018, Dr. Pitts served as an Associate at McKinsey & Company. From 2009 to 2010, Dr. Pitts served as a Research Associate at Regeneron Pharmaceuticals, Inc. Dr. Pitts received a B.S. in Neuroscience from Cornell University and a Ph.D. in Neuroscience from The Rockefeller University. We believe that Dr. Pitts is qualified to serve on our board of directors due to his experience in guiding multiple companies in his role as a venture capital investor and his experience in healthcare investing.

Mahendra G. Shah, Ph.D. has served as a member of our board of directors since September 2016. Since 2010, Dr. Shah has served in multiple positions at Vivo Capital, LLC and currently serves as Managing Director. From 2005 to 2009, Dr. Shah served as Chairman and Chief Executive Officer of NextWave Pharmaceuticals, Inc., a company which he also founded. From 1993 to 2003, Dr. Shah served as the Chairman and Chief Executive Officer of First Horizon Pharmaceutical Corporation. From 1991 to 1999, Dr. Shah served as Vice President of E. J. Financial Enterprises, Inc., a healthcare-fund management company. From 1987 to 1991, Dr. Shah served as the Senior Director of New Business Development at Fujisawa USA Inc. Dr. Shah received a B.A. and M.A. in Pharmacy from L.M. College of Pharmacy in Gujarat, India and a Ph.D. in Industrial Pharmacy from St. John’s University. We believe that Dr. Shah is qualified to serve on our board of directors due to his expertise and experience in the biopharmaceutical industry and his experience in healthcare investing.

Family Relationships

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

Composition of Our Board of Directors

Certain members of our board of directors were elected pursuant to the provisions of a voting agreement, as amended. Under the terms of this voting agreement, the stockholders who are party to the voting agreement have agreed to vote their respective shares so as to elect: (1) one director designated by Sofinnova Venture Partners X, L.P., currently Dr. Pitts; (2) one director designated by Pivotal bioVenture Partners Fund I, L.P., currently Dr. Khanna; (3) one director designated by Novo Holdings A/S, currently Dr. Moldt; (4) one director designated by Vivo PANDA Fund, L.P. currently Dr. Shah; (5) one director designated by the holders of a majority of our shares then held by Key Holders, as defined in the voting agreement, currently Dr. Engleman; (6) our Chief Executive Officer, currently Dr. Schatzman; and (7) one director designated by the board of directors, currently Dr. Miller. The voting agreement will terminate upon the closing of this offering and none of our stockholders will have any special rights regarding the election or designation of members of our board of directors.

The primary responsibilities of our board of directors are to provide oversight, strategic guidance, counseling and direction to our management. Our board of directors meets on a regular basis and additionally as required. Our board of directors currently consists of seven directors. Our amended and restated certificate of incorporation, which will become effective upon the closing of this offering, will provide that the authorized number of directors may be changed only by a resolution approved by a majority of our board of directors. In accordance with our amended and restated certificate of incorporation to be effective in connection with this offering, immediately after this offering, our board of directors will be divided into three classes with staggered three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors will be divided among the three classes as follows:

- the Class I directors will be and their terms will expire at the annual meeting of stockholders to be held in 2021;
- the Class II directors will be and their terms will expire at the annual meeting of stockholders to be held in 2022; and
- the Class III directors will be and their terms will expire at the annual meeting of stockholders to be held in 2023.

Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control.

Director Independence

Under the listing requirements and rules of the Nasdaq Global Market, independent directors must comprise a majority of our board of directors as a listed company within one year of the closing of this offering.

Our board of directors has undertaken a review of its composition, the composition of its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that Drs. Engleman, Khanna, Miller, Moldt, Pitts and Shah do not have any relationships that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is “independent” as that term is defined under the applicable rules and regulations of the SEC and the listing requirements and rules of the Nasdaq Global Market. In making this determination, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director.

Committees of our Board of Directors

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. The composition and responsibilities of each of the committees of our board of directors are described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Our board of directors may establish other committees as it deems necessary or appropriate from time to time.

Audit Committee

Our audit committee consists of , and . Our board of directors has determined that each member of the audit committee satisfies the independence requirements under the Nasdaq Global Market listing standards and Rule 10A-3(b)(1) of the Exchange Act. The chairperson of our audit committee is . Our board of directors has determined that is an "audit committee financial expert" within the meaning of SEC regulations. Each member of our audit committee can read and understand fundamental financial statements in accordance with applicable requirements. In arriving at these determinations, our board of directors has examined each audit committee member's scope of experience and the nature of their employment.

The primary purpose of the audit committee is to discharge the responsibilities of our board of directors with respect to our corporate accounting and financial reporting processes, systems of internal control and financial statement audits, and to oversee our independent registered public accounting firm. Specific responsibilities of our audit committee include:

- helping our board of directors oversee our corporate accounting and financial reporting processes;
- reviewing and discussing with our management the adequacy and effectiveness of our disclosure controls and procedures;
- assisting with design and implementation of our risk assessment functions;
- managing the selection, engagement, qualifications, independence and performance of a qualified firm to serve as the independent registered public accounting firm to audit our financial statements;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and the independent accountants, our interim and year-end operating results;
- developing procedures for employees to submit concerns anonymously about questionable accounting or audit matters;
- reviewing related person transactions;
- obtaining and reviewing a report by the independent registered public accounting firm at least annually that describes our internal quality control procedures, any material issues with such procedures and any steps taken to deal with such issues when required by applicable law; and
- approving or, as permitted, pre-approving, audit and permissible non-audit services to be performed by the independent registered public accounting firm.

Our audit committee will operate under a written charter, to be effective upon the closing of this offering, that satisfies the applicable listing standards of the Nasdaq Global Market.

Compensation Committee

Our compensation committee consists of , and . The chairperson of our compensation committee is . Our board of directors has determined that each member of the compensation committee is independent under the listing standards of the Nasdaq Global Market, and a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act.

The primary purpose of our compensation committee is to discharge the responsibilities of our board of directors in overseeing our compensation policies, plans and programs and to review and determine the compensation to be paid to our executive officers, directors and other senior management, as appropriate. Specific responsibilities of our compensation committee include:

- reviewing and recommending to our board of directors the compensation of our chief executive officer and other executive officers;
- reviewing and recommending to our board of directors the compensation of our directors;
- administering our equity incentive plans and other benefit programs;
- reviewing, adopting, amending and terminating incentive compensation and equity plans, severance agreements, profit sharing plans, bonus plans, change-of-control protections and any other compensatory arrangements for our executive officers and other senior management;
- reviewing and establishing general policies relating to compensation and benefits of our employees, including our overall compensation philosophy; and
- reviewing and evaluating with the chief executive officer the succession plans for our executive officers.

Our compensation committee will operate under a written charter, to be effective upon the closing of this offering, that satisfies the applicable listing standards of the Nasdaq Global Market.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of , and . The chairperson of our nominating and corporate governance committee is . Our board of directors has determined that each member of the nominating and corporate governance committee is independent under the listing standards of the Nasdaq Global Market.

Specific responsibilities of our nominating and corporate governance committee include:

- identifying and evaluating candidates, including the nomination of incumbent directors for reelection and nominees recommended by stockholders, to serve on our board of directors;
- considering and making recommendations to our board of directors regarding the composition and chairmanship of the committees of our board of directors;
- reviewing with our chief executive officer the plans for succession to the offices of our executive officers and make recommendations to our board of directors with respect to the selection of appropriate individuals to succeed to these positions;
- developing and making recommendations to our board of directors regarding corporate governance guidelines and matters; and
- overseeing periodic evaluations of the board of directors' performance, including committees of the board of directors.

Our nominating and corporate governance committee will operate under a written charter, to be effective upon the closing of this offering, that satisfies the applicable listing standards of the Nasdaq Global Market.

Code of Business Conduct and Ethics

We intend to adopt a code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. Upon the closing of this offering, our code of business conduct and ethics will be available under the Corporate Governance section of our website at www.boltbio.com. In addition, we intend to post on our website all disclosures that are required by law or the listing standards of the

Nasdaq Global Market concerning any amendments to, or waivers from, any provision of the code. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this prospectus.

Compensation Committee Interlocks and Insider Participation

None of the members of the compensation committee is currently or has been at any time one of our officers or employees. None of our executive officers currently serves, or has served during the last year, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

Non-Employee Director Compensation

We currently provide equity-based compensation to our non-employee directors who are not affiliated with our investors for the time and effort necessary to serve as a member of our board of directors. In addition, all of our independent directors are entitled to reimbursement of direct expenses incurred in connection with attending meetings of the board or committees thereof.

The following table sets forth information regarding the compensation earned for service on our board of directors during the year ended December 31, 2019. Randall C. Schatzman, Ph.D., our Chief Executive Officer, is also a member of our board of directors, but did not receive any additional compensation for his service as a director. Dr. Schatzman's compensation as an executive officer is set forth in "Executive Compensation—Summary Compensation Table."

Name	Fees Earned or Paid in Cash	Option Awards(1)(2)	Total
Peter Moldt, Ph.D.	$ —	$ —	$ —
Edgar G. Engleman, M.D.	—	—	—
Ashish Khanna, Ph.D.	—	—	—
Richard A Miller, M.D.	—	29,135	29,135
Jason Pitts, Ph.D.	—	—	—
Mahendra G. Shah, Ph.D.	—	—	—

(1) The amounts reported in this column do not reflect dollar amounts actually received by the non-employee director. Instead, the amounts reflect the aggregate grant date fair value of the stock options granted to the non-employee directors during 2019 under our 2015 Equity Incentive Plan, computed in accordance with ASC 718. As required by SEC rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. The amounts reported in this column reflect the accounting cost for these stock options and do not correspond to the actual economic value that may be received by the non-employee directors upon the exercise of the stock options or any sale of the underlying shares of common stock.

(2) As of December 31, 2019, Dr. Miller has a stock option outstanding to purchase 75,656 shares of our common stock. In January 2019, we granted Dr. Miller a stock option to purchase 55,567 shares of our common stock at an exercise price of $0.32 per share and in November 2019, we granted Dr. Miller a stock option to purchase 75,656 shares of our common stock at an exercise price of $0.39 per share. The shares subject to each option vest in 48 equal monthly installments measured from July 23, 2018 and July 2, 2019, respectively, for so long as Dr. Miller continues to provide service to us as an employee, officer, director, contractor or consultant through each such vesting date. The stock option granted in January 2019 is immediately exercisable and was exercised in full by Dr. Miller in March 2019. In the event that, upon or within 12 months after an acquisition or other combination, (i) Dr. Miller's service as an employee, officer, director, contractor or consultant, is terminated by us other than for cause, death or disability or (ii) Dr. Miller terminates his service with good reason, 100% of the unvested shares subject to the stock option granted in November 2019 shall immediately vest and become exercisable.

EXECUTIVE COMPENSATION

Our named executive officers for the year ended December 31, 2019, consisting of our principal executive officer and two other most highly compensated officers serving at the end of such year, were:

- Randall Schatzman, Ph.D., our Chief Executive Officer and Director;
- Grant Yonehiro, our Chief Business Officer; and
- David Dornan, Ph.D., our Senior Vice President of Research.

Summary Compensation Table

The following table presents all of the compensation awarded to, earned by or paid to our named executive officers during the year ended December 31, 2019:

Name	Year	Salary	Bonus(1)	Other Compensation	Option Awards(2)	Total
Randall C. Schatzman, Ph.D. *Chief Executive Officer*	2019	$ 206,250	$ 96,411	$ 35,995(3)	$ 1,335,341	$ 1,673,997
Grant Yonehiro *Chief Business Officer*	2019	300,000	120,750	—	201,795	622,545
David Dornan, Ph.D. *Senior Vice President of Research and Manufacturing*	2019	275,000	80,438	—	168,633	524,071

(1) Represents amounts earned in 2019, which were paid in February 2020, upon the achievement of 2019 corporate goals and other factors deemed relevant by our board of directors or compensation committee. Our 2019 corporate goals related to clinical, pipeline development, partnering, and financing milestones and objectives. For 2019, we determined our named executive officers' annual performance bonus based on attainment of company objectives. For 2019, the compensation committee of our board of directors determined that Dr. Schatzman, Mr. Yonehiro and Dr. Dornan were entitled to 115%, 115% and 125% of their target bonuses, respectively.

(2) The amounts reported in this column do not reflect dollar amounts actually received by the executive officer. Instead, the amounts reflect the aggregate grant date fair value of the stock options granted to the executive officer during 2019 under our 2015 Equity Incentive Plan, computed in accordance with ASC 718. As required by SEC rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. The amounts reported in this column reflect the accounting cost for these stock options and do not correspond to the actual economic value that may be received by the non-employee directors upon the exercise of the stock options or any sale of the underlying shares of common stock.

(3) Dr. Schatzman received $16,331 for commuting reimbursements and $19,664 for housing and other living expenses reimbursements.

Outstanding Equity Awards as of December 31, 2019

The following table presents the outstanding equity incentive plan awards held by each named executive officer as of December 31, 2019. All awards were granted under our 2015 Equity Incentive Plan.

			Option Awards			
Name	Grant Date	Vesting Commencement Date	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price ($)(6)	Option Expiration Date
Randall C. Schatzman, Ph.D.	9/6/2019	7/15/2019(1)(2)(3)	5,538,300	—	$ 0.39	9/5/2029
Grant Yonehiro	1/18/2017	11/1/2016(1)(4)	346,875	103,125	$ 0.30	1/17/2027
	1/17/2018	11/1/2016(1)(4)	71,265	21,187	$ 0.29	1/16/2028
	4/4/2018	2/14/2018(1)(4)	52,760	62,354	$ 0.29	4/3/2028
	1/11/2019	7/23/2018(1)(4)	82,000	149,531	$ 0.32	1/10/2029
	11/13/2019	7/2/2019(4)(5)	67,708	582,292	$ 0.39	11/12/2029
David Dornan, Ph.D.	1/17/2018	12/1/2017(1)(4)	226,000	—	$ 0.29	1/16/2028
	4/4/2018	2/14/2018(1)(4)	43,962	51,957	$ 0.29	4/3/2028
	1/11/2019	7/23/2018(1)(4)	65,600	119,625	$ 0.32	1/10/2029
	11/13/2019	7/2/2019(4)(5)	57,291	492,709	$ 0.39	11/13/2029

(1) Twenty-five percent of the shares subject to the option vest on the one-year anniversary of the vesting commencement date and 1/48th of the shares subject to the option vest monthly thereafter.

(2) Dr. Schatzman's stock option is early exercisable and, to the extent shares subject to this option are issued and unvested as of a given date, such shares will remain subject to a right of repurchase held by us. As of December 31, 2019, Dr. Schatzman had not early exercised the option.

(3) In the event of a change of control, subject to continued employment through the date of such change of control, 100% of the shares subject to this option shall immediately vest and become exercisable.

(4) In the event that, upon or within 12 months after a change of control, (i) the option recipient's service is terminated by us other than for cause, death or disability or (ii) the option recipient terminates his employment with good reason, 100% of the shares subject to this option shall immediately vest and become exercisable.

(5) 1/48th of the shares subject to the option vest monthly measured from the vesting commencement date.

(6) All of the option awards were granted with a per share exercise price equal to the fair market value of one share of our common stock on the date of grant, as determined in good faith by our board of directors or compensation committee.

Emerging Growth Company Status

We are an emerging growth company, as defined in the JOBS Act. As an emerging growth company, we will be exempt from certain requirements related to executive compensation, including, but not limited to, the requirements to hold a nonbinding advisory vote on executive compensation and to provide information relating to the ratio of total compensation of our Chief Executive Officer to the median of the annual total compensation of all of our employees, each as required by the Investor Protection and Securities Reform Act of 2010, which is part of the Dodd-Frank Wall Street Reform and Consumer Protection Act.

Nonqualified Deferred Compensation

Our named executive officers did not participate in, or earn any benefits under, any nonqualified deferred compensation plan sponsored by us during the year ended December 31, 2019. Our board of directors may elect to provide our officers and other employees with nonqualified deferred compensation benefits in the future if it determines that doing so is in our best interests.

Pension and Defined Benefit Plan Retirement Benefits

Our named executive officers did not participate in, or otherwise receive any benefits under, any pension or defined benefit retirement plan sponsored by us during 2019.

Employment Arrangements

The employment agreements and offer letters with our executive officers generally provide for at-will employment and set forth the executive officer's initial base salary, annual target bonus and eligibility to participate in our employee benefit plans. In addition, each of our executive officers has executed our standard confidential information and invention assignment agreement. The key terms of these agreements are described below.

Randall C. Schatzman, Ph.D.

In June 2019, we entered into an offer letter with Dr. Schatzman, which governs the terms of his employment with us. For 2020, Dr. Schatzman is entitled to an annual base salary of $458,384, and is eligible to receive an annual performance bonus with a target amount of 40% of his annual base salary, payable based on the achievement of certain annual performance milestones or objectives as agreed by and between him and the board of directors on an annual basis, and subject to his continued employment through the time of payment of the bonus. Dr. Schatzman is also entitled to receive reimbursement for reasonable travel and lodging expenses of up to $15,000 per month. To the extent that these travel and lodging expenses are taxable to Dr. Schatzman, we also provide Dr. Schatzman with tax gross-up payments, subject to his continued service through and including such gross-up payment date.

In September 2019, pursuant to his offer letter Dr. Schatzman was granted an option to purchase 5,538,300 shares of our common stock at an exercise price of $0.39 per share. This option is immediately exercisable and vests over a four year period with 25% of the shares vesting in July 2020 and the remainder vesting monthly over 36 months from July 2020. In addition, all equity awards held by Dr. Schatzman, including the initial option grant, are entitled to accelerated vesting upon the closing of an acquisition (as defined in our 2015 Equity Incentive Plan), subject to his continued service through the closing.

Dr. Schatzman is also entitled to receive certain severance benefits under his offer letter, subject to his execution of a release of claims, and resignation from all positions with us, including resignation from the board. If we terminate Dr. Schatzman's employment without cause (as defined in his offer letter) and other than as a result of his death or disability or if he resigns for good reason (as defined in his offer letter), then he will be eligible to receive the following severance benefits:

- 12 months of his base salary, or the Cash Severance;
- any performance bonus that is earned but unpaid for the prior calendar year as of the date of his employment termination, or the Unpaid Bonus;
- if termination occurs within 12 months following our acquisition, the prorated amount of his target performance bonus that he otherwise would have been entitled to receive for the year his employment terminated, or the Bonus Severance; and
- either (A) up to 12 months of company paid premiums for continued health benefits under the Consolidated Omnibus Budget Reconciliation Act, or the COBRA Premiums; or (B) up to 12 months payment of a fully taxable cash payment amount equal to the applicable COBRA premiums for the month (subject to applicable tax withholdings).

The Cash Severance will be paid in 12 equal installments over the 12 months following his separation from service and the Unpaid Bonus and Bonus Severance, if any, will be paid no later than when corresponding bonuses are paid to our senior executive officers for the applicable year.

William P. Quinn

In April 2020, we entered into an offer letter with Mr. Quinn, which governs the terms of his employment with us. For 2020, Mr. Quinn is entitled to an annual base salary of $360,000 and is eligible to receive an annual performance bonus with a target amount of 35% of his annual base salary, based on his achievement of certain individual and company performance goals and his continued employment through the time of payment of the bonus, and with the 2020 annual bonus opportunity pro-rated to reflect his period of employment during 2020.

In July 2020, pursuant to his offer letter Mr. Quinn was granted two options to purchase an aggregate of 1,155,000 shares of our common stock at an exercise price of $0.40 per share. The first option was for 88,888 shares of our common stock. This option is immediately exercisable and vests over a four year period with 25% of the shares vesting in May 2021 and the remainder vesting monthly over 36 months from May 2021. The second option was for 1,066,112 shares of our common stock. This option vests over a four-year period with 25% of the shares vesting in May 2021 and the remainder vesting monthly over 36 months from May 2021. If we terminate Mr. Quinn's employment without cause (as defined in his offer letter) or he resigns for good reason (as defined in his offer letter), then he will be eligible to receive the following severance benefits:

- a lump sum amount equal to nine months of his base salary;
- nine months of premium reimbursements for continued health benefits under COBRA; and
- a pro-rated bonus for the year of his termination of employment.

Mr. Quinn's offer letter also provides that if we establish an executive severance program, his equity awards will be eligible for accelerated vesting in accordance with the terms of such program in the event of a change of control or covered termination.

David Dornan, Ph.D.

In November 2017, we entered into an offer letter with Dr. Dornan, which governs the terms of his employment with us. For 2020, Dr. Dornan is entitled to an annual base salary of $286,000, and is eligible to receive an annual performance bonus with a target amount of 25% of his annual base salary, based on his achievement of certain personal annual performance milestones, as established by us, and corporate goals as outlined in our performance incentive program, and subject to his continued employment through the time of payment of the bonus.

