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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2020

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number 001-39988

Bolt Biotherapeutics, Inc.
(Exact name of Registrant as specified in its Charter)

Delaware	**47-2804636**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
900 Chesapeake Drive Redwood City, CA	**94063**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 665-9295

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.00001 par value	BOLT	The Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☐ NO ☒

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). YES ☒ NO ☐

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The registrant did not have a public float on the last business day of its most recently completed second fiscal quarter because there was no public market for the registrant's common equity as of such date.

As of March 26, 2021, the registrant had 36,327,914 shares of common stock outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical facts contained in this Annual Report are forward-looking statements, including statements regarding:

- *any impact of the COVID-19 pandemic, or responses to the pandemic, on our business, collaborations, clinical trials or personnel;*
- *our expectations regarding the potential benefits of our strategy and technology;*
- *our expectations regarding the operation of our product candidates, collaborations and related benefits;*
- *our beliefs regarding our industry;*
- *our beliefs regarding the success, cost and timing of our product candidate development and collaboration activities and current and future clinical trials and studies;*
- *our beliefs regarding the potential markets for our product candidates, collaborations and our and our collaborators' ability to serve those markets;*
- *our ability to attract and retain key personnel;*
- *our ability to obtain funding for our operations, including funding necessary to complete further development and any commercialization of our product candidates; and*
- *regulatory developments in the United States, or U.S., and foreign countries, with respect to our product candidates.*

These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance and achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "could," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology. These forward-looking statements are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K and are subject to a number of risks, uncertainties and assumptions, including those described in Part I, Item 1A, "Risk Factors." The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

We have common law trademark rights in the unregistered marks "Bolt Biotherapeutics, Inc..," "Boltbody," and the Bolt logo in certain jurisdictions. Solely for convenience, trademarks and tradenames referred to in this Annual Report appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights, to these trademarks and tradenames.

PART I

Item 1. 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 immune stimulating antibody conjugate ("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. We have demonstrated robust single agent anti-tumor activity in multiple preclinical models, including elimination of large tumors (~500 mm^3), as well as tumors that are refractory to trastuzumab or ado-trastuzumab emtansine. In our preclinical safety studies, BDC-1001 was well tolerated and no adverse safety signals were observed. We believe these findings 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 believe that our preliminary Phase 1/2 data 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 ("CEA") and PD-L1, both of which are currently in preclinical development. We anticipate advancing our CEA Boltbody ISAC BDC-2034 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 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;*
- *Well tolerated in preclinical studies 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 in mice, we have demonstrated that systemic administration of HER2 Boltbody ISACs exhibited localized immune activation that resulted in single agent activity that eliminated large (~500 mm^3) tumors and generated immunological memory against cancers with epitope spreading. Furthermore, preclinical data showed anti-tumor activity 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 lack of adverse safety signals in our non-human primate 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 believe that our preliminary Phase 1/2 data provide us with clinical proof of concept for our HER2 Boltbody ISAC approach.

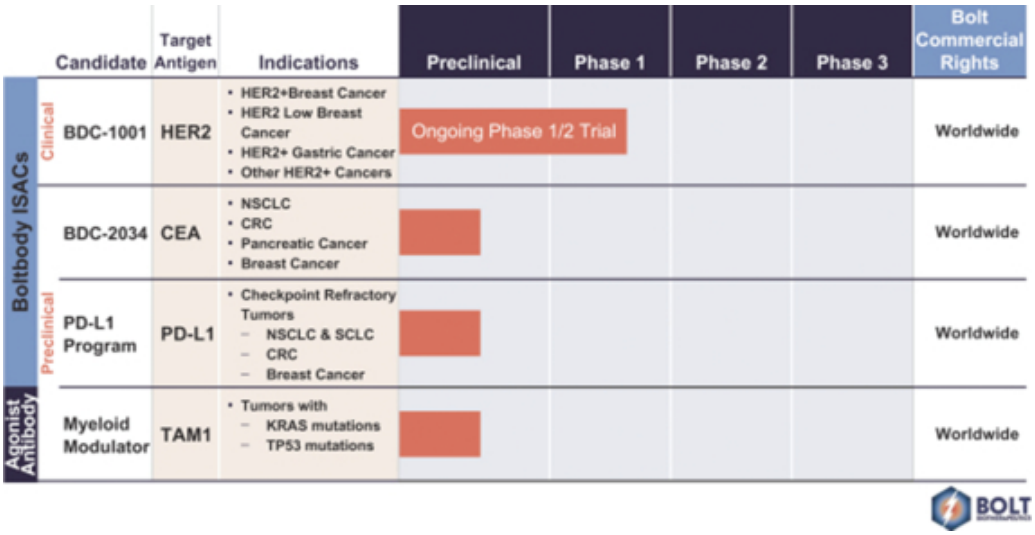
Our second program, BDC-2034, focuses on CEA, a well-known tumor antigen that is overexpressed in various solid tumors with significant unmet medical need including, but not limited to, colorectal cancer, non-small cell lung cancer, pancreatic cancer and breast cancer. CEA is upregulated on the cell 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 BDC-2034 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 enhanced anti-tumor activity 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 along with Dr. Engleman 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. Prior to the completion of our initial public offering in February 2021, we funded our operations primarily through private placements of our convertible preferred stock for gross proceeds of $173.7 million, including the January 2021 issuance and sale of 5,611,059 shares of Series C-2 preferred stock for net proceeds of $51.9 million. In February 2021, we completed our initial public offering of 13,225,000 shares of our common stock at a price to the public of $20.00 per share, including the exercise in full by the underwriters of their option to purchase

1,725,000 additional shares of our common stock. Including this option exercise, the aggregate net proceeds to us from the offering was approximately $241.7 million, net of approximately $22.8 million in underwriting discounts, commissions and other offering expenses.

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 BDC-2034 targeting CEA 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. We expect to designate our next clinical candidate in 2021.
- **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 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 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

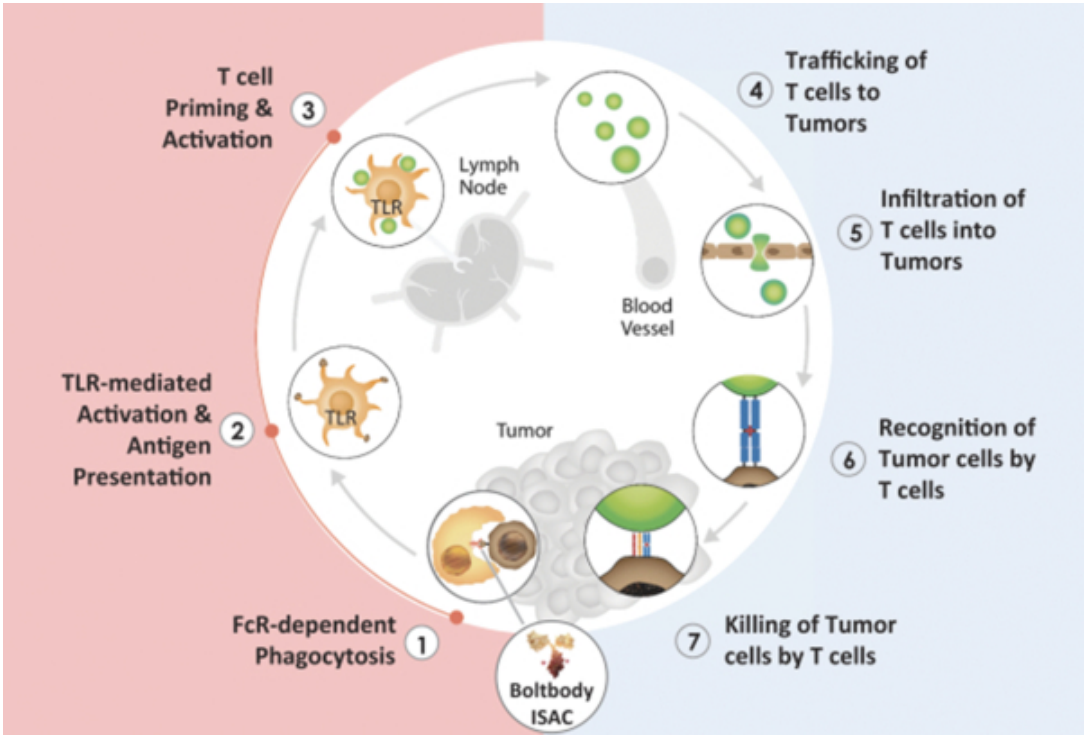
Toll-like receptors, or TLRs, are a class of pattern recognition receptors that bind to molecules present on bacteria, viruses and other microorganisms. They are highly expressed by myeloid APCs and other innate immune cells and play a key role in the activation of the immune system in response to microbial 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, or pDCs. Furthermore, pDCs produce interferon alpha that amplifies the immune response by bolstering dendritic cell and T cell activity. 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 activity 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

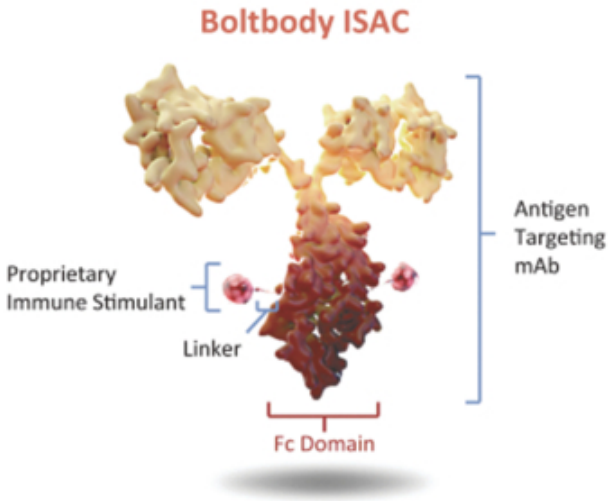
We address each of these pitfalls by engaging an entirely new immune response via our tumor-targeted Boltbody ISACs, which have the potential to safely stimulate the TLRs within the myeloid cells ultimately leading to a T cell-driven anti-tumor response.

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.

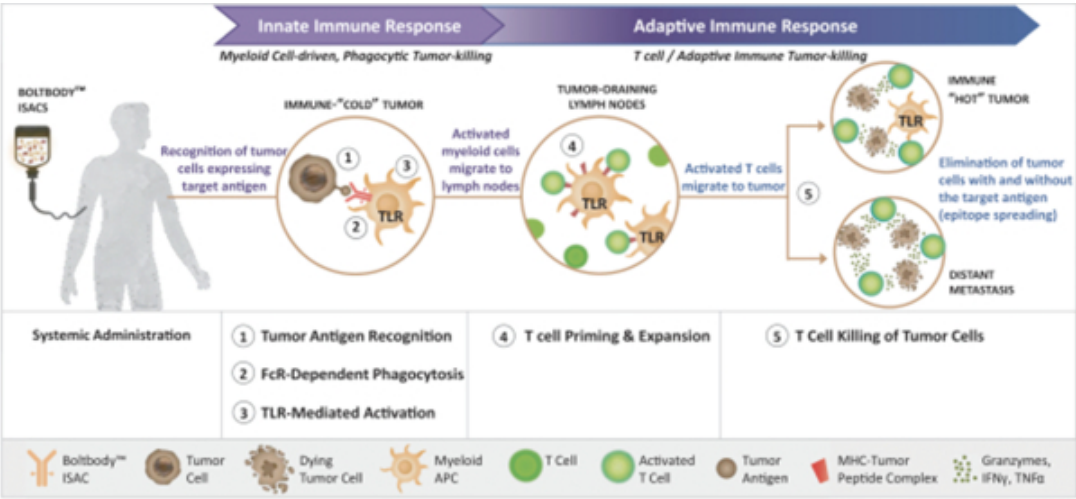
The “Three-Factor Authentication” process provides an added safety benefit to ensure that the immune system is selectively targeted and only fully activated when all three steps have been met. This ensures an initially localized immune effect. During the “Three-Factor Authentication,” tumor-associated 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 us to believe that our Boltbody ISACs have the potential 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 activity.

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 *in vivo* anti-tumor activity 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 activity 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;
- *Well tolerated in preclinical studies 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. In our preclinical safety studies,

BDC-1001 was well tolerated and no adverse safety signals were observed. We believe this 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 activity.

Our Lead Program: BDC-1001

BDC-1001—*Overview*

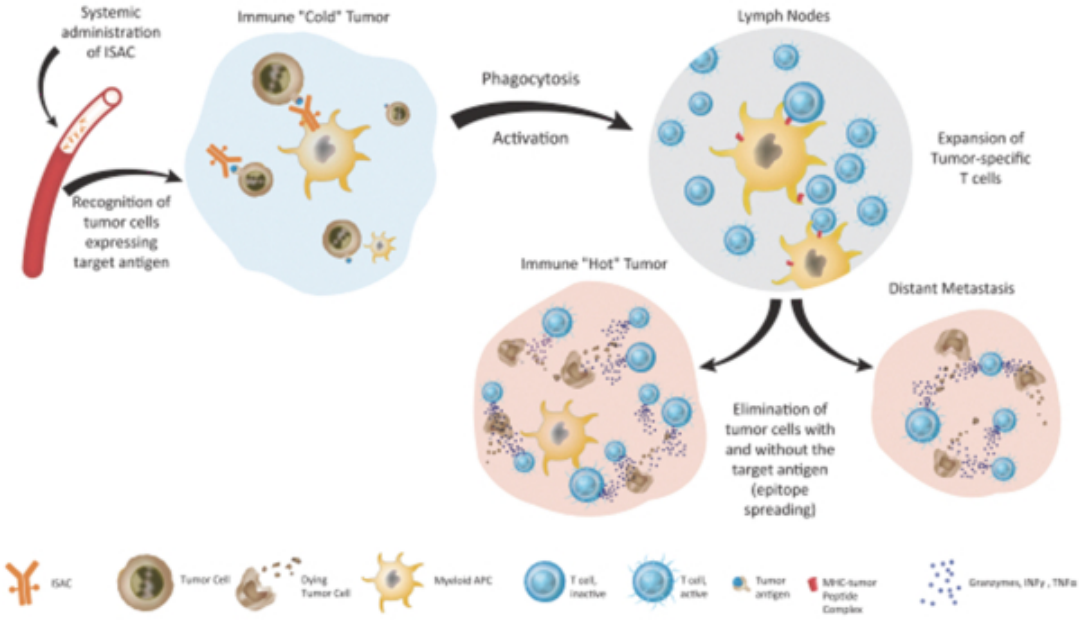
Our lead product candidate, BDC-1001, is currently in clinical development for the treatment of patients with HER2-expressing solid tumors, including those with HER2-low tumors. BDC-1001 provides a compelling example of the potential of Boltbody ISACs to address unmet medical needs in solid tumors. BDC-1001 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 lack of adverse safety signals in our non-human primate 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 believe that our preliminary Phase 1/2 data 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 tumor elimination 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 tumor elimination 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.

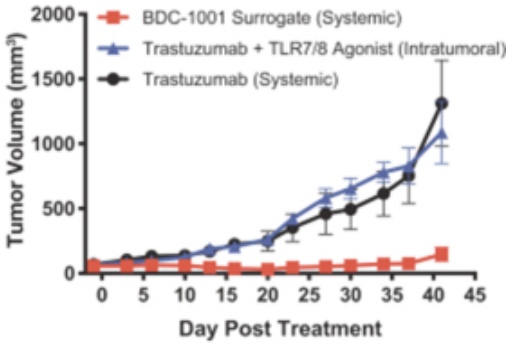
BDC-1001 was designed with safety in mind. The final linker-payload selection was motivated by the goal to demonstrate a favorable safety profile in IND-enabling toxicology studies. Our preclinical data demonstrated that non-cleavable linkers lead to increased myeloid activation and provide a favorable pharmacokinetic profile and a lack of adverse safety signals, 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 (HCC1954) and treated mice that have functional murine myeloid cells but are deficient in B, T, and NK cells 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 activity 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 activity of otherwise intratumorally administered, unconjugated TLR agonists.

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



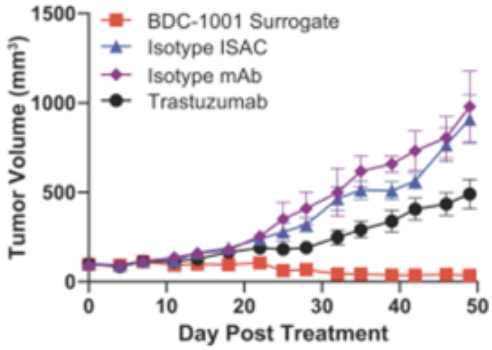
SCID/beige mice were dosed once with 5 mg/kg of BDC-1001 Surrogate, trastuzumab, or an equimolar mixture of trastuzumab and TLR7/8 agonist. Data are shown as mean and standard error of the mean, or SEM, with 3-5 mice per group.

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 tumor elimination, an isotype ISAC that does not recognize the HER2 tumor antigen showed no anti-tumor activity.

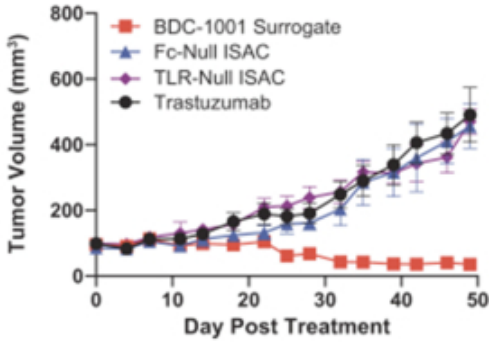
Figure 2: BDC-1001 Surrogate Activity Requires Tumor-Targeting



NSG mice were dosed systemically with 5 mg/kg every 5 days through day 25.
Data are shown as mean and SEM with 5 mice per group.

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 anti-tumor activity, confirming the requirement for both Fc-mediated engagement and TLR agonism.

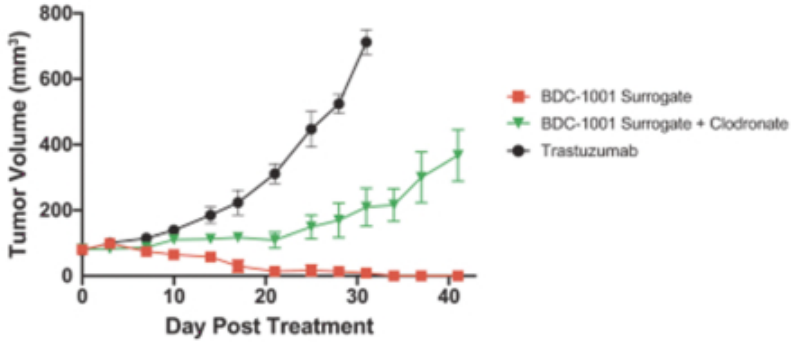
Figure 3: BDC-1001 Surrogate Activity Dependent on Both FcR Engagement and TLR Agonism



NSG mice were dosed systemically with 5 mg/kg every 5 days through day 25.
Data are shown as mean and SEM with 5 mice per group.

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 liposomes. We observed that depletion of phagocytes, including myeloid APCs, significantly reduced our BDC-1001 surrogate-mediated anti-tumor activity.

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



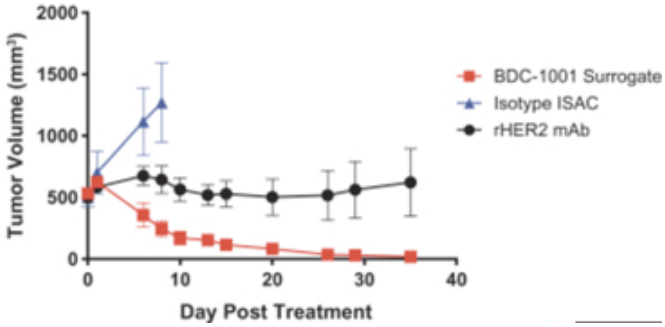
SCID/Beige were dosed systemically with 5 mg/kg on day 0, 5 and 10. Phagocytes were depleted using clodronate loaded liposomes through day 21.
Data are shown as mean and SEM with 4-6 mice per group.