In January 2018, pursuant to the offer letter Dr. Dornan was granted an option to purchase 452,000 shares of our common stock at an exercise price of $0.29 per share. This option vests over a four year period with 25% of the shares vesting in December 2018 and the remainder vesting monthly over 36 months from December 2018. All of the shares subject to this option will vest and become exercisable upon or within 12 months after the closing of an acquisition or other combination (as such terms are defined in our 2015 Equity Incentive Plan) if (i) we terminate Dr. Dornan's service as an employee, officer, director, contractor or consultant other than for cause, death or disability (as such terms are defined in our 2015 Equity Incentive Plan) or (ii) Dr. Dornan terminates employment with good reason (as defined in the stock option agreements governing such stock options). Please see "—Outstanding Equity Awards as of December 31, 2019" for information regarding equity awards granted to Dr. Dornan.

Edith A. Perez, M.D.

In March 2020, we entered into an offer letter with Dr. Perez, which governs the terms of her employment with us. For 2020, Dr. Perez is entitled to an annual base salary of $400,000 and is eligible to receive an annual performance bonus with a target amount of 35% of her annual base salary, based on her achievement of certain individual and company performance goals and her continued employment through the time of payment of the bonus. Additionally, we paid Dr. Perez a one-time cash signing bonus of $175,000. The signing bonus is subject

to 100% repayment in the event of Dr. Perez's voluntary resignation without good reason (as defined in her offer letter) prior to the first anniversary of her employment start date and 50% repayment in the event of her voluntary resignation without good reason prior to the second anniversary of her employment start date. Dr. Perez is also entitled to receive a $1,000 monthly travel allowance.

In July 2020, pursuant to her offer letter Dr. Perez was granted an option to purchase 1,575,000 shares of our common stock at an exercise price of $0.40 per share. This option vests over a four-year period with 25% of the shares vesting in April 2021 and the remainder vesting monthly over 36 months from April 2021.

Dr. Perez is also entitled to receive certain severance benefits. Pursuant to her offer letter, if we terminate Dr. Perez's employment without cause (as defined in her offer letter) or she resigns for good reason, then she will be eligible to receive the following severance benefits:

- a lump sum amount equal to nine months of her annual base salary;
- nine months of premium reimbursements for continued health benefits under COBRA; and
- a pro-rated bonus for the year of her termination of employment.

Grant Yonehiro

In October 2016, we entered into an offer letter with Mr. Yonehiro, which governs the terms of his employment with us. For 2020, Mr. Yonehiro is entitled to an annual base salary of $309,000, and is eligible to receive an annual performance bonus with a target amount of 35% of his annual base salary, based on his achievement of certain annual performance milestones, as determined by us, and subject to his continued employment through the time of payment of the bonus.

In January 2017, pursuant to his offer letter Mr. Yonehiro was granted an option to purchase 450,000 shares of our common stock at an exercise price of $0.30 per share. This option vests over a four year period with 25% of the shares vesting in November 2017 and the remainder vesting monthly over 36 months from November 2017. All of the shares subject to this option will vest and become exercisable upon or within 12 months after the closing of an acquisition or other combination (as such terms are defined in our 2015 Equity Incentive Plan) if (i) we terminate Mr. Yonehiro's service as an employee, officer, director, contractor or consultant other than for cause, death or disability (as such terms are defined in our 2015 Equity Incentive Plan) or (ii) Mr. Yonehiro terminates employment with good reason (as defined in the stock option agreements governing such stock options). Please see "—Outstanding Equity Awards as of December 31, 2019" for information regarding equity awards granted to Mr. Yonehiro.

Pursuant to a severance benefit agreement we entered into with Mr. Yonehiro in January 2017, if we terminate Mr. Yonehiro's employment for reasons other than for cause (as defined in our 2015 Equity Incentive Plan), disability or death, then he will be eligible to receive the following severance benefits subject to his timely provision of an effective release of claims:

- continued payment of six months of his base salary; and
- six months' accelerated vesting of the option grant described above.

Employee Benefit and Stock Plans

2020 Equity Incentive Plan

Our board of directors adopted the 2020 Equity Incentive Plan, or the 2020 Plan, in 2020, and our stockholders approved the 2020 Plan in 2020. The 2020 Plan will become effective upon the execution of the underwriting agreement for this offering. The 2020 Plan will be the successor to our 2015 Equity Incentive Plan, or the 2015 Plan, which is described below. Once the 2020 Plan becomes effective, no further grants will be made under the 2015 Plan.

Types of Awards. Our 2020 Plan provides for the grant of incentive stock options, or ISOs, nonstatutory stock options, or NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance-based awards and other awards, or collectively, awards. ISOs may be granted only to our employees, including our officers, and the employees of our affiliates. All other awards may be granted to our employees, including our officers, our non-employee directors and consultants and the employees and consultants of our affiliates.

Authorized Shares. The maximum number of shares of common stock that may be issued under our 2020 Plan is shares. The number of shares of common stock reserved for issuance under our 2020 Plan will automatically increase on January 1 of each year, beginning on January 1, 2021, and continuing through and including January 1, 2030, by % of the total number of shares of common stock outstanding on December 31 of the immediately preceding calendar year, or a lesser number of shares determined by our board prior to the applicable January 1st. The maximum number of shares that may be issued upon the exercise of ISOs under our 2020 Plan is three times the share reserve, or shares.

Shares issued under our 2020 Plan will be authorized but unissued or reacquired shares of common stock. Shares subject to awards granted under our 2020 Plan that expire or terminate without being exercised in full, or that are paid out in cash rather than in shares, will not reduce the number of shares available for issuance under our 2020 Plan. Additionally, shares issued pursuant to awards under our 2020 Plan that we repurchase or that are forfeited, as well as shares used to pay the exercise price of an award or to satisfy the tax withholding obligations related to an award, will become available for future grant under our 2020 Plan.

The maximum number of shares of common stock subject to stock awards granted under the 2020 Plan or otherwise during any period commencing on the date of the company's annual meeting of stockholders for a particular year and ending on the day immediately prior to the date of the company's annual meeting of stockholders for the next subsequent year to any non-employee director, taken together with any cash fees paid by us to such non-employee director during such period for service on the board of directors, will not exceed $ in total value (calculating the value of any such stock awards based on the grant date fair value of such stock awards for financial reporting purposes), or, with respect to the period in which a non-employee director is first appointed or elected to our board of directors, $.

Plan Administration. Our board, or a duly authorized committee of our board, may administer our 2020 Plan. Our board has delegated concurrent authority to administer our 2020 Plan to the compensation committee under the terms of the compensation committee's charter. We sometimes refer to the board, or the applicable committee with the power to administer our equity incentive plans, as the administrator. The administrator may also delegate to one or more of our officers the authority to (1) designate employees (other than officers) to receive specified awards, and (2) determine the number of shares subject to such awards.

The administrator has the authority to determine the terms of awards, including recipients, the exercise, purchase or strike price of awards, if any, the number of shares subject to each award, the fair market value of a share of common stock, the vesting schedule applicable to the awards, together with any vesting acceleration, and the form of consideration, if any, payable upon exercise or settlement of the award and the terms of the award agreements for use under our 2020 Plan.

In addition, subject to the terms of the 2020 Plan, the administrator also has the power to modify outstanding awards under our 2020 Plan, including the authority to reprice any outstanding option or stock appreciation right, cancel and re-grant any outstanding option or stock appreciation right in exchange for new stock awards, cash or other consideration, or take any other action that is treated as a repricing under generally accepted accounting principles, with the consent of any materially adversely affected participant.

Stock Options. ISOs and NSOs are granted pursuant to stock option agreements adopted by the administrator. The administrator determines the exercise price for a stock option, within the terms and conditions

of the 2020 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of common stock on the date of grant. Options granted under the 2020 Plan vest at the rate specified in the stock option agreement by the administrator.

The administrator determines the term of stock options granted under the 2020 Plan, up to a maximum of ten years. Unless the terms of an optionholder's stock option agreement provide otherwise, if an optionholder's service relationship with us, or any of our affiliates, ceases for any reason other than disability, death or cause, the optionholder may generally exercise any vested options for a period of three months following the cessation of service. The option term may be extended in the event that either an exercise of the option or an immediate sale of shares acquired upon exercise of the option following such a termination of service is prohibited by applicable securities laws or our insider trading policy. If an optionholder's service relationship with us or any of our affiliates ceases due to disability or death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, options generally terminate immediately upon the termination of the individual for cause. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the administrator and may include (1) cash, check, bank draft or money order, (2) a broker-assisted cashless exercise, (3) the tender of shares of common stock previously owned by the optionholder, (4) a net exercise of the option if it is an NSO, and (5) other legal consideration approved by the administrator.

Options may not be transferred to third-party financial institutions for value. Unless the administrator provides otherwise, options generally are not transferable except by will, the laws of descent and distribution or pursuant to a domestic relations order. An optionholder may designate a beneficiary, however, who may exercise the option following the optionholder's death.

Tax Limitations on ISOs. The aggregate fair market value, determined at the time of grant, of common stock with respect to ISOs that are exercisable for the first time by an option holder during any calendar year under all of our stock plans may not exceed $100,000. Options or portions thereof that exceed such limit will be treated as NSOs. No ISOs may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our parent or subsidiary corporations, unless (1) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant and (2) the term of the ISO does not exceed five years from the date of grant.

Restricted Stock Awards. Restricted stock awards are granted pursuant to restricted stock award agreements adopted by the administrator. Restricted stock awards may be granted in consideration for cash, check, bank draft or money order, services rendered to us or our affiliates or any other form of legal consideration. Common stock acquired under a restricted stock award may, but need not, be subject to a share repurchase option in our favor in accordance with a vesting schedule to be determined by the administrator. A restricted stock award may be transferred only upon such terms and conditions as set by the administrator. Except as otherwise provided in the applicable award agreement, restricted stock awards that have not vested may be forfeited or repurchased by us upon the participant's cessation of continuous service for any reason.

Restricted Stock Unit Awards. Restricted stock unit awards are granted pursuant to restricted stock unit award agreements adopted by the administrator. Restricted stock unit awards may be granted in consideration for any form of legal consideration. A restricted stock unit award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the administrator, or in any other form of consideration set forth in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit award. Except as otherwise provided in the applicable award agreement, restricted stock units that have not vested will be forfeited upon the participant's cessation of continuous service for any reason.

Stock Appreciation Rights. Stock appreciation rights are granted pursuant to stock appreciation right grant agreements adopted by the administrator. The administrator determines the strike price for a stock appreciation right, which generally cannot be less than 100% of the fair market value of common stock on the date of grant. Upon the exercise of a stock appreciation right, we will pay the participant an amount equal to the product of (1) the excess of the per share fair market value of common stock on the date of exercise over the strike price, multiplied by (2) the number of shares of common stock with respect to which the stock appreciation right is exercised. A stock appreciation right granted under the 2020 Plan vests at the rate specified in the stock appreciation right agreement as determined by the administrator.

The administrator determines the term of stock appreciation rights granted under the 2020 Plan, up to a maximum of ten years. Unless the terms of a participant's stock appreciation right agreement provide otherwise, if a participant's service relationship with us or any of our affiliates ceases for any reason other than cause, disability or death, the participant may generally exercise any vested stock appreciation right for a period of three months following the cessation of service. The stock appreciation right term may be further extended in the event that exercise of the stock appreciation right following such a termination of service is prohibited by applicable securities laws. If a participant's service relationship with us, or any of our affiliates, ceases due to disability or death, or a participant dies within a certain period following cessation of service, the participant or a beneficiary may generally exercise any vested stock appreciation right for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, stock appreciation rights generally terminate immediately upon the occurrence of the event giving rise to the termination of the individual for cause. In no event may a stock appreciation right be exercised beyond the expiration of its term.

Performance Awards. Our 2020 Plan permits the grant of performance-based stock and cash awards. The compensation committee can structure such awards so that the stock or cash will be issued or paid pursuant to such award only following the achievement of certain pre-established performance goals during a designated performance period. Performance awards that are settled in cash or other property are not required to be valued in whole or in part by reference to, or otherwise based on, the common stock.

The performance goals may be based on any measure of performance selected by the board of directors. The compensation committee may establish performance goals on a company-wide basis, with respect to one or more business units, divisions, affiliates or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise (i) in the award agreement at the time the award is granted or (ii) in such other document setting forth the performance goals at the time the goals are established, the compensation committee will appropriately make adjustments in the method of calculating the attainment of the performance goals as follows: (1) to exclude restructuring and/or other nonrecurring charges; (2) to exclude exchange rate effects; (3) to exclude the effects of changes to generally accepted accounting principles; (4) to exclude the effects of any statutory adjustments to corporate tax rates; (5) to exclude the effects of items that are "unusual" in nature or occur "infrequently" as determined under generally accepted accounting principles; (6) to exclude the dilutive effects of acquisitions or joint ventures; (7) to assume that any business divested by us achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; (8) to exclude the effect of any change in the outstanding shares of common stock by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (9) to exclude the effects of stock-based compensation and the award of bonuses under our bonus plans; (10) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles; and (11) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles.

Other Awards. The administrator may grant other awards based in whole or in part by reference to common stock. The administrator will set the number of shares under the award and all other terms and conditions of such awards.

Changes to Capital Structure. In the event there is a specified type of change in our capital structure, such as a stock split, reverse stock split or recapitalization, appropriate adjustments will be made to (1) the class and maximum number of shares reserved for issuance under the 2020 Plan; (2) the class and maximum number of shares by which the share reserve may increase automatically each year; (3) the class and maximum number of shares that may be issued upon the exercise of ISOs and (4) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding awards.

Corporate Transactions. The following applies to stock awards under the 2020 Plan in the event of a corporate transaction, unless otherwise provided in a participant's stock award agreement or other written agreement with us or one of our affiliates or unless otherwise expressly provided by the administrator at the time of grant. Under the 2020 Plan, a corporate transaction is generally the consummation of (1) a sale or other disposition of all or substantially all of our assets, (2) a sale or other disposition of at least 50% of our outstanding securities, (3) a merger, consolidation or similar transaction following which we are not the surviving corporation or (4) a merger, consolidation or similar transaction following which we are the surviving corporation but the shares of common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction.

In the event of a corporate transaction, the administrator has the discretion to take any of the following actions with respect to stock awards:

- arrange for the assumption, continuation or substitution of a stock award by a surviving or acquiring entity or parent company;
- arrange for the assignment of any reacquisition or repurchase rights held by us to the surviving or acquiring entity or parent company;
- accelerate the vesting of the stock award and provide for its termination prior to the effective time of the corporate transaction;
- arrange for the lapse of any reacquisition or repurchase right held by us;
- cancel or arrange for the cancellation of the stock award in exchange for such cash consideration, if any, as our board of directors may deem appropriate; or
- make a payment equal to the excess of (A) the value of the property the participant would have received upon exercise of the stock award over (B) the exercise price otherwise payable in connection with the stock award.

Our administrator is not obligated to treat all stock awards, even those that are of the same type, in the same manner.

In the event of a change in control, as defined under our 2020 Plan, awards granted under our 2020 Plan will not receive automatic acceleration of vesting and exercisability, although this treatment may be provided for in an award agreement.

Transferability. A participant may not transfer awards under our 2020 Plan other than by will, the laws of descent and distribution or as otherwise provided under our 2020 Plan.

Plan Amendment or Termination. Our board has the authority to amend, suspend or terminate our 2020 Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. Certain material amendments also require the approval of our stockholders. No ISOs may be granted after the tenth anniversary of the date our board adopted our 2020 Plan. No awards may be granted under our 2020 Plan while it is suspended or after it is terminated.

2015 Equity Incentive Plan

Our board and stockholders adopted the 2015 Plan in April 2015. The 2015 Plan provides for the grant of ISOs, NSOs, stock appreciation rights, restricted stock awards and restricted stock unit awards to our employees, directors and consultants or our affiliates. ISOs may be granted only to our employees or employees of our affiliates.

The 2015 Plan will be terminated on the date the 2020 Plan becomes effective. However, any outstanding awards granted under the 2015 Plan will remain outstanding, subject to the terms of our 2015 Plan and the applicable award agreements, until such outstanding options are exercised or until any awards terminate or expire by their terms.

Authorized Shares. Upon the effective date of the 2020 Plan, we will no longer grant awards under our 2015 Plan. As of December 31, 2019, options to purchase 14,109,134 shares were outstanding and 6,233,461 shares of common stock remained available for future grants under our 2015 Plan. The options outstanding as of December 31, 2019 had a weighted-average exercise price of $0.37 per share.

Plan Administration. Our board or a duly authorized committee of our board administers our 2015 Plan and the awards granted under it. Our board has delegated concurrent authority to administer our 2015 Plan to the compensation committee under the terms of the compensation committee's charter. The administrator has the unilateral authority to reprice any outstanding option. The administrator may otherwise modify outstanding awards with the consent of any adversely affected participant.

Our board has delegated limited authority to grant options under the 2015 Plan for up to 250,000 shares to an equity grant committee with Dr. Schatzman serving as the sole committee member in his capacity as a director. The equity grant committee has the authority to select the non-officer employees and consultants to receive such option grants, whether the option will be an ISO or NSO, and the number of shares subject to those grants.

Acquisitions or Other Combinations of the Company. Our 2015 Plan provides that if we are subject to an acquisition or other combination, as such terms are defined under our 2015 Plan, outstanding awards will be subject to the treatment specified in the transaction agreement. Under the 2015 Plan, an acquisition is generally (1) a sale or other disposition of all or substantially all of our assets, (2) a sale or other disposition of at least 50% of our outstanding voting securities by our stockholders, or (3) a merger, consolidation or similar transaction following which our stockholders do not own at least 50% of the surviving entity. Under the 2015 Plan, an other combination is generally (1) a consolidation or merger involving us where we are not the surviving corporation or (2) our conversion into another form of entity; provided, in each case, that such transaction is not also an acquisition.

In the event we are subject to an acquisition or other combination, the transaction agreement will provide for one or more of the following treatments with respect to all outstanding 2015 Plan awards:

- the assumption, continuation or substitution of the award by a successor corporation, or the acquiring corporation's parent company;
- acceleration, in whole or in part, of the vesting or exercisability of the award and its termination prior to the transaction if not exercised prior to the effective time of the corporate transaction;
- cancellation of the award prior to the transaction in exchange for the full value of the award if any, as determined by the administrator, and payable in cash, cash equivalents or securities of the successor entity (or its parent, if any); or
- cancellation of the award prior to the transaction in exchange for no consideration.

Transferability. Except as otherwise permitted by the administrator and the 2015 Plan terms, a participant may not transfer awards under our 2015 Plan other than by will, the laws of descent and distribution.

Plan Amendment or Termination. Our administrator has the authority to suspend or terminate our 2015 Plan at any time, provided that such action will not impair a participant's rights under such participant's outstanding award without his or her written consent. Certain material amendments also require the approval of our stockholders. As described above, our 2015 Plan will be terminated upon the effective date of the 2020 Plan so that no future awards will be granted under the 2015 Plan following the effectiveness of the 2020 Plan.

2020 Employee Stock Purchase Plan

Our board of directors adopted our 2020 Employee Stock Purchase Plan, or the ESPP, in 2020, and our stockholders adopted the ESPP in 2020. The ESPP will become effective upon the execution of the underwriting agreement for this offering. The purpose of the ESPP is to secure the services of new employees, to retain the services of existing employees and to provide incentives for such individuals to exert maximum efforts toward our success and that of our affiliates. The ESPP includes two components. One component is designed to allow our eligible U.S. employees to purchase common stock in a manner that may qualify for favorable tax treatment under Section 423 of the Internal Revenue Code. In addition, purchase rights may be granted under a component that does not qualify for such favorable tax treatment when necessary or appropriate to permit participation by our eligible employees who are foreign nationals or employed outside of the United States while complying with applicable foreign laws.

Authorized Shares. The maximum aggregate number of shares of common stock that may be issued under our ESPP is shares. The number of shares of common stock reserved for issuance under our ESPP will automatically increase on January 1 of each calendar year, beginning on January 1, 2021 and continuing through and including January 1, 2030, by the lesser of (1) % of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, (2) shares, and (3) a number of shares determined by our board. Shares subject to purchase rights granted under our ESPP that terminate without having been exercised in full will not reduce the number of shares available for issuance under our ESPP.

Plan Administration. Our board, or a duly authorized committee thereof, will administer our ESPP. Our board has delegated concurrent authority to administer our ESPP to the compensation committee under the terms of the compensation committee's charter. The ESPP is implemented through a series of offerings with specific terms approved by the administrator and under which eligible employees are granted purchase rights to purchase shares of common stock on specified dates during such offerings. Under the ESPP, we may specify offerings with durations of not more than 27 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of common stock will be purchased for our eligible employees participating in the offering. An offering under the ESPP may be terminated under certain circumstances.

Payroll Deductions. Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, may participate in the ESPP and may contribute, normally through payroll deductions, up to 15% of their earnings (as defined in the ESPP) for the purchase of common stock under the ESPP. Unless otherwise determined by the administrator, common stock will be purchased for the accounts of employees participating in the ESPP at a price per share equal to the lower of (a) 85% of the fair market value of a share of common stock on the first date of an offering or (b) 85% of the fair market value of a share of common stock on the date of purchase. For the initial offering, which we expect will commence upon the execution and delivery of the underwriting agreement relating to this offering, the fair market value on the first day of the initial offering will be the price at which shares are first sold to the public.

Limitations. Our employees, including executive officers, or any of our designated affiliates may have to satisfy one or more of the following service requirements before participating in our ESPP, as determined by the administrator: (1) customary employment with us or one of our affiliates for more than 20 hours per week and more than five months per calendar year, or (2) continuous employment with us or one of our affiliates for a minimum period of time, not to exceed two years, prior to the first date of an offering. An employee may not be

granted rights to purchase stock under our ESPP if such employee (1) immediately after the grant would own stock possessing 5% or more of the total combined voting power or value of common stock, or (2) holds rights to purchase stock under our ESPP that would accrue at a rate that exceeds $25,000 worth of our stock for each calendar year that the rights remain outstanding.

Changes to Capital Structure. In the event that there occurs a change in our capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or similar transaction, the board of directors will make appropriate adjustments to (1) the number of shares reserved under the ESPP, (2) the maximum number of shares by which the share reserve may increase automatically each year, (3) the number of shares and purchase price of all outstanding purchase rights and (4) the number of shares that are subject to purchase limits under ongoing offerings.

Corporate Transactions. In the event of certain corporate transactions, including: (1) a sale of all or substantially all of our assets, (2) the sale or disposition of 50% of our outstanding securities, (3) the consummation of a merger or consolidation where we do not survive the transaction, and (4) the consummation of a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately before such transaction are converted or exchanged into other property by virtue of the transaction, any then-outstanding rights to purchase our stock under the ESPP may be assumed, continued or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue or substitute for such purchase rights, then the participants' accumulated payroll contributions will be used to purchase shares of common stock within 10 business days prior to such corporate transaction, and such purchase rights will terminate immediately.

ESPP Amendment or Termination. The administrator has the authority to amend or terminate our ESPP, provided that except in certain circumstances such amendment or termination may not materially impair any outstanding purchase rights without the holder's consent. We will obtain stockholder approval of any amendment to our ESPP as required by applicable law or listing requirements.

Health and Welfare Benefits

All of our current named executive officers are eligible to participate in our employee benefit plans, including our medical, dental, vision, life, disability and accidental death and dismemberment insurance plans, in each case on the same basis as all of our other employees. We pay the premiums for the life, disability and accidental death and dismemberment insurance for all of our employees, including our named executive officers. We generally do not provide perquisites or personal benefits to our named executive officers.

401(k) Plan

We currently maintain a 401(k) retirement savings plan for our employees, including our named executive officers, who satisfy certain eligibility requirements. The 401(k) plan is intended to qualify as a tax-qualified plan under the Internal Revenue Code. Our named executive officers are eligible to participate in the 401(k) plan on the same basis as our other employees. The Internal Revenue Code allows eligible employees to defer a portion of their compensation, within prescribed limits, on a pre-tax basis through contributions to the 401(k) plan.

Limitations of Liability and Indemnification Matters

Upon the closing of this offering, our amended and restated certificate of incorporation will contain provisions that limit the liability of our current and former directors for monetary damages to the fullest extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to the corporation or its stockholders;

- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions; or
- any transaction from which the director derived an improper personal benefit.

Such limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated certificate of incorporation that will be in effect on the closing of this offering will authorize us to indemnify our directors, officers, employees and other agents to the fullest extent permitted by Delaware law. Our amended and restated bylaws that will be in effect upon the closing of this offering will provide that we are required to indemnify our directors and officers to the fullest extent permitted by Delaware law and may indemnify our other employees and agents. Our amended and restated bylaws that will be in effect on the closing of this offering will also provide that, on satisfaction of certain conditions, we will advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and 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 that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. We have entered and expect to continue to enter into agreements to indemnify our directors and executive officers. With certain exceptions, these agreements provide for indemnification for related expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in connection with any action, proceeding or investigation. We believe that these amended and restated certificate of incorporation and amended and restated bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain customary directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted for directors, executive officers or persons controlling us, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Rule 10b5-1 Sales Plans

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or executive officer when entering into the plan, without further direction from them. The director or executive officer may amend a Rule 10b5-1 plan in some circumstances and may terminate a plan at any time. Our directors and executive officers also may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material nonpublic information, subject to compliance with the terms of our insider trading policy. Prior to the end of the 180th day after the date of execution of the underwriting agreement for this offering (subject to potential early release or termination without notice), the sale of any shares under such plan would be subject to the lock-up agreement that the director or executive officer has entered into with Morgan Stanley & Co. LLC and SVB Leerink LLC on behalf of the underwriters.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a summary of transactions since January 1, 2017, to which we have been a participant in which the amount involved exceeded or will exceed $120,000, and in which any of our directors, executive officers or holders of more than five percent of our capital stock, or any member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest, other than compensation arrangements which are described in "Executive Compensation" and "Management—Non-Employee Director Compensation."

We believe the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that would be paid or received, as applicable, in arm's-length transactions.

Preferred Stock Financings

In February 2018, we issued an aggregate of 6,395,227 of our Series A-1 preferred stock to six accredited investors at a purchase price of $0.9382 per share, for an aggregate purchase price of $6.0 million.

In multiple closings held between July 2018 and July 2019, we issued and sold an aggregate of 46,521,416 shares of our Series B preferred stock and issued warrants to purchase an aggregate of 1,206,223 of common stock to 11 accredited investors at a purchase price of $1.1494 per share for an aggregate purchase price of $53.5 million.

In June 2020, we issued and sold an aggregate of 36,135,260 shares of our Series C-1 preferred stock to 17 accredited investors at a purchase price of $1.15 per share for an aggregate purchase price of $41.6 million.

The following table summarizes the Series A-1, Series B and Series C-1 preferred stock purchased by holders of more than five percent of our capital stock and their affiliated entities and our directors since January 1, 2017. None of our executive officers purchased shares of preferred stock.

Name of Stockholder	Series A-1 Preferred Stock	Series B Preferred Stock	Common Stock Warrants	Series C-1 Preferred Stock	Aggregate Purchase Price
Novo Holdings A/S(1)	2,877,852	14,355,314	538,324	2,951,696	$ 22,594,449
Entities affiliated with Vivo Capital(2)	2,478,149	12,006,262	450,233	2,532,768	19,037,680
Pivotal bioVenture Partners Fund I, L.P.(3)	—	8,700,190	326,257	1,180,585	11,357,671
Sofinnova Venture Partners X, L.P.(4)	—	—	—	7,729,468	8,888,888
NFLS Beta Limited	—	5,655,124	212,067	767,380	7,382,487

(1) Dr. Moldt, a member of our board of directors, is a senior partner of Novo Ventures (US), Inc., which provides certain consultancy services to Novo Holdings A/S.

(2) Includes shares of preferred stock and warrants to purchase common stock purchased by (a) Vivo Capital Fund VIII, L.P., (b) Vivo Capital Surplus Fund VIII, L.P. and (c) Vivo PANDA Fund, L.P., of which Vivo PANDA, LLC ("Vivo PANDA GP") is the general partner. Dr. Engleman, a member of our board of directors, is a founding member of Vivo Capital Fund. Mahendra G. Shah, Ph.D., one of our directors, is a managing director of Vivo PANDA GP.

(3) Dr. Khanna, a member of our board of directors, is a venture partner of Pivotal BioVenture Partners.

(4) Dr. Pitts, a member of our board of directors, is a principal at Sofinnova Investments, Inc.

Upon the closing of this offering, each share of preferred stock will convert into one share of common stock. For a description of the material rights and privileges of the preferred stock, see Note 8 to our audited financial statements included elsewhere in this prospectus.

Investor Rights Agreement

In June 2020, we entered into an amended and restated investor rights agreement, or IRA, with certain holders of our preferred stock and common stock, including entities affiliated with Novo Holdings A/S, Vivo Capital, Pivotal bioVenture Partners LLC and Sofinnova Investments, Inc. and including certain members of, and affiliates of, our directors. The IRA provides the holders of our preferred stock with certain registration rights, including the right to demand that we file a registration statement or request that their shares be covered by a registration statement that we are otherwise filing. Dr. Moldt, Dr. Khanna and Dr. Pitts, members of our board of directors, are affiliated with Novo Holdings A/S, Pivotal bioVenture Partners LLC and Sofinnova Investments, Inc., respectively. Dr. Engleman and Dr. Shah, members of our board of directors, are both affiliated with Vivo Capital. The IRA also provides these stockholders with information rights, which will terminate upon the closing of this offering, and a right of first refusal with regard to certain issuances of our capital stock, which will not apply to, and will terminate upon, the closing of this offering. After the closing of this offering, the holders of 106,626,123 shares of common stock issuable on conversion of outstanding preferred stock, will be entitled to rights with respect to the registration of their shares of common stock under the Securities Act under this agreement. For a description of these registration rights, see "Description of Capital Stock—Registration Rights."

Relationship with Stanford University

In May 2015, we entered into a license agreement with Stanford, pursuant to which Stanford was issued 262,863 shares of our common stock and two co-inventors were issued an aggregate of 103,956 shares of our common stock in September 2016. In June 2018, we entered into a second license agreement with Stanford covering two additional inventions. During 2017, 2018 and 2019, we made payments to Stanford of $65,546, $135,565 and $193,420, respectively, for annual license fees and patent expense reimbursement.

Dr. Engleman, a member of our board of directors, is a professor at Stanford. Dr. Engleman is a co-inventor of some of the patents that we license from Stanford. Pursuant to our 2015 license agreement with Stanford, a trust associated with Dr. Engleman was issued 51,978 shares of our common stock in September 2016. Under Stanford's policies, as a co-inventor Dr. Engleman is entitled to receive a share of any royalties that we pay to Stanford under the agreements with respect to the covered intellectual property. No royalty payments have been made to date.

Employment Arrangements

We have entered into employment agreements and offer letters with certain of our executive officers. For more information regarding these agreements with our executive officers, see "Executive Compensation—Employment Arrangements."

Equity Grants

We have granted options to certain of our directors and executive officers. For more information regarding the options granted to our directors and named executive officers, see "Executive Compensation" and "Management—Non-Employee Director Compensation."

Indemnification Agreements

Our amended and restated certificate of incorporation that will be in effect upon the closing of this offering will contain provisions limiting the liability of directors, and our amended and restated bylaws that will be in effect on the closing of this offering will provide that we will indemnify each of our directors and officers to the fullest extent permitted under Delaware law. Our amended and restated certificate of incorporation and amended and restated bylaws that will be in effect on the closing of this offering will also provide our board of directors with discretion to indemnify our employees and other agents when determined appropriate by the board.

In addition, we have entered into an indemnification agreement with each of our directors and executive officers, which requires us to indemnify them. For more information regarding these agreements, see "Executive Compensation—Limitations of Liability and Indemnification Matters."

Policies and Procedures for Related Person Transactions

Our board of directors will adopt a related person transaction policy setting forth the policies and procedures for the identification, review and approval or ratification of related person transactions. This policy covers, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and a related person were or will be participants and the amount involved exceeds $120,000, including purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness and guarantees of indebtedness. In reviewing and approving any such transactions, our audit committee will consider all relevant facts and circumstances as appropriate, such as the purpose of the transaction, the availability of other sources of comparable products or services, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction, management's recommendation with respect to the proposed related person transaction and the extent of the related person's interest in the transaction.

All of the transactions described in this section were entered into prior to the adoption of this policy.

PRINCIPAL STOCKHOLDERS

The following table sets forth information with respect to the beneficial ownership of our common stock as of June 30, 2020, for:

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

We have determined beneficial ownership in accordance with the rules and regulations of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Except as indicated by the footnotes below, we believe, based on information furnished to us, that the persons and entities named in the table below have sole voting and sole investment power with respect to all shares that they beneficially own, subject to applicable community property laws.

Applicable percentage ownership before the offering is based on 120,201,625 shares of common stock outstanding as of June 30, 2020, assuming the conversion of all outstanding shares of convertible preferred stock into shares of common stock upon the closing of this offering. Applicable percentage ownership after the offering is based on shares of common stock outstanding immediately after the closing of this offering, assuming (i) shares of common stock will be issued upon the automatic net exercise of outstanding warrants, with an exercise price of $0.01 per share, immediately prior to the closing of 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 (ii) no exercise by the underwriters of their option to purchase additional shares in full. In computing the number of shares beneficially owned by a person and the percentage ownership of such person, we deemed to be outstanding all shares subject to options and warrants held by the person that are currently exercisable, or exercisable within 60 days of June 30, 2020. However, except as described above, we did not deem such shares outstanding for the purpose of computing the percentage ownership of any other person. The information contained in the following table is not necessarily indicative of beneficial ownership for any other purpose, and the inclusion of any shares in the table does not constitute an admission of beneficial ownership of those shares.

Unless otherwise indicated, the address of each beneficial owner listed below is c/o Bolt Biotherapeutics, Inc., 900 Chesapeake Drive, Redwood City, California 94063. We believe, based on information provided to us, that each of the stockholders listed below has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
		Before Offering	After Offering
Principal Stockholders			
Novo Holdings A/S(1)	25,519,604	21.2%	%
Entities affiliated with Vivo Capital(2)	21,447,430	17.8	
Pivotal bioVenture Partners Fund I, L.P.(3)	9,880,775	8.2	
Sofinnova Venture Partners X, L.P.(4)	7,729,468	6.4	
NFLS Beta Limited(5)	6,422,504	5.3	
Directors and Executive Officers			
Randall C. Schatzman, Ph.D.(6)	5,538,300	4.4	
David Dornan, Ph.D.(7)	606,711	*	
Grant Yonehiro(8)	877,124	*	
Peter Moldt, Ph.D.	—	—	
Edgar G. Engleman, M.D.(2)(9)	20,380,560	17.0	
Ashish Khanna, Ph.D.	—	—	
Richard A. Miller, M.D.(10)	129,714	*	
Jason Pitts, Ph.D.	—	—	
Mahendra G. Shah, Ph.D.(11)	10,014,472	8.3	
All directors and executive officers as a group (11 persons)(12)	37,546,881	29.5%	%

* Represents beneficial ownership of less than 1%.

(1) Consists of 25,519,604 shares of common stock held directly by Novo Holdings A/S. Novo Holdings A/S, through its board of directors (the "Novo Board"), has the sole power to vote and dispose of the shares. The Novo Board may exercise voting and dispositive control over the shares only with the support of a majority of the Novo Board. As such, no individual member of the Novo Board is deemed to hold any beneficial ownership or reportable pecuniary interest in the shares. Peter Moldt, Ph.D., one of our directors, is employed as a senior partner at Novo Ventures (US), Inc., which provides certain consultancy services to Novo Holdings A/S, and Dr. Moldt is not deemed to have beneficial ownership of the shares held by Novo Holdings A/S. The business address of Novo Holdings A/S is Tuborg Havnevej 19, 2900 Hellerup, Denmark.

(2) Consists of: (i) 10,045,760 shares of common stock held directly by Vivo Capital Fund VIII, L.P., of which Vivo Capital VIII, LLC ("Vivo GP") is the general partner, and shares of common stock that would be issued upon the net exercise of warrants; (ii) 1,387,198 shares of common stock held directly by Vivo Capital Surplus Fund VIII, L.P., of which Vivo GP is the general partner, and shares of common stock that would be issued upon the net exercise of warrants; and (iii) 10,014,472 shares of common stock held directly by Vivo PANDA Fund, L.P. ("Vivo PANDA LP"), of which Vivo PANDA, LLC ("Vivo PANDA GP") is the general partner, and shares of common stock that would be issued upon the net exercise of warrants. The voting members of Vivo GP are Frank Kung, Albert Cha, Edgar Engleman, Chen Yu and Shan Fu. Dr. Engleman is a member of our board of directors. Mahendra G. Shah, Ph.D., one of our directors, is a managing director of Vivo PANDA GP. The principal business address of Vivo Capital is 192 Lytton Avenue, Palo Alto, CA 94301.

(3) Consists of 9,880,775 shares of common stock held directly by Pivotal bioVenture Partners Fund I, L.P., and shares of common stock that would be issued upon the net exercise of warrants. Pivotal bioVenture Partners Fund I G.P., L.P. is the general partner of Pivotal bioVenture Partners Fund I, L.P. and Pivotal bioVenture Partners Fund I U.G.P., Ltd is the general partner of Pivotal bioVenture Partners Fund I G.P., L.P. Richard Coles, Peter Bisgaard and Vincent Sai Sing Cheung are directors of Pivotal bioVenture Partners Fund I U.G.P., Ltd, and may, along with Pivotal bioVenture Partners Fund I U.G.P., Ltd be deemed to have shared voting and investment control and power over the shares owned by Pivotal bioVenture Partners Fund I, L.P. Such persons disclaim beneficial ownership of such securities except to the extent of any pecuniary interest therein. The principal business address of Pivotal bioVenture Partners Fund I, L.P. is 501 Second Street, Suite 200, San Francisco, CA 94107.

(4) Consists of 7,729,468 shares of common stock held directly by Sofinnova Venture Partners X, L.P. (“SVP X”). Sofinnova Management X, L.L.C. (“SM X”) is the general partner of SVP X. Each of James I. Healy, Maha Katabi and Michael F. Powell is a managing member of SM X and may, along with SM X, be deemed to have shared voting and dispositive power over the shares owned by SVP X. Dr. Pitts, a member of our board of directors, is a principal at Sofinnova Investments, Inc. The address for these entities is 3000 Sand Hill Road, Bldg. 4, Suite 250, Menlo Park, CA 94025.

(5) Consists of 6,422,504 shares of common stock held directly by NFLS Beta Limited, and shares of common stock that would be issued upon the net exercise of warrants.

(6) Consists of 5,538,300 shares issuable pursuant to stock options exercisable within 60 days of June 30, 2020.

(7) Consists of 606,711 shares issuable pursuant to stock options exercisable within 60 days of June 30, 2020.

(8) Consists of 877,124 shares issuable pursuant to stock options exercisable within 60 days of June 30, 2020.

(9) Consists of: (i) 4,447,602 shares of common stock held directly by the Engleman Family Trust; (ii) 2,250,000 shares of common stock held directly by the Erik Nathan Engleman Irrevocable Trust dated December 6, 2012; (iii) 2,250,000 shares of common stock held directly by the Jason Engleman Irrevocable GST Trust dated December 06, 2012; (iv) 10,045,760 shares of common stock held directly by Vivo Capital Fund VIII, L.P. and shares of common stock that would be issued upon the net exercise of warrants; and (v) 1,387,198 shares of common stock held directly by Vivo Capital Surplus Fund VIII, L.P., and shares of common stock that would be issued upon the net exercise of warrants. Dr. Engleman is trustee of the Engleman Family Trust. Dr. Engleman’s spouse is the trustee of the Erik Nathan Engleman Irrevocable Trust and the Jason Engleman Irrevocable GST Trust. Vivo GP is the general partner of both Vivo Capital Fund VIII, L.P. and Vivo Capital Surplus Fund VIII, L.P. The voting members of Vivo GP are Frank Kung, Albert Cha, Edgar Engleman, Chen Yu and Shan Fu and may be deemed to have shared voting and dispositive power over the shares owned by both Vivo Capital Fund VIII, L.P. and Vivo Capital Surplus Fund VIII, L.P

(10) Consists: of (i) 109,224 shares of common stock held directly, of which 28,942 shares were unvested and remained subject to a repurchase right in favor of us as of June 30, 2020; and (ii) 20,490 shares issuable pursuant to stock options exercisable within 60 days of June 30, 2020.

(11) Consists of 10,014,472 shares of common stock held directly by Vivo PANDA LP and shares of common stock that would be issued upon the net exercise of warrants. Dr. Shah is a managing director of Vivo PANDA GP and has shared voting and dispositive power over the shares owned by Vivo PANDA LP. Dr. Shah disclaims beneficial ownership of such shares except to the extent of any pecuniary interest therein.