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

To assess the capacity of ISACs to mediate anti-tumor activity in the presence of 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 (~500 mm^3) 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 tumor elimination.

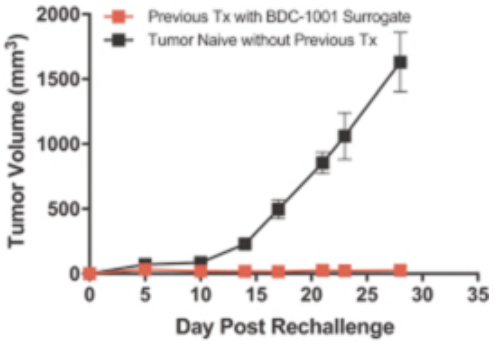
Figure 5: BDC-1001 Surrogate Mediated Tumor Elimination in Very Large Well-Established Tumors



FVB Erbb2 transgenic mice were dosed systemically with 5 mg/kg on days 0 and 5. Data are shown as mean and SEM with 4-7 mice per group.

To demonstrate the induction of immunological memory, BDC-1001 surrogate treated mice with tumor elimination 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 immunological memory as the previously treated, tumor-free mice were protected against tumor re-challenge and remained tumor-free without retreatment for the duration of the study.

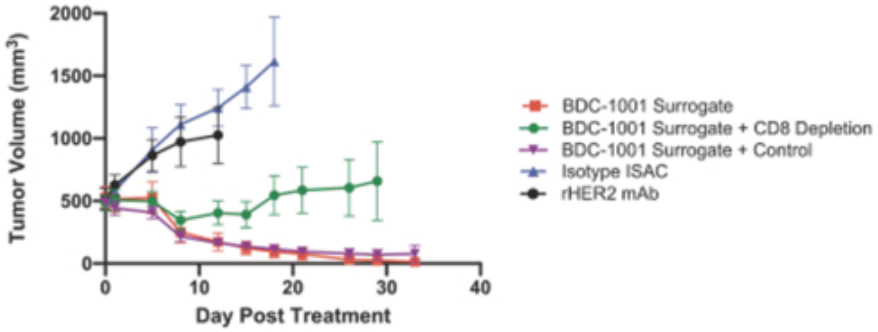
Figure 6: BDC-1001 Surrogate Generated Immunological Memory



FVB Erbb2 transgenic mice that eliminated their tumors for >60 days after the last treatment with BDC-1001 surrogate or tumor naïve mice were challenged with MMC tumor cells. Date are shown as mean and SEM with 5 mice per group.

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 activity. 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



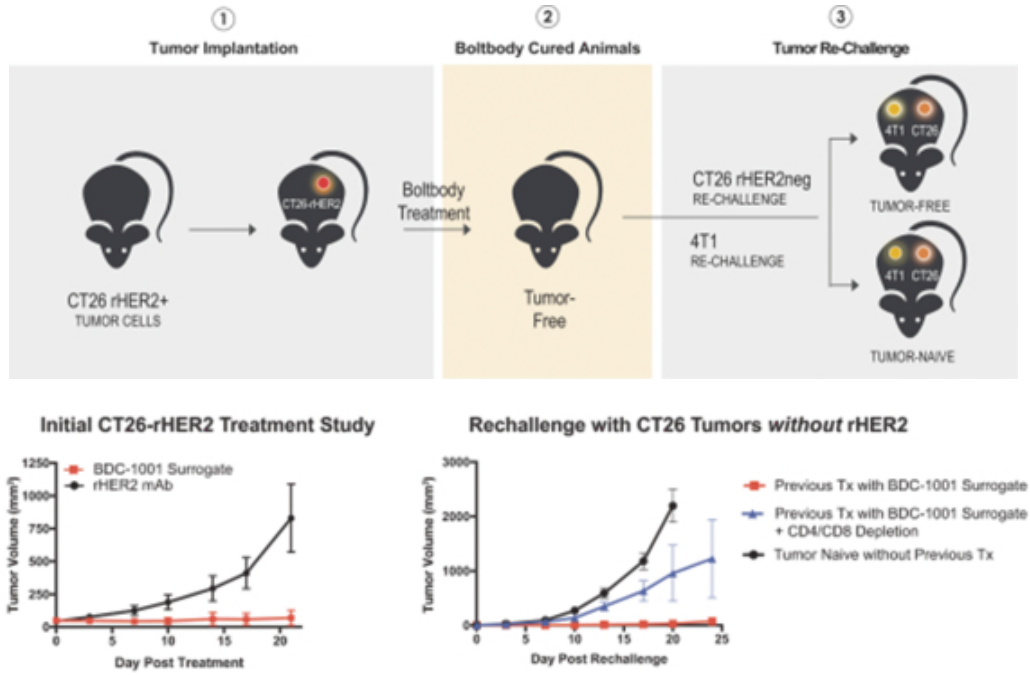
FVB Erbb2 transgenic mice were treated systemically with 5 mg/kg at days 0 and 5 with BDC-1001 surrogate or rHER2 mAb. CD8 T cells were depleted through day 21. Data are shown as mean and SEM with 6 mice per group.

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 tumor elimination in approximately 75% of mice whereas none of the mice treated with the unconjugated antibody had their tumors eliminated. 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 tumor elimination, 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 Elimination with Epitope Spreading and Immunological Memory

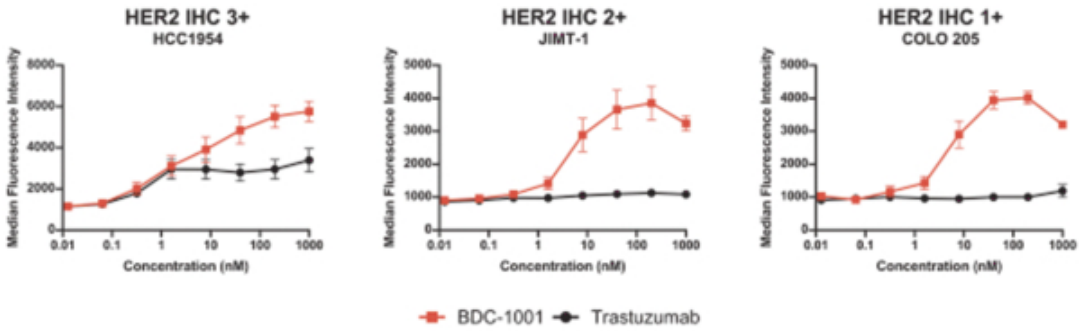


Balb/c mice were dosed systemically with 10 mg/kg every 5 days through day 25. Mice that eliminated their tumors for >21 days after the last treatment with BDC-1001 surrogate or tumor naïve mice were challenged with CT26 tumor cells without rHER2 expression. Data are shown as mean and SEM with 3-8 mice per group.

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 TNFα 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



Pooled myeloid APCs were incubated with the indicated cancer cell line and trastuzumab or BDC-1001. Median fluorescence intensity of CD86 is shown. Data are shown as mean and SEM from 3 experiments with 18 donors.

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

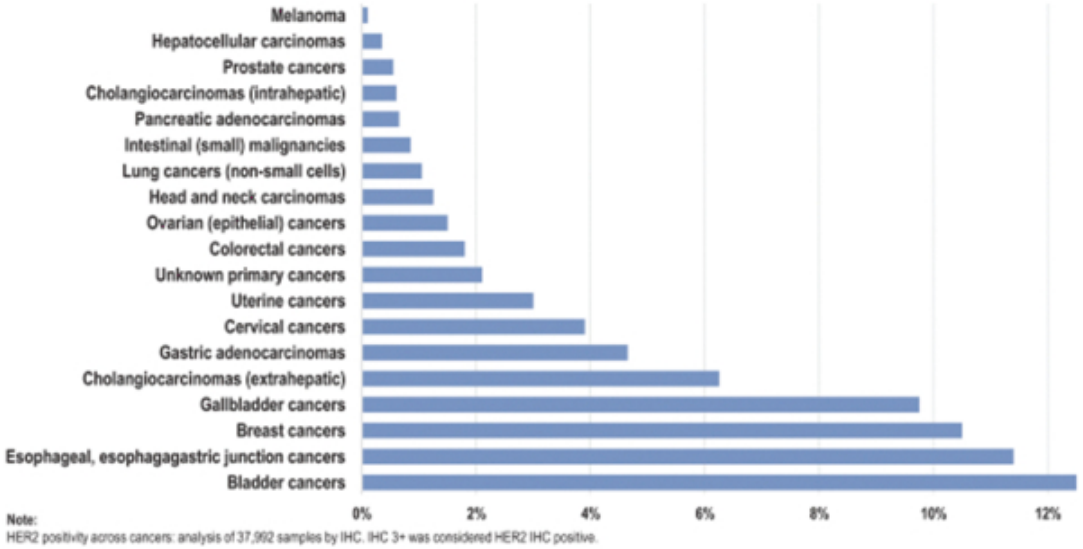
To assess the potential safety and tolerability of BDC-1001, we performed a multi-dose non-human primate GLP toxicology study where we administered vehicle, 10, 30 or 90 mg/kg of BDC-1001 at weekly intervals for a total of 4 dose administrations (n=7 per group). We did not observe any BDC-1001-related 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.

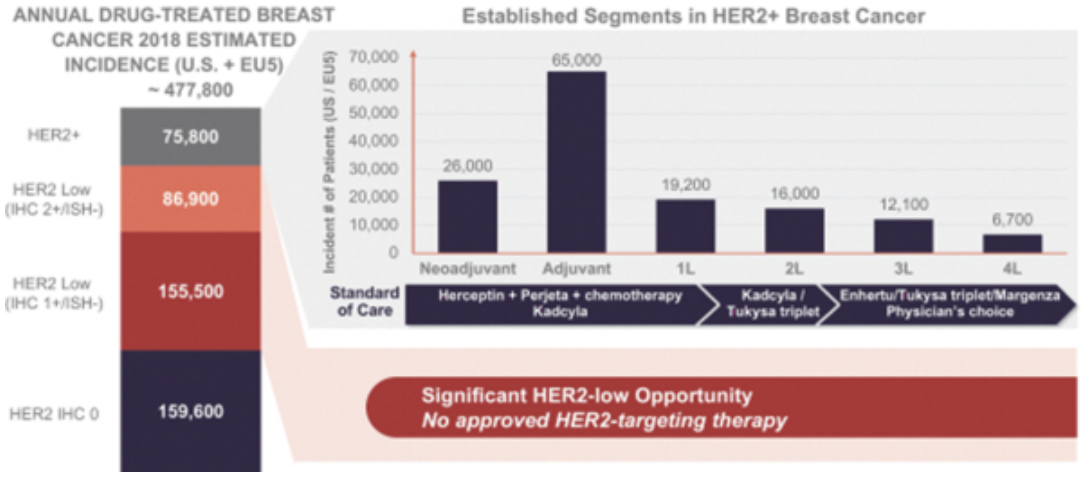
Figure 10: Estimated Percentage Prevalence of HER2 Positivity by Protein Expression Across Solid Tumor Indications



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 for HER2-positive breast cancer include the following: pertuzumab, trastuzumab emtansine, trastuzumab-hyaluronidase-oysk, lapatinib, neratinib, and most recently, trastuzumab-deruxtecan and tucatinib.

According to epidemiology data publicly presented by F. Hoffmann-La Roche AG/Genentech, Inc., the 2018 annual drug-treated incidence of breast cancer in the United States and in France, Germany, Italy, Spain and the UK (formerly known as the “EU5”) was estimated to be approximately 477,800 patients in the aggregate. Of these, we estimate that only approximately 75,800 patients are HER2-positive. We estimate HER2-low patients to be more than 50% of the total population, including approximately 86,900 patients who are IHC2+ without gene amplification and approximately 155,500 patients who are IHC1+ without gene amplification. We plan to explore this HER2-low population in breast cancer starting with the IHC2+ group first.

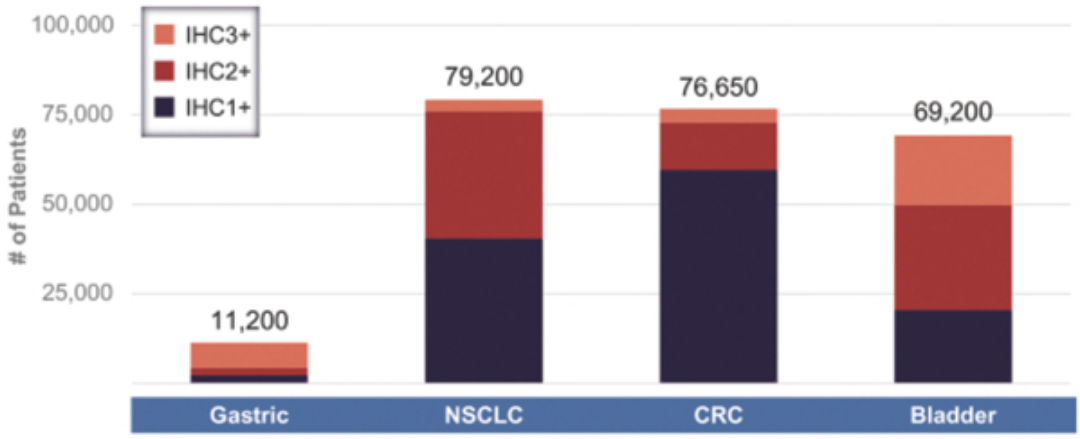
Figure 11: Annual Drug-Treated Breast Cancer Incidence and Established Segments in HER2+ Breast Cancer



Trastuzumab-deruxtecan and tucatinib are important recently approved 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.

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. This unmet medical need includes patients with other tumor types, such as gastric cancer, NSCLC, CRC and bladder cancer, both for HER2-positive and HER2-low cancers. HER2 protein expression and overexpression have been well documented in a wide range of malignancies. Relative patient numbers for HER2 protein expression in these select tumor types are detailed in the figure below. This represents a large opportunity for a HER2 therapy utilizing our Boltbody ISAC approach.

Figure 12: 2020 Estimated Incidence in the U.S. of Selected Tumor Types by HER2 Protein Status



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 or more 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.

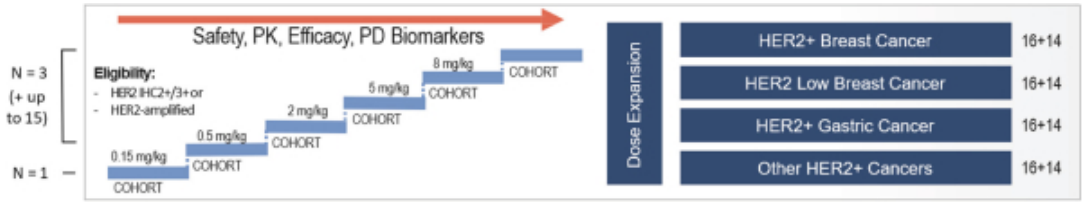
Monotherapy

- 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.

BDC-1001—*Preliminary Clinical Results*

As of January 29, 2021, we have enrolled 20 patients across four cohorts at escalating dose levels. The lowest dose cohort of 0.15 mg/kg required a single patient to assess tolerability to proceed to the next dose level. Each subsequent cohort enrolls an initial three patients to evaluate for dose-limiting toxicities, after which we are able to enroll up to an additional 12 patients to such cohort and escalate to the next dose level if the safety criteria are met. We enrolled one patient in the 0.15 mg/kg cohort and three patients in the 0.5 mg/kg cohort. These dose levels were well tolerated by all four patients and they completed the safety evaluation period without incident. Neither dose was expected to be therapeutically active based on our preclinical modeling. We enrolled four patients, which includes one additional patient, in the 2 mg/kg cohort and we have enrolled 12 patients, which includes nine additional patients, in the 5 mg/kg cohort. In the 2 mg/kg and 5 mg/kg cohorts, we have observed early signs of clinical activity as well as changes in pharmacodynamic biomarkers that we believe are consistent with our proposed mechanism of action.

In the 2 mg/kg cohort, we enrolled four patients with the following cancers: biliary, gastric, rectal and uterine. These patients remained on study with treatment duration ranging from five weeks to 17 weeks, to date. We observed one unconfirmed stable disease in the patient with rectal cancer, who remained on study for 11 weeks. We also observed confirmed stable disease in the patient with microsatellite-stable uterine cancer with visceral lung metastases. This patient remains on study, has received six doses of BDC-1001 and is in her 17th week of treatment.

In the 5 mg/kg cohort, we have enrolled 12 patients as of January 29, 2021, with the following cancers: cervix, uterine, colon, esophageal, GE junction, rectal, lung, salivary ductal and bladder. Five patients remain on study at this dose level with treatment durations ranging up to 12 weeks, to date. We observed stable disease in two patients with microsatellite-stable colorectal cancer, both of whom have visceral lung or both lung and liver

metastases. Both of these patients remain on study and had their first CT scan at six weeks, after two doses of BDC-1001. We have also observed a confirmed partial response in a patient with microsatellite-stable colorectal cancer. The first CT scan for this patient demonstrated a 36% reduction in the sum of the longest diameters of all four measurable tumor lesions. Their second CT scan at 12 weeks demonstrated a 39% reduction in the sum of the longest diameters of all four measurable tumor lesions, and qualified as a confirmed partial response using RECIST 1.1 criteria. This patient remains on study, and is in his 12th week of treatment.

BDC-1001 has been well tolerated to date in all 20 patients. All subjects have completed their 21-day DLT evaluation period (excluding the 20th patient who was recently enrolled and is still in the DLT period) and no DLTs or drug-related serious adverse events have been observed. Treatment-emergent adverse events deemed to be related to BDC-1001 have been mild or moderate in severity, including mild infusion-related reactions without interruption to dosing. We continue to enroll patients in the study and we are proceeding to open enrollment in the next higher dose level cohort at 8 mg/kg.

In addition to our clinical observations, elevations in pharmacodynamic markers such as plasma cytokines and chemokines were observed with a trend towards greater magnitude in patients with increasing dose level. These include increases in plasma levels of MCP-1, MIP1α and IP-10, which are chemokines consistent with myeloid cell activation. We have also observed transient increases in plasma levels of TNFα, an indicator of TLR activation. The plasma cytokine and chemokine data are consistent with our preclinical data and we believe they are also consistent with the proposed mechanism of action of BDC-1001.

We are currently in the Part 1 dose escalation portion of the trial and expect to move into monotherapy Phase 2 dose expansions, as well as the dose escalation evaluating the combination with an immune checkpoint inhibitor, in 2021.

BDC-2034

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, designated BDC-2034, into the clinic in 2022.

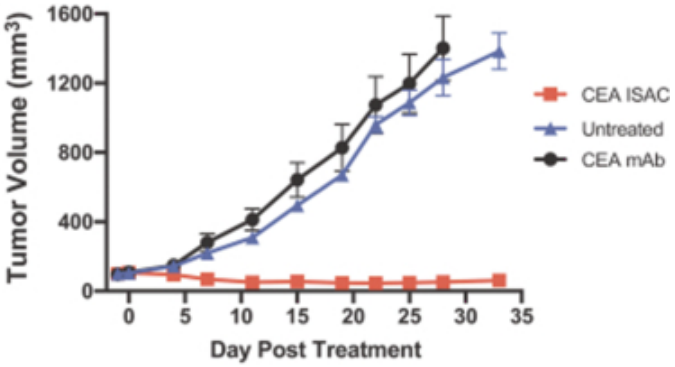
Preclinical Data

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 serves as a strong foundational mAb for BDC-2034 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 activity of our lead CEA mAb to a CEA Boltbody ISAC (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 activity compared to the Untreated group of animals. In contrast, CEA ISAC displayed anti-tumor activity in all animals. We believe that these data support continued research and development of BDC-2034 for patients with CEA-expressing cancers.

Figure 13: *In vivo* Activity of CEA Boltbody ISAC in HPAFII Human Pancreatic Xenograft Model



SCID/beige mice were dosed systemically with 5 mg/kg every 5 days through day 15. Data are shown as mean and SEM with 6 mice per group.

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

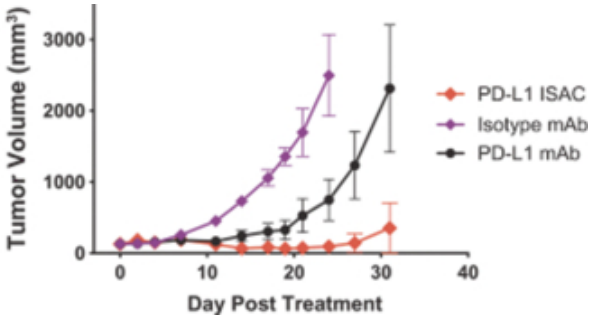
In our preclinical experiments, we have identified PD-L1-targeting mAbs that have the desired activity in a cellular-based assay that measures ADCP. Our PD-L1-targeting mAbs have ADCP activity and meet the criteria for the PD-L1 Boltbody ISAC given ADCP is a key part of the ISAC mechanism that leads 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 tumor elimination 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 tumor elimination 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 14: *In vivo* Activity of PD-L1 Boltbody ISAC in MC38-hPD-L1 Colorectal Syngeneic Tumor Model



C57BL/6J mice were dosed systemically with 5 mg/kg every 3 days through day 9. Data are shown as mean and SEM with 4 mice per group.

Myeloid Modulators and Future Research

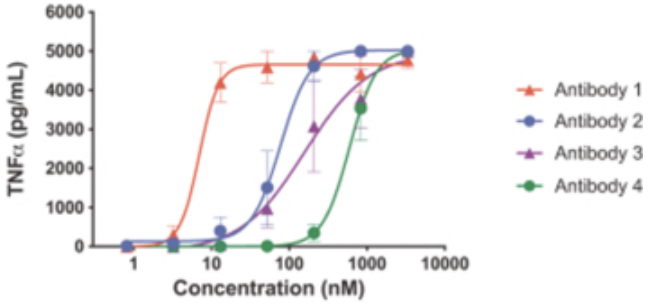
Our expertise in myeloid biology and immuno-oncology has led us to research various tumor antigens across solid tumors where significant unmet medical need remains. In addition, we have expertise in modulating

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 15: Capacity of TAM1 Binding mAbs to Enhance TNFα Secretion from Tumor-Supportive Macrophages



TNFα secretion by human M-CSF differentiated macrophages stimulated with TAM1 binding mAbs for 20 hours. Data are shown as mean and SEM with 5 donors.

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 52,401 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 United States (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 sub-teen double digit to low teen double-digit percentage 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 717,514 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, MacroGenics' Margenza, 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, 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 December 31, 2020, we have one issued U.S. patent which we co-own with Stanford and for which Stanford has exclusively licensed their rights to us under the 2015 Stanford Agreement. The issued U.S. patent contains claims to our lead product candidate BDC-1001 and will expire in 2037. In addition, as of December 31, 2020, we own, co-own with Stanford or exclusively license from Stanford one issued Australian patent and approximately 71 pending patent applications in various countries (21 of which are pending in the United States).

In particular, we have 21 pending patent applications, including two pending U.S. nonprovisional patent applications, 18 pending foreign patent applications and one Patent Cooperation Treaty (PCT) application that has yet to enter the national phase in any countries, which contain claims to our lead product candidate BDC-1001 and which we co-own with Stanford and for which Stanford has exclusively licensed its rights to us under the 2015 Stanford Agreement. These pending patent applications, if issued, are expected to expire between 2037 and 2040, excluding any extension of patent term that may be available. We also have two pending U.S. provisional patent applications, which we solely own, directed to the clinical use of our lead product candidate

BDC-1001, as well as one pending U.S. nonprovisional patent application and one pending European patent application, which we solely own, directed to a method of preparing immunoconjugates, which could be utilized to prepare our lead product candidate BDC-1001 or other Boltbody ISACs. These pending patent applications, if issued, are expected to expire between 2038 and 2040, excluding any extension of patent term that may be available.

In addition, we have 46 pending patent applications directed to potential products and methods other than our lead product candidate BDC-1001 and the use thereof, including 28 pending patent applications that are solely owned by us, five pending patent applications that we co-own with Stanford and have exclusively licensed under the 2015 Stanford Agreement, five pending patent applications that are solely owned by Stanford and that we have exclusively licensed under the 2015 Stanford Agreement and eight pending patent applications that are solely owned by Stanford and that we have exclusively licensed under the 2018 Stanford Agreement. Of these 46 pending patent applications, 10 are U.S. provisional patent applications, 12 are PCT applications that have yet to enter the national phase in one or more countries, six are U.S. nonprovisional patent applications and 18 are foreign patent applications. These pending patent applications, if issued, are expected to expire between 2035 and 2040 excluding any extension of patent term that may be available.

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.

For more information regarding our license agreements with Stanford, please see "—License and Collaboration Agreements."

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, based on their independent medical judgment, 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 was adopted and entered into force in 2014. The Regulation harmonizes the assessment and supervision of clinical trials throughout the European Union, via a single EU Portal, the Clinical Trials Information System, or the CTIS. 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. The Regulation will not apply until six months following the European Commission confirming that the CTIS is fully functional. The current expectation is that the CTIS will go live by 31 January 2022.

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 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. 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.

Brexit and the Regulatory Framework in the United Kingdom

On June 23, 2016, the electorate in the United Kingdom voted in favor of Brexit and the United Kingdom officially withdrew from the European Union on January 31, 2020. Pursuant to the formal withdrawal arrangements agreed between the United Kingdom and the European Union, the United Kingdom was subject to a transition period until December 31, 2020, during which European Union rules continued to apply. A trade and cooperation agreement, or the Trade and Cooperation Agreement, which outlines the future trading relationship between the United Kingdom and the European Union was agreed in December 2020.

Great Britain is no longer covered by the European Union's procedures for the grant of marketing authorizations (Northern Ireland is covered by the centralized authorization procedure and can be covered under the decentralized or mutual recognition procedures). A separate marketing authorization will be required to market drugs in Great Britain. For two years from 1 January 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, may adopt decisions taken by the European Commission on the approval of new marketing authorizations through the centralized procedure, and the MHRA will have regard to marketing authorizations approved in a country in the European Economic Area (although in both cases a marketing authorization will only be granted if any Great Britain-specific requirements are met). Various national procedures are now available to place a drug on the market in the United Kingdom, Great Britain, or Northern Ireland, with the main national procedure having a maximum timeframe of 150 days (excluding time taken to provide any further information or data required). The data exclusivity periods in the United Kingdom are currently in line with those in the European Union, but the Trade and Cooperation Agreement provides that the periods for both data and market exclusivity are to be determined by domestic law, and so there could be divergence in the future. It is currently unclear whether the MHRA in the United Kingdom is sufficiently prepared to handle the increased volume of marketing authorization applications that it is likely to receive.

Gaining orphan drug designation in Great Britain following Brexit is based on the prevalence of the condition in Great Britain (rather than in the European Union). It is therefore possible that conditions that are currently designated as orphan conditions in Great Britain will no longer be and that conditions that are not currently designated as orphan conditions in the European Union will be designated as such in Great Britain. Unlike in the European Union, applications for orphan drug designation in Great Britain are reviewed in parallel with the corresponding marketing authorization application.

The European Union's regulatory environment for clinical trials is being harmonized as part of the Clinical Trial Regulations, which are due to enter into full effect at the end of 2021, but it is currently unclear as to what extent the United Kingdom will seek to align its regulations with the European Union.

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, and their covered subcontractors. 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, (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), and teaching hospitals and physician ownership and investment interests, including such ownership and investment interests held by a physician's immediate family members, and, beginning in 2022, will require applicable manufacturers to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year.
- 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 now 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 have been executive judicial and congressional challenges to certain aspects of the Health Care Reform Act, and several bills affecting the implementation of certain taxes under the Health Care Reform Act have been signed into law. 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." In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. 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. The U.S. Supreme Court is currently reviewing the case, although it is unknown when a decision will be made. Further, although the U.S. Supreme Court has not yet ruled on the constitutionality of the Health Care Reform Act, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the Health Care Reform Act marketplace. The executive order also instructs certain governmental

agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Health Care Reform Act. It is unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the Health Care Reform 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 with the exception of a temporary suspension from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic, absent additional congressional action. 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 Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempted to implement several of the administration's proposals. As a result, the FDA released a final rule on September 24, 2020, effective November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed pending review by the Biden administration until March 22, 2021. On November 20, 2020, CMS issued an interim final rule implementing the Trump administration's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the U.S. District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. 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. It is also possible that additional governmental action will be taken in response to the COVID-19 pandemic.

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. 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.

Human Capital

As of December 31, 2020, we had 65 employees, all of whom were full-time. 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.

We recognize that attracting, motivating and retaining talent at all levels is vital to our continued success. Our employees are a significant asset and we aim to create an equitable, inclusive and empowering environment in which our employees can grow and advance their careers, with the overall goal of developing, expanding and retaining our workforce to support our current pipeline and future business goals. By focusing on employee retention and engagement, we also improve our ability to support our clinical trials, our pipeline, our platform technologies, business and operations, and also protect the long-term interests of our securityholders. Our success also depends on our ability to attract, engage and retain a diverse group of employees. Our efforts to recruit and retain a diverse and passionate workforce include providing competitive compensation and benefits packages and ensuring we listen to our employees.

We value innovation, passion, data-driven decision making, persistence and honesty, and are building a diverse environment where our employees can thrive and be inspired to make exceptional contributions to bring novel and more effective therapies to cancer patients.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, motivating and integrating our existing and future employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through grants of stock-based compensation awards and payments of cash-based performance bonus awards, in order to increase stockholder value and the success of our company by motivating our employees to perform to the best of their abilities and achieve our objectives. We are committed to providing a competitive and comprehensive benefits package to our employees. Our benefits package provides a balance of protection along with the flexibility to meet the individual health and wellness needs of our employees. We plan to continue to refine our efforts related to optimizing our use of human capital as we grow, including improvements in the way we hire, develop, motivate and retain employees.

Corporate History

We were incorporated under the laws of Delaware under the name Bolt Therapeutics, Inc. as a private company in January 2015. We changed our name to Bolt Biotherapeutics, Inc. on July 29, 2015 and we completed our initial public offering in February 2021. Our principal executive offices are located at 900 Chesapeake Drive, Redwood City, California 94063 and our telephone number is (650) 665-9295. Information contained on, or that can be accessed through, our website is not incorporated by reference into this Annual Report, and you should not consider information on our website to be part of this Annual Report on Form 10-K. We have included our website address as an inactive textual reference only.

We file annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to reports filed or furnished pursuant to Sections 13(a), 14 and 15(d) of the Exchange Act. The SEC maintains a website at https://www.sec.gov that contains reports, and other information regarding us and other companies that file materials with the SEC electronically. Copies of our reports on Forms 10-K, Forms 10-Q, and Forms 8-K, may be obtained, free of charge, electronically through our website at www.boltbio.com as soon as reasonably practicable after we file such material with, or furnish such material to, the SEC.

Item 1A. Risk Factors.

Our business involves significant risks, some of which are described below. You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this Annual Report on Form 10-K, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and the related notes. If any of the following risks actually occur, it could harm our business, prospects, operating results and financial condition and future prospects. In such event, the market price of our common stock could decline and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. This report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Annual Report.

Select Risk Factors Affecting Our Business

Our business is subject to a number of risks and uncertainties, including those risks discussed at-length below. 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 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.
- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish proprietary rights.
- We might not be able to utilize a significant portion of our net operating loss carryforwards.
- 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.
- 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 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 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, 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 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.
- 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.
- The trading price of the shares of our common stock may be volatile, and purchasers of our common stock could incur substantial losses.

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 $60.7 million and $30.5 million in 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of $108.4 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, 2020, we had cash, cash equivalents and short-term investments of $22.8 million. Based upon our current operating plan and assumptions, we believe that our existing cash, cash equivalents and short-term investments, together with the net proceeds of $51.9 million from the sale of shares of our Series C-2 convertible preferred stock in January 2021 and net proceeds of $241.7 million from our initial public offering in February 2021, will be sufficient to fund our operations for at least the next 12 months. 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, 2020, we had federal and state net operating loss, or NOL, carryforwards of $94.2 million and $46.5 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 $89.8 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 our initial public 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 BDC-2034 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 Biologics License Application, or 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. For example, prescription drugs may be promoted only for the approved indications in accordance with the approved label. However, physicians may, in their independent medical judgment, prescribe legally available products for off-label uses. The FDA does not regulate the behavior of physicians in their choice of treatments but the FDA does restrict manufacturer's communications on the subject of off-label use of their products. Companies may only share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. 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.

The United Kingdom's withdrawal from the European Union could adversely affect us.

The United Kingdom held a referendum on June 23, 2016, in which a majority voted for the United Kingdom's withdrawal from the European Union, or Brexit. As a result of this vote, the United Kingdom left the European Union on January 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the United Kingdom and the European Union, the United Kingdom was subject to a transition period until December 31, 2020, or the Transition Period, during which European Union rules continued to apply. The Trade and Cooperation Agreement, or the Trade and Cooperation Agreement, which outlines the future trading relationship between the United Kingdom and the European Union was agreed in December 2020. The effects of Brexit have been and are expected to continue to be far-reaching. Brexit and the perceptions as to its impact may adversely affect business activity and economic conditions in Europe and globally and could continue to contribute to instability in global financial and foreign exchange markets. Since a significant proportion of the regulatory framework in the United Kingdom applicable to our business and our product candidates is derived from European Union directives and regulations, Brexit has had, and may continue to have, a material impact upon the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the United Kingdom and in the European Union, given that certain development activities relating to our products take place in the United Kingdom.

It is currently unclear whether the MHRA is sufficiently prepared to handle the increased volume of marketing authorization applications that it is likely to receive. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, could make it more difficult to commercialize, or prevent us from commercializing our product candidates in the European Union or in the United Kingdom and restrict our ability to generate revenue and achieve and sustain profitability. While the Trade and Cooperation Agreement provides for the tariff-free trade of medicinal products between the United Kingdom and the European Union, there may be additional non-tariff costs to such trade which did not exist prior to the end of the Transition Period. Further, should the United Kingdom diverge from the European Union from a regulatory perspective in relation to medicinal products, tariffs could be put into place in the future. We could therefore, both now and in the future, face significant additional expenses (when compared to the position prior to the end of the Transition Period) to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business.

Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the United Kingdom.

As a result of the Brexit, other European countries may seek to conduct referenda with respect to their continuing membership in the European Union. Given these possibilities and others we may not anticipate, as well as the lack of comparable precedent, we cannot be certain of the full extent to which Brexit could adversely affect our business, results of operations and financial condition.

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 current good manufacturing practice, or cGMP, good clinical practice, or GCP, and good laboratory practice, or 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 Health Care Reform 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. There have been executive judicial and congressional challenges to certain aspects of the Health Care Reform Act. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the Affordable Care Act such as removing penalties, starting January 1, 2019, for not

complying with the Health Care Reform Act's individual mandate to carry health insurance. Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the Health Care Reform 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 Health Care Reform 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 Health Care Reform Act are invalid as well. The U.S. Supreme Court is currently reviewing the case, although it is unknown when a decision will be made. Further, although the U.S. Supreme Court has not yet ruled on the constitutionality of the Health Care Reform Act, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the Health Care Reform Act marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Health Care Reform Act. It is unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the Health Care Reform Act. We continue to evaluate the effect that the Health Care Reform Act and its possible repeal and replacement has on our business.

In addition, other legislative changes have been proposed and adopted since the Health Care Reform Act was enacted. For example, in August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction, 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 2030 with the exception of a temporary suspension from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic, 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. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control costs pharmaceutical and biological products. It is also possible that additional governmental action will be taken in response to the COVID-19 pandemic.

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; and their covered subcontractors,

- 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 Health Care Reform 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, and, beginning in 2022, will require applicable manufacturers to report information regarding payments and other transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants, and certified nurse midwives during the previous year;
- 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. Additionally, a new privacy law, the California Privacy Rights Act, or the CPRA, was approved by California voters in the election of November 3, 2020. The CPRA, which will take effect in most material respects on January 1, 2023, modifies the CCPA significantly, including by expanding consumers' rights with respect to certain sensitive personal information and creating a new state agency to oversee implementation and enforcement efforts, potentially resulting in further uncertainty and requiring us to incur additional costs and expenses in an effort to comply. At this time, we do not collect personal data on residents of California but should we begin to do so, the CCPA and CPRA 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.

Further, the vote in the United Kingdom in favor of exiting the EU, referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. Specifically, while the Data Protection Act of 2018, that "implements" and complements the GDPR achieved Royal Assent on May 23, 2018 and is now effective in the United Kingdom, aspects of data protection in the United Kingdom, such as the transfer of data from the EEA to the United Kingdom, remain uncertain. In particular, with the expiry of the transition period on December 31, 2020, companies must comply with both the GDPR and the GDPR as incorporated into United Kingdom national law, the latter regime having the ability to separately fine up to the greater of £17.5 million or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, including, for example, around how data can lawfully be transferred between each jurisdiction, which exposes us to further compliance risk. At this time, we do not believe we are subject to the GDPR or the Data Protection Act of 2018, but should this change, the GDPR and/or the Data Protection Act of 2018 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 these 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 December 31, 2020, we only have two issued patents namely a U.S. patent that is co-owned with, and exclusively licensed to us by, Stanford and an Australian patent that is owned by Stanford and exclusively licensed to us. Many of our patent applications that we own, co-own with Stanford, or have licensed from Stanford are U.S. provisional patent applications. A U.S. provisional patent application is not eligible to become an issued patents until, among other things, we file non-provisional patent application within 12 months of filing of the provisional patent application. 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 dates 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 United States 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 in the future may be, affected by the COVID-19 pandemic. For example, some early site activations, and related patient enrollments, were delayed by approximately two months. We have increased the number of planned study sites in an effort to mitigate any potential future impact. In the future, 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 December 31, 2020, we had 65 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 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 have adopted 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-intrusions, 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 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 our initial public 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 Stock 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 the completion of our initial public offering, there was 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 the initial public 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 was 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 the initial public offering. Although our common stock has been approved for listing on the Nasdaq Global Select Market, an active trading market for our shares may never develop or be sustained following the initial public 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 the initial public 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 our initial public 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.

A significant portion of our total outstanding common stock 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, the market price of our common stock could decline significantly.

In addition, we filed a registration statement on Form S-8 registering the issuance of approximately 8.4 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 this registration statement on Form S-8 will be available for sale in the public market subject to vesting arrangements and exercise of options, outstanding lock-up agreements and, in the case of our affiliates, the restrictions of Rule 144.

Additionally, the holders of an aggregate of 21,712,540 shares of our common stock, or their transferees, 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, or the DGCL, 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, 2020 and including the shares sold in our initial public offering, our executive officers, directors and current beneficial owners of 5% or more of our common stock, in the aggregate, beneficially own approximately 59% of our outstanding common stock. These stockholders, acting together, are 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 were sold in our initial public 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 Stock 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. 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).

We are also a "smaller reporting company," as defined in the Exchange Act. 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 certain of the scaled disclosures available to "smaller reporting companies." 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.

We are 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 Stock 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, which is the year covered by the second annual report following the completion of our initial public offering, 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 requires that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. 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.

As a public company, we are required to maintain internal controls 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 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 Stock Market, the SEC or other regulatory authorities. In addition, our common stock may not be able to remain listed on the Nasdaq Stock Market or any other securities exchange.

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

Our management will have broad discretion in the application of the net proceeds from our initial public offering and can 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 our initial public 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 our initial public 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 provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America are 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 DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

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.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

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.

Item 3. 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.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock began trading on the Nasdaq Global Select Market on February 5, 2021 and trades under the symbol "BOLT". Prior to February 5, 2021, there was no public market for our common stock.

Holders of Common Stock

On March 26, 2021, there were approximately 66 holders of record of our common stock. Certain shares are held in "street" name and accordingly, the number of beneficial owners of such shares is not known or included in the foregoing number.

Dividend Policy

We have never declared or paid any dividends on our common stock. We currently intend to retain all available funds and any 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 related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

Stock Price Performance Graph

As a "smaller reporting company" as defined by Item 10 of Regulation S-K, we are not required to provide this information.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Recent Repurchases of Equity Securities.