(12) Consists of: (i) 30,504,256 shares of common stock directly or indirectly held by all current executive officers and directors as a group; (ii) 7,042,625 shares of common stock issuable pursuant to options exercisable within 60 days of June 30, 2020; and (iii) shares of common stock issuable upon automatic net exercise of outstanding warrants immediately prior to the closing of this offering.

DESCRIPTION OF CAPITAL STOCK

The description below of our capital stock and provisions of our amended and restated certificate of incorporation and amended and restated bylaws are summaries and are qualified by reference to the amended and restated certificate of incorporation and the amended and restated bylaws to be in effect upon the closing of this offering, which are filed as exhibits to the registration statement of which this prospectus is part, and by the applicable provisions of Delaware law.

General

Upon the closing of this offering, our amended and restated certificate of incorporation will authorize us to issue up to shares of common stock, $0.00001 par value per share, and shares of preferred stock, par value $0.00001 per share.

As of December 31, 2019, there were 13,451,593 shares of common stock issued and outstanding, held by 24 stockholders of record.

As of December 31, 2019, after giving effect to the conversion of all 70,490,863 outstanding shares of preferred stock into an equal number of shares of common stock and the issuance of shares of common stock upon the automatic net exercise of outstanding warrants with an exercise price of $0.01 per share immediately prior to the closing of 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, there would have been shares of common stock outstanding, held by 40 stockholders of record.

Common Stock

Voting Rights

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Under our amended and restated certificate of incorporation, our stockholders will not have cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election.

Dividend Rights

Subject to preferences that may apply to any then-outstanding preferred stock, the holders of common stock are entitled to receive ratably those dividends, if any, as may be declared from time to time by the board of directors out of legally available funds. We do not anticipate paying any cash dividends in the foreseeable future.

Liquidation Rights

In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then-outstanding shares of preferred stock.

Preemptive or Similar Rights

Holders of common stock have no preemptive, conversion or subscription rights and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate in the future.

Preferred Stock

As of December 31, 2019, there were 70,490,863 shares of convertible preferred stock outstanding. Upon the closing of this offering, each outstanding share of convertible preferred stock will convert into one share of common stock. Under our amended and restated certificate of incorporation to be in effect upon the closing of this offering, our board of directors may, without further action by our stockholders, fix the rights, preferences, privileges and restrictions of up to an aggregate of shares of preferred stock in one or more series and authorize their issuance. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of common stock. Any issuance of preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders would receive dividend payments and payments on liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deterring or preventing a change of control or other corporate action. No shares of preferred stock will be outstanding immediately following the closing of this offering. We have no present plans to issue any shares of preferred stock.

Stock Options

As of December 31, 2019, options to purchase an aggregate of 14,109,134 shares of common stock were outstanding under our 2015 Equity Incentive Plan. As of December 31, 2019, 6,233,461 shares of common stock were reserved for future issuance under our 2015 Equity Incentive Plan. Upon the effectiveness of the 2020 Equity Incentive Plan, all shares reserved and available for issuance under our 2015 Equity Incentive Plan, and any shares subject to stock options or other awards granted under our 2015 Equity Incentive Plan that, on or after the effective date of the 2020 Equity Incentive Plan, terminate or expire prior to exercise or settlement, will be added to the available reserve under the 2020 Equity Incentive Plan. For additional information regarding the terms of these plans, see “Executive Compensation—Employee Benefit and Stock Plans.”

Warrants

As of December 31, 2019, warrants to purchase an aggregate of 1,206,223 shares of common stock with an exercise price of $0.01 per share were outstanding. Each of these warrants has a net exercise provision under which its holders may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares based on the fair market value of our common stock at the time of exercise of the warrants after deduction of the aggregate exercise price. The warrants also provide for the adjustment of the number of shares issuable upon the exercise of the warrants in the event of stock splits, recapitalizations, reclassifications and consolidations. Warrants to purchase up to an aggregate of 1,206,223 shares will be automatically net exercised in connection with this offering if not previously exercised, resulting in shares of common stock to be issued upon the automatic net exercise of these warrants, 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. Unless exercised earlier, the warrants that are not net exercised in connection with this offering shall terminate upon closing of the initial public offering.

Registration Rights

We are party to the IRA which provides various rights to certain holders of shares of common stock, including those shares of common stock that will be issued upon conversion of preferred stock and shares of common stock that will be issued upon the automatic net exercise of warrants in connection with this offering. These shares are referred to as registrable securities. The holders of these registrable securities possess registration rights pursuant to the terms of the IRA and are described in additional detail below. We, along with NFLS Beta Limited, Novo Holdings A/S, Pivotal bioVenture Partners LLC, Sofinnova Investments, Inc. and entities affiliated with Vivo Capital, as well as other stockholders, are parties to the IRA. We entered into the IRA in connection with the issuance of Series C-1 preferred stock in June 2020. The following summary discusses certain material provisions of the IRA and is qualified by the full text of the agreement, which is filed as an exhibit to the registration statement of which this prospectus is a part.

Certain stockholders who are party to the IRA have waived their registration rights and the registration rights of the other stockholders who are party to the IRA, in each case, with respect to this offering.

The registration of shares of common stock pursuant to the exercise of registration rights described below would enable the holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective. We will pay the registration expenses (other than underwriting discounts, selling commissions and stock transfer taxes) of the shares registered pursuant to the demand, piggyback and Form S-3 registrations described below.

Generally, in an underwritten offering, if we determine in good faith in consultation with the underwriters, we have the right, subject to specified conditions, to limit the number of shares the holders may include. The demand, piggyback and Form S-3 registration rights described below will terminate on the date five years following the closing of this offering.

Demand Registration Rights

As of December 31, 2019, the holders of an aggregate of 70,490,863 shares of common stock issuable upon conversion of outstanding shares of preferred stock, 4,880,302 shares of common stock already outstanding and shares of common stock issuable upon the exercise of outstanding warrants upon the closing of this offering will be entitled to certain demand registration rights. Beginning on the date 180 days following the effective date of the registration statement of which this prospectus is a part, upon the written request of the holders of more than 50% of our registrable securities then outstanding that we file a registration statement under the Securities Act, if the anticipated aggregate offering price, net of selling expenses, would exceed $10.0 million we are obligated to register the sale of all registrable securities that the holders may request in writing to be registered. We are required to effect no more than two registration statements that are declared or ordered effective. We may postpone the filing of a registration statement for up to 120 days twice in a 12-month period if in the good faith judgment of our board of directors such registration would be materially detrimental to us.

Piggyback Registration Rights

As of December 31, 2019, the holders of an aggregate of 70,490,863 shares of common stock issuable upon conversion of outstanding shares of preferred stock, 4,880,302 shares of common stock already outstanding and shares of common stock issuable upon the exercise of outstanding warrants upon the closing of this offering will be entitled to certain piggyback registration rights. If we register any of our securities for public sale, either for our own account or for the account of other security holders, we will also have to register all registrable securities that the holders of such securities request in writing be registered. This piggyback registration right does not apply to a registration relating to any of our stock plans, stock purchase or similar plan, a transaction under Rule 145 of the Securities Act or a registration related to stock issued upon conversion of debt securities. We, based on consultation with the underwriters of any underwritten offering will have the right to limit the number of shares registered by these holders if the underwriters determine that including all registrable securities will jeopardize the success of the offering.

Form S-3 Registration Rights

As of December 31, 2019, the holders of an aggregate of 70,490,863 shares of common stock issuable upon conversion of outstanding shares of preferred stock, 4,880,302 shares of common stock already outstanding and shares of common stock issuable upon the exercise of outstanding warrants upon the closing of this offering will be entitled to certain registration rights on Form S-3. The holders of these shares, constituting more than 20% of our registrable securities then outstanding, can request that we register all or a portion of their shares on Form S-3 if we are eligible to file a registration statement on Form S-3 and the aggregate price to the public of the shares offered is in excess of $2.0 million. We are required to effect no more than two Form S-3 registration statements that are declared or ordered effective in any 12-month period. We may postpone the filing of a

registration statement for up to 120 days not more than twice in a 12-month period if in the good faith judgment of our board of directors such registration would be materially detrimental to us. The foregoing Form S-3 rights are subject to a number of additional exceptions and limitations.

Anti-Takeover Provisions

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a publicly held Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, those shares owned (1) by persons who are directors and also officers and (2) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a “business combination” to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an “interested stockholder” as an entity or person who, together with the person’s affiliates and associates, beneficially owns or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

A Delaware corporation may “opt out” of these provisions with an express provision in its original certificate of incorporation or an express provision in its amended and restated certificate of incorporation or amended and restated bylaws resulting from a stockholders’ amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of us may be discouraged or prevented.

Certificate of Incorporation and Bylaws to Be in Effect upon the Closing of This Offering

Among other things, our amended and restated certificate of incorporation and amended and restated bylaws will:

- permit our board of directors to issue up to shares of preferred stock, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change of control;
- provide that the authorized number of directors may be changed only by resolution of our board of directors;
- provide that our board of directors will be classified into three classes of directors;
- provide that, subject to the rights of any series of preferred stock to elect directors, directors may only be removed for cause, which removal may be effected, subject to any limitation imposed by law, by the holders of at least 66 2/3% of the voting power of all of our then-outstanding shares of the capital stock entitled to vote generally at an election of directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent or electronic transmission;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice;
- provide that special meetings of our stockholders may be called only by the chairperson of our board of directors, our chief executive officer or by our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and
- not provide for cumulative voting rights, therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose.

The amendment of any of these provisions would require approval by the holders of at least 66 2/3% of the voting power of all of our then-outstanding capital stock entitled to vote generally in the election of directors, voting together as a single class.

The combination of these provisions will make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock.

Choice of Forum

Our amended and restated certificate of incorporation to be in effect upon the closing of this offering will provide that the Court of Chancery of the State of Delaware will be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty owed by any of our directors, officers, employees or stockholders to us or our stockholders; any action asserting a claim against us arising pursuant to the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. In addition, our amended and restated certificate of incorporation to be in effect upon the closing of this offering will further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. These provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any claim for which the federal district courts of the United States of America have exclusive jurisdiction. Any person or entity purchasing or otherwise acquiring or holding any interest in any shares of our common stock shall be deemed to have notice of and consented to these exclusive forum provisions and will not be deemed to have waived our compliance with the federal securities laws and the regulations promulgated thereunder. See "Risk Factors—Risks Related to This Offering and Our Common Stock—Our amended and restated certificate of incorporation that will be in effect upon the closing of this offering will provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees."

Limitations of Liability and Indemnification

See "Executive Compensation—Limitations of Liability and Indemnification Matters."

Exchange Listing

Our common stock is currently not listed on any securities exchange. We intend to apply to list our common stock on the Nasdaq Global Market under the symbol "BOLT."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock upon the closing of this offering will be . The transfer agent's address is and the telephone number is .

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock. Future sales of substantial amounts of common stock in the public market, or the perception that such sales may occur, could adversely impact the market price of our common stock and impair our ability to raise equity capital in the future. Although we intend to apply to list our common stock on the Nasdaq Global Market, we cannot assure you that there will be an active public market for our common stock.

Following the closing of this offering, based on the number of shares of common stock outstanding as of December 31, 2019 and assuming no exercise of the underwriters' option to purchase additional shares, we will have an aggregate of shares of common stock outstanding. Of these shares, all shares of common stock sold in this offering will be freely tradable without restriction or further registration under the Securities Act, except for any shares of common stock purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act, or subject to lock-up agreements with the underwriters or market stand-off provisions in agreements with us. Shares purchased by our affiliates will be subject to the Rule 144 resale restrictions described below, other than the holding period requirement.

The remaining shares of common stock outstanding after this offering will be "restricted securities," as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rule 144 or Rule 701 under the Securities Act, each of which is summarized below. We expect that substantially all of these shares will be subject to a 180-day lock-up period under the lock-up and market stand-off agreements described below.

We may issue shares of common stock from time to time as consideration for future acquisitions, investments or other corporate purposes. In the event that any such acquisition, investment or other transaction is significant, the number of shares of common stock that we may issue may also be significant. We may also grant registration rights covering those shares of common stock issued in connection with any such acquisition, investment or other transaction.

In addition, shares of common stock that are either subject to outstanding options or warrants or reserved for future issuance under our equity incentive plans 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 market stand-off agreements described below, and Rules 144 and 701 under the Securities Act.

Rule 144

In general, under Rule 144 as currently in effect, once we have been subject to public company reporting requirements of Section 13 or Section 15(d) of the Exchange Act for at least 90 days, an eligible stockholder is entitled to sell such shares without complying with the manner of sale, volume limitation or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. To be an eligible stockholder under Rule 144, such stockholder must not be deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and must have beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then such person is entitled to sell such shares without complying with any of the requirements of Rule 144, subject to the expiration of the lock-up agreements described above.

In general, under Rule 144, as currently in effect, our affiliates or persons selling shares on behalf of our affiliates are entitled to sell shares on expiration of the lock-up agreements described above. Beginning 90 days

after the date of this prospectus, within any three-month period, such stockholders may sell a number of shares that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately shares immediately after this offering based on the number of shares of common stock outstanding as of December 31, 2019; or
- the average weekly trading volume in our common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale

provided in each case that we have been subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

Rule 701

Rule 701 generally allows a stockholder who was issued shares under a written compensatory plan or contract and who is not deemed to have been an affiliate of our company during the immediately preceding 90 days, to sell these shares in reliance on Rule 144, but without being required to comply with the public information, holding period, volume limitation or notice provisions of Rule 144. Rule 701 also permits affiliates of our company to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required by that rule to wait until 90 days after the date of this prospectus before selling those shares under Rule 701, subject to the expiration of the lock-up agreements described below and in “Underwriting.”

Form S-8 Registration Statement

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of common stock subject to outstanding stock options and common stock issued or issuable under the 2015 Plan, the 2020 Plan and the ESPP. We expect to file the registration statement covering shares offered pursuant to these stock plans shortly after the date of this prospectus, permitting the resale of such shares by non-affiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market subject to compliance with the resale provisions of Rule 144.

Lock-Up Agreements and Market Stand-Off Provisions

We, our directors, executive officers and the holders of substantially all of our equity securities have agreed with the underwriters that for a period of 180 days, after the date of this prospectus, subject to specified exceptions as detailed further in “Underwriting” below, we or they will not, except with the prior written consent of Morgan Stanley & Co. LLC and SVB Leerink LLC, 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 sale of or otherwise dispose of or transfer any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock, request or demand that we file a registration statement related to our common stock, or enter into any swap or other agreement that transfers to another, in whole or in part, directly or indirectly, the economic consequence of ownership of the common stock. All of our optionholders are subject to a market stand-off agreement with us which imposes similar restrictions.

Upon expiration of the lock-up period, certain of our stockholders will have the right to require us to register their shares under the Securities Act. See “—Registration Rights” below and “Description of Capital Stock—Registration Rights.”

Upon the expiration of the lock-up period, substantially all of the shares subject to such lock-up and market stand-off restrictions will become eligible for sale, subject to the limitations discussed above.

Registration Rights

As of December 31, 2019, holders of an aggregate of 76,577,388 shares of our common stock, which includes all of the shares of common stock issuable upon the conversion of convertible preferred stock upon the closing of this offering, or their transferees, 4,880,302 shares of common stock already outstanding and the shares issuable upon the exercise of warrants to purchase an aggregate of 1,206,223 shares of common stock, are entitled to various rights with respect to the registration of these shares under the Securities Act upon the closing of this offering and the expiration of lock-up agreements. 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, except for shares subsequently purchased by affiliates. See “Description of Capital Stock—Registration Rights” for additional information. Shares covered by a registration statement will be eligible for sale in the public market upon the expiration or release from the terms of the lock-up agreement.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF OUR COMMON STOCK

The following summary describes the material U.S. federal income tax consequences of the acquisition, ownership and disposition of our common stock acquired in this offering by Non-U.S. Holders (as defined below). This discussion is not a complete analysis of all potential U.S. federal income tax consequences relating thereto, and does not deal with foreign, state and local consequences that may be relevant to Non-U.S. Holders in light of their particular circumstances, nor does it address U.S. federal tax consequences (such as gift and estate taxes) other than income taxes. Special rules different from those described below may apply to certain Non-U.S. Holders that are subject to special treatment under the Internal Revenue Code, such as financial institutions, insurance companies, tax-exempt organizations, broker-dealers and traders in securities, U.S. expatriates, "controlled foreign corporations," "passive foreign investment companies," corporations that accumulate earnings to avoid U.S. federal income tax, persons that hold our common stock as part of a "straddle," "hedge," "conversion transaction," "synthetic security" or integrated investment or other risk reduction strategy, persons subject to the alternative minimum tax or federal Medicare contribution tax on net investment income, "qualified foreign pension funds" as defined in Section 897(l)(2) of the Internal Revenue Code and entities all of the interests of which are held by qualified foreign pension funds, partnerships and other pass-through entities or arrangements and investors in such pass-through entities or arrangements. Such Non-U.S. Holders are urged to consult their own tax advisors to determine the U.S. federal, state, local and other tax consequences that may be relevant to them. Furthermore, the discussion below is based upon the provisions of the Internal Revenue Code, and Treasury Regulations, rulings and judicial decisions thereunder as of the date hereof, and such authorities may be repealed, revoked or modified, perhaps retroactively, so as to result in U.S. federal income tax consequences different from those discussed below. We have not requested a ruling from the U.S. Internal Revenue Service, or the IRS, with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS will agree with such statements and conclusions. This discussion assumes that the Non-U.S. Holder holds our common stock as a "capital asset" within the meaning of Section 1221 of the Internal Revenue Code (generally, property held for investment).

This discussion is for informational purposes only and is not tax advice. Persons considering the purchase of our common stock pursuant to this offering should consult their own tax advisors concerning the U.S. federal income, estate and other tax consequences of acquiring, owning and disposing of our common stock in light of their particular situations as well as any consequences arising under the laws of any other taxing jurisdiction, including any state, local or foreign tax consequences.

For the purposes of this discussion, a "Non-U.S. Holder" is, for U.S. federal income tax purposes, a beneficial owner of common stock that is neither a U.S. Holder, nor a partnership (or other entity treated as a partnership for U.S. federal income tax purposes regardless of its place of organization or formation). A "U.S. Holder" means a beneficial owner of common stock that is for U.S. federal income tax purposes any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation or other entity treated as a corporation for U.S. federal income tax purposes created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust if it (1) is subject to the primary supervision of a court within the United States and one or more U.S. persons have the authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a U.S. person.

Distributions

Distributions, if any, made on our common stock to a Non-U.S. Holder to the extent made out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles) generally will

constitute dividends for U.S. tax purposes and will be subject to withholding tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty, subject to the discussions below regarding effectively connected income, backup withholding and foreign accounts. To obtain a reduced rate of withholding under a treaty, a Non-U.S. Holder generally will be required to provide a properly executed IRS Form W-8BEN (in the case of individuals) or IRS Form W-8BEN-E (in the case of entities), or other appropriate form, certifying the Non-U.S. Holder's entitlement to benefits under that treaty. This certification must be provided to us or our paying agent prior to the payment of dividends and must be updated periodically. In the case of a Non-U.S. Holder that is an entity, Treasury Regulations and the relevant tax treaty provide rules to determine whether, for purposes of determining the applicability of a tax treaty, dividends will be treated as paid to the entity or to those holding an interest in that entity. If a Non-U.S. Holder holds stock through a financial institution or other agent acting on the Non-U.S. Holder's behalf, the Non-U.S. Holder will be required to provide appropriate documentation to such agent. The Non-U.S. Holder's agent will then be required to provide certification to us or our paying agent, either directly or through other intermediaries. If a Non-U.S. Holder is eligible for a reduced rate of U.S. federal withholding tax under an income tax treaty and does not timely file the required certification, the Non-U.S. Holder may be able to obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim for a refund with the IRS.

We generally are not required to withhold tax on dividends paid to a Non-U.S. Holder that are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, are attributable to a permanent establishment or fixed base that such Non-U.S. Holder maintains in the United States) if a properly executed IRS Form W-8ECI, stating that the dividends are so connected, is furnished to us (or, if stock is held through a financial institution or other agent, to such agent). In general, such effectively connected dividends will be subject to U.S. federal income tax, on a net-income basis at the regular rates applicable to U.S. residents. A corporate Non-U.S. Holder receiving effectively connected dividends may also be subject to an additional "branch profits tax," which is imposed, under certain circumstances, at a rate of 30% (or such lower rate as may be specified by an applicable income tax treaty) on the corporate Non-U.S. Holder's effectively connected earnings and profits, subject to certain adjustments. Non-U.S. Holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

To the extent distributions on our common stock, if any, exceed our current and accumulated earnings and profits, they will first reduce the Non-U.S. Holder's adjusted basis in our common stock, but not below zero, and then will be treated as gain to the extent of any excess amount distributed, and taxed in the same manner as gain realized from a sale or other disposition of common stock as described in the next section.