None.

Recent Sales of Unregistered Securities.

During the year ended December 31, 2020, we issued and sold the following unregistered securities:

(1) From January 1, 2020 to February 5, 2021 (the date of filing our registration statement on Form S-8, File No. 333-252815), we granted stock options under our 2015 Equity Incentive Plan to purchase up to an aggregate of 2,033,153 shares of our common stock to its employees and directors, at exercise prices per share ranging from $2.80 to $4.41 Options to purchase a total of 52,950 of these shares were exercised through March 26, 2021.

(2) In June 2020, pursuant to a Series C stock purchase agreement, we issued an aggregate of 5,162,173 shares of our Series C-1 convertible preferred stock at a purchase price of approximately $8.05 per share, for aggregate consideration of $41.3 million. As a result of our initial public offering, these Series C-1 convertible preferred shares were converted into 5,162,173 shares of our common stock.

The offers, sales and issuances of the securities described in paragraph (1) above were deemed to be exempt from registration under the Securities Act in reliance on Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of such securities were our employees, directors or bona fide consultants and received the securities under our 2011

Equity Incentive Plan. Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about our company.

The offers, sales and issuances of the securities described in paragraph (2) above were deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act and Rule 506 promulgated under Regulation D promulgated thereunder as transactions by an issuer not involving a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited investor within the meaning of Rule 501 of Regulation D under the Securities Act and had adequate access, through employment, business or other relationships, to information about our company. No underwriters were involved in these transactions.

Use of Proceeds

On February 9, 2021, we completed our initial public offering pursuant to a registration statement on Form S-1 (File No. 333-252136) that was declared effective by the SEC on February 4, 2021 and sold an aggregate of 13,225,000 shares of our common stock, including the exercise in full by the underwriters of their option to purchase 1,725,000 additional shares of our common stock, at a price of $20.00 per share. Morgan Stanley & Co. LLC, SVB Leerink LLC, Stifel, Nicolaus & Company, Incorporated and Guggenheim Securities, LLC acted as joint book-running managers of our initial public offering, which has now terminated. After deducting underwriting discounts, commissions and offering costs paid by us of approximately $22.8 million, the net proceeds from the offering were approximately $241.7 million. No offering expenses were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities, or to any of our affiliates.

The net proceeds from the offering have been invested according to our approved investment policy in a mix of money market funds and high-quality, fixed income securities with a weighted average maturity of less than 13 months. Our investment policy emphasizes preservation of principal, availability of cash to meet cash flow requirements, and maximizing total net returns after satisfying the first two conditions. There has been no material change in the expected use of the net proceeds from our initial public offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b).

Item 6. Selected Financial Data.

As a “smaller reporting company” as defined by Item 10 of Regulation S-K, we are not required to provide this information.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our audited financial statements and related notes thereto included elsewhere in this Annual Report on Form-10K for the period ended December 31, 2020. Except as otherwise indicated herein or as the context otherwise requires, references in this Annual Report on Form 10-K to "Bolt" "the Company," "we," "us" and "our" 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 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. We have demonstrated robust single agent anti-tumor activity in multiple preclinical models, including elimination of large tumors (~500 mm^3), as well as tumors that are refractory to trastuzumab or ado-trastuzumab emtansine. In our preclinical safety studies, BDC-1001 was well tolerated and no adverse safety signals were observed. We believe these findings 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 believe that our preliminary Phase 1/2 data 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 BDC-2034 into the clinic in 2022. We expect to designate our next clinical candidate in 2021.

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. Prior to the completion of our initial public offering in February 2021, we funded our operations primarily through private placements of our convertible preferred stock for gross proceeds of $173.7 million, including Toray's purchase of 717,514 shares of Series T convertible preferred stock for gross proceeds of $10.0 million and the January 2021 issuance and sale of 5,611,059 shares of Series C-2 preferred stock for net proceeds of $51.9 million. In February 2021, we completed our initial public offering of 13,225,000 shares of our common stock at a price to the public of $20.00 per share, including the exercise in full by the underwriters of their option to purchase 1,725,000 additional shares of our common stock. Including the option exercise, the aggregate net proceeds to us from the offering was approximately $241.7 million, net of underwriting discounts, commissions and other offering expenses, for aggregate expenses of approximately $22.8 million.

We have incurred operating losses since our inception. Our net losses were $60.7 million and $30.5 million in 2020 and 2019. As of December 31, 2020, we had an accumulated deficit of $108.4 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 717,514 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, 2020, 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, cash equivalents and short-term investments.

Change in Fair Value of Preferred Stock Purchase Right Liability

In connection with the issuance of our Series B convertible preferred stock in July 2018 and our Series C-1 convertible preferred stock in June 2020, 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 July 2019, we issued such additional shares of Series B convertible preferred stock, respectively, and accordingly, this contractual obligation was settled and the preferred stock purchase right liability was remeasured to fair value on the purchase date and reclassified to permanent equity. In January 2021, with the completion of the Series C-2 convertible preferred stock, this contractual obligation was settled and the preferred stock purchase right liability was remeasured to fair value on the purchase date and reclassified to permanent equity.

Results of Operations

Comparison of the Years Ended December 31, 2020 and 2019

	Years Ended December 31,		
	2020	2019	Change
		(In thousands)	
Collaboration revenue	$ 231	$ 215	$ 16
Operating expenses:			
Research and development	40,357	26,002	14,355
General and administrative	9,056	5,182	3,874
Total operating expenses	49,413	31,184	18,229
Loss from operations	(49,182)	(30,969)	(18,213)
Other income (expense), net:			
Interest income, net	199	524	(325)
Change in fair value of preferred stock purchase right liability	(11,745)	(42)	(11,703)
Other income (expense), net	(11,546)	482	(12,028)
Net loss and comprehensive loss	$(60,728)	$ (30,487)	$(30,241)

Collaboration Revenue

Revenue increased from $215,000 in 2019 to $231,000 in 2020. Revenue was generated from the execution of the Toray Development Agreement in March 2019 and the recognition of revenue over time as we fulfill our performance obligations to Toray. We did not perform any services towards satisfying the performance obligation as defined in the Toray Development Agreement during the second half of the year 2020. We expect to perform services to further the collaboration in the year 2021.

Research and Development Expenses

Research and development expenses increased by $14.4 million from $26.0 million in 2019 to $40.4 million in 2020. The increase was primarily due to $5.9 million in higher personnel-related expenses due to an increase in headcount from 29 to 53 employees as of the end of the respective period, $3.2 million of higher expenses related to the ongoing BDC-1001 clinical trial, increase of $3.2 million in manufacturing expenses related to the timing of batch production of our product candidates, and $2.3 million in higher facility-related expenses.

General and Administrative Expenses

General and administrative expenses increased by $3.9 million from $5.2 million in 2019 to $9.1 million in 2020. The increase was primarily due to $1.7 million of higher personnel-related expenses due to an increase in headcount from four to 12 employees as of the end of the respective period, $1.5 million in higher professional services expenses related to accounting services, legal fees and other professional services, and $0.8 million in higher facility and marketing-related expenses.

Other Income (Expense), Net

Other Income (Expense), Net

Interest income was $0.5 million and $0.2 million in 2019 and 2020, respectively. The decrease of $0.3 million is primarily due to lower yields on cash, cash equivalents and short-term investment balances.

Change in Fair Value of Convertible Preferred Stock Purchase Right Liability

The change in fair value of convertible preferred stock purchase right liability increased $11.7 million from a charge of $42,000 in 2019 to $11.7 million in 2020, primarily due to the increase in the fair value of the outstanding Series C-2 preferred stock purchase right liability as a result of closer time proximity to achieving different outcome scenarios and higher probabilities of occurrence. We issued the shares associated with the Series B convertible preferred stock purchase right liability in July 2019, accordingly, this obligation no longer exists. Upon the exercise of the preferred stock purchase right with the completion of the Series C-2 Closing in January 2021, we remeasured the Series C-2 preferred stock purchase right liability to fair value and reclassified to permanent equity on the balance sheets.

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, 2020, we had an accumulated deficit of $108.4 million. Our net loss was $60.7 million and $30.5 million in 2020 and 2019, respectively, and we expect to incur additional losses in the future. We evaluated our current cash position, historical results, forecasted cash flows and plans in regards to liquidity.

Prior to the completion of our initial public offering in February 2021, we funded our operations primarily through the private placement of our convertible preferred stock and raised gross proceeds of $173.7 million from such sales including the sale of 5,611,059 shares of Series C-2 convertible preferred stock at $9.2575 per

share. issuance for aggregate gross proceeds of $51.9 million in January 2021. As of December 31, 2020, we had cash, cash equivalents and short-term investments of $22.8 million. In February 2021, we completed our initial public offering of 13,225,000 shares of our common stock, including the exercise in full by the underwriters of their option to purchase 1,725,000 additional shares of our common stock, at a price of $20.00 per share for net proceeds to us from the offering was approximately $241.7 million, net of underwriting discounts, commissions and other offering expenses, for aggregate expenses of approximately $22.8 million.

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

	Years Ended December 31,	
	2020	2019
	(In thousands)	
Net cash provided by (used in)		
Operating activities	$(47,308)	$(26,343)
Investing activities	(20,592)	(508)
Financing activities	39,597	48,627
Net increase (decrease) in cash, cash equivalents and restricted cash	$(28,303)	$ 21,776

Operating Activities

Net cash used in operating activities was $47.3 million and $26.3 million for 2020 and 2019, respectively. Net cash used in operating activities for 2020 was primarily due to our net loss of $60.7 million, adjusted for $15.7 million of non-cash charges and a $2.3 million change in operating assets and liabilities. The non-cash charges were primarily comprised of $11.7 million related to the change in fair value of Series C convertible preferred stock purchase right liabilities, $1.9 million of non-cash lease related expense, $1.4 million for stock-based compensation and $0.6 million for depreciation and amortization expense. 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 and increases in our operating lease liabilities. 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 non-cash 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 in March 2019, partially offset by a decrease in our operating lease liabilities.

Investing Activities

Net cash used in investing activities in the year ended December 31, 2020 was due to purchases of property and equipment and net purchases of short-term investments. Net cash used in investing activities in the year ended December 31, 2019 was due to purchases of other assets and property and equipment.

Financing Activities

Net cash provided by financing activities was $39.6 million for 2020 was due to net proceeds of $41.3 million for the issuance of 5,162,173 shares of our convertible preferred stock in July 2020, partially offset by payments of $1.9 million for deferred offering costs incurred in connection with our initial public offering that was completed in February 2021. 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 5,701,946 shares of our convertible preferred stock.

Funding Requirements

Based upon our current operating plans, we believe that our existing cash, cash equivalents and short-term investments and net proceeds of $51.9 million from the sale of shares of Series C-2 convertible preferred stock in January 2021 and net proceeds of $241.7 million from our initial public offering that was completed in February 2021, will be sufficient to fund our operations for at least the next 12 months. 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

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 sub-teen double digit to low teen double-digit 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 2020 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, 2020, our cash, cash equivalents and short-term investments consist of cash in readily available checking accounts, money market accounts and corporate debt securities with strong credit ratings. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant for us. Due to the short-term maturities of our cash equivalents and short-term investments, and the low risk profile of our short-term investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents and short-term investments.

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, 2020, we had liabilities of $0.7 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 Annual Report on Form 10-K, we believe the following accounting policies and estimates to be most critical to the preparation of our financial statements.

Revenue Recognition

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 we expect to deliver our 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 our 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 agreed to buy, and we agreed to sell, additional shares of that convertible preferred stock at a fixed price in the event that certain agreed-upon milestones are achieved. We evaluated this purchase right and assessed whether it meets the definition of a freestanding instrument and, if it did, we determined the fair value of the purchase right liability and recorded it on the balance sheet with the remainder of the proceeds raised being allocated to convertible preferred stock. The preferred stock purchase right liability was 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 was revalued at settlement and the resultant fair value was reclassified to convertible preferred stock at that time. The estimated fair value of the preferred stock purchase right liability was 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 the probability of the consummation of an initial public offering, as applicable. The completion of our initial public offering resulted in the conversion of all of our convertible preferred stock into common stock.

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 Annual Report on Form 10-K 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 2020 and 2019.

In 2020 and 2019, stock-based compensation expense related to stock options was $1.4 million and $0.5 million, respectively. As of December 31, 2020, the unrecognized stock-based compensation expense related to stock options was $7.2 million and is expected to be recognized as expense over a weighted-average period of approximately 3.2 years.

Determination of the fair value of common stock

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, because of a near-term potential IPO scenario that also factored in the inherent uncertainty associated with being able to complete an IPO. 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 our initial public offering, our board of directors determines the fair value of our common stock based on the closing price as reported on the date of grant by the Nasdaq Global Select Market.

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 aggregate amount of gross proceeds to us as a result of our initial public 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 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, 2020, we had federal and state NOL carryforwards of $94.2 million and $46.5 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 $89.8 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, 2020, we also had federal and state research credit carryforwards of $2.7 million and $2.3 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 Adopted Accounting Pronouncements

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. We adopted the standard on January 1, 2020, and the adoption did not have a material impact on our financial statements and related disclosures.

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes, which is intended to simplify various aspects related to accounting for income taxes. The pronouncement is effective for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2021. ASU 2019-12 is effective for us beginning January 1, 2022. Early adoption is permitted. We adopted the standard during the year ended December 31, 2020, and the adoption did not have a material impact on our financial statements and related disclosures.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 8. Financial Statements and Supplementary Data.

Our financial statements and the report of our independent registered accounting firm required pursuant to this item are incorporated by reference herein from the applicable information included in Item 15 of this Annual Report on Form 10-K and are presented beginning on page F-1.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Based on their evaluation as of December 31, 2020, our management, including the Chief Executive Officer and Chief Financial Officer, has concluded that our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) were not effective to provide reasonable assurance because of the material weakness in our internal control over financial reporting described below.

Material Weakness

A material weakness was identified in our internal control over financial reporting.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

We have the following material weakness in our internal control over financial reporting as of December 31, 2020:

- We did not design or maintain an effective control environment commensurate with the financial reporting requirements. 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 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 material misstatement of our previously issued financial statements, 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.

Remediation Activities

In order to address the material weakness in internal control over financial reporting described above, management, with direction from the Audit Committee, has begun the process of remediation to address control deficiencies that led to the material weakness. Specifically, management has:

- Increased the number of accounting personnel;
- Begun discussions with third party experts to assist management in completing a comprehensive risk assessment to identify, design and implement control activities; and
- Begun reviewing and enhancing business policies, procedures, and related internal controls to standardize business processes.

Management will continue to review and make necessary changes to the overall design of our internal control environment, as well as policies and procedures to improve the overall effectiveness of internal control over financial reporting. The material weakness will not be considered remediated, however, until the applicable controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

Management's Report on Internal Control Over Financial Reporting

This Annual Report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting during the three months ended December 31, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on the Effectiveness Over Financial Reporting

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute assurances. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business, but there can be no assurance that such improvements will be sufficient to provide us with effective internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Executive Officers and Directors

The following table sets forth certain information for our executive officers and directors as of December 31, 2020:

Name	Age	Position(s)
Executive Officers		
Randall C. Schatzman, Ph.D.	66	Chief Executive Officer and Director
William P. Quinn	50	Chief Financial Officer
David Dornan, Ph.D.	43	Chief Scientific Officer
Edith A. Perez, M.D.	64	Chief Medical Officer
Grant Yonehiro	57	Chief Business Officer
Non-Employee Directors		
Peter Moldt, Ph.D.(2)	61	Chairman of the Board
Edgar G. Engleman, M.D.	75	Director
James I. Healy(3)	55	Director
Ashish Khanna, Ph.D.(1)(2)	49	Director
Kathleen LaPorte(1)	59	Director
Richard A. Miller, M.D.(2)(3)	69	Director
Mahendra G. Shah, Ph.D.(1)(3)	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 Chief Scientific Officer since January 2021. From November 2017 to January 2021, Dr. Dornan served as our Senior Vice President of Research and Manufacturing. 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 2015 to 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 1995, 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. Dr. Perez did her training in Internal Medicine at Loma Linda University and completed a Fellowship in Hematology/Oncology at the University of California at Davis. Dr. Perez is board certified in Internal Medicine, Hematology and Oncology.

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, which was acquired by Astellas Pharma, Inc. in 2011. 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 in various roles at GenVec, Inc., most recently serving as its Vice President, Drug Development. 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 been employed as a Senior Partner at 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 served as a post-doc with Yale University's department of organic chemistry. 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.

James I. Healy, M.D. has served as a member of our board of directors since January 2021. Dr. Healy has been a General Partner of Sofinnova Investments (formerly Sofinnova Ventures), a biotech investment firm, since June 2000. Prior to June 2000, Dr. Healy held various positions at Sanderling Ventures, Bayer Healthcare Pharmaceuticals (as successor to Miles Laboratories) and ISTA Pharmaceuticals, Inc. Dr. Healy is currently on the board of directors of Ascendis Pharma A/S, Coherus BioSciences, Inc., Karuna Therapeutics, Inc., Natera, Inc., NuCana PLC, ObsEva SA, and Y-mAbs Therapeutics, Inc. and several private companies. Previously, he served as a board member of Amarin Corporation, Auris Medical Holding AG, Edge Therapeutics, Inc., Hyperion Therapeutics, Inc., InterMune, Inc., Anthera Pharmaceuticals, Inc., Durata Therapeutics, Inc., CoTherix, Inc., Iterum Therapeutics, plc, Movetis NV and several private companies. In 2011, Dr. Healy won the IBF Risk Innovator Award and was named as one of the industry's top leading Life Science investors in 2013 by Forbes Magazine. Dr. Healy received a B.A. in Molecular Biology and a B.A. in Scandinavian Studies from the University of California, Berkeley, and received an M.D. and Ph.D. in Immunology from Stanford University School of Medicine. We believe that Dr. Healy is qualified to serve on our board of directors due to his extensive experience in the biopharmaceutical industry, including as a venture capital investor and a member of the boards of directors of other biopharmaceutical companies.

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 Bombay, 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.

Kathleen LaPorte has served as a member of our board of directors since December 2020. Since 2016, Ms. LaPorte has served on several company boards and currently serves as a director of Precipio, Inc. and as a director of several private biotechnology and biopharmaceutical companies. From 2014 to 2016, Ms. LaPorte served in multiple senior leadership positions at Nodality Inc., including Chief Business Officer and, most recently, Chief Executive Officer. From 2001 to 2013, Ms. LaPorte served on the board of Affymax, Inc. From 2002 to 2011, she served as a director for ISTA Pharmaceuticals, Inc. From 2005 to 2011, she was a Managing Director of New Leaf Venture Partners, a spinout from the Sprout Group. From 1994 to 2000, Ms. LaPorte served on the board of Onyx Pharmaceuticals Inc. From 1993 to 2005, she served as a General Partner of the Sprout Group. Ms. LaPorte received a B.S. in Biology from Yale University and an M.B.A. from the Stanford University Graduate School of Business. We believe that Ms. LaPorte is qualified to serve on our board of directors due to her experience in the biotechnology and biopharmaceutical industries, her substantial professional experience and the fact that she is a qualified financial expert.

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.

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

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 provides 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, our board of directors are 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 are divided among the three classes as follows:

- the Class I directors are Drs. Moldt and Shah and their terms expire at the annual meeting of stockholders to be held in 2022;
- the Class II directors are Drs. Engleman, Healy and Schatzman and their terms expire at the annual meeting of stockholders to be held in 2023; and
- the Class III directors are Ms. LaPorte and Drs. Khanna and Miller and their terms expire at the annual meeting of stockholders to be held in 2024.

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 Stock Market, independent directors must comprise a majority of our board of directors as a listed company within one year of the closing of our initial public 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, Healy, Khanna, Miller, Moldt and Shah and Ms. LaPorte 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 Stock 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. Each committee operates under a charter that has been approved by our board and has the composition and responsibilities described below. The charters for each committee are available at the investor relations section of our website at www.boltbio.com. Information contained on, or that can be accessed through, our website is not incorporated by reference into this Annual Report, and you should not consider information on or accessible through our website to be part of this Annual Report.