Gain on Disposition of Our Common Stock

Subject to the discussions below regarding backup withholding and foreign accounts, a Non-U.S. Holder generally will not be subject to U.S. federal income tax with respect to gain realized on a sale or other disposition of our common stock unless (a) the gain is effectively connected with a trade or business of such Non-U.S. Holder in the United States (and, if required by an applicable income tax treaty, is attributable to a permanent establishment or fixed base that such holder maintains in the United States), (b) the Non-U.S. Holder is a nonresident alien individual and is present in the United States for 183 or more days in the taxable year of the disposition and certain other conditions are met or (c) we are or have been a "United States real property holding corporation" within the meaning of Code Section 897(c)(2) at any time within the shorter of the five-year period preceding such disposition or such Non-U.S. Holder's holding period. In general, we would be a United States real property holding corporation if our interests in U.S. real estate comprise (by fair market value) at least half of our business assets. We believe that we have not been and we are not, and do not anticipate becoming, a United States real property holding corporation. Even if we are treated as a United States real property holding corporation, gain realized by a Non-U.S. Holder on a disposition of our common stock will not be subject to U.S. federal income tax so long as (1) the Non-U.S. Holder owned, directly and constructively, no more than 5% of our common stock at all times within the shorter of (i) the five-year period preceding the disposition or (ii) the

Non-U.S. Holder's holding period and (2) our common stock is regularly traded on an established securities market. There can be no assurance that our common stock will continue to qualify as regularly traded on an established securities market. If any gain on a Non-U.S. Holder's disposition is taxable because we are a United States real property holding corporation and your ownership of our common stock exceeds 5%, the Non-U.S. Holder will be taxed on such disposition generally in the manner as gain that is effectively connected with the conduct of a U.S. trade or business (subject to the relevant provisions under any applicable income tax treaty), except that the branch profits tax generally will not apply.

A Non-U.S. Holder described in (a) above will be required to pay tax on the net gain derived from the sale at regular U.S. federal income tax rates, and corporate Non-U.S. Holders described in (a) above may be subject to the additional branch profits tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty. Gain described in (b) above will be subject to U.S. federal income tax at a flat 30% rate or such lower rate as may be specified by an applicable income tax treaty, which gain may be offset by certain U.S.-source capital losses (even though the Non-U.S. Holder 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.

Information Reporting Requirements and Backup Withholding

Generally, we must report information to the IRS with respect to any dividends we pay on our common stock (even if the payments are exempt from withholding), including the amount of any such dividends, the name and address of the recipient and the amount, if any, of tax withheld. A similar report is sent to the Non-U.S. Holder to whom any such dividends are paid. Pursuant to tax treaties or certain other agreements, the IRS may make its reports available to tax authorities in the recipient's country of residence.

Dividends paid by us (or our paying agents) to a Non-U.S. Holder may also be subject to U.S. backup withholding (currently at a rate of 24%). U.S. backup withholding generally will not apply to a Non-U.S. Holder who provides a properly executed IRS Form W-8BEN, IRS Form W-8BEN-E or IRS Form W-ECI (as applicable), or otherwise establishes an exemption. Notwithstanding the foregoing, backup withholding may apply if the payer has actual knowledge, or reason to know, that the beneficial owner is a U.S. person who is not an exempt recipient.

U.S. information reporting and backup withholding requirements generally will apply to the proceeds of a disposition of our common stock effected by or through a U.S. office of any broker, U.S. or foreign, except that information reporting and such requirements may be avoided if the Non-U.S. Holder provides a properly executed IRS Form W-8BEN or IRS Form W-8BEN-E or otherwise meets documentary evidence requirements for establishing non-U.S. person status or otherwise establishes an exemption. Generally, U.S. information reporting and backup withholding requirements 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 non-U.S. broker. Information reporting and backup withholding requirements may, however, apply to a payment of disposition proceeds if the broker has actual knowledge, or reason to know, that the beneficial owner is, in fact, a U.S. person. For information reporting purposes, certain brokers with substantial U.S. ownership or operations will generally be treated in a manner similar to U.S. brokers.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be credited against the tax liability of persons subject to backup withholding, provided that the required information is timely furnished to the IRS.

Foreign Accounts

Sections 1471 through 1474 of the Internal Revenue Code (commonly referred to as FATCA) impose a U.S. federal withholding tax of 30% on certain payments, including dividends paid on, and, the gross proceeds of a disposition of, our common stock paid to a foreign financial institution (as specifically defined by applicable

rules) unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding U.S. account holders of such institution (which includes certain equity holders of such institution, as well as certain account holders that are foreign entities with U.S. owners). FATCA also generally imposes a federal withholding tax of 30% on certain payments, including dividends paid on, and the gross proceeds of a disposition of, our common stock to a non-financial foreign entity unless such entity provides the withholding agent with either a certification that it does not have any substantial direct or indirect U.S. owners or provides information regarding substantial direct and indirect U.S. owners of the entity. An intergovernmental agreement between the United States and an applicable foreign country may modify those requirements. The withholding tax described above will not apply if the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from the rules.

The withholding provisions described above currently apply to payments of dividends, and, subject to the recently released proposed Treasury Regulations described below, will apply to payments of gross proceeds from a sale or other disposition of common stock.

The U.S. Treasury Department 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 disposition of our common stock. In its preamble to such proposed regulations, the U.S. Treasury Department stated that taxpayers may generally rely on the proposed regulations until final regulations are issued. Non-U.S. Holders are encouraged to consult with their own tax advisors regarding the possible implications of FATCA on their investment in our common stock.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY RECENT OR PROPOSED CHANGE IN APPLICABLE LAW.

UNDERWRITERS

Under the terms and subject to the conditions in an underwriting agreement dated the date of this prospectus, the underwriters named below, for whom Morgan Stanley & Co. LLC and SVB Leerink LLC are acting as representatives, have severally agreed to purchase, and we have agreed to sell to them, severally, the number of shares of common stock indicated below:

Underwriter	Number of Shares
Morgan Stanley & Co. LLC	
SVB Leerink LLC	
Stifel, Nicolaus & Company, Incorporated	
Guggenheim Securities, LLC	
Total	

The underwriters and the representatives are collectively referred to as the "underwriters" and the "representatives," respectively. The underwriters are offering the shares of common stock subject to their acceptance of the shares from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of common stock offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the shares of common stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters' option to purchase additional shares described below.

The underwriters initially propose to offer part of the shares of common stock directly to the public at the offering price listed on the cover page of this prospectus and part to certain dealers at a price that represents a concession not in excess of $ per share under the public offering price. After the initial offering of the shares of common stock, the offering price and other selling terms may from time to time be varied by the representatives.

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to additional shares of common stock at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the shares of common stock offered by this prospectus. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase about the same percentage of the additional shares of common stock as the number listed next to the underwriter's name in the preceding table bears to the total number of shares of common stock listed next to the names of all underwriters in the preceding table.

The following table shows the per share and total public offering price, underwriting discounts and commissions, and proceeds before expenses to us. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase up to an additional shares of common stock.

	Per Share	Total	
		No Exercise	Full Exercise
Public offering price	$	$	$
Underwriting discounts and commissions to be paid by us:	$	$	$
Proceeds, before expenses, to us	$	$	$

The estimated offering expenses payable by us, exclusive of the underwriting discounts and commissions, are approximately $. We have agreed to reimburse the underwriters for expenses of up to $

relating to clearance of this offering with the Financial Industry Regulatory Authority, Inc. and compliance with state securities or "blue sky" laws.

The underwriters have informed us that they do not intend sales to discretionary accounts to exceed 5% of the total number of shares of common stock offered by them.

We intend to apply to list our common stock on the Nasdaq Global Market under the trading symbol "BOLT."

We and all of our directors and officers and the holders of substantially all of our common stock, stock options and other securities convertible into, exercisable or exchangeable for our common stock outstanding immediately prior to the closing of this offering have agreed that, without the prior written consent of the representatives on behalf of the underwriters, we and they will not, and will not publicly disclose an intention to, during the period ending on and including the 180th day after the date of this prospectus (the "restricted period"):

- 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, any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock;
- file any registration statement with the Securities and Exchange Commission relating to the offering of any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock; or
- enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock whether any such transaction described above is to be settled by delivery of common stock or such other securities, in cash or otherwise. In addition, we and each such person agrees that, without the prior written consent of the representatives on behalf of the underwriters, we or such other person will not, during the restricted period, make any demand for, or exercise any right with respect to, the registration of any shares of common stock or any security convertible into or exercisable or exchangeable for common stock.

The restrictions described in the immediately preceding paragraph are subject to specified exceptions, including, without limitation:

- the sale of shares to the underwriters;
- the issuance by us of shares of common stock upon the exercise of an option or a warrant or the conversion of a security outstanding on the date of this prospectus of which the underwriters have been advised in writing;
- transactions by any person other than us relating to shares of common stock or other securities acquired in this offering or in open market transactions after the closing of this offering, provided that no filing under Section 16(a) of the Exchange Act and no other public or filing is required or voluntarily made in connection with subsequent sales of the common stock or other securities acquired in this offering or such open market transactions;
- transfers of shares of common stock or any security convertible into common stock (a) as a bona fide gift or charitable contribution, (b) to an immediate family member or any trust for the direct or indirect benefit of the person subject to such restrictions or the immediate family of such person, (c) to a trustor or beneficiary of the trust or to the estate of a beneficiary of such trust, or (d) distributions of shares of common stock to limited partners, members, stockholders or holders of similar equity interests of the party making such distribution or to direct or indirect subsidiaries of such party, provided that (i) each donee or other distributee shall sign and deliver a lock-up letter substantially in the form attached as an exhibit to the underwriting agreement and (ii) no filing under Section 16(a) of the Exchange Act, reporting a reduction in beneficial ownership of shares of common stock, and no other public announcement or filing, shall be required or shall be voluntarily made during the restricted period;

- in connection with the disposition or transfer of shares of common stock or any security convertible into common stock to us upon the "net" or "cashless" exercise of stock options or other equity awards outstanding as of the date of this prospectus and granted pursuant to an employee benefit plan described in this prospectus, provided that (i) such shares of common stock received upon exercise shall continue to be subject to the restrictions on transfer set forth in the lock-up agreement and (ii) no filing under Section 16(a) of the Exchange Act and no other public announcement or filing shall be required or voluntarily made during the restricted period;
- the exercise solely with cash of stock options outstanding as of the date of this prospectus granted under an employee benefit plan or stock purchase plan described in this prospectus, provided that (i) the shares received upon exercise shall continue to be subject to the restrictions on transfer set forth in the lock-up agreement, (ii) if required, any public report or filing under Section 16(a) of the Exchange Act shall clearly indicate in the footnotes thereto that the filing relates to the exercise of a stock option, that no shares were sold by the reporting person and that the shares received upon exercise are subject to a lock-up agreement with the underwriters, and (iii) no other public announcement or filing shall be required or voluntarily made during the restricted period;
- transfers of shares of common stock or other securities to us in connection with a repurchase by us pursuant to a repurchase right arising upon the termination of the transferee's employment with us pursuant to contractual agreements with us, provided that (i) any filing required by Section 16(a) of the Exchange Act shall clearly indicate in the footnotes thereto that such transfer is being made pursuant to such repurchase right under such agreement and (ii) no other public announcement or filing shall be required or voluntarily made during the restricted period;
- transfers by operation of law pursuant to a qualified domestic order or in connection with a divorce settlement, provided that (i) any filing required by Section 16(a) of the Exchange Act shall clearly indicate in the footnotes thereto that such transfer is being made pursuant to such court order and that such shares remain subject to a lock-up agreement with the underwriters, and (ii) no other public announcement or filing shall be required or voluntarily made during the restricted period;
- transfers of shares of our common stock or other securities 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 of our company that has been approved by our board of directors, provided that in the event that such tender offer, merger, consolidation or other such transaction is not completed, the securities shall continue to be subject to the restrictions on transfer set forth in the lock-up agreement; and
- the establishment or amendment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of common stock, provided that (i) such plan does not provide for the transfer of common stock during the restricted period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required or voluntarily made regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of common stock may be made under such plan during the restricted period.

The representatives, in their sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time with or without notice.

In order to facilitate the offering of the common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the common stock. Specifically, the underwriters may sell more shares than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of shares available for purchase by the underwriters under the option to purchase additional shares described above. The underwriters can close out a covered short sale by exercising such option or purchasing shares in the open market. In determining the source of shares to close out a covered short sale, the underwriters will consider, among other things, the open market

price of shares compared to the price available under such option. The underwriters may also sell shares in excess of such option, creating a naked short position. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in this offering. As an additional means of facilitating this offering, the underwriters may bid for, and purchase, shares of common stock in the open market to stabilize the price of the common stock. These activities may raise or maintain the market price of the common stock above independent market levels or prevent or retard a decline in the market price of the common stock. The underwriters are not required to engage in these activities and may end any of these activities at any time.

We and the underwriters have agreed to indemnify each other against certain liabilities, including liabilities under the Securities Act.

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

Other Relationships

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Certain of the underwriters and their respective affiliates have, from time to time, performed, and may in the future perform, various financial advisory and investment banking services for us, for which they received or will receive customary fees and expenses.

In addition, in the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investment and securities activities may involve our securities and instruments. The underwriters and their respective affiliates may also make investment recommendations or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long or short positions in such securities and instruments.

Pricing of the Offering

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. Among the factors to be considered in determining the initial public offering price are our future prospects and those of our industry in general, our results of operations and certain other financial and operating information in recent periods, and the price-earnings ratios, price-sales ratios, market prices of securities and certain financial and operating information of companies engaged in activities similar to ours.

Selling Restrictions

Canada

The shares of our common stock 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 of our common stock must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable restrictions 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 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) 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.

European Economic Area and United Kingdom

In relation to each Member State of the European Economic Area and the United Kingdom, each a Relevant State, no shares have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that offers of shares may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

(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 under the Prospectus Regulation), subject to obtaining the prior consent of the underwriters; or

(c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation and each person who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with each of the underwriters and us that it is a "qualified investor" within the meaning of Article 2(e) of the Prospectus Regulation. In the case of any shares being offered to a financial intermediary as that term is used in the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares to the public other than their offer or resale in a Relevant State to qualified investors as so defined or in circumstances in which the prior consent of the underwriters have been obtained to each such proposed offer or resale.

For the purposes of this provision, the expression an "offer to the public" in relation to shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129 (as amended).

United Kingdom

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are "qualified investors" (as defined in the

Prospectus Regulation) (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, or 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.

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LEGAL MATTERS

The validity of the shares of common stock being offered by this prospectus will be passed upon for us by Cooley LLP, Seattle, Washington. Davis Polk & Wardwell LLP, Menlo Park, California is representing the underwriters.

EXPERTS

The financial statements as of December 31, 2019 and December 31, 2018, and for each of the two years in the period ended December 31, 2019 included in this prospectus have been so included in reliance on the report (which contains an explanatory paragraph relating to our ability to continue as a going concern as described in Note 1 to the financial statements) of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

We have submitted with the SEC a registration statement on Form S-1, including exhibits and schedules, under the Securities Act, with respect to the shares of common stock being offered by this prospectus. This prospectus, which constitutes part of the registration statement, does not contain all of the information in the registration statement and its exhibits. For further information with respect to us and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference. You can read our SEC filings, including the registration statement, over the Internet at the SEC's website at www.sec.gov.

Upon the closing of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection at the web site of the SEC referred to above. We also maintain a website at www.boltbio.com, at which, following the closing of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. However, the information contained in or accessible through our website is not part of this prospectus or the registration statement of which this prospectus forms a part, and investors should not rely on such information in making a decision to purchase our common stock in this offering. We have included our website address in this prospectus solely as an inactive textual reference.

BOLT BIOTHERAPEUTICS, INC.

INDEX TO FINANCIAL STATEMENTS

Years ended December 31, 2018 and 2019

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Bolt Biotherapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Bolt Biotherapeutics, Inc. (the "Company") as of December 31, 2019 and 2018 and the related statements of operations and comprehensive loss, 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 "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, 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 financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency 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 financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Change in Accounting Principle

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for leases in 2019.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these 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 financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP
San Jose, California
August 10, 2020

We have served as the Company's auditor since 2019.

BOLT BIOTHERAPEUTICS, INC.
Balance Sheets
(in thousands, except share and per share amounts)

	December 31, 2018	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 13,634	$ 34,826
Prepaid expenses and other current assets	466	1,074
Total current assets	14,100	35,900
Property and equipment, net	1,442	1,387
Operating lease right-of-use assets	—	10,079
Finance lease right-of-use assets	—	51
Restricted cash	—	584
Other assets	433	446
Total assets	$ 15,975	$ 48,447
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 892	$ 2,095
Accrued expenses and other current liabilities	1,823	2,866
Deferred revenue	—	599
Operating lease liabilities	—	3,096
Current maturities of capital lease obligations	40	—
Total current liabilities	2,755	8,656
Deferred rent	257	—
Operating lease liabilities, net of current portion	—	7,089
Deferred revenue	—	972
Convertible preferred stock purchase right liability, non-current	501	—
Other long-term liabilities	38	71
Total liabilities	3,551	16,788
Commitments and contingencies (Note 7)		
Convertible preferred stock—$0.00001 par value; 78,518,549 shares and 83,541,150 shares authorized at December 31, 2018 and 2019, respectively; 30,577,190 shares and 70,490,863 shares issued and outstanding at December 31, 2018 and 2019, respectively; liquidation preference of $80,172 at December 31, 2019	28,367	77,505
Stockholders' equity (deficit):		
Common stock—$0.00001 par value; 120,000,000 shares and 126,000,000 shares authorized as of December 31, 2018 and 2019, respectively; 13,379,526 shares and 13,451,593 shares issued and outstanding at December 31, 2018 and December 31, 2019, respectively	—	—
Additional-paid in capital	1,241	1,825
Accumulated deficit	(17,184)	(47,671)
Total stockholders' equity (deficit)	(15,943)	(45,846)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 15,975	$ 48,447

See accompanying notes to the financial statements.

BOLT BIOTHERAPEUTICS, INC.
Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Years Ended December 31,	
	2018	2019
Collaboration revenue	$ —	$ 215
Operating expenses:		
Research and development	9,420	26,002
General and administrative	2,209	5,182
Total operating expenses	11,629	31,184
Loss from operations	(11,629)	(30,969)
Other income (expense), net:		
Interest income	193	524
Change in fair value of convertible preferred stock purchase right liability	(153)	(42)
Total other income (expense), net	40	482
Net loss and comprehensive loss	$ (11,589)	$ (30,487)
Net loss per share, basic and diluted	$ (1.00)	$ (2.18)
Weighted-average shares outstanding, basic and diluted	11,555,760	13,954,354
Pro forma net loss per share, basic and diluted (unaudited) (Note 11)		$
Pro forma weighted-average shares outstanding, basic and diluted (unaudited) (Note 11)		

See accompanying notes to the financial statements.

BOLT BIOTHERAPEUTICS, INC.
Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2017	12,551,619	$ 9,987	12,790,476	$ —	$ 312	$ (5,595)	$ (5,283)
Issuance of Series A-1 convertible preferred stock for cash and extinguishment of convertible preferred stock purchase right liability of $533, net of issuance costs of $28	6,395,227	6,505	—	—	—	—	—
Issuance of Series B convertible preferred stock for cash, net of issuance costs of $228 and convertible preferred stock purchase right liability of $485, and common stock warrants of $781	11,630,344	11,875	—	—	—	—	—
Issuance of common stock warrants in connection with issuance of Series B convertible preferred stock	—	—	—	—	781	—	781
Exercise of common stock warrants	—	—	538,324	—	5	—	5
Issuance of common stock upon exercise of stock options	—	—	50,726	—	6	—	6
Vesting of early exercised options and restricted stock awards	—	—	—	—	14	—	14
Stock-based compensation	—	—	—	—	123	—	123
Net loss	—	—	—	—	—	(11,589)	(11,589)
Balance at December 31, 2018	30,577,190	28,367	13,379,526	—	1,241	(17,184)	(15,943)
Issuance of Series T convertible preferred stock for cash, net of issuance costs of $2	5,022,601	8,509	—	—	—	—	—
Issuance of Series B convertible preferred stock for cash and extinguishment of convertible preferred stock purchase right liability of $543, net of issuance costs of $18	34,891,072	40,629	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	72,067	—	55	—	55
Vesting of early exercised options and restricted stock awards	—	—	—	—	21	—	21
Stock-based compensation	—	—	—	—	508	—	508
Net loss	—	—	—	—	—	(30,487)	(30,487)
Balance at December 31, 2019	70,490,863	$77,505	13,451,593	$ —	$ 1,825	$ (47,671)	$ (45,846)

See accompanying notes to the financial statements.

BOLT BIOTHERAPEUTICS, INC.
Statements of Cash Flows
(in thousands)

	Years Ended December 31, 2018	2019
Cash flows from operating activities:		
Net loss	$ (11,589)	$ (30,487)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	302	335
Stock-based compensation expenses	123	508
Change in fair value of convertible preferred stock purchase right liabilities	153	42
Amortization of operating lease right-of-use asset	—	994
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(305)	(620)
Accounts payable and accrued expenses	1,337	2,121
Operating lease liabilities	—	(823)
Deferred revenue	—	1,571
Other long-term liabilities	107	16
Net cash used in operating activities	(9,872)	(26,343)
Cash flows from investing activities:		
Purchase of property and equipment	(290)	(508)
Net cash used in investing activities	(290)	(508)
Cash flows from financing activities:		
Repayments of capital lease obligations	(39)	—
Repayments of financing lease obligations	—	(40)
Proceeds from issuance of convertible preferred stock, purchase rights and warrants, net of issuance costs	19,113	48,595
Proceeds from issuance of common stock and warrants	20	72
Net cash provided by financing activities	19,094	48,627
Net increase in cash, cash equivalents and restricted cash	8,932	21,776
Cash, cash equivalents and restricted cash at beginning of year	4,702	13,634
Cash, cash equivalents and restricted cash at end of year	$ 13,634	$ 35,410
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 13,634	$ 34,826
Restricted cash	—	584
Total cash, cash equivalents and restricted cash	$ 13,634	$ 35,410
Supplemental disclosures:		
Cash paid for interest	$ 4	$ —
Supplemental schedule of non-cash investing and financing activities:		
Issuance of convertible preferred stock upon extinguishment of convertible preferred stock purchase liabilities	$ 533	$ 543
Vesting of early exercised options and restricted stock awards	$ 14	$ 21
Purchases of property and equipment included in accounts payable and accrued liabilities	$ 215	$ 161

See accompanying notes to the financial statements.

BOLT BIOTHERAPEUTICS, INC.
Notes to Financial Statements

1. Description of the Business

Bolt Biotherapeutics, Inc. (the "Company") was incorporated in Delaware on January 22, 2015 under the name Bolt Therapeutics, Inc. and is headquartered in Redwood City, California. The Company changed its name to Bolt Biotherapeutics, Inc. on July 29, 2015. The Company is a clinical-stage immuno-oncology company developing tumor-targeted therapies that leverage the innate and adaptive immune systems.

Basis of Presentation

The Company's financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP").

Liquidity and Going Concern

The Company has incurred operating losses and negative cash flows from operations since its inception and had an accumulated deficit of $47.7 million as of December 31, 2019. To date, none of the Company's product candidates have been approved for sale and therefore the Company has not generated any revenue from product sales. The Company has historically financed its operations primarily through private placements of convertible preferred stock.

The Company expects operating losses and negative cash flows from operations to continue for the foreseeable future. The Company believes its cash and cash equivalents of $34.8 million as of December 31, 2019 will not be sufficient for the Company to continue as a going concern for at least one year from the issuance date of these annual financial statements. The Company believes that this raises substantial doubt about its ability to continue as a going concern.

As a result, the Company will be required to raise additional capital, however, there can be no assurance as to whether additional financing will be available on terms acceptable to the Company, if at all. If sufficient funds on acceptable terms are not available when needed, it would have a negative impact on the Company's financial condition and could force the Company to delay, limit, reduce, or terminate product development or future commercialization efforts or grant rights to develop and market product candidates that the Company would otherwise plan to develop and market itself.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The accompanying financial statements do not reflect any adjustments relating to the recoverability and reclassifications of assets and liabilities that might be necessary if the Company is unable to continue as a going concern.

Other Risks and Uncertainties

The Company is subject to a number of risks similar to other early-stage biopharmaceutical companies, including, but not limited to, changes in any of the following areas that the Company believes could have a material adverse effect on its future financial position or results of operations: risks related to the successful discovery and development of its product candidates, ability to raise additional capital, development of new technological innovations by its competitors and delay or inability to obtain chemical or biological intermediates from such suppliers required for the synthesis of the Company's product candidates, including due to the impact of the current COVID-19 pandemic, protection of intellectual property rights, litigation or claims against the Company based on intellectual property rights, and regulatory clearance and market acceptance of the Company's products.

The current COVID-19 pandemic, which is impacting worldwide economic activity, poses the risk that the Company or its employees, contractors, suppliers, and other partners may be prevented from conducting business activities for an indefinite period of time, including due to shutdowns that may be requested or mandated by governmental authorities. The extent to which the COVID-19 pandemic will impact the Company's business will depend on future developments that are highly uncertain and cannot be predicted at this time.

The Company relies on single source manufacturers and suppliers for the supply of its product candidates. Disruption from these manufacturers or suppliers would have a negative impact on the Company's business, financial position and results of operations.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. On an ongoing basis, the Company evaluates its estimates and assumptions, including those related to revenue recognition, the valuation of common stock, stock-based compensation and convertible preferred stock purchase right liabilities. Management bases its estimates on historical experience and on various other assumptions that are believed to be 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. Actual results may differ materially from those estimates.

Unaudited Pro Forma Financial Information

The unaudited pro forma balance sheet information as of December 31, 2019 reflects (i) the conversion of all outstanding shares of the Company's convertible preferred stock into 70,490,863 shares of the Company's common stock, (ii) the related reclassification of the carrying value of the convertible preferred stock to permanent equity, and (iii) the issuance of shares of common stock upon the net exercise of all outstanding common stock warrants, all of which will occur immediately prior to the completion of the Company's planned initial public offering ("IPO"). The unaudited pro forma balance sheet does not include the shares expected to be sold and related proceeds to be received from the completion of the IPO.

Unaudited pro forma net loss per common share is computed using the weighted-average number of common shares outstanding after giving effect to the conversion of all the outstanding convertible preferred stock into shares of common stock as if such conversion had occurred at the beginning of the period presented, or the date of original issuance, if later.

Deferred Offering Costs

The Company capitalizes certain legal, accounting and other third-party fees that are directly related to the Company's in-process equity financings, including the planned IPO, until such financings are consummated. After consummation of the equity financing, these costs are recorded as a reduction of the proceeds received as a result of the offering. Should a planned equity financing be abandoned, terminated or significantly delayed, the deferred offering costs are immediately written off to operating expenses. There were no deferred offering costs capitalized as of December 31, 2018 and 2019.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash and cash equivalents. At December 31, 2019, most of the Company's funds are invested with a registered

investment manager and custodied at one financial institution, with working capital kept at a separate financial institution, and account balances may at times exceed federally insured limits. Management believes that the Company is not exposed to significant credit risk due to the financial strength of the depository institutions where the funds are held.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. As of December 31, 2018 and 2019, cash and cash equivalents consisted primarily of bank deposits and money market funds which were unrestricted as to withdrawal or use.

Restricted Cash

As of December 31, 2019, the Company had $0.6 million of long-term restricted cash deposited with a financial institution. The entire amount is held in a separate bank account to support a letter of credit agreement related to the Company's headquarter facility lease which expires in 2025 (see Note 7).

Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation and amortization. Depreciation and amortization begin at the time the asset is placed in service. Depreciation and amortization are computed using the straight-line method over the estimated useful lives of the assets of five years. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful lives of the assets. Maintenance and repairs are expensed as incurred. Upon sale or retirement of assets, the cost and accumulated depreciation and amortization are removed from the balance sheet and any resulting gain or loss is reflected in the statement of operations and comprehensive loss in the period realized.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, primarily comprised of property and equipment, for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparison of the carrying amount to the estimated undiscounted future cash flows, which the assets or asset groups are expected to generate. If such assets are considered to be impaired, the impairment to be recognized at the amount by which the carrying amount of the assets or asset groups exceeds the estimated fair value of the assets or asset groups. There have been no such impairments of long-lived assets during the periods presented.

Convertible Preferred Stock Purchase Right Liability

The Company determined the right of the investors to purchase shares of Series A-1 and Series B convertible preferred stock at a future date met the definition of a freestanding instrument and was recognized as a liability at fair value upon the initial issuance of Series A-1 convertible preferred stock in September 2016 and Series B convertible preferred stock in July 2018. The liabilities were subject to remeasurement at each balance sheet date, with changes in fair value recognized in other income (expense) in the statement of operations and comprehensive loss. Upon the closing of the convertible preferred stock, the convertible preferred stock purchase rights liabilities were extinguished and the marked-to-market fair value of the liability was included in the carrying value of the convertible preferred stock issued.

Convertible Preferred Stock

The Company records convertible preferred stock at fair value on the dates of issuance, net of issuance costs. The convertible preferred stock is recorded outside of stockholders' deficit because the shares contain

liquidation features that are not solely within the Company's control. The Company has elected not to adjust the carrying values of the convertible preferred stock to the liquidation preferences of such shares because it is uncertain whether or when an event would occur that would obligate the Company to pay the liquidation preferences to holders of shares of convertible preferred stock. Subsequent adjustments to the carrying values to the liquidation preferences will be made only when it becomes probable that such a liquidation event will occur.

Common Stock Purchase Warrants

The Company classifies common stock purchase warrants and other freestanding derivative financial instruments as equity in accordance with ASC 480. Warrants that meet the definition are classified as a component of equity and no subsequent remeasurement is required.

Revenue Recognition

Effective January 1, 2018, the Company adopted the provisions of ASC Topic 606 using a modified retrospective method of transition. Under ASC 606, the Company recognizes revenue as research and development activities are performed in an amount that reflects the consideration the Company expects to receive in exchange for those goods and services.

To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the following steps are performed: (i) identification of a contract to provide goods or services to a customer; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration, if any; (iv) where a contract contains multiple performance obligations, the Company must allocate the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when (or as) each performance obligation is satisfied.

The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer.

At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

As part of the accounting for these arrangements, the Company develops assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company uses key assumptions to determine the stand-alone selling price, which may include development timelines, reimbursement rates for personnel costs, discount rates, and probabilities of technical and regulatory success. The Company evaluates each performance obligation and determines if it is satisfied over time. In addition, variable consideration must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.

If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promised goods or services, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. Any change made to estimated progress towards completion of a performance obligation due to changes in the estimated activities required to complete the performance obligation and, therefore, revenue recognized will be recorded as a change in estimate.

The Company receives payments from its collaborators based on billing schedules established in each contract. Upfront payments and other payments may require deferral of revenue recognition to a future period until the Company performs its obligation under its collaboration arrangements. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the payment by the customer is akin to a deposit for research and development services.

To date, all of the Company's revenue has been derived from its development agreement with Toray Industries, Inc. ("Toray") as described in Note 6.

Research and Development Expenses

Research and development costs are charged to expense as incurred. Research and development expenses include certain payroll and personnel expenses, laboratory supplies, consulting costs, external contract research and development expenses, and allocated overhead, including rent, equipment depreciation and utilities. Advance payments for goods or services for future research and development activities are deferred and expensed as the goods are delivered or the related services are performed.

The Company estimates preclinical studies and clinical trial expenses based on the services performed pursuant to contracts with research institutions and clinical research organizations that conduct and manage preclinical studies and trials on the Company's behalf. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. These estimates are based on communications with the third-party service providers and the Company's estimates of accrued expenses and on information available at each balance sheet date. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly.

Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. The carrying amounts of the Company's financial instruments, including cash, accounts payable, accrued expenses and other current liabilities approximate fair value due to their short-term maturities. Refer to Note 3 for the methodologies and assumptions used in valuing financial instruments.

Stock-Based Compensation Expense

The Company accounts for stock-based compensation by measuring and recognizing compensation expense for all share-based payments made to employees and non-employees based on estimated grant-date fair values. The Company uses the straight-line method to allocate compensation cost to reporting periods over each award's requisite service period, which is generally the vesting period. The Company estimates the fair value of stock options using the Black-Scholes option-pricing model. The Black-Scholes model requires the input of subjective assumptions, including expected volatility, expected dividend yield, expected term, risk-free interest rate, and the estimated fair value of the underlying common stock on the date of grant. The Company accounts for forfeitures as they occur.

The fair value of restricted stock awards is valued as of the grant date using the estimated fair value of the Company's common stock.

Fair Value of Common Stock

The absence of an active market for the Company's common stock requires the Company's board of directors to determine the fair value of its common stock for purposes of granting stock options. The fair value of

the Company's common stock is determined by the Company's board of directors with assistance from management and an independent third-party valuation firm. Management's approach to estimating the fair value of the Company's common stock is consistent with the methods outlined in the American Institute of Certified Public Accountants' Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation.* Determining the best estimated fair value of the Company's common stock requires significant judgement and management considers several factors, including the Company's stage of development, equity market conditions affecting comparable public companies, significant milestones and progress of research and development efforts.

Income Taxes

The Company accounts for income taxes using the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax reporting bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes.

Realization of deferred tax assets is dependent upon future earnings, the timing and amount of which are uncertain. A valuation allowance is provided against deferred tax assets unless it is more likely than not that they will be realized.

The Company utilizes a two-step approach to recognize and measure uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained upon tax authority examination, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon ultimate settlement. The Company's policy is to recognize interest and penalties related to the underpayment of income taxes as a component of income tax expense or benefit. To date, there have been no interest or penalties charged in relation to the unrecognized tax benefits.

Net Loss Per Share

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, convertible preferred stock, stock options, common stock subject to repurchase related to unvested restricted stock awards and early exercise of stock options are considered to be potentially dilutive securities. Basic and diluted net loss attributable to common stockholders per share is presented in conformity with the two-class method required for participating securities as the convertible preferred stock is considered a participating security because it participates in dividends with common stock. The Company also considers the shares issued upon the early exercise of stock options subject to repurchase to be participating securities because holders of such shares have non-forfeitable dividend rights in the event a dividend is paid on common stock. The holders of all series of convertible preferred stock and the holders of early exercised shares subject to repurchase do not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to common stockholders. Because the Company has reported a net loss for all periods presented, diluted net loss per share is the same as basic net loss per share for those periods.

Comprehensive Loss

Comprehensive loss includes all changes in equity (net assets) during a period from non-owner sources. There have been no items qualifying as other comprehensive loss and, therefore, for all periods presented, the Company's comprehensive loss was the same as its reported net loss.

Segment Reporting

The Company has one operating segment. Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance.

Recent Accounting Standards

From time to time, new accounting standards are issued by the Financial Accounting Standards Board (the "FASB"), or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on the Company's financial position or results of operations upon adoption.

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-02, *Leases (Topic 842)*. ASU 2016-02 provides new comprehensive lease accounting guidance that supersedes existing lease guidance. The new standard establishes a right-of-use ("ROU") model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The guidance is effective for all public business entities and certain not-for-profit entities in fiscal years beginning after December 15, 2018, and for all other entities in fiscal years beginning after December 15, 2021. The Company adopted ASU 2016-02 on January 1, 2019 using the modified retrospective method and did not restate comparative periods. The Company has elected to apply the "practical expedient package," which permits it to not reassess previous conclusions around lease identification, lease classification, and initial direct costs. Further, the Company made an accounting policy election to exclude leases with terms of twelve months or less from the recognition requirements. The Company did not elect the use of the hindsight practical expedient. As a result of the adoption of the standard on January 1, 2019, the Company recognized lease liabilities based on the present value of the total fixed payments for its leases in the amount of $1.9 million and ROU assets in the amount of $2.0 million on its balance sheet. The adoption of the new standard did not have a material impact on the Company's Statement of Operations and Comprehensive Loss or Cash Flows.

In August 2017, the FASB issued ASU No. 2017-12, *Derivatives and Hedging (Topic 815)*, *Targeted Improvements to Accounting for Hedging Activities*. The new guidance better aligns an entity's risk management activities and financial reporting for hedging relationships through changes to both the designation and measurement guidance for qualifying hedging relationships and the presentation of hedge results. The new guidance also makes certain targeted improvements to simplify the application of hedge accounting guidance and ease the administrative burden of hedge documentation requirements and assessing hedge effectiveness. The standard is effective for fiscal years beginning after December 15, 2018, and early adoption is permitted. The Company elected to early adopt the standard on January 1, 2018. The adoption of the new standard did not have a material impact on the financial statements and related disclosures.

New Accounting Pronouncements Not Yet Adopted

In August 2018, the FASB issued ASU No. 2018-13, *Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*. The primary focus of the standard is to improve the effectiveness of the disclosure requirements for fair value measurements. The standard is effective for fiscal years and interim periods beginning after December 15, 2019. The Company is currently evaluating the impact of adopting this standard.

3. Fair Value Measurements and Fair Value of Financial Instruments

The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

Level 1—Quoted prices in active markets for identical assets or liabilities.

Level 2—Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

The Company's financial instruments consist of Level 1 assets and Level 3 liabilities. There were no transfers within the hierarchy during the years ended December 31, 2018 and 2019. Level 1 assets that are measured at fair value on a recurring basis consist of cash invested in money market accounts totaling $13.6 and $34.4 million at December 31, 2018 and 2019, respectively.

Level 3 liabilities that are measured at fair value on a recurring basis consist of the convertible preferred stock purchase right liabilities. The following table provides a summary of changes in the estimated fair value of the financial instruments using significant Level 3 inputs (in thousands):

	Series A Convertible Preferred Stock Purchase Right Liability	Series B Convertible Preferred Stock Purchase Right Liability	Total Convertible Preferred Stock Purchase Right Liabilities
Balance at December 31, 2017	$ 396	$ —	$ 396
Fair value of purchase right liability recognized in connection with the issuance of Series B convertible preferred stock	—	485	485
Change in fair value	137	16	153
Extinguishment of Series A convertible preferred stock purchase right liability	(533)	—	(533)
Balance at December 31, 2018	—	501	501
Change in fair value	—	42	42
Extinguishment of Series B convertible preferred stock purchase right liability	—	(543)	(543)
Balance at December 31, 2019	$ —	$ —	$ —

The fair value of the convertible preferred stock purchase right liabilities is estimated using an income-based approach incorporating probability considerations for different scenarios. The main assumptions include the probability and timing of the tranche closing. The estimated probability and timing related to the second closing of Series A-1 convertible preferred stock was 75% and 0.09 years as of January 1, 2018. In February 2018, the Company issued the second tranche of the Series A-1 convertible preferred stock and the Series A-1 convertible preferred stock purchase right liability was extinguished. The estimated probability and timing related to the second closing of Series B convertible preferred stock was 95% and 0.68 years at the July 2018

issuance date and 95% and 0.25 years as of December 31, 2018. In July 2019, the Company issued the second tranche of the Series B convertible preferred stock and the Series B convertible preferred stock purchase right liability was extinguished.

4. License and Equity Agreement

License and Equity Agreement with Related Party

In May 2015, the Company entered into an exclusive Equity and License Agreement (the "2015 Stanford Agreement"), as amended, with The Board of Trustees of the Leland Stanford Junior University ("Stanford"). The 2015 Stanford Agreement provides the Company exclusive licenses to certain inventions in order to further develop and commercialize the resulting products. As consideration, the Company issued Stanford shares of its common stock in September 2016. Dr. Engleman, a founder and member of the board of directors of the Company, who is a professor at Stanford, was issued shares of common stock as part of the transaction in September 2016. Additionally, the Company is obligated to pay Stanford annual license and milestone fees and royalties once commercial sales of the licensed products commence.

In November 2016 and June 2018, the Company entered into an agreement with Stanford for the exclusive license of two additional product candidates in order to develop and commercialize the products (together with the 2015 Stanford Agreement, the "Stanford Agreements").

During the years ended December 31, 2018 and 2019, the Company paid Stanford $35,000 and $40,000, respectively, in license and milestone fees under each of the Stanford Agreements, respectively. In addition, the Company paid Stanford $0.1 million and $0.2 million during the years ended December 31, 2018 and 2019, respectively, for reimbursement of patent maintenance costs.

The Company is required in each of the Stanford Agreements to make milestone payments up to an aggregate of $0.4 million for the first licensed product that meets certain patent issuance, clinical and regulatory milestones, and an additional milestone payment of $0.2 million for each additional regulatory approval. The Company also agreed in each of the Stanford Agreements to pay Stanford tiered royalties on its and its sublicensees' net sales of licensed products, at a low single digit percentage rates, subject to certain reductions. Dr. Engleman is entitled to receive a share of any royalties that the Company pays to Stanford under each of the Stanford Agreements with respect to the covered intellectual property. No royalty payments have been made to date.