Audit Committee

Our audit committee consists of Kathleen LaPorte, Ashish Khanna and Mahendra Shah. Our board of directors has determined that each member of the audit committee satisfies the independence requirements under the Nasdaq Stock Market listing standards and Rule 10A-3(b)(1) of the Exchange Act. The chairperson of our audit committee is Ms. LaPorte. Our board of directors has determined that Ms. LaPorte 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.

Compensation Committee

Our compensation committee consists of Ashish Khanna, Peter Moldt and Richard Miller. The chairperson of our compensation committee is Dr. Moldt. Our board of directors has determined that each member of the compensation committee is independent under the listing standards of the Nasdaq Stock 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.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of James Healy, Richard Miller and Mahendra Shah. The chairperson of our nominating and corporate governance committee is Dr. Healy. 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 Stock 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.

Code of Business Conduct and Ethics

We have adopted 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. Our code of business conduct and ethics is available under the Corporate Governance section of our website at www.boltbio.com. In addition, we post on our website all disclosures that are required by law or the listing standards of the Nasdaq Stock 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 Annual Report on Form 10-K.

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.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our executive officers and directors, and persons who own more than 10% of our common stock, to file reports of ownership on Forms 3, 4 and 5 with the SEC. Officers, directors and greater than 10% stockholders are required to furnish us with copies of all Forms 3, 4 and 5 they file.

We did not have a class of equity securities registered pursuant Section 12 of the Exchange Act during the fiscal year ended December 31, 2020, as our initial public offering was completed in February 2021. As a result, our executive officers and directors, and persons who own more than 10% of a registered class our common stock, were not subject to Section 16(a) during the fiscal year ended December 31, 2020.

Process for Stockholder Nominations

The Nominating and Corporate Governance Committee shall have the power and authority to consider recommendations for board nominees and proposals submitted by our stockholders and to establish any policies, requirements, criteria and procedures, including policies and procedures to facilitate stockholder communications with the board of directors, to recommend to the board of directors appropriate action on any such proposal or recommendation and to make any disclosures required by applicable law in the course of exercising its authority. At this time, the Nominating and Corporate Governance Committee does not have a policy with regard to the consideration of director candidates recommended by stockholders.

Item 11. Executive Compensation.

EXECUTIVE COMPENSATION

Our named executive officers for the year ended December 31, 2020, consisting of our principal executive officer and four other most highly compensated officers serving at the end of such year, were:

- Randall Schatzman, Ph.D., our Chief Executive Officer and Director;
- William P. Quinn, our Chief Financial Officer;
- David Dornan, Ph.D., our Chief Scientific Officer;
- Edith A. Perez, M.D., our Chief Medical Officer; and
- Grant Yonehiro, our Chief Business Officer.

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, 2020:

Name	Year	Salary	Bonus	Option Awards(1)	Other Compensation	Total
Randall C. Schatzman, Ph.D.	2020	$458,384	$209,023(2)	$ 897,237	$ 38,647(3)	$1,603,291
Chief Executive Officer	2019	206,250	96,411(4)	1,335,341	49,044(5)	1,687,046
William P. Quinn	2020(6)	238,636	96,051(2)	603,376	689	938,752
Chief Financial Officer						
David Dornan, Ph.D.	2020	310,167	109,620(2)	154,286	2,708	576,781
Chief Scientific Officer	2019	275,000	80,438(4)	168,633	—	524,071
Edith A. Perez, M.D.	2020(7)	300,000	295,750(2)(8)	661,347	11,743(9)	1,268,840
Chief Medical Officer						
Grant Yonehiro	2020	309,000	124,373(2)	138,130(2)	700	572,203
Chief Business Officer	2019	300,000	120,750(4)	201,795	—	622,545

(1) 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 or 2020, as applicable under our 2015 Equity Incentive Plan, computed in accordance with ASC 718. Assumptions used in the calculation of these amounts are included in Note 10 to our financial statements included elsewhere in this Annual Report on Form 10-K. During 2020, we granted stock options to our executive officers that will commence time-based vesting upon the achievement of a financing milestone. We determined that the achievement of the financing milestone is probable and therefore the amounts reported in this column reflect the full grant date fair value of such stock options. On January 15, 2021, the financing milestone was achieved. As required by SEC rules, the amounts shown for all grants exclude the impact of estimated forfeitures related to service-based vesting conditions.

(2) Represents amounts earned in 2020, which will be paid in 2021. We based the 2020 annual performance bonuses for Mr. Quinn, Dr. Perez and Mr. Yonehiro on company performance goals. We based the 2020 annual performance bonuses for Drs. Schatzman and Dornan on company performance (80%) and individual performance (20%). Our 2020 corporate goals related to clinical, pipeline development, partnering, and financing milestones and objectives. For 2020, the compensation committee of our board of directors determined that Dr. Schatzman, Mr. Quinn, Dr. Dornan, Dr. Perez, and Mr. Yonehiro were entitled to 114%, 115%, 116%, 115% and 115% of their target bonuses, respectively.

(3) Dr. Schatzman received $12,449 for commuting reimbursements, $16,419 for housing and other living expenses reimbursements and $9,779 to cover the tax gross up for such costs.

(4) Represents amounts earned in 2019, which were paid in February 2020, upon the achievement of 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.

(5) Dr. Schatzman received $16,631 for commuting reimbursements, $19,665 for housing and other living expenses reimbursements and $12,748 to cover the tax gross up for such costs.

(6) Mr. Quinn commenced his employment with us in May 2020.

(7) Dr. Perez commenced her employment with us in April 2020.

(8) Dr. Perez received a $175,000 signing bonus in 2020 in connection with the commencement of her employment.

(9) Dr. Perez received commuting reimbursements, an electronics stipend, and payments for waiver of healthcare insurance.

Outstanding Equity Awards as of December 31, 2020

The following table presents the outstanding equity incentive plan awards held by each named executive officer as of December 31, 2020. All awards were granted under our 2015 Equity Incentive Plan.

			Option Awards				Stock Awards	
Name	Grant Date	Vesting Commencement Date(1)	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price ($)(2)	Option Expiration Date	Number of Shares of Stock That Have Not Vested (#)	Market Value of Shares of Stock That Have Not Vested ($)
Randall C. Schatzman, Ph.D.	9/6/2019	7/15/2019(3)(4)	791,185	—	$ 2.73	9/5/2029	—	—
	9/3/2020	9/3/2020(4)(5)	100,000	—	$ 4.34	9/2/2030	—	—
	9/3/2020	1/15/2021(6)	178,571	—	$ 4.34	9/2/2030	—	—
William P. Quinn	—	5/4/2020(7)	—	—	$ —	—	12,698	55,999(7)(8)
	7/29/2020	5/4/2020(9)	—	152,301	$ 2.80	7/28/2030	—	—
	9/3/2020	9/3/2020(10)	35,714	—	$ 4.34	9/2/2030	—	—
	9/3/2020	1/15/2021(11)	42,857	—	$ 4.34	9/2/2030	—	—
David Dornan, Ph.D.	1/17/2018	12/1/2017(3)	48,428	16,143	$ 2.03	1/16/2028	—	—
	4/4/2018	2/14/2018(3)	9,706	3,996	$ 2.03	4/3/2028	—	—
	1/11/2019	7/23/2018(3)	15,986	10,474	$ 2.24	1/10/2029	—	—
	11/13/2019	7/2/2019(5)	27,827	50,744	$ 2.73	11/13/2029	—	—
	9/3/2020	9/3/2020(4)(5)	12,142	—	$ 4.34	9/2/2030	—	—
	9/3/2020	1/15/2021(6)	35,714	—	$ 4.34	9/2/2030	—	—
Edith A. Perez, M.D.	7/29/2020	4/1/2020(3)	—	225,000	$ 2.80	7/28/2030	—	—
	9/3/2020	9/3/2020(12)	12,142	—	$ 4.34	9/2/2030	—	—
	9/3/2020	1/15/2021(13)	45,000	—	$ 4.34	9/2/2030	—	—
Grant Yonehiro	1/18/2017	11/1/2016(3)	64,285	—	$ 2.10	1/17/2027	—	—
	1/17/2018	11/1/2016(3)	13,207	—	$ 2.03	1/16/2028	—	—
	4/4/2018	2/14/2018(3)	11,648	4,796	$ 2.03	4/3/2028	—	—
	1/11/2019	7/23/2018(3)	19,983	13,092	$ 2.24	1/10/2029	—	—
	11/13/2019	7/2/2019(5)	32,886	59,971	$ 2.73	11/12/2029	—	—
	9/3/2020	9/3/2020(4)(5)	12,142	—	$ 4.34	9/2/2030	—	—
	9/3/2020	1/15/2021(6)	30,714	—	$ 4.34	9/2/2030	—	—

(1) The unvested shares underlying these options became subject to accelerated vesting as described in “Item 11. Executive Compensation—Severance and Change in Control Plan” below.

(2) 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.

(3) 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.

(4) This 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, 2020, the named executive officer had not early exercised the option.

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

(6) This option is immediately exercisable and vests monthly over a four-year period beginning upon the closing of our Series C-2 financing on January 15, 2021. As of December 31, 2020, the named executive officer had not early exercised the option.

(7) The shares, which were acquired pursuant to an early exercise provision, vest in full on May 4, 2021 and such shares will remain subject to a right of repurchase held by us until such date.

(8) This amount reflects the fair market value of our common stock of $4.41 per share as of December 31, 2020 as determined by our compensation committee.

(9) This option vests over a four-year period with 28,551 shares vesting on May 4, 2021 and the remainder vesting monthly over 36 months from May 4, 2021.

(10) This option is immediately exercisable and vests over a four-year period with 6,696 shares vesting on June 3, 2021 and the remainder vesting monthly over 39 months from June 3, 2021.
(11) This option is immediately exercisable and vests over a four-year period with 3,571 shares vesting on May 15, 2021 and the remainder vesting monthly over 44 months from May 15, 2021.
(12) This option is immediately exercisable and vests over a four-year period with 1,770 shares vesting on April 3, 2021 and the remainder vesting monthly over 41 months from April 3, 2021.
(13) This option is immediately exercisable and vests over a four-year period with 2,812 shares vesting on April 15, 2021 and the remainder vesting monthly over 45 months from April 15, 2021.

Emerging Growth Company Status

We are an emerging growth company, as defined in the JOBS Act. As an emerging growth company, we are 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, 2020. 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 2020.

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 2021, Dr. Schatzman was entitled to an annual base salary of $545,000, and is eligible to receive an annual performance bonus with a target amount of 50% 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 were 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 791,185 shares of our common stock at an exercise price of $2.73 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. Upon execution of the underwriting agreement for our initial public offering, Dr. Schatzman was granted an additional option to purchase 340,000 shares of our common stock at an exercise price equal to our initial public offering price. This option is immediately exercisable and vests monthly over a four year period commencing upon the date of grant. Please see "Item 11. Executive Compensation—Outstanding Equity Awards as of December 31, 2020" for information regarding equity awards granted to Dr. Schatzman.

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 2021, Mr. Quinn is entitled to an annual base salary of $395,000 and is eligible to receive an annual performance bonus with a target amount of 40% 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.

In July 2020, pursuant to his offer letter Mr. Quinn was granted two options to purchase an aggregate of 164,999 shares of our common stock at an exercise price of $2.80 per share. The first option was for 12,698 shares of our common stock. This option was immediately exercisable and vests in full in May 2021. Mr. Quinn exercised the option in full in August 2020. The second option was for 152,301 shares of our common stock. This option vests over a four-year period with 28,551 vesting in May 2021 and the remainder vesting monthly over 36 months from May 2021. Upon execution of the underwriting agreement for our initial public offering, Mr. Quinn was granted an additional option to purchase 100,000 shares of our common stock at an exercise price equal to our initial public offering price. This option is immediately exercisable and vests monthly over a four year period commencing upon the date of grant. Please see "Item 11. Executive Compensation—Outstanding Equity Awards as of December 31, 2020" for information regarding equity awards granted to Mr. Quinn.

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 2021, Dr. Dornan is entitled to an annual base salary of $405,000, and is eligible to receive an annual performance bonus with a target amount of 40% 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 64,571 shares of our common stock at an exercise price of $2.03 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. Upon execution of the underwriting agreement for our initial public offering, Dr. Dornan was granted an additional option to purchase 110,000 shares of our common stock at an exercise price equal to our initial public offering price. This option is immediately exercisable and vests monthly over a four-year period commencing upon the date of grant. Please see "Item 11. Executive Compensation—Outstanding Equity Awards as of December 31, 2020" 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 2021, Dr. Perez is entitled to an annual base salary of $435,000 and is eligible to receive an annual performance bonus with a target amount of 40% 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. In 2020, 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 225,000 shares of our common stock at an exercise price of $2.80 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. Upon execution of the underwriting agreement for our initial public offering, Dr. Perez was granted an additional option to purchase 100,000 shares of our common stock at an exercise price equal to our initial public offering price. This option is immediately exercisable and vests monthly over a four-year period commencing upon the date of grant. Please see "Item 11. Executive Compensation—Outstanding Equity Awards as of December 31, 2020" for information regarding equity awards granted to Dr. Perez.

Grant Yonehiro

In October 2016, we entered into an offer letter with Mr. Yonehiro, which governs the terms of his employment with us. For 2021, Mr. Yonehiro is entitled to an annual base salary of $370,000, and is eligible to receive an annual performance bonus with a target amount of 40% 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 64,285 shares of our common stock at an exercise price of $2.10 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. Upon execution of the underwriting agreement for our initial public offering, Mr. Yonehiro was granted an additional option to purchase 100,000 shares of our common stock at an exercise price equal to our initial public offering price. This option is immediately exercisable and vests monthly over a four-year period commencing upon the date of grant. Please see "Item 11. Executive Compensation—Outstanding Equity Awards as of December 31, 2020" for information regarding equity awards granted to Mr. Yonehiro.

Severance and Change in Control Plan

The Severance and Change in Control Plan, or the Severance Plan, provides severance benefits to each of our employees selected for participation in the Severance Plan, subject to execution of a participation agreement for the Severance Plan. Upon the closing of our initial public offering, each of our executive officers and vice presidents, including our named executive officers, became participants in the Severance Plan. The benefits provided under the Severance Plan supersede any similar severance benefits described in a participant's offer letter or employment agreement. Participants in our Severance Plan will be entitled to receive continued payment of their base salary (12 months for our Chief Executive Officer, nine months for our other executive officers, senior vice presidents and certain other executives as designated by our board of directors and six months base salary for our vice presidents and all other participants so designated by our board) upon either an involuntary termination without cause or a resignation for good reason (as each such term is defined in the Severance Plan) following such termination. In addition, each such participant with a qualifying termination is also eligible for payment of continued group health plan premiums during the period of base salary continuation. Our chief executive officer, our other executive officers and senior vice presidents are also eligible to receive a prorated bonus at the target level for the year of termination, paid in equal installments over the period of base salary continuation. Our chief executive officer will also be entitled to an additional amount equal to any then earned but unpaid performance bonus for the calendar year preceding such termination, if our annual performance bonus plan is amended so that it does not require the chief executive officer's continued service through the bonus payment date in order to earn such annual performance bonus, such that this provision will become applicable.

In the event that an involuntary termination without cause or a resignation for good reason occurs in the period commencing three months prior to and ending 12 months following a change in control, the participant will be entitled to receive a lump sum cash payment (equal to 18 of months base salary for our Chief Executive Officer, 12 months of base salary for our other executive officers, senior vice presidents and certain other executives as designated by our board of directors and nine months of base salary for our vice presidents and all other participants so designated by our board) and a lump such cash payment in respect of such participant's target annual cash bonus (such payment at 150% of the annual target amount for the chief executive officer, 100% of target for our other executive officers, senior vice presidents and other executives as designated by our board of directors or 75% of target for our vice presidents and all other participants so designated by our board). In addition, each such participant with a qualifying change in control termination is also eligible for payment of continued group health plan premiums for a period of time equal to the number of months of base salary severance that is paid in a lump sum as specified above. Also in the event of a change in control termination, the unvested portion of any equity awards granted to any participant will fully vest and become exercisable at the later of such participant's execution of a release or the effective date of such change in control. All such severance benefits are subject to the participant signing a general release of all known and unknown claims in substantially the form provided in the Severance Plan, as well as the participant's compliance with certain post-termination restrictive covenants.

Our chief executive officer is also entitled to immediate vesting acceleration of any equity awards granted to our chief executive officer if the chief executive officer remains in our continued services through the date of such change in control.

Employee Benefit and Stock Plans

2021 Equity Incentive Plan

Our board of directors adopted the 2021 Equity Incentive Plan, or the 2021 Plan, in January 2021, and our stockholders approved the 2021 Plan in January 2021. The 2021 Plan became effective upon the execution of the underwriting agreement for our initial public offering. The 2021 Plan is the successor to our 2015 Equity Incentive Plan, or the 2015 Plan, which is described below. No further grants will be made under the 2015 Plan.

Types of Awards. Our 2021 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. Initially, the maximum number of shares of our common stock that may be issued under our 2021 Plan is 8,075,000 shares, which is the sum of (1) 4,200,000 new shares, plus (2) returning shares, if any, subject to outstanding stock options or other stock awards as of the effective date of the 2021 Plan that were granted under the 2015 Plan and which are forfeited, terminate, expire or are otherwise not issued. In addition, the number of shares of our common stock reserved for issuance under our 2021 Plan will automatically increase on January 1 of each calendar year that commences after our 2021 Plan becomes effective and continuing through and including January 1, 2031, in an amount equal to 5% of the total number of shares of our common stock outstanding on the last day of the calendar month before the date of each automatic increase, or a lesser number of shares determined by our board of directors or compensation committee. The maximum number of shares of our common stock that may be issued on the exercise of incentive stock options under our 2021 Plan is 24,000,000 shares.

Shares issued under our 2021 Plan are authorized but unissued or reacquired shares of common stock. Shares subject to awards granted under our 2021 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 2021 Plan. Additionally, shares issued pursuant to awards under our 2021 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 2021 Plan.

The maximum number of shares of common stock subject to stock awards granted under the 2021 Plan or otherwise during any period that begins after the 2021 Plan becomes effective and commences on the date of the company's annual meeting of stockholders for a particular year and ends 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 retainers paid by us to such non-employee director during such period for service on the board of directors, will not exceed $1.0 million 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, $1.5 million.

Plan Administration. Our board, or a duly authorized committee of our board, may administer our 2021 Plan. Our board has delegated concurrent authority to administer our 2021 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 2021 Plan.

In addition, subject to the terms of the 2021 Plan, the administrator also has the power to modify outstanding awards under our 2021 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 2021 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 2021 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 2021 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 2021 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 2021 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 2021 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 2021 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 2021 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 2021 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, outstanding stock awards may be assumed, continued or substituted for similar stock awards by the surviving or acquiring corporation. If any surviving or acquiring corporation fails to assume, continue or substitute such stock awards, the vesting of stock awards held by participants whose continuous service has not terminated will be accelerated in full to a date prior to the corporate transaction as determined by the plan administrator. All stock awards not assumed, continued or substituted for similar stock awards by the surviving or acquiring corporation will terminate upon the corporate transaction. In addition, the plan administrator may also provide, in its sole discretion, that the holder of a stock award that will terminate upon the occurrence of a corporate transaction will receive a payment, if any, equal to the excess of the value of the property the participant would have received upon exercise of the stock award over the exercise price otherwise payable in connection with the stock award.

Transferability. A participant may not transfer awards under our 2021 Plan other than by will, the laws of descent and distribution or as otherwise provided under our 2021 Plan.

Plan Amendment or Termination. Our board has the authority to amend, suspend or terminate our 2021 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 2021 Plan. No awards may be granted under our 2021 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 terminated on the date the 2021 Plan became 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 2021 Plan, we will no longer grant awards under our 2015 Plan. As of December 31, 2020, options to purchase 3,800,402 shares were outstanding and 147,852 shares of common stock remained available for future grants under our 2015 Plan. The options outstanding as of December 31, 2020 had a weighted-average exercise price of $3.16 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 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 terminated upon the effective date of the 2021 Plan so that no future awards will be granted under the 2015 Plan.