5. Balance Sheet Components

Property and Equipment, net

Property and equipment, net, consist of the following (in thousands):

	December 31,	
	2018	2019
Laboratory equipment	$1,440	$2,004
Leasehold improvements	409	—
Office equipment	7	28
	1,856	2,032
Less accumulated depreciation and amortization	(414)	(645)
Total	$1,442	$1,387

Depreciation and amortization expense related to property and equipment was $0.3 million for each of the years ended December 31, 2018 and 2019.

As of December 31, 2018, equipment recorded under a capital lease was approximately $85,000 and accumulated amortization associated with the capital lease was approximately $17,000. The lease matured on December 31, 2019.

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following (in thousands):

	December 31,	
	2018	2019
Accrued research and development	$ 978	$1,031
Accrued compensation	740	1,452
Accrued other	105	383
Total	$1,823	$2,866

6. Collaborations

Joint Development and License Agreement with Toray Industries, Inc.

In March 2019, the Company entered into a Joint Development and License Agreement (the "Toray Development Agreement") with Toray to jointly develop and commercialize a Boltbody ISAC containing Toray's proprietary antibody to treat cancer. The Company determined that the Toray Development Agreement is a contract with a customer and should be accounted for under ASC 606. In conjunction with the Toray Development Agreement, the Company entered into a Series T Convertible Preferred Stock Purchase Agreement (the "Series T Agreement") for the issuance of 5,022,601 shares of Series T convertible preferred stock to Toray (see Note 8). These contracts have been evaluated together and the consideration in excess of the fair value of the Series T convertible preferred stock of $1.5 million has been allocated to the Toray Development agreement and included in the total consideration for collaboration revenue. In the Toray Development Agreement, the Company has identified one performance obligation which includes the license rights, research and development services, and services associated with participation on a joint steering committee. The Toray Development Agreement includes optional additional items which will be accounted for as contract modifications when development advances past certain milestones and the parties both exercise their opt-in rights. Under the Toray Development Agreement, no material right was determined to exist. Although the legal term of the agreement is until collaboration products are no longer sold in the Territory, the parties have present enforceable rights and obligations through the end of the first Phase I clinical trial, after which both parties can opt out of continued development under the agreement. As such, the accounting term of the Toray Development Agreement was considered to terminate upon completion of the first Phase I clinical trial.

The Toray Development Agreement contains one performance obligation so the full transaction price is allocated to the single bundled performance obligation. The Toray Development Agreement includes both fixed and variable consideration. Under the Toray Development Agreement, the Company will receive full reimbursement for early stage development and manufacturing activities based on agreed full-time equivalent rates and actual out of pocket costs incurred through the completion of the first Phase I clinical trial for the lead product candidate. After the completion of the Phase I clinical trial, either party may exercise step-down or opt-out rights which allow for either party to decrease or eliminate their financial participation in later stage development activities. If the jointly developed intellectual property or products are monetized, in any case, the Company's share of any revenue will initially go to Toray until 50% of the early stage development costs are repaid. Unless earlier terminated by either party, the Toray Development Agreement will continue until collaboration products are no longer sold in the Territory, but the royalty obligations will terminate on a region by region basis until the expiration of the last valid claim under the patent rights of the party receiving a royalty or under the collaboration product specific patent rights, whichever is longer.

The Company has one bundled performance obligation under the Toray Development Agreement comprised of a development license and funded research and development services. The Company determined that the development license is not capable of being distinct due to the specialized nature of the research services to be provided by the Company, and, accordingly, this promise was combined with the research and development services and participation in the joint research committee as one single performance obligation.

Collaboration revenue is recognized over time proportionate to the costs that the Company has incurred to perform the services using an input method as a measure of progress towards satisfying the performance obligation, which is based on project hours. Using the hours-based input method, which the Company determined most faithfully measures the fulfillment of its performance obligation to Toray, the Company recognizes revenue based on actual FTE hours incurred as a percentage of total estimated FTE hours as the Company completes its performance obligation. Amounts are billed based on estimated variable consideration in the quarter ahead of performance and are trued up on the subsequent quarter's invoice following the work performed. Payments are typically due within 45 days. The cumulative effect of revisions to estimated hours to complete the Company's performance obligation will be recorded in the period in which changes are identified and amounts can be reasonably estimated. Deferred revenue allocated to the unsatisfied performance obligation is recorded as a contract liability on the balance sheet and will be recognized over time as the services are performed, which is expected to take place through 2022.

The following table presents changes in the Company's contract liability for the year ended December 31, 2019 (in thousands). There were no contract liabilities for the year ended December 31, 2018.

Balance at December 31, 2018	$ —
Addition – upfront payment	1,489
Addition – variable consideration	297
Revenue recognized	(215)
Balance at December 31, 2019	$1,571

As of December 31, 2019, amounts receivable under the Toray Development Agreement totaled $0.3 million and was recorded in Prepaids and other current assets on the balance sheet.

7. Commitments and Contingencies

Leases

The Company adopted ASU 2016-02 as of January 1, 2019, using the modified retrospective method as described in Note 2, without adjusting prior comparative periods.

The Company determines whether an arrangement is a lease at inception. Specifically, it considers whether it controls the underlying asset and has the right to obtain substantially all the economic benefits or outputs from the asset. If the contractual arrangement contains a lease, the Company then determines the classification of the lease, operating or finance, using the classification criteria described in ASU 2016-02. The Company has elected not to separate lease components from non-lease components, such as common area maintenance charges, and instead accounts for the lease and non-lease components as a single component.

On October 31, 2017, the Company executed a non-cancelable operating lease agreement for 9,400 square feet of office and laboratory space for its former headquarters facility in Redwood City, California, which began in November 2017 and expires in January 2023 (2017 lease). At December 31, 2019, minimum rental commitments under this sublease are approximately $0.5 million for each of the years ended December 31, 2020, 2021 and 2022. The Company has accounted for the lease as an operating lease.

On July 15, 2019, the Company executed a non-cancellable lease agreement for 25,956 square feet of office and laboratory space for its new headquarters facility in Redwood City, California, which began in July 2019 and

expires in July 2025 (2019 lease). At December 31, 2019, minimum rental commitments under this lease are approximately $1.4 million, $1.5 million, $1.5 million, $1.6 million, and $2.6 million during the years ended December 31, 2020, 2021, 2022, 2023, and thereafter, respectively. The Company has accounted for the lease as an operating lease.

As of December 31, 2019, the Company's operating lease right-of-use assets and finance lease right-of-use assets were $10.1 million and $0.1 million, respectively. Finance right-of-use leases are used to finance capital equipment such as printers or ozone generators. As of December 31, 2019, the Company's current operating lease liabilities were $3.1 million and long-term operating lease liabilities were $7.1 million. Each of these amounts appears as a separate line within the Company's balance sheet.

Deposits in the amount of approximately $0.2 million are held by the lessor in connection with the Company's 2017 lease agreement as of December 31, 2018 and 2019. Cash required as security for the 2019 lease is secured by a letter of credit on behalf of the lessor in the amount of approximately $0.6 million and is recorded as restricted cash on the balance sheet as of December 31, 2019.

The components of lease expense during the year ended December 31, 2019 were as follows (in thousands):

Operating lease expense	$1,367
Finance lease expense:	
Amortization of right-of-use assets	$ 17
Interest on lease liabilities	1
Total finance lease expense	$ 18

For the year ended December 31, 2018, rent expense was $0.4 million.

Supplemental cash flow information related to leases was as follows for the year ended December 31, 2019 (in thousands):

Cash paid for amounts included in the measurement of lease liabilities (in thousands):

Operating cash flows from operating leases	$1,196
Operating cash flows from finance leases	$ 1
Financing cash flows from finance leases	$ 40

Right-of-use assets obtained in exchange for lease obligations (in thousands):

Operating leases	$ 11,072
Finance leases	$ 68

The following is a schedule by year for future maturities of the Company's operating lease liabilities as of December 31, 2019 (in thousands):

2020	$ 3,644
2021	1,994
2022	2,057
2023	1,572
2024	1,626
2025	970
Total lease payments	11,863
Less imputed interest	(1,678)
Total	$10,185

The weighted-average remaining lease term and discount rate related to the Company's lease liabilities as of December 31, 2019 were 5.2 years and 6.7%, respectively, for the operating leases. The Company lease discount rates are based on estimates of its incremental borrowing rate, as the discount rates implicit in the Company's leases cannot be readily determined. As the Company does not have any outstanding debt the Company estimates the incremental borrowing rate based on its estimated credit rating and available market information.

Supply Agreement

The Company has entered into a supply agreement with a contract manufacturer pursuant to which the Company may be required to pay milestone payments upon the achievement of specified regulatory milestones. The agreement is cancelable by the Company upon delivering the appropriate prior written notice. At December 31, 2019, potential future milestone payments under this agreement were up to $2.0 million.

Guarantees and Indemnifications

In the normal course of business, the Company enters into agreements that contain a variety of representations and provide for general indemnification. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. As of December 31, 2019, the Company does not have any material indemnification claims that were probable or reasonably possible and consequently has not recorded related liabilities.

Legal Proceedings

The Company is subject to claims and assessments from time to time in the ordinary course of business but is not aware of any such matters, individually or in the aggregate, that will have a material adverse effect on the Company's financial position, results of operations or cash flows.

8. Convertible Preferred Stock

Amended and Restated Certificate of incorporation

In March 2019, the Company amended and restated its certificate of incorporation and increased the total authorized convertible preferred shares to 83,541,150, which included the designation of 5,022,601 shares of Series T convertible preferred stock with a par value of $0.00001.

Issuance of Series A-1 Convertible Preferred Stock

In September 2016, the Company entered into a convertible preferred stock purchase agreement (the "Series A-1 Agreement") with new investors to raise up to $16.0 million in two separate tranches. The Company raised

$9.8 million, net of issuance costs of $0.2 million, and issued 10,658,706 shares at $0.9382 per share in September 2016 in the first tranche. The investors agreed to buy, and the Company agreed to sell, additional shares of such convertible preferred stock at the original issue price upon the achievement of pre-defined milestones. In February 2018, the Company received the second tranche of $6.0 million, net of issuance costs, and issued 6,395,227 shares of Series A-1 convertible preferred stock at $0.9382 per share.

The commitment is considered a separate freestanding financial instrument and was recorded as a Convertible Preferred Stock Purchase Right Liability in the amount of $0.4 million upon the issuance of the first tranche of the Series A-1 convertible preferred stock in September 2016. The commitment was accounted for at fair value during the period it was outstanding with changes in fair value at these reporting dates recorded as other income (expense) in the statement of operations and comprehensive loss. In February 2018, simultaneously with the issuance of the second tranche of the Series A-1 convertible preferred stock, the Series A-1 Convertible Preferred Stock Purchase Right Liability was extinguished.

Issuance of Series B Convertible Preferred Stock

In July 2018, the Company entered into a convertible preferred stock purchase agreement (the “Series B Agreement”) with existing and new investors to raise up to $68.5 million in two separate tranches. The first tranche closed in July 2018 and the Company raised $13.1 million, net of issuance costs of $0.2 million, and allocated value for the common stock warrants of $0.8 million issued in conjunction with the financing. The investors agreed to buy, and the Company agreed to sell, additional shares of such convertible preferred stock at the original issue price upon the achievement of pre-defined milestones. The Company issued 11,630,344 shares of Series B convertible preferred stock at $1.1494 per share and 1,744,547 common stock warrants.

The commitment is considered a separate freestanding financial instrument and was recorded as a Convertible Preferred Stock Purchase Right Liability in the amount of $0.5 million upon the issuance of the first tranche of the Series B convertible preferred stock in July 2018. The commitment was accounted for at fair value during the period it was outstanding with changes in fair value at these reporting dates recorded as other income (expense) in the statement of operations and comprehensive loss.

On July 1, 2019, the Company received proceeds from the second tranche of the Series B convertible preferred stock financing of $40.1 million, net of issuance costs, and issued 34,891,072 shares of Series B convertible preferred stock at $1.1494 per share. Simultaneously with the issuance of the second tranche of the Series B convertible preferred stock in July 2019, the Series B Convertible Preferred Stock Purchase Right Liability was extinguished.

Issuance of Series T Convertible Preferred Stock

On March 20, 2019, the Company entered into a convertible preferred stock purchase agreement (the “Series T Agreement”) concurrent with the Toray Development Agreement with a new investor (see Note 6). The Company raised a total of $10.0 million, net of issuance costs, from the sale of shares of Series T convertible preferred stock, including consideration allocated to the Toray Development Agreement. The fair value of the shares of Series T convertible preferred stock at the issuance date was $8.5 million, net of issuance costs. If the Company issues equity in conjunction with any exclusive development and commercialization license before December 31, 2020 at a price less than the Series T convertible preferred stock issue price, the Series T convertible preferred stock conversion price will be adjusted to reflect the price per share of the capital stock issued in that transaction.

As of December 31, 2018, convertible preferred stock consisted of (in thousands, except share and per-share numbers):

	Shares Authorized	Shares Issued and Outstanding	Per Share Original Issue Price	Liquidation Preference	Carrying Value
Series Seed	1,892,913	1,892,913	$ 0.3698	$ 700	$ 685
Series A-1	17,053,933	17,053,933	0.9382	16,000	15,807
Series B	59,571,703	11,630,344	1.1494	13,368	11,875
Total	78,518,549	30,577,190		$ 30,068	$ 28,367

As of December 31, 2019, convertible preferred stock consisted of (in thousands, except share and per-share numbers):

	Shares Authorized	Shares Issued and Outstanding	Per Share Original Issue Price	Liquidation Preference	Carrying Value
Series Seed	1,892,913	1,892,913	$ 0.3698	$ 700	$ 685
Series A-1	17,053,933	17,053,933	0.9382	16,000	15,807
Series B	59,571,703	46,521,416	1.1494	53,472	52,504
Series T	5,022,601	5,022,601	1.9910	10,000	8,509
Total	83,541,150	70,490,863		$ 80,172	$ 77,505

The rights, preferences and privileges of the convertible preferred stock as of December 31, 2019 were as follows:

Voting Rights

The holders of the Company's convertible preferred stock are entitled to that number of votes on all matters presented to stockholders equal to the number of shares of common stock then issuable upon conversion of such convertible preferred stock.

Dividends

Dividends on convertible preferred stock are payable in preference to and prior to any payments of any dividends on common stock. The holders of the Company's convertible preferred stock are entitled to receive, when, as and if declared by the board of directors, noncumulative dividends of $0.159280, $0.09195, $0.075056, and $0.02958 per share (as adjusted for any stock dividends, stock splits, combinations or other similar recapitalizations with respect to such series of the Company's convertible preferred stock) for Series T convertible preferred stock, Series B convertible preferred stock, Series A-1 convertible preferred stock and Series Seed convertible preferred stock, respectively, and any dividends declared and paid to common stockholders on a pro rata basis based on the number of as converted shares. No dividends have been declared as of December 31, 2019.

Conversion

Preferred stock is convertible, at the option of the holder, into fully paid, non-assessable shares of common stock as determined by dividing the original issue price by the conversion price for such series of convertible preferred stock in effect on the date of the conversion.

Each share of convertible preferred stock will automatically convert into 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 three times the original

issue price of the Series B convertible preferred stock (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 $60,000,000 of gross proceeds to the Company or (b) the date and time, or the occurrence of an event, specified by vote or written consent of holders of at least 78% percent of the outstanding shares of the Series B convertible preferred stock.

Liquidation

In the event of a Deemed Liquidation Event, as defined below, each holder of Series T convertible preferred stock and Series B convertible preferred stock is entitled to receive, prior and in preference to any distributions to the holders of Series A-1 convertible preferred stock, Series Seed convertible preferred stock and common stock, an amount equal to the greater of (i) the original issue price per share respectively, plus any declared but unpaid dividends thereon or (ii) the amount such holder would have received if such holder had converted its shares of Series T convertible preferred stock and/or Series B convertible preferred stock, as applicable, into shares of common stock immediately prior to such Deemed Liquidation Event. Subject to the prior payment of all amounts due to holders of Series T convertible preferred stock and Series B convertible preferred stock, each holder of Series A-1 convertible preferred stock and Series Seed convertible preferred stock is entitled to receive, prior and in preference to any distributions to the holders of common stock, an amount equal to the greater of (i) the original issue price per share respectively, plus any declared but unpaid dividends thereon or (ii) the amount such holder would have received if such holder had converted its shares of Series A-1 convertible preferred stock or Series Seed convertible preferred stock, as applicable, into shares of common stock immediately prior to such Deemed Liquidation Event. In the event that the assets available for distribution to the holders of convertible preferred stock are insufficient to pay such holders the full amounts to which they are entitled, the assets available for distribution will be distributed on a pro rata basis among the holders of the convertible preferred stock in proportion to the respective amounts that would otherwise be payable in respect of such stock. After all preferential payments have been made to the holders of convertible preferred stock, the remaining amounts will be distributed among the holders of the common stock, pro rata based on the number of shares held by each holder.

Deemed Liquidation

Each of the following events are considered a “Deemed Liquidation Event”: (i) a liquidation, dissolution or winding up of the Company, either voluntary or involuntary, (ii) a merger or consolidation of the Company, and (iii) the closing or the sale, lease or transfer, exclusive license or other disposition of all or substantially all of the Company’s assets.

9. COMMON STOCK

Amended and Restated Certificate of Incorporation

On March 26, 2019, the Company amended and restated its certificate of incorporation to increase the authorized number of shares of common stock to 126,000,000.

Common Stock Warrants

In July 2018, the Company issued 1,744,547 warrants to purchase common stock to the Series B investors in the first tranche. The warrants were deemed to be freestanding instruments indexed to the Company’s common stock and also met the requirements for equity classification. At the date of issuance, the fair value of the warrants of approximately $0.8 million was recorded as additional issuance costs of the convertible preferred stock and as an increase to additional paid-in capital. The warrants expire on July 26, 2028 and are exercisable at the option of the warrant holder for $0.01 per share. In September 2018, 538,324 warrants were exercised and common stock was issued. As of December 31, 2018 and 2019, 1,206,223 warrants were outstanding.

Common Stock

In 2015, the Company issued an aggregate of 5,500,000 shares of common stock to the founders of the Company, which were fully vested on the date of issuance. In 2016, the Company entered into agreements with the founders that provided that an aggregate of 3,656,250 of the shares would vest over a specified period of time, ranging from one to four years. As of December 31, 2018 and 2019, 843,750 shares and no shares of common stock remained unvested, respectively.

In 2016, 1,100,000 shares of common stock were sold to one of the Company's employees in exchange for a note receivable of $99,000. The note is subject to repayment over five years and is collateralized only by the stock purchased. Of the total 1,100,000 common shares issued, 375,000 shares were vested upon grant, 200,000 shares vest upon the achievement of a milestone, which was achieved in 2019, and 525,000 shares vest ratably over 48 months. As of December 31, 2018 and 2019, there was a remaining principal receivable balance of $74,000 and $24,000, respectively.

For accounting purposes, the unvested shares related to restricted stock awards and common stock issued in exchange for notes are not considered to be outstanding. The following table summarizes the activity of the issuances of unvested stock for the years ended December 31, 2018 and 2019:

	Years Ended December 31,	
	2018	2019
Unvested at beginning of year	2,635,417	1,335,417
Vested	(1,300,000)	(1,218,750)
Unvested at end of year	1,335,417	116,667

Common Stock Reserved for Future Issuance

The following shares of common stock were reserved for future issuance as of December 31, 2018 and 2019:

	December 31,	
	2018	2019
Convertible preferred stock	30,577,190	70,490,863
Conversion of convertible preferred stock issuable in future closings	34,891,072	—
Common stock options issued and outstanding	2,013,100	14,109,134
Common stock available for future issuance under the 2015 Plan	7,877,849	6,233,461
Warrants to purchase common stock	1,206,223	1,206,223
Total	76,565,434	92,039,681

10. STOCK-BASED COMPENSATION

In 2015, the Company adopted the 2015 Equity Incentive Plan (the "2015 Plan"), under which stock options, restricted stock awards, restricted stock units, stock appreciation rights could be granted to employees, officers, directors, and consultants of the Company. Under the 2015 Plan, both incentive stock options ("ISOs") and non-qualified stock options ("NSOs") could be granted. ISOs may be granted only to Company employees. The exercise price of other ISO's generally may not be less than 100% of the fair market value of the related common stock on the grant date and shall have terms no more than ten years from the date of grant. Stock options generally include a one-year cliff vest of 25% of the respective award, followed by monthly vesting in equal installments over the next 36 months, and grants that vest monthly over 48 months. The terms and conditions governing the other stock awards under the 2015 Plan are at the sole discretion of the board of directors.