2021 Employee Stock Purchase Plan

Our board of directors and stockholders adopted our 2021 Employee Stock Purchase Plan, or the ESPP, in January 2021. The ESPP became effective upon the execution of the underwriting agreement for our initial public 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 420,000 shares. The number of shares of common stock reserved for issuance under our ESPP will automatically increase on January 1 of each calendar year that commences after the ESPP becomes effective and continuing through and including January 1, 2031, by the lesser of (1) 1% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, (2) 840,000 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 commenced upon the execution and delivery of the underwriting agreement relating to our initial public offering, the fair market value on the first day of the initial offering will be the price at which shares were 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

Our amended and restated certificate of incorporation contains provisions that limit the liability of our current and former directors for monetary damages to the fullest extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to the corporation or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions; 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 authorizes us to indemnify our directors, officers, employees and other agents to the fullest extent permitted by Delaware law. Our amended and restated bylaws 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 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 the 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 our initial public 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.

Non-Employee Director Compensation

Prior to the adoption of the Non-Employee Director Compensation Policy described below, we provided 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 were 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, 2020. 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 "Item 11. 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.	—	—	—
James I. Healy, M.D.(3)	—	—	—
Ashish Khanna, Ph.D.	—	—	—
Kathleen LaPorte(4)	—	$ 91,915(5)	$91,915
Richard A Miller, M.D.	—	—	—
Jason Pitts, Ph.D.(6)	—	—	—
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 2020 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, 2020, our non-employee directors held options to purchase the following number of shares of our common stock: Ms. LaPorte, 27,857 shares; Dr. Miller, 10,808 shares. In addition, Dr. Miller holds 7,708 shares, which were acquired pursuant to an early exercise provision and subject to a right of repurchase, which lapses in accordance with the vesting schedule.
(3) Dr. Healy became a member of our board of directors in January 2021.
(4) Ms. LaPorte became a member of our board of directors in December 2020.
(5) In December 2020, we granted Ms. LaPorte an option to purchase 27,857 shares with an exercise price of $4.41 per share, which vests in 36 equal monthly installments, for so long as Ms. LaPorte continues to provide service to us through such vesting date.
(6) Dr. Pitts resigned as a member of our board of directors in January 2021.

Non-Employee Director Compensation Policy

We adopted a non-employee director compensation policy which became effective upon the closing of our initial public offering in February 2021 pursuant to which our non-employee directors are eligible to receive cash and equity compensation for service on our board of directors and committees of our board of directors.

Commencing upon our initial public offering, each non-employee director received an annual cash retainer of $35,000 for serving on our board of directors.

The chairperson of our board of directors is entitled to a cash retainer of $65,000 in lieu of the annual retainer received by other non-employee directors for serving as our lead director.

The chairperson and members of the following three committees of our board of directors are entitled to the following additional annual cash retainers:

Board Committee	Chairperson Fee	Member Fee
Audit Committee	$ 15,000	$ 7,500
Compensation Committee	10,000	5,000
Nominating and Corporate Governance Committee	8,000	4,000

All annual cash retainers are payable in equal quarterly installments in arrears, on the last day of each fiscal quarter for which the service occurred, pro-rated based on the number of days served in the applicable fiscal quarter, provided that for the fiscal quarter which includes the closing date of our initial public offering, the cash compensation amounts will be pro-rated based on the number of days served in such fiscal quarter commencing on the closing date of our initial public offering.

Each new non-employee director who joins our board of directors after our initial public offering will receive an option to purchase 27,860 shares of our common stock under our 2021 Equity Incentive Plan. The shares subject to this option will vest on a monthly basis over 36 months commencing on the grant date, subject to the non-employee director's continuous service with us on each applicable vesting date. Such newly joining director will also receive a prorated initial annual option grant consisting of an option to purchase a number of shares of our common stock determined by multiplying 13,930 by the percentage obtained by dividing the number of calendar days from the date such new director joins us to the date of the next scheduled annual stockholder meeting by the total number of calendar days scheduled to follow the date of the last annual stockholder meeting through the date of the next annual stockholder meeting. Such prorated initial annual option will vest in full on the date immediately preceding the date of next annual stockholder meeting, subject to the non-employee director's continuous service through such vesting date.

On the date of each annual meeting of our stockholders, each continuing non-employee director will receive an option to purchase 13,930 shares of our common stock under the 2021 Equity Incentive Plan, vesting on the earlier of the one-year anniversary of the grant date or the date immediately prior to the next annual stockholder meeting date, subject to the non-employee director's continuous service with us on the applicable vesting date.

The exercise price per share of each stock option granted under the non-employee director compensation policy will be the closing price of our common stock as reported by the Nasdaq Stock Market on the date of grant. Each stock option will have a term of ten years from the date of grant, subject to earlier termination in connection with a termination of the non-employee director's continuous service with us. Each stock option and other equity award granted to our non-employee directors is also entitled to immediate vesting acceleration upon a change in control if the non-employee director remains in our continued services through the date of such change in control.

Each non-employee director is subject to an annual director compensation limit. In any one-year period measured as commencing on the date of each annual meeting of shareholders that is held following the closing of our initial public offering and ending on the day immediately prior to the date of the subsequent annual meeting of shareholders, the aggregate value of all compensation granted or paid to each non-employee director may not exceed (i) $1,000,000 in total value or (ii) in the event such non-employee director is first appointed or elected during such annual period, $1,500,000 in total value, in each case calculating the value of any equity awards based on the grant date fair market value for financial reporting purposes.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

PRINCIPAL STOCKHOLDERS

The following table sets forth information with respect to the beneficial ownership of our common stock as of March 1, 2021, 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 is based on 36,319,766 shares of common stock outstanding as of March 1, 2021. 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 March 1, 2021. However, except as described above, we did not deem such shares outstanding for the purpose of computing the percentage ownership of any other person.

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	Shares Beneficially Owned	
	Shares	%
Principal Stockholders		
Novo Holdings A/S(1)	4,503,991	12.4%
Entities affiliated with Vivo Capital(2)	3,871,291	10.7
Sofinnova Venture Partners X, L.P.(3)	2,754,437	7.6
Citadel Multi-Strategy Equities Master Fund Ltd.(4)	2,942,007	8.1
Entities affiliated with RA Capital(5)	2,378,325	6.5
Pivotal bioVenture Partners Fund I, L.P.(6)	1,891,467	5.2
Entities affiliated with Rock Springs Capital Management LP(7)	2,205,494	6.1
Directors and Executive Officers		
Randall C. Schatzman, Ph.D.(8)	1,411,256	3.7
William P. Quinn(9)	192,469	*
David Dornan, Ph.D.(10)	275,077	*
Edith A. Perez, M.D.(11)	213,392	*
Grant Yonehiro(12)	296,729	*
Peter Moldt, Ph.D.	—	—
Edgar G. Engleman, M.D.(13)	3,551,232	9.8
James I. Healy, M.D.(3)	2,754,437	7.6
Ashish Khanna, Ph.D.(14)	5,741	*
Kathleen LaPorte(15)	4,295	*
Richard A. Miller, M.D.(16)	20,330	*
Mahendra G. Shah, Ph.D.(17)	1,448,286	4.0
All directors and executive officers as a group (12 persons)(18)	10,173,244	26.3%

* Represents beneficial ownership of less than 1%.

(1) Consists of 4,503,991 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) 1,997,216 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; (ii) 275,789 shares of common stock held directly by Vivo Capital Surplus Fund VIII, L.P., of which Vivo GP is the general partner; (iii) 1,448,286 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 (iv) 150,000 shares of common stock held directly by Vivo Opportunity Fund, L.P. ("Vivo Opportunity LP"), of which Vivo Opportunity, LLC ("Vivo Opportunity GP") is the general partner. The voting members of Vivo GP are Frank Kung, Edgar Engleman 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 member of Vivo PANDA GP. The principal business address of Vivo Capital is 192 Lytton Avenue, Palo Alto, CA 94301.

(3) Consists of 2,754,437 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. Such persons disclaim beneficial ownership of such shares except to the extent of their pecuniary interest therein. Dr. Healy, a member of our board of directors, is a general partner at Sofinnova Investments, Inc. The address for SM X is 3000 Sand Hill Road, Bldg. 4, Suite 250, Menlo Park, CA 94025.

(4) Consists of 2,942,007 shares of common stock held directly by Citadel Multi-Strategy Equities Master Fund Ltd., or Citadel. Citadel Advisors LLC, or Citadel Advisors, acts as the portfolio manager of Citadel. Citadel Advisors Holdings LP, or CAH, is the sole member of Citadel Advisors, and Citadel GP LLC, or CGP, is the general partner of CAH. Kenneth Griffin owns a controlling interest in CGP and may be deemed to share voting and dispositive power over shares held by Citadel. The address for this entity is c/o Citadel Advisors, 601 Lexington Avenue, New York, New York 10022.

(5) Consists of: (i) 139,937 shares of common stock held directly by Blackwell Partners LLC—Series A; (ii) 1,806,307 shares of common stock held directly by RA Capital Healthcare Fund, L.P.; and (iii) 432,081 shares of common stock held directly by RA Capital Nexus Fund, L.P. RA Capital Management, L.P. is the investment manager for Blackwell Partners LLC—Series A ("Blackwell"), RA Capital Healthcare Fund, L.P. ("RA Healthcare") and RA Capital Nexus Fund L.P. ("Nexus Fund"). The general partner of RA Capital Management, L.P. is RA Capital Management GP, LLC, of which Peter Kolchinsky and Rajeev Shah are the managing members. RA Capital Management, L.P., RA Capital Management GP, LLC, Peter Kolchinsky and Rajeev Shah may be deemed to have voting and investment power over the shares held of record by Blackwell, RA Healthcare and Nexus Fund. RA Capital Management, L.P., RA Capital Management GP, LLC, Peter Kolchinsky and Rajeev Shah disclaim beneficial ownership of such shares, except to the extent of any pecuniary interest therein. The address of the entities listed above is 200 Berkeley Street, 18th Floor, Boston, Massachusetts 02116.

(6) Consists of 1,891,467 shares of common stock held directly by Pivotal bioVenture Partners Fund I, L.P. 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.

(7) Consists of: (i) 1,946,246 shares of common stock held directly by Rock Springs Capital Master Fund LP (the "Master Fund"); and (ii) 259,248 shares of common stock held directly by Four Pines Master Fund LP ("Four Pines"). Rock Springs Capital Management LP ("RSCM") serves as the investment manager to each of the Master Fund and Four Pines. Rock Springs Capital LLC ("RSC") is the general partner of RSCM. In such capacities, RSCM and RSC, and Kris Jenner, Gordon "Margraf" Bussard and Graham McPhail, the members of RSC, may be deemed to share voting and dispositive power of the shares held by the Master Fund and Four Pines. Messrs. Jenner, Bussard and McPhail disclaim beneficial ownership over such shares, expect to the extent of their pecuniary interest therein. The principal business address of RSCM and RSC is 650 South Exeter, Suite 1070, Baltimore, Maryland 21202, and the principal business address of the Master Fund and Four Pines is c/o Walkers Corporate Limited, Cayman Corporate Centre, 27 Hospital Road, George Town, Grand Cayman KY1-9008, Cayman Islands.

(8) Consists of: (i) 1,500 shares of common stock held directly; and (ii) 1,409,756 shares issuable pursuant to stock options exercisable within 60 days of March 1, 2021.

(9) Consists of: (i) 13,898 shares of common stock held directly, 12,698 of which were unvested and remained subject to a repurchase right in favor of us as of March 1, 2021; and (ii) 178,571 shares issuable pursuant to stock options exercisable within 60 days of March 1, 2021.

(10) Consists of 275,077 shares issuable pursuant to stock options exercisable within 60 days of March 1, 2021.

(11) Consists of 213,392 shares issuable pursuant to stock options exercisable within 60 days of March 1, 2021.

(12) Consists of 296,729 shares issuable pursuant to stock options exercisable within 60 days of March 1, 2021.
(13) Consists of: (i) 635,371 shares of common stock held directly by the Engleman Family Trust; (ii) 321,428 shares of common stock held directly by the Erik Nathan Engleman Irrevocable Trust dated December 6, 2012; (iii) 321,428 shares of common stock held directly by the Jason Engleman Irrevocable GST Trust dated December 06, 2012; (iv) 1,997,216 shares of common stock held directly by Vivo Capital Fund VIII, L.P.; and (v) 275,789 shares of common stock held directly by Vivo Capital Surplus Fund VIII, L.P.. 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, Edgar Engleman 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.
(14) Consists of: (i) 1,200 shares of common stock and 3,541 shares issuable pursuant to stock options exercisable within 60 days of March 1, 2021 held by Dr. Khanna's spouse; and (ii) 1,000 shares of common stock held directly by Dr. Khanna.
(15) Consists of (i) 1,200 shares of common stock held directly, and (ii) 3,095 shares issuable pursuant to stock options exercisable within 60 days of March 1, 2021.
(16) Consists of (i) 15,602 shares of common stock held directly, and (ii) 4,728 shares issuable pursuant to stock options exercisable within 60 days of March 1, 2021.
(17) Consists of 1,448,286 shares of common stock held directly by Vivo PANDA LP. Dr. Shah is a managing member 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.
(18) Consists of: (i) 7,132,255 shares of common stock directly or indirectly held by all current executive officers and directors as a group; and (ii) 2,384,889 shares of common stock issuable pursuant to options exercisable within 60 days of March 1, 2021.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table shows certain information with respect to all of our equity compensation plans in effect as of December 31, 2020.

Plan Category	Number of securities to be issued upon exercise of outstanding stock options (a)	Weighted-average exercise price of outstanding stock options (b)	Number of securities remaining available for issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by stockholders(1)	3,800,402	$ 3.16	147,852
Equity compensation plans not approved by stockholders	—	—	—
Total	3,800,402	$ 3.16	147,852

(1) The equity compensation plans approved by security holders are described in Note 10 to our financial statements included in this Annual Report on Form 10-K for the year ended December 31, 2020.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The following is a summary of transactions since January 1, 2019, 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 "Item 11. Executive 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 multiple closings held between July 2018 and July 2019, we issued and sold an aggregate of 6,645,906 shares of our Series B preferred stock and issued warrants to purchase an aggregate of 249,218 of common stock to 11 accredited investors at a purchase price of $8.0458 per share for an aggregate purchase price of $53.5 million.

In June 2020, we issued and sold an aggregate of 5,162,173 shares of our Series C-1 preferred stock to 17 accredited investors at a purchase price of $8.05 per share for an aggregate purchase price of $41.6 million.

In January 2021, we issued and sold an aggregate of 5,611,059 shares of our Series C-2 preferred stock to 17 accredited investors at a purchase price of $9.2575 per share for an aggregate purchase price of $51.9 million.

The following table summarizes the Series C-1 and Series C-2 preferred stock purchased by holders of more than five percent of our capital stock and their affiliated entities and our directors since January 1, 2020. None of our executive officers purchased shares of preferred stock.

Name of Stockholder	Series B Preferred Stock	Common Stock Warrants	Series C-1 Preferred Stock	Series C-2 Preferred Stock	Aggregate Purchase Price
Novo Holdings A/S(1)	2,050,758	76,903	421,670	458,337	$ 24,137,511
Entities affiliated with Vivo Capital(2)	1,715,178	64,319	361,823	393,286	22,353,535
Sofinnova Venture Partners X, L.P.(3)	—	—	1,104,209	1,200,228	19,999,999
Citadel Multi-Strategy Equities Master Fund Ltd.	—	—	828,157	900,171	14,999,999
Entities affiliated with RA Capital Management(4)	—	—	828,156	900,169	14,999,999
Rock Springs Capital Master Fund LP(5)	—	—	745,341	810,153	13,499,998
Pivotal bioVenture Partners Fund I, L.P.(6)	1,242,884	46,608	168,655	183,320	13,054,761

(1) Dr. Moldt, a member of our board of directors, is employed as a Senior Partner at 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., or Vivo PANDA LP. 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. Healy, a member of our board of directors, is a General Partner of Sofinnova Investments.

(4) Includes shares of preferred stock purchased by (a) RA Capital Healthcare Fund, L.P., (b) RA Capital Nexus Fund, L.P. and (c) Blackwell Partners LLC—Series A.

(5) Includes shares of preferred stock purchased by (a) Rock Springs Capital Master Fund LP and (b) Four Pines Master Fund LP.

(6) Dr. Khanna, a member of our board of directors, is a venture partner of Pivotal BioVenture Partners.

Upon the closing of our initial public offering, each share of preferred stock was converted 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 Annual Report on Form 10-K.

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 Citadel Multi-Strategy Equities Master Fund Ltd., Novo Holdings A/S, Pivotal bioVenture Partners LLC, entities affiliated with RA Capital Management, entities affiliated with Rock Springs Capital, Sofinnova Investments, Inc. and Vivo Capital 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. Healy, 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 terminated upon the closing of our initial public offering, and a right of first refusal with regard to certain issuances of our capital stock, which did not apply to, and terminated upon, the closing of our initial public offering. After the closing of our initial public offering, the holders of 21,712,540 shares of common stock issuable on conversion of outstanding preferred stock, are entitled to rights with respect to the registration of their shares of common stock under the Securities Act under this agreement.

Relationship with Stanford University

In May 2015, we entered into a license agreement with Stanford, pursuant to which Stanford was issued 37,551 shares of our common stock and two co-inventors were issued an aggregate of 14,850 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 2019 and 2020, we made payments to Stanford of $193,420 and $155,457 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 7,425 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 "Item 11. 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 "Item 11. Executive Compensation."

Indemnification Agreements

Our amended and restated certificate of incorporation contains provisions limiting the liability of directors, and our amended and restated bylaws provides 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 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 "Item 11. Executive Compensation—Limitations of Liability and Indemnification Matters."

Policies and Procedures for Related Person Transactions

Our board of directors adopted 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.

Director Independence

Please see "Item 10. Directors, Executive Officers and Corporate Governance—Director Independence" and "—Committees of our Board of Directors" for information regarding the independence of the board of directors and the committees of the board of directors.

Item 14. Principal Accounting Fees and Services.

Audit and All Other Fees

The following table presents fees for services rendered by PricewaterhouseCoopers LLP, our independent registered public accounting firm, for 2019 and 2020 in the following categories:

	Years ended December 31,	
	2019	2020
Audit Fees(1)	$ 310,000	$ 1,300,000
Tax Fees	—	—
All Other Fees	—	—
	$ 310,000	$ 1,300,000

(1) Audit fees consist of fees professional services rendered for the annual audit, of our financial statements and review of the interim financial statements and services normally provided in connection with documents filed with the SEC. For the year ended December 31, 2020, the audit fees included professional services rendered for Form S-1 related to our initial public offering.

Pre-Approval Policies and Procedures

The audit committee is required to pre-approve the audit and non-audit services performed by our independent registered public accounting firm in order to assure that the provision of such services does not impair the auditor's independence. Any proposed services exceeding pre-approved cost levels require specific pre-approval by the audit committee.

The audit committee at least annually reviews and provides general pre-approval for the services that may be provided by the independent registered public accounting firm; the term of the general pre-approval is 12 months from the date of approval, unless the audit committee specifically provides for a different period. If the audit committee has not provided general pre-approval, then the type of service requires specific pre-approval by the audit committee.

The audit committee may delegate pre-approval authority to its chairman. The chairman must report any pre-approval decisions to the full audit committee at its next scheduled meeting. The annual audit services, engagement terms, and fees are subject to the specific pre-approval of the audit committee. All services performed and related fees billed by PricewaterhouseCoopers LLP during 2020 and 2019 were pre-approved by the audit committee pursuant to regulations of the SEC.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a)(1) The financial statements required to be filed by Items 8 and 15(c) of this Annual Report on Form 10-K, and filed herewith, are as follows:

(a)(2) Financial statement schedules required to be filed by Item 8 of this form, and by paragraph (b) below have been omitted as they are not applicable.

(a)(3) **Exhibits**

The following is a list of Exhibits filed, furnished or incorporated by reference as part of the Annual Report on Form 10-K:

Exhibit Number	Description of Exhibit	Form	File No.	Exhibit	Filing Date	Filed Herewith
3.1	Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect.	8-K	001-39988	3.1	2/9/2021	
3.2	Amended and Restated Bylaws of the Registrant, as currently in effect.	S-1	333-252136	3.4	1/15/2021	
4.1	Reference is made to Exhibits 3.1 and 3.2.					
4.2	Form of common stock certificate of the Registrant.	S-1	333-252136	4.1	1/15/2021	
4.3	Description of Securities.					X
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.	S-1	333-252136	10.1	1/15/2021	
10.2+	2015 Equity Incentive Plan, as amended.	S-1/A	333-252136	10.2	2/1/2021	
10.3+	Forms of Option Agreement, Stock Option Grant Notice and Notice of Exercise under the 2015 Equity Incentive Plan.	S-1	333-252136	10.3	1/15/2021	
10.4+	2021 Equity Incentive Plan.	S-1/A	333-252136	10.4	2/1/2021	
10.5+	Forms of Option Agreement, Stock Option Grant Notice and Notice of Exercise under the 2021 Equity Incentive Plan.	S-1/A	333-252136	10.5	2/1/2021	
10.6+	Forms of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the 2021 Equity Incentive Plan.	S-1/A	333-252136	10.6	2/1/2021	
10.7+	2021 Employee Stock Purchase Plan,	S-1/A	333-252136	10.7	2/1/2021	

Exhibit Number	Description of Exhibit	Form	File No.	Exhibit	Filing Date	Filed Herewith
10.8	Form of Indemnification Agreement, by and between the Registrant and each of its directors and executive officers.	S-1	333-252136	10.8	1/15/2021	
10.9	Form of Warrant to Purchase Common Stock.	S-1	333-252136	10.9	1/15/2021	
10.10+	Offer of Employment by and between the Registrant and Randall C. Schatzman, dated June 10, 2019.	S-1	333-252136	10.10	1/15/2021	
10.11+	Offer Letter by and between the Registrant and William Quinn, dated April 14, 2020.	S-1	333-252136	10.11	1/15/2021	
10.12+	Offer Letter by and between the Registrant and David Dornan, dated November 29, 2017.	S-1	333-252136	10.12	1/15/2021	
10.13+	Offer Letter by and between the Registrant and Edith Perez, dated March 16, 2020.	S-1	333-252136	10.13	1/15/2021	
10.14+	Offer Letter by and between the Registrant and Grant Yonehiro, dated October 26, 2016.	S-1	333-252136	10.14	1/15/2021	
10.15+	Severance Agreement by and between the Registrant and Grant Yonehiro, dated January 26, 2017.	S-1	333-252136	10.15	1/15/2021	
10.16	Lease Agreement by and between the Registrant and Metropolitan Life Insurance Company, dated August 31, 2017.	S-1	333-252136	10.16	1/15/2021	
10.17	Sublease Agreement by and between the Registrant and Armo Biosciences, Inc., dated April 18, 2019.	S-1	333-252136	10.17	1/15/2021	
10.18	Consent to Sublease Agreement by and between the Registrant, Armo Biosciences, Inc. and HCP LS Redwood City, LLC, dated June 14, 2019.	S-1	333-252136	10.18	1/15/2021	
10.19	Britannia Seaport Centre Lease by and between the Registrant and HCP LS Redwood City, LLC, dated August 7, 2020	S-1	333-252136	10.19	1/15/2021	
10.20	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, 2016, 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.	S-1	333-252136	10.20	1/15/2021	

Exhibit Number	Description of Exhibit	Form	File No.	Exhibit	Filing Date	Filed Herewith
10.21	Exclusive Agreement by and between the Registrant and The Board of Trustees of the Leland Stanford Junior University, dated June 1, 2018.	S-1	333-252136	10.21	1/15/2021	
10.22	Supply Agreement by and between the Registrant and EirGenix, Inc., dated March 10, 2019.	S-1	333-252136	10.22	1/15/2021	
10.23	Master Services Agreement by and between the Registrant and Piramal Healthcare UK Ltd, dated June 26, 2018	S-1	333-252136	10.23	1/15/2021	
10.24+	Severance and Change in Control Plan.	S-1	333-252136	10.24	1/15/2021	
23.1	Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm.					X
24.1	Power of Attorney (see signature page to this Annual Report on Form 10-K).					X
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1†	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2†	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X

+ Indicates a management contract or compensatory plan, contract or arrangement.

† The certifications attached as Exhibit 32.1 and Exhibit 32.2 that accompany this Annual Report on Form 10-K, are deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Bolt Biotherapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 31, 2021

BOLT BIOTHERAPEUTICS, INC.

By: /s/ Randall C. Schatzman, Ph.D.
Randall C. Schatzman, Ph.D.
Chief Executive Officer

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 of them, as his or her true and lawful attorneys-in-fact and agents, each with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this report, 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 might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or either of them, or their or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Randall C. Schatzman, Ph.D. Randall C. Schatzman, Ph.D.	Chief Executive Officer and Director *(Principal Executive Officer)*	March 31, 2021
/s/ William P. Quinn William P. Quinn	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 31, 2021
/s/ Peter Moldt, Ph.D. Peter Moldt, Ph.D.	Chairman of the Board of Directors	March 31, 2021
/s/ Edgar G. Engleman, M.D. Edgar G. Engleman, M.D.	Director	March 31, 2021
/s/ James I. Healy, M.D. James I. Healy, M.D.	Director	March 31, 2021
/s/ Ashish Khanna, Ph.D. Ashish Khanna, Ph.D.	Director	March 31, 2021
/s/ Kathleen LaPorte Kathleen LaPorte	Director	March 31, 2021

Signature	Title	Date
/s/ Richard A. Miller, M.D. Richard A. Miller, M.D.	Director	March 31, 2021
/s/ Mahendra G. Shah, Ph.D. Mahendra G. Shah, Ph.D.	Director	March 31, 2021

BOLT BIOTHERAPEUTICS, INC.
INDEX TO FINANCIAL STATEMENTS

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, 2020 and 2019, and the related statements of operations and comprehensive loss, of convertible preferred stock and stockholders' equity (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, 2020 and 2019, 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.

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. 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
March 31, 2021

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, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 5,542	$ 34,826
Short-term investments	17,296	—
Prepaid and other current assets	2,523	1,074
Total current assets	25,361	35,900
Property and equipment, net	4,083	1,387
Operating lease right-of-use asset	12,267	10,079
Finance lease right-of-use asset	34	51
Restricted cash	1,565	584
Deferred offering costs	2,357	—
Other assets	875	446
Total assets	$ 46,542	$ 48,447
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 1,598	$ 2,095
Accrued expenses and other current liabilities	6,663	2,866
Deferred revenue	1,502	599
Operating lease liabilities	1,501	3,096
Total current liabilities	11,264	8,656
Operating lease liabilities, net of current portion	9,376	7,089
Deferred revenue	—	972
Convertible preferred stock purchase right liability, non-current	25,224	—
Other long-term liabilities	329	71
Total liabilities	46,193	16,788
Commitments and contingencies (Note 7)		
Convertible preferred stock, $0.00001 par value, authorized shares—20,843,367 shares and 11,934,449 shares authorized at December 31, 2020 and 2019, respectively; 15,232,275 shares and 10,070,102 shares issued and outstanding at December 31, 2020 and 2019, respectively; liquidation preference of $121,728 and $80,172 at December 31, 2020 and 2019, respectively	105,296	77,505
Stockholders' equity (deficit)		
Common stock, $0.00001 par value; 198,000,000 shares and 126,000,000 shares authorized at December 31, 2020 and 2019; respectively; 2,130,139 and 1,921,642 shares issued and outstanding at December 31, 2020 and 2019, respectively	—	—
Additional paid-in capital	3,452	1,825
Accumulated deficit	(108,399)	(47,671)
Total stockholders' equity (deficit)	(104,947)	(45,846)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 46,542	$ 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,	
	2020	2019
Collaboration revenue	$ 231	$ 215
Operating expenses:		
Research and development	40,357	26,002
General and administrative	9,056	5,182
Total operating expenses	49,413	31,184
Loss from operations	(49,182)	(30,969)
Other income (expense), net:		
Interest income	199	524
Change in fair value of convertible preferred stock purchase right liability	(11,745)	(42)
Total other income (expense), net	(11,546)	482
Net loss and comprehensive loss	$ (60,728)	$ (30,487)
Net loss per share, basic and diluted	$ (28.89)	$ (15.29)
Weighted-average shares outstanding, basic and diluted	2,102,328	1,993,477

See accompanying notes to the financial statements.

BOLT BIOTHERAPEUTICS, INC.
STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balance at December 31, 2018	4,368,156	$ 28,367	1,911,349	$ —	$ 1,241	$ (17,184)	$ (15,943)
Issuance of Series T convertible preferred stock for cash, net of issuance costs of $2	717,514	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	4,984,432	40,629	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	10,293	—	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	10,070,102	77,505	1,921,642	—	1,825	(47,671)	(45,846)
Issuance of Series C-1 convertible preferred stock, net of issuance costs of $285 and convertible preferred stock purchase right liability of $13,479	5,162,173	27,791	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	119,077	—	158	—	158
Issuance of common stock upon exercise of warrants	—	—	89,420	—	6	—	6
Vesting of early exercise options and restricted stock awards	—	—	—	—	43	—	43
Stock-based compensation	—	—	—	—	1,420	—	1,420
Net loss	—	—	—	—	—	(60,728)	(60,728)
Balance at December 31, 2020	15,232,275	$105,296	2,130,139	$ —	$ 3,452	$ (108,399)	$ (104,947)

See accompanying notes to the financial statements.

BOLT BIOTHERAPEUTICS, INC.
STATEMENTS OF CASH FLOWS
(in thousands)

	Years Ended December 31, 2020	2019
Cash flows from operating activities		
Net loss	$ (60,728)	$ (30,487)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	611	335
Stock-based compensation	1,420	508
Accretion of premium/discount on short-term investments	34	—
Change in fair value of convertible preferred stock purchase right liabilities	11,745	42
Non-cash lease expense	1,893	994
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(1,878)	(620)
Accounts payable and accrued expenses	2,882	2,121
Operating lease liabilities	(3,389)	(823)
Deferred revenue	(69)	1,571
Other long-term liabilities	171	16
Net cash used in operating activities	(47,308)	(26,343)
Cash flows from investing activities		
Purchase of property and equipment	(3,262)	(508)
Purchases of short-term investments	(33,229)	—
Maturities of short-term investments	15,899	—
Net cash used in investing activities	(20,592)	(508)
Cash flows from financing activities		
Repayments of financing lease obligations	—	(40)
Proceeds from issuance of convertible preferred stock, purchase rights and warrants, net of issuance costs	41,270	48,595
Payments of deferred offering costs	(1,967)	—
Proceeds from issuance of common stock and warrants	294	72
Net cash provided by financing activities	39,597	48,627
Net (decrease) increase in cash, cash equivalents and restricted cash	(28,303)	21,776
Cash, cash equivalents and restricted cash at beginning of year	35,410	13,634
Cash, cash equivalents and restricted cash at end of year	$ 7,107	$ 35,410
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 5,542	$ 34,826
Restricted cash	1,565	584
Total cash, cash equivalents and restricted cash	$ 7,107	$ 35,410
Supplemental schedule of non-cash investing and financing activities		
Issuance of convertible preferred stock upon extinguishment of convertible preferred stock purchase liabilities	$ —	$ 543
Vesting of early exercised options and restricted stock awards	$ 49	$ 21
Purchases of property and equipment included in accounts payable and accrued liabilities	$ 28	$ 161
Deferred offering costs included in accounts payable and accrued liabilities	$ 390	$ —

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").

Reverse Stock Split

On January 26, 2021, the Company amended and restated its amended and restated certificate of incorporation to effect a 1-for-7 reverse stock split of the Company's common stock and convertible preferred stock. The par value and authorized shares of the common stock were not adjusted as a result of the reverse stock split. All issued and outstanding common stock, options to purchase common stock, early exercised options and per share amounts contained in the financial statements have been retroactively adjusted to give effect to the reverse stock split for all periods presented.

Liquidity

The Company has incurred operating losses and negative cash flows from operations since its inception and had an accumulated deficit of $108.4 million as of December 31, 2020. 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 expects operating losses and negative cash flows from operations to continue for the foreseeable future. Based on the Company's current business plan, management believes that existing cash and cash equivalents, in addition to the net proceeds of $51.9 million received from the sale of 5,611,059 shares of C-2 convertible preferred stock in January 2021 and net proceeds of $241.7 million from its initial public offering (IPO) which closed in February 2021 (see Note 14) will be sufficient to fund the Company's obligations for at least 12 months after these financial statements are issued.

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.

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.

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 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, 2019. At December 31, 2020, deferred offering costs totaling $2.4 million are included as non-current assets in the accompanying balance sheet.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash, cash equivalents and short-term investments. At December 31, 2020 and 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, 2020 and 2019, cash and cash equivalents consisted primarily of bank deposits and money market funds which were unrestricted as to withdrawal or use.

Short-Term Investments

The Company classifies its short-term investments as available-for-sale and records such assets at estimated fair value in the balance sheets, with unrealized gains and losses that are determined to be temporary, if any,

reported as a component of other comprehensive income (loss) within the statements of operations and comprehensive loss and as a separate component of stockholders' equity. Investments are regularly reviewed for other-than-temporary declines in fair value. The review includes the consideration of the cause of the impairment, including the creditworthiness of the security issuers, the number of investments in an unrealized loss position, the severity and duration of the unrealized losses, and whether it is more likely than not that the Company will be required to sell the investments before the recovery of their amortized cost basis. A decline in the fair value of any security below cost that is deemed other than temporary results in a charge to earnings and the establishment of a new cost basis for the security. The Company classifies short-term investments with remaining maturities greater than one year, if any, as current assets because such marketable securities are available to fund the Company's current operations. The Company invests its excess cash balances primarily in corporate debt securities with strong credit ratings. Realized gains and losses are calculated on the specific identification method and recorded as interest income and were immaterial for all periods presented.

Restricted Cash

As of December 31, 2020 and 2019, the Company had $1.6 million and $0.6 million, respectively, of long-term restricted cash deposited with a financial institution. The restricted cash is held in separate bank accounts to support letter of credit agreements related to the Company's facility leases which expire in 2025 and 2031 (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 B and Series C-2 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 B convertible preferred stock in July 2018 and Series C-1 convertible preferred stock in June 2020. The liabilities are subject to remeasurement at each balance sheet date, with changes in fair value recognized in other income (expense), net in the statement of operations and comprehensive loss. Upon the closing of the convertible preferred stock, the associated liabilities are extinguished and the marked-to-market fair value of the liability is included in the carrying value of the convertible preferred stock issued. In January 2021, the Company issued the additional shares of Series C-2 convertible preferred stock and accordingly, this contractual obligation was settled and the preferred stock purchase right liability was remeasured to fair value and reclassified to permanent equity (see Note 14).

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. In February 2021, in connection with the Company's IPO, all outstanding shares of convertible preferred stock were converted into shares of the Company's common stock (see Note 14).

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

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. For stock-based payments with service conditions only, 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. For stock-based payments with both performance and service conditions, the Company recognizes expense based on the fair value of the Performance Awards over the estimated service period (under the graded vesting method) to the extent the achievement of the related performance criteria is estimated to be probable. 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.

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 is calculated by dividing the net loss 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 is computed by dividing the net loss 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 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 all periods presented as potentially dilutive securities were anti-dilutive.

Comprehensive Loss

Comprehensive loss includes all changes in equity (net assets) during a period from non-owner sources, including unrealized gains and losses on short-term investments. During the year ended December 31, 2020, the items qualifying as other comprehensive loss was immaterial, and, therefore, the Company's comprehensive loss was the same as its reported net loss for these periods. During the year ended December 31, 2019, there were no items qualifying as other comprehensive loss and, therefore, the Company's comprehensive loss was the same as its reported net loss for these periods.

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 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 adopted the standard on January 1, 2020 and the adoption did not have a material impact on the financial statements and related disclosures.

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes, which is intended to simplify various aspects related to accounting for income taxes. The pronouncement is effective for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2021. ASU 2019-12 is effective for the Company beginning January 1, 2022. Early adoption is permitted. The Company has early adopted the standard during the year ended December 31, 2020 and the adoption did not have a material impact on the financial statements and related disclosures.

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.

During the year ended December 31, 2020, financial assets measured on a recurring basis consist of cash invested in money market accounts and short-term investments. The fair value of short-term investments is based upon market prices quoted on the last day of the fiscal period or other observable market inputs. The Company obtains pricing information from its investment manager and generally determines the fair value of investment securities using standard observable inputs, including reported trades, broker/dealer quotes, bids and/or offers.

Financial liabilities measured at fair value on a recurring basis include the convertible preferred stock purchase rights liabilities described below.

During the year ended December 31, 2019, the Company's financial instruments consist of Level 1 assets and Level 3 liabilities. Level 1 assets that are measured at fair value on a recurring basis consist of cash invested in money market accounts totaling $34.4 million at December 31, 2019.

There were no transfers within the hierarchy during the years ended December 31, 2020 and 2019.

Short-term investments, all of which are classified as available-for-sale securities, consisted of the following at December 31, 2020 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Asset backed securities	$ 2,639	$ —	$ —	$ 2,639
U.S treasury securities	1,300	—	—	1,300
Commercial paper	6,795	—	—	6,795
Corporate debt securities	6,562	1	(1)	6,562
	$ 17,296	$ 1	$ (1)	$ 17,296

All short-term investments held at December 31, 2020 had maturity dates of less than 12 months.

At December 31, 2020, the fair values of the Company's assets and liabilities, which are measured at fair value on a recurring basis, were determined using the following inputs (in thousands):

	Fair Value Measurements at Reporting Date Using			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds, included in cash and cash equivalents and restricted cash	$ 3,921	$ 3,921	$ —	$ —
U.S. treasury securities, included in short-term investments	1,300	1,300	—	—
Asset backed securities, included in short-term investments	2,640	—	2,640	—
Commercial paper, included in short-term investments	6,795	—	6,795	—
Corporate debt securities, included in short-term investments	6,561	—	6,561	$ —
Total	$21,217	$ 5,221	$ 15,996	$ —
Liabilities:				
Preferred stock purchase rights liability	$25,224	$ —	$ —	$ 25,224

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 B Convertible Preferred Stock Purchase Right Liability	Series C Convertible Preferred Stock Purchase Right Liability	Total Convertible Preferred Stock Purchase Right Liabilities
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	—	—	—
Fair value of purchase right liability recognized in connection with the issuance of Series C convertible preferred stock	—	13,479	13,479
Change in fair value	—	11,745	11,745
Balance at December 31, 2020	$ —	$ 25,224	$ 25,224

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 B convertible preferred stock was 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. The estimated probability and timing related to the second closing of Series C convertible preferred stock was 35% and 0.68 years at the June 26, 2020 issuance date. At December 31, 2020, the fair value of the convertible preferred stock purchase right liability increased to $25.2 million as a result of the estimated probability of the occurrence of the second closing of Series C convertible preferred stock increasing to 70%, timing related to the occurrence of the second closing decreasing to 0.10 years and the increase in the future expected value of the Series C preferred shares to $2.25 per share. In January 2021, the Company issued the additional shares of Series C-2 convertible preferred stock and accordingly, this contractual obligation was settled and the preferred stock purchase right liability was remeasured to fair value and reclassified to permanent equity (see Note 14).

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, 2020 and 2019, the Company paid Stanford $50,000 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, 2020 and 2019, respectively, for reimbursement of patent maintenance costs which is included as part of general and administration expense.

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,	
	2020	2019
Laboratory equipment	$ 5,253	$2,004
Office equipment	69	28
	5,322	2,032
Less accumulated depreciation and amortization	(1,239)	(645)
Total	$ 4,083	$1,387

Depreciation expense related to property and equipment was $0.6 million and $0.3 million for the years ended December 31, 2020 and 2019, respectively.