In 2018 and 2019, the 2015 Plan was amended to increase the shares of common stock available for issuance under the 2015 Plan by 5,147,569 shares and 10,523,713 shares, respectively. As of December 31, 2018 and 2019, there were 11,361,244 shares and 21,884,957 shares, respectively, authorized for issuance under the 2015 Plan, of which 7,877,849 shares and 6,233,461 shares, respectively, remained available for future issuance.

Stock option activity under the 2015 Plan for the years ended December 31, 2018 and 2019 is as follows:

	Number	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Weighted-Average Grant Date Fair Value	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2017	1,225,000	$ 0.30			
Granted	1,168,187	$ 0.29		$ 0.20	
Exercised	(50,726)	$ 0.29			
Canceled/forfeited	(329,361)	$ 0.30			
Outstanding at December 31, 2018	2,013,100	$ 0.29			$ 51
Granted	12,274,578	$ 0.38		$ 0.23	
Exercised	(72,067)	$ 0.32			
Canceled/forfeited	(106,477)	$ 0.31			
Outstanding at December 31, 2019	14,109,134	$ 0.37	9.3		$ 319
Exercisable at December 31, 2019	7,920,835	$ 0.37	9.2		$ 164
Vested or expected to vest as of December 31, 2019	14,109,134	$ 0.37	9.3		$ 319

The intrinsic value of options exercised was immaterial during the years ended December 31, 2018 and December 31, 2019. The fair value of options vested was $0.1 million and $0.4 million during the years ended December 31, 2018 and December 31, 2019, respectively. As of December 31, 2019, there was approximately $2.6 million of unrecognized stock-based compensation related to unvested stock options, which the Company expects to recognize over a weighted-average period of 3.3 years.

The fair value of each option grant was estimated on the date of grant using the Black-Scholes option-pricing model with the following assumptions for the years ended December 31, 2018 and 2019:

	Years Ended December 31,	
	2018	2019
Risk-free interest rate	2.4–2.8%	1.4–2.6%
Expected volatility	77–78%	68–70%
Expected term (in years)	5.5–6.0	5.5–6.1
Expected dividend yield	—%	—%

Expected Term—The expected term of options granted represents the period of time that the options are expected to be outstanding. Due to the lack of historical exercise history, the expected term of the Company's employee stock options has been determined utilizing the simplified method for awards that qualify as plain-vanilla options.

Expected Volatility—The estimated volatility was based on the historical volatility of the common stock of a group of publicly traded companies deemed comparable to the Company.

Risk-Free Interest Rate—The risk-free interest rate is the implied yield in effect at the time of the option grant based on U.S. Treasury securities with contract maturities equal to the expected term of the Company's stock options.

Dividend Rate—The Company has not paid any cash dividends on common stock since inception and does not anticipate paying any dividends in the foreseeable future. Consequently, an expected dividend yield of zero was used.

Stock-Based Compensation Expense

The following table summarizes the components of stock-based compensation expense recognized in the Company's statement of operations and comprehensive loss (in thousands):

	Years Ended December 31,	
	2018	2019
Research and development	$ 75	$ 295
General and administrative	48	213
Total stock-based compensation	$ 123	$ 508

Early Exercise Liability

Some of the options granted under the 2015 Plan may be exercised prior to the time that the options have vested, provided that such shares remain subject to repurchase until such time as they have vested. The right to repurchase these shares lapses over the four-year vesting period. As of December 31, 2018 and 2019, there were 123,296 and 113,520 unvested shares representing an early exercise liability of approximately $38,000 and $35,000, respectively. The unvested shares purchased by the employees are not deemed, for accounting purposes, to be outstanding.

The following table summarizes the activity of the unvested stock outstanding from the early exercise of stock options for the years ended December 31, 2018 and 2019:

	Years Ended December 31,	
	2018	2019
Unvested at beginning of year	134,986	123,296
Early exercised during the period	31,976	47,463
Vested	(43,666)	(57,239)
Unvested at end of year	123,296	113,520

11. Net Loss Per Share

The following table sets forth the computation of the Company's basic and diluted net loss per share attributable to common stockholders, which excludes shares which are legally outstanding, but subject to repurchase by the Company (in thousands, except share and per share amounts):

	December 31,	
	2018	2019
Numerator:		
Net loss	$ (11,589)	$ (30,487)
Denominator:		
Weighted-average common shares outstanding	12,964,771	13,437,881
Warrants to purchase common stock	705,109	1,206,223
Common stock outstanding subject to repurchase related to unvested early exercised stock options and restricted stock awards	(2,114,120)	(689,750)
	11,555,760	13,954,354
Net loss per share attributable to common stockholders, basic and diluted	$ (1.00)	$ (2.18)

Potentially dilutive securities not included in the calculation of diluted net loss per share because to do so would be anti-dilutive are as follows (in common stock equivalent shares):

	December 31,	
	2018	2019
Convertible preferred stock outstanding	30,577,190	70,490,863
Common stock options issued and outstanding	2,013,100	14,109,134
Common stock outstanding subject to repurchase related to unvested early exercised stock options and restricted stock awards	1,458,715	230,187
Total	34,049,005	84,830,184

The following table summarizes the Company's unaudited pro forma net loss per share for the year ended December 31, 2019 (in thousands, except share and per share data). The common stock warrants with a strike price of $0.01 per share have been included in the issued and outstanding balance of the denominator of the unaudited proforma net loss per share:

Numerator	
Net loss attributable to common stockholders	
Change in fair value of convertible preferred stock purchase right liability	
Denominator	
Weighted-average common shares outstanding, basic and diluted	
Pro forma adjustments to reflect:	
Assumed conversion of convertible preferred stock	
Shares used to compute pro forma net loss per share, basic and diluted	
Pro forma net loss per share attributable to common stockholders, basic and diluted	

12. 401(K) Savings Plan

The Company established a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code of 1986, as amended ("Code"). The 401(k) Plan covers all employees who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pretax basis. The Company has not made any contributions to the 401(k) Plan as of December 31, 2019.

13. Income Taxes

The Company recorded a current state tax provision of approximately $2,000 related to state minimum taxes for the years ended December 31, 2018 and 2019, which is recorded in general and administrative expenses in the accompanying statement of operations and comprehensive loss.

A reconciliation of the Company's effective tax rate and federal statutory tax rate is summarized as follows (in thousands):

	Years Ended December 31,	
	2018	2019
Income tax expense (benefit) at statutory rates	$ (2,433)	$ (6,402)
State income tax, net of federal benefit	1	1
Permanent items	45	28
Valuation allowance	2,488	7,437
Stock-based compensation	22	72
Research and development tax credits	(121)	(1,134)
	$ 2	$ 2

Deferred income taxes reflect the net tax effects of loss and credit carryforwards and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities for federal and state income taxes are as of December 31, 2018 and 2019 (in thousands) are summarized as follows:

	December 31,	
	2018	2019
Deferred tax assets:		
Net operating loss carryforward	$ 4,776	$ 13,801
Research tax credits	446	2.227
Intangible assets	249	230
Reserves and accruals	121	98
Stock-based compensation	8	57
Lease liability	—	3,039
Total deferred tax assets	5,600	19,452
Less valuation allowance	(5,519)	(16,330)
Net deferred tax assets	81	3,122
Deferred tax liabilities:		
Right-of-use assets	—	(3,008)
Property and equipment	(76)	(107)
Prepaid assets	(5)	(7)
Total deferred tax liabilities	(81)	(3,122)
Net deferred tax assets	$ —	$ —

A valuation allowance is required to be established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. Realization of deferred tax assets is dependent upon future earnings, the timing and amount of which are uncertain. A full review of all positive and negative evidence needs to be considered. The Company has established a full valuation allowance against the net deferred tax assets as of December 31, 2018 and 2019 due to historical losses and uncertainty surrounding the use of such assets. The valuation allowance increased by $3.8 million between December 31, 2017 and December 31, 2018 and by $10.8 million between December 31, 2018 and December 31, 2019 due primarily to the generation of operating losses.

As of December 31, 2019, the Company has net operating loss carryforwards for federal and state income tax purposes of $46.2 million and $46.3 million, respectively. The federal net operating loss carryforwards generated prior to 2018 and state net operating loss carryforwards, if not utilized, will expire beginning in 2035. Federal net operating losses aggregating $41.8 million are not subject to expiration.

The Company has research credit carryforwards for federal and state income tax purposes of approximately $1.5 million and $1.3 million, respectively, as of December 31, 2019. The federal credits begin to expire in 2038 and the state credits can be carried forward indefinitely.

Utilization of some of the federal and state net operating loss and credit carryforwards may be subject to annual limitations due to the change in ownership provisions of the Code and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization. The Company has not performed a study under Section 382 of the Code to determine if a change in control did occur and, as such, is not able to determine the impact on the net operating loss carryforwards, if any, as of the date of the financial statements.

The Company files tax returns in the United States and California. The Company is not currently under examination in any of these jurisdictions and all of the Company's tax years remain effectively open to examination due to net operating loss carryforwards.

The Company recognizes a tax benefit from uncertain tax positions when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits. Due to the existence of the full valuation allowance, future changes in unrecognized tax benefits will not impact the Company's effective tax rate. The Company does not foresee material changes to its liability for uncertain tax benefits within the next 12 months.

The following table summarizes the activity in the Company's gross unrecognized tax benefits (in thousands):

	December 31,	
	2018	2019
Balance at beginning of period	$ 31	$227
Increase related to current year positions	196	378
Balance at the end of the year	$227	$605

During the years ended December 31, 2018 and 2019, no interest or penalties were recorded. In the event the Company should need to recognize interest and penalties related to unrecognized income tax liabilities, this amount will be recorded as an increase to income tax expense.

14. Subsequent Events

The Company has evaluated subsequent events for financial statement purposes occurring through August 10, 2020, the date when these financial statements are available to be issued.

Amended and Restated Certificate of Incorporation

On June 26, 2020, the Company amended its certificate of incorporation to increase the number of authorized shares of common stock to a total of 198,000,000 shares and increase the number of authorized shares of convertible preferred stock to a total of 145,903,585. Further the amendment decreased the number of authorized shares of Series B convertible preferred stock to 46,521,416 and created two new series of convertible preferred stock, par value $0.00001, designated Series C-1 and C-2, with total authorized shares of 36,135,263 and 39,277,459, respectively.

Issuance of Series C-1 Convertible Preferred Stock

On June 26, 2020, pursuant to the Series C Convertible Preferred Stock Purchase Agreement, the Company issued 36,135,260 shares of Series C-1 convertible preferred stock for a purchase price of $1.15 per share for net

proceeds of $41.3 million to new and existing investors. The agreement also provides for an additional issuance of 39,277,459 shares of Series C-2 convertible preferred stock for a purchase price of $1.3225 per share for gross proceeds of $51.9 million upon the achievement of certain milestones as defined in the agreement.

Amendment of 2015 Plan

On June 26, 2020, concurrent with the close of the Series C convertible preferred stock financing, the 2015 Plan was amended to increase the number of shares of common stock available for issuance by 3,612,793 shares to a total of 25,497,750 shares.

Issuance of New Option Awards

On July 29, 2020, the Company's board of directors approved new option grants to employees under the 2015 Plan. These options vest over four years and total 4,369,950 shares at a strike price of $0.40 per share.

New Lease and Subleases

On August 7, 2020, the Company executed a non-cancellable 10-year lease agreement for 45,690 square feet of office and laboratory space adjacent to its headquarters facility in Redwood City, California (2020 Lease Agreement). Lease commencement will begin the later of 6 months from signing and the date the premises are ready for occupancy. The 2020 Lease Agreement includes an extension of the lease for the Company's current 25,956 square foot facility to be coterminous with the new facility, as well as an option for renewal of both premises for an eight-year term. In addition, as of August 7, 2020, we have subleased approximately 10,000 square feet of this space for 2 years and approximately 10,500 square feet of this space for 3 years.

Shares

COMMON STOCK

PROSPECTUS

MORGAN STANLEY *SVB LEERINK* *STIFEL* *GUGGENHEIM SECURITIES*

, 2020

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table indicates the expenses to be incurred in connection with the offering described in this registration statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimated except the SEC registration fee, the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee and the exchange listing fee.

	Amount
SEC registration fee	$ *
FINRA filing fee	*
Exchange listing fee	*
Accountants' fees and expenses	*
Legal fees and expenses	*
Transfer agent's fees and expenses	*
Printing and engraving expenses	*
Miscellaneous	*
Total expenses	$ *

* To be provided by amendment.

Item 14. Indemnification of Directors and Officers.

Section 145 of the Delaware General Corporation Law authorizes a court to award, or a corporation's board of directors to grant, indemnity to directors and officers in terms sufficiently broad to permit such indemnification under certain circumstances for liabilities, including reimbursement for expenses incurred, arising under the Securities Act. Our amended and restated certificate of incorporation that will be in effect on the closing of this offering permits indemnification of our directors, officers, employees and other agents to the maximum extent permitted by the Delaware General Corporation Law, and our amended and restated bylaws that will be in effect on the closing of this offering provide that we will indemnify our directors and officers and permit us to indemnify our employees and other agents, in each case to the maximum extent permitted by the Delaware General Corporation Law.

We have entered into indemnification agreements with our directors and officers, whereby we have agreed to indemnify our directors and officers to the fullest extent permitted by law, including indemnification against expenses and liabilities incurred in legal proceedings to which the director or officer was, or is threatened to be made, a party by reason of the fact that such director or officer is or was a director, officer, employee or agent of Bolt Biotherapeutics, Inc., provided that such director or officer acted in good faith and in a manner that the director or officer reasonably believed to be in, or not opposed to, our best interests. At present, there is no pending litigation or proceeding involving any of our directors or officers regarding which indemnification is sought, nor are we aware of any threatened litigation that may result in claims for indemnification.

We maintain insurance policies that indemnify our directors and officers against various liabilities arising under the Securities Act and the Exchange Act that might be incurred by any director or officer in his or her capacity as such.

The underwriters are obligated, under certain circumstances, pursuant to the underwriting agreement filed as Exhibit 1.1 hereto, to indemnify us, our officers and our directors against liabilities under the Securities Act.

Item 15. Recent Sales of Unregistered Securities.

The following sets forth information regarding all unregistered securities sold since January 1, 2017.

(1) In February 2018, we issued an aggregate of 6,395,227 of our Series A-1 preferred stock to six accredited investors at a purchase price of $0.9382 per share, for an aggregate purchase price $6.0 million.

(2) In multiple closings held between July 2018 and July 2019, we issued and sold an aggregate of 46,521,416 shares of our Series B preferred stock and issued warrants to purchase an aggregate of 1,206,223 of common stock to 11 accredited investors at a purchase price of $1.1494 per share, for an aggregate purchase price of $53.5 million.

(3) In March 2019, we issued an aggregate of 5,022,601 of our Series T preferred stock to one accredited investor at a purchase price of $1.991 per share, for an aggregate purchase price $10 million.

(4) In June 2020, we issued an aggregate of 36,135,260 of our Series C-1 preferred stock to 17 accredited investors at a purchase price of $1.15 per share, for an aggregate purchase price $42 million.

(5) From January 18, 2017 through June 30, 2020, we granted to certain employees, consultants and directors options to purchase an aggregate of 14,871,910 shares of our common stock under our 2015 Equity Incentive Plan at exercise prices ranging from $0.29 to $0.39 per share.

(6) From January 18, 2017 through June 30, 2020, we issued and sold an aggregate of 410,321 shares of our common stock upon the exercise of options under our 2015 Equity Incentive Plan, at exercise prices ranging from $0.29 to $0.39 per share, for an aggregate exercise price of $125,624.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. Unless otherwise specified above, we believe these transactions were exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act (and Regulation D promulgated thereunder), or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or under benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed on the share certificates issued in these transactions. All recipients had adequate access, through their relationships with us, to information about us. The sales of these securities were made without any general solicitation or advertising.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits.

Exhibit Number	Description of Exhibit
1.1*	Form of Underwriting Agreement.
3.1*	Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect.
3.2*	Form of Amended and Restated Certificate of Incorporation of the Registrant, to be in effect upon the closing of this offering.
3.3*	Amended and Restated Bylaws of the Registrant, as currently in effect.
3.4*	Form of Amended and Restated Bylaws of the Registrant, to be in effect upon the closing of this offering.
4.1*	Form of common stock certificate of the Registrant.
5.1*	Opinion of Cooley LLP.
10.1*	Amended and Restated Investor Rights Agreement, dated June 26, 2020, by and among the Registrant and the investors listed on Schedule A thereto.
10.2*+	2015 Equity Incentive Plan, as amended.
10.3*+	Forms of Option Agreement, Stock Option Grant Notice and Notice of Exercise under the 2015 Equity Incentive Plan.
10.4*+	2020 Equity Incentive Plan.
10.5*+	Forms of Option Agreement, Stock Option Grant Notice and Notice of Exercise under the 2020 Equity Incentive Plan.
10.6*+	Forms of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the 2020 Equity Incentive Plan.
10.7*+	2020 Employee Stock Purchase Plan.
10.8*	Form of Indemnification Agreement, by and between the Registrant and each of its directors and executive officers.
10.9*	Form of Warrant to Purchase Common Stock.
10.10*+	Offer of Employment by and between the Registrant and Randall C. Schatzman dated June 10, 2019.
10.11*+	Offer Letter by and between the Registrant and William Quinn dated April 14, 2020.
10.12*+	Offer Letter by and between the Registrant and Edith Perez dated March 16, 2020.
10.13*+	Offer Letter by and between the Registrant and Grant Yonehiro dated October 26, 2016.
10.14*+	Severance Agreement by and between the Registrant and Grant Yonehiro dated January 26, 2017.
10.15*	Lease Agreement by and between the Registrant and Metropolitan Life Insurance Company dated August 31, 2017.
10.16*	Sublease Agreement by and between the Registrant and Armo Biosciences, Inc. dated April 18, 2019.
10.17*	Consent to Sublease Agreement by and between the Registrant, Armo Biosciences, Inc. and HCP LS Redwood City, LLC dated June 14, 2019.
10.18*	Britannia Seaport Centre Lease by and between the Registrant and HCP LS Redwood City, LLC dated August 7, 2020

Exhibit Number	Description of Exhibit
10.19*	Exclusive (Equity) Agreement by and between the Registrant and The Board of Trustees of the Leland Stanford Junior University dated May 18, 2015, as amended by Amendment No. 1 to Exclusive (Equity) Agreement by and between the Registrant and The Board of Trustees of the Leland Stanford Junior University dated August 2, 2017 and Amendment No. 2 to Exclusive (Equity) Agreement by and between the Registrant and The Board of Trustees of the Leland Stanford Junior University dated June 25, 2018.
10.20*	Exclusive Agreement by and between the Registrant and The Board of Trustees of the Leland Stanford Junior University dated June 1, 2018.
10.21*	Supply Agreement by and between the Registrant and EirGenix, Inc. dated March 10, 2019.
10.22*	Master Services Agreement by and between the Registrant and Piramal Healthcare UK Ltd dated June 26, 2018.
23.1*	Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm.
23.2*	Consent of Cooley LLP (included in Exhibit 5.1).
24.1*	Power of Attorney (see signature page to this registration statement on Form S-1).

* To be filed by amendment.
\+ Indicates management contract or compensatory plan.
† Portions of this exhibit have been omitted as the Registrant has determined that the omitted information (i) is not material and (ii) would likely cause competitive harm to the Registrant if publicly disclosed.

(b) Financial Statement Schedules.

All financial statement schedules are omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or the notes thereto.

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

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

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Redwood City, State of California, on , 2020.

BOLT BIOTHERAPEUTICS, INC.

By: _____
Randall C. Schatzman, Ph.D.
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Randall C. Schatzman, Ph.D. and William P. Quinn, and each one of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him in their 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 this registration statement that is to be effective on filing pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and all post-effective amendments thereto, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she 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 her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
Randall C. Schatzman, Ph.D.	Chief Executive Officer and Director *(Principal Executive Officer)*	, 2020
William P. Quinn	Chief Financial Officer *(Principal Financial and Accounting Officer)*	, 2020
Peter Moldt, Ph.D.	Chairman of the Board of Directors	, 2020
Edgar G. Engleman, M.D.	Director	, 2020
Ashish Khanna, Ph.D.	Director	, 2020
Richard A. Miller, M.D.	Director	, 2020
Jason Pitts, Ph.D.	Director	, 2020
Mahendra G. Shah, Ph.D.	Director	, 2020