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following (in thousands):

	December 31,	
	2020	2019
Accrued research and development	$3,199	$1,031
Accrued compensation	2,885	1,452
Accrued other	579	383
Total	$6,663	$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 717,514 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 (in thousands).

Balance at December 31, 2018	$ —
Addition—upfront payment	1,489
Addition—variable consideration	297
Revenue recognized	(215)
Balance at December 31, 2019	1,571
Addition—variable consideration	162
Revenue recognized	(231)
Balance at December 31, 2020	$1,502

As of December 31, 2020 and 2019, amounts receivable under the Toray Development Agreement totaled $12,000 and $0.3 million, respectively, and were recorded in Prepaid expenses and other current assets on the balance sheet.

7. Commitments and Contingencies

Leases

2017 and 2019 Leases

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 (the "2017 Lease"). At December 31, 2020, minimum rental commitments under this lease are approximately $0.5 million for each of the years ended December 31, 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 (the "2019 Lease"). At December 31, 2020, minimum rental commitments under this lease are approximately $1.4 million, $1.5 million, $1.6 million, $1.6 million and $1.0 million during the years ended December 31, 2021, 2022, 2023, 2024, and thereafter, respectively. The Company accounted for the lease as an operating lease.

2020 Lease

On August 7, 2020, the Company executed a non-cancellable lease agreement for 71,646 square feet of space in Redwood City, California (the "Chesapeake Master Lease"). The Chesapeake Master Lease consists of 45,690 square feet of additional office, laboratory and vivarium space and includes an extension of the 25,956 square feet under the 2019 Lease. The Chesapeake Master Lease has an initial term of ten years, following the Commencement Date with an option to extend the lease for an eight-year term. The Chesapeake Master Lease contains rent escalation and the Company is also responsible for certain operating expenses and taxes throughout the lease term. In addition, the Company is entitled to up to $4.8 million of tenant improvement allowance, which the Company has not received as of December 31, 2020.

Upon execution of the non-cancellable lease agreement, the Company took control of 10,000 square feet of space. The Company expects the remaining 35,690 square feet of additional office, laboratory, and vivarium space to commence in the second quarter of 2021 and the extension of the 25,956 square feet under the 2019 Lease to commence in 2025.

As of December 31, 2020, the operating lease right-of-use assets and operating lease liabilities were $3.6 million and $3.8 million, respectively, which represents the portion of the Chesapeake Master Lease that was controlled by the Company. As the Company had not taken control of the remaining space and the lease term had not yet commenced, no operating lease right-of-use assets or operating lease liabilities for the remaining space has been recorded.

In connection with the execution of the Chesapeake Master Lease, the Company entered into two operating lease agreements to sublease portions of the premises to two unrelated third parties. The first sublease agreement is to sublease 10,000 square feet which commenced on August 7, 2020 and expires on July 31, 2022. Rent is subject to scheduled annual increases and the subtenant (“Subtenant A”) is responsible for certain operating expenses and taxes throughout the term under the first sublease agreement. Subtenant A has no option to extend the sublease term. Sublease income under the first sublease agreement for the year ended December 31, 2020, was approximately $0.2 million.

The second sublease agreement is to sublease 10,500 square feet, is expected to commence in the second quarter of 2021 and will expire 36 months thereafter. Rent is subject to scheduled annual increases and the subtenant (“Subtenant B”) is responsible for certain operating expenses and taxes throughout the term under the second sublease agreement. Subtenant B has no option to extend the sublease term. No sublease income under the second sublease agreement was recognized for the year ended December 31, 2020 as the lease term had not yet commenced.

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, 2020. 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, 2020 and 2019. Cash required as security for the 2020 Lease is secured by a letter of credit on behalf of the lessor in the amount of approximately $1.0 million and is recorded as restricted cash on the balance sheet as of December 31, 2020.

At December 31, 2020 and 2019, finance right-of-use leases are used to finance capital equipment such as printers or ozone generators.

The weighted-average remaining lease term and discount rate related to the Company’s lease liabilities as of December 31, 2020 were 6.3 years and 9.5%, respectively, for the operating leases. 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.

The components of lease expense were as follows (in thousands):

	Years Ended December 31,	
	2020	2019
Total operating lease cost	$2,508	$1,367
Finance lease cost:		
Amortization of right-of-use assets	$ 17	$ 17
Interest on lease liabilities	—	1
Total finance lease cost	$ 17	$ 18

Supplemental cash flow information related to leases was as follows (in thousands):

	Years Ended December 31,	
	2020	2019
Operating cash flows from operating leases	$4,144	$1,196
Operating cash flows from finance leases	$ —	$ 1
Financing cash flows from finance leases	$ —	$ 40

The following is a schedule by year for future maturities of the Company's operating lease liabilities and sublease income to be received as of December 31, 2020 (in thousands):

	Operating Lease	Sublease income
2021	$ 2,299	$ 459
2022	2,701	362
2023	2,239	—
2024	2,317	—
2025	1,685	—
Thereafter	4,254	—
Total minimum lease payments/sublease income	15,495	$ 821
Less: imputed interest	(4,618)	
Total future minimum lease payments	10,877	
Less: current obligations under leases	(1,501)	
Noncurrent lease obligations	$ 9,376	

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, 2020, 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, 2020, 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 11,934,450, which included the designation of 717,514 shares of Series T convertible preferred stock with a par value of $0.00001.

In June 2020, the Company amended its certificate of incorporation to increase the number of authorized shares of convertible preferred stock to a total of 20,843,367 shares. Further, the amendment decreased the number of authorized shares of Series B convertible preferred stock to 6,645,916 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 5,162,180 and 5,611,065, respectively.

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 1,661,474 shares of Series B convertible preferred stock at $8.0458 per share and 249,218 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 issued 4,984,432 shares of Series B convertible preferred stock at $8.0458 per share for proceeds of $40.1 million, net of issuance costs, $17.7 million of which was received in June 2019. 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.

Issuance of Series C-1 Convertible Preferred Stock

In June 2020, the Company entered into a preferred stock purchase agreement (the "Series C Agreement") with existing and new investors to raise up to $93.5 million in two separate tranches. The first tranche closed in June 2020 and the Company raised $41.3 million, net of issuance costs of $0.2 million, and issued 5,162,173 shares of Series C-1 convertible preferred stock at $8.05 per share. In addition, the investors agreed to buy and the Company agreed to sell up to 5,611,065 shares of Series C-2 convertible preferred stock at a price per share of $9.2575, for potential additional gross proceeds of $51.9 million, upon the achievement of certain milestones as defined in the agreement. In the event that an investor that participated in the June 2020 Series C Closing fails to purchase all of their required shares in the subsequent Series C-2 closing, each of the Series C-1 convertible preferred shares held by such purchaser shall automatically convert into one share of common stock.

The commitment made by the investors to invest in the second tranche of the Series C Agreement is considered a separate freestanding financial instrument and was recorded as a Convertible Preferred Stock Purchase Right Liability in the amount of $13.5 million upon the issuance of the first tranche of the Series C-1 convertible preferred stock in June 2020. The commitment was accounted for at fair value during the period it was outstanding with changes in fair value recorded as other income (expense) in the statement of operations and comprehensive loss. Since issuance and as of December 31, 2020, changes in fair value of this liability totaling $11.7 million have been recorded in other income (expense) in the statement of operations and comprehensive loss. In January 2021, the Company issued the additional shares of Series C-2 convertible preferred stock and accordingly, this contractual obligation was settled and the preferred stock purchase right liability was remeasured to fair value and reclassified to permanent equity (see Note 14).

As of December 31, 2020, convertible preferred stock consisted of (in thousands, except share and per share numbers):

	Shared Authorized	Shares Issued and Outstanding	Per Share Original Issuance Price	Liquidation Preference	Carrying Value
Series Seed	270,416	270,411	$ 2.5886	$ 700	$ 685
Series A-1	2,436,276	2,436,271	6,5674	16,000	15,807
Series B	6,645,916	6,645,906	8.0458	53,472	52,504
Series C-1	5,162,180	5,162,173	8.0500	41,556	27,791
Series C-2	5,611,065	—	9.2575	—	—
Series T	717,514	717,514	13.9370	10,000	8,509
Total	20,843,367	15,232,275		$ 121,728	$ 105,296

As of December 31, 2019, convertible preferred stock consisted of (in thousands, except share and per share numbers):

	Shared Authorized	Shares Issued and Outstanding	Per Share Original Issuance Price	Liquidation Preference	Carrying Value
Series Seed	270,416	270,411	$ 2.5886	$ 700	$ 685
Series A-1	2,436,276	2,436,271	6,5674	16,000	15,807
Series B	8,510,243	6,645,906	8.0458	53,472	52,504
Series T	717,514	717,514	13.9370	10,000	8,509
Total	11,934,449	10,070,102		$ 80,172	$ 77,505

The rights, preferences and privileges of the convertible preferred stock 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 $8.05, $9.2575, $1.11496, $0.64365, $0.52539, and $0.20706 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 C-1 convertible preferred stock, Series C-2 convertible preferred stock, 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, 2020.

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 1.25 times the original issue price of the Series C-1 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 $75,000,000 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 a majority of the outstanding shares of the Series C-1 and C-2 convertible preferred stock.

Liquidation

In the event of a Deemed Liquidation Event, as defined below, each holder of Series C-1 convertible preferred stock and Series C-2 convertible preferred stock is entitled to receive, on a pari passu basis, prior and in preference to any distributions to the holders of Series T convertible preferred stock, Series B convertible preferred stock, 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 C-1 convertible preferred stock and/or Series C-2 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 C-1 convertible preferred stock and Series C-2 convertible preferred stock, 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 C-1 convertible preferred stock, Series C-2 convertible preferred stock, 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

In March 2019 and June 2020, the Company amended and restated its certificate of incorporation to increase the authorized number of shares of common stock to 126,000,000 and 198,000,000, respectively.

Common Stock Warrants

In July 2018, the Company issued 249,218 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. The warrants expire on July 26, 2028 and are exercisable at the option of the warrant holder for $0.07 per share. As of December 31, 2020 and 2019, 82,895 and 172,315 warrants, respectively, were outstanding.

Common Stock

In 2016, 157,130 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 157,130 common shares issued, 53,571 shares were vested upon grant, 28,571 shares vested upon the achievement of a milestone, which was achieved in 2019, and 74,988 shares vested ratably over 48 months.

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. As of December 31, 2020 and December 31, 2019, the unvested shares are zero and 16,664, respectively.

Common Stock Reserved for Future Issuance

The following shares of common stock were reserved for future issuance:

	December 31,	
	2020	2019
Convertible preferred stock	15,232,275	10,070,102
Conversion of convertible preferred stock issuable in future closings	5,611,065	—
Common stock options issued and outstanding	3,800,402	2,015,544
Common stock available for future issuance under the 2015 Plan	147,852	890,546
Warrants to purchase common stock	82,895	172,315
Total	24,874,489	13,148,507

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 2019, the 2015 Plan was amended to increase the shares of common stock available for issuance under the 2015 Plan by 1,503,387 shares to a total of 3,126,421 shares. In June 2020, concurrent with the close of the Series C-1 convertible preferred stock financing, the 2015 Plan was amended to increase the number of shares of common stock available for issuance by 516,113 shares to a total of 3,642,534 shares. On September 3, 2020, the 2015 Plan was amended to increase the number of shares of common stock available for issuance by 645,143 shares to a total of 4,287,677 shares. At December 31, 2020 and 2019, 147,852 shares and 890,546 shares respectively, remained available for future issuance.

Performance and Service Based Stock Options

In September 2020, the compensation committee of the Company's board of directors granted 526,018 options to employees that will commence vesting upon the achievement of a certain financing milestone and, once achieved, generally vest monthly over 48 months (the "Performance Awards"). The Company recognizes expense based on the fair value of the Performance Awards over the estimated service period (under the graded vesting method) to the extent the achievement of the related performance criteria is estimated to be probable. The Company determined that the achievement of the financing milestone is probable as of December 31, 2020 and stock-based compensation expense for the year ended December 31, 2020 related to the Performance Awards was recognized approximately $0.1 million. The weighted-average grant date fair value of the Performance Awards was $3.24 per share.

Stock option activity under the 2015 Plan is as follows:

	Options Outstanding	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, 2018	287,573	$ 2.06			$ 51
Granted	1,753,477	$ 2.65		$ 1.64	
Exercised	(10,293)	$ 2.21			
Canceled/forfeited	(15,213)	$ 2.15			
Outstanding at December 31, 2019	2,015,544	$ 2.57	9.3		$ 319
Granted	1,941,024	$ 3.71		$ 2.76	
Exercised	(119,092)	$ 2.47			
Cancelled / Forfeited	(37,074)	$ 2.43			
Outstanding at December 31, 2020	3,800,402	$ 3.16	9.1		$ 4,721
Exercisable at December 31, 2020	1,634,553	$ 2.83	8.5		$ 2,585
Vested or expected to vest at December 31, 2020	3,800,402	$ 3.16	9.1		$ 4,721

The intrinsic value of options exercised was $0.2 million during the year ended December 31, 2020 and was immaterial during the year ended December 31, 2019. The fair value of options vested was $1.1 million and $0.4 million during the years ended December 31, 2020 and December 31, 2019, respectively. As of December 31, 2020, there was approximately $7.2 million of unrecognized stock-based compensation related to unvested stock options, which the Company expects to recognize over a weighted-average period of 3.2 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:

	Years Ended December 31,	
	2020	2019
Expected volatility	90-97%	68-70%
Risk-free interest rate	0.3-0.5%	1.4-2.6%
Expected option life (in years)	5.0-6.3	5.5-6.1
Expected dividend yield	0.0%	0.0%
Fair value per share of common stock	$2.80-$4.41	$2.24-$2.73

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.

Fair Value of Common Stock—Prior to our IPO in February 2021, the fair value of the Company's common stock was determined by the Company's board of directors with assistance from management and

an independent third-party valuation firm using an approach 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 required significant judgment and management considered 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.

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,	
	2020	2019
Research and development	$ 734	$295
General and administrative	686	213
Total stock-based compensation expense	$1,420	$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, 2020 and 2019, there were 47,180 and 16,215, respectively, of unvested shares representing an early exercise liability of approximately $0.1 million 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:

	Years Ended December 31,	
	2020	2019
Unvested at beginning of year	16,215	17,613
Early exercised during the year	48,412	6,780
Vested	(17,447)	(8,178)
Unvested at end of year	47,180	16,215

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):

	Years Ended December 31,	
	2020	2019
Numerator:		
Net loss	$ (60,728)	$ (30,487)
Denominator:		
Weighted-average common shares outstanding	1,989,208	1,919,696
Warrants to purchase common stock	147,550	172,318
Common stock outstanding subject to repurchase related to unvested early exercised stock options and restricted stock awards	(34,430)	(98,537)
	2,102,328	1,993,477
Net loss per share attributable to common stockholders, basic and diluted	$ (28.89)	$ (15.29)

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,	
	2020	2019
Convertible preferred stock	15,232,275	10,070,102
Common stock options issued and outstanding	3,800,402	2,015,544
Common stock outstanding subject to repurchase related to unvested early exercised stock options and restricted stock awards	47,180	32,879
Total	19,079,857	12,118,525

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, 2020.

13. Income Taxes

The Company recorded a current state tax provision of zero and approximately $2,000 related to state minimum taxes for the years ended December 31, 2020 and 2019, respectively, 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,	
	2020	2019
Income tax expense (benefit) at statutory rates	$(12,753)	$(6,402)
State income tax, net of federal benefit	—	1
Permanent items	11	19
Valuation allowance	11,002	7,437
Stock-based compensation	192	72
Research and development tax credits	(918)	(1,134)
Preferred tranche liability fair value adjustment	2,466	9
Provision for income taxes	$ —	$ 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 summarized as follows (in thousands):

	December 31,	
	2020	2019
Deferred tax assets:		
Net operating loss carryforward	$ 23,901	$ 13,801
Research tax credits	3,840	2,227
Intangible assets	210	230
Reserves and accruals	588	98
Stock-based compensation	190	57
Lease liability	3,240	3,039
Total deferred tax assets	31,969	19,452
Less valuation allowance	(28,050)	(16,330)
Net deferred tax assets	3,919	3,122
Deferred tax liabilities:		
Right-of-use assets	(3,654)	(3,008)
Property and equipment	(198)	(107)
Prepaid assets	(67)	(7)
Total deferred tax assets	(3,919)	(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, 2020 and 2019 due to historical losses and uncertainty surrounding the use of such assets. The valuation allowance increased by $11.7 million between December 31, 2020 and December 31, 2019 and by $10.8 million between December 31, 2019 and December 31, 2018 due primarily to the generation of operating losses.

As of December 31, 2020, the Company has net operating loss carryforwards for federal and state income tax purposes of $94.2 million and $46.5 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 $89.8 million are not subject to expiration.

The Company has research credit carryforwards for federal and state income tax purposes of approximately $2.7 million and $2.3 million, respectively, as of December 31, 2020. 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):

	Years Ended December 31,	
	2020	2019
Balance at beginning of period	$ 605	$227
Increase related to current year positions	520	378
Balance at end of the year	$1,125	$605

During the years ended December 31, 2020 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.

On March 27, 2020, the Coronavirus Aid, Relief and Economic Security ("CARES Act") was signed into law. Among other things, the CARES Act permits NOL carryovers and carrybacks to offset 100% of taxable income for taxable years beginning before 2021. In addition, the CARES Act allows NOLs incurred in 2018, 2019, and 2020 to be carried back to each of the five preceding taxable years to generate a refund of previously paid income taxes. The CARES Act also contains modifications on the limitation of business interest for tax years beginning in 2019 and 2020. The modifications to Section 163(j) increase the allowable business interest deduction from 30% of adjusted taxable income to 50% of adjusted taxable income. The CARES Act did not have a significant impact to the Company for any years.

On June 29, 2020, California Governor Newsom signed to law the state's budget package which included Assembly Bill 85 (AB 85). AB 85 contained two major tax changes: (1) it suspends the usage of net operating losses (NOLs) for certain taxpayers; and (2) it limits certain business tax credits for tax years 2020, 2021, and 2022. The Company is in a taxable loss position in 2020 and thus the bill has no impact on the 2020 provision. The Company will continue monitor the impact of AB 85, if any, on future periods.

14. Subsequent Events

Series C-2 Preferred Stock Financing

In January 2021, the Company sold 5,611,059 shares of its Series C-2 preferred stock for net proceeds of $51.9 million.

Initial Public Offering and Related Transactions

In February 2021, the Company completed its IPO of 13,225,000 shares of its common stock, including the full exercise of the underwriters' option to purchase 1,725,000 shares, at a price per share of $20.00. Proceeds from the IPO, net of underwriting discounts, commissions and offering costs of approximately $22.8 million, were approximately $241.7 million.

In addition, each of the following occurred on February 4, 2021 in connection with the completion of the Company's IPO:

- the conversion of all outstanding shares of convertible preferred stock into 20,843,334 shares of the Company's common stock; and
- the amendment and restatement of the Company's certificate of incorporation, authorizing 200,000,000 shares of common stock and 10,000,000 shares of undesignated preferred stock.

Approval of 2021 Equity Incentive Plan and 2021 Employee Stock Purchase Plan

In January 2021, the Company's board of directors adopted the 2021 Equity Incentive Plan, or the 2021 Plan, and the Company's stockholders approved the 2021 Plan. The 2021 Plan authorize issuance of up to 8,074,373 shares of common stock and it became effective upon the execution of the underwriting agreement for the Company's initial public offering.

In addition, in January 2021, the Company's board of directors and stockholders adopted the 2021 Employee Stock Purchase Plan, or the ESPP. The ESPP authorize issuance of up to 840,000 shares of common stock and it became effective upon the execution of the underwriting agreement for the Company's initial public offering.

Issuance of New Option Awards

In January 2021, the Company's compensation committee of the board of directors approved option grants to employees under the 2015 Plan. These options vest over four years and total 92,141 shares with an exercise price of $4.41 per share.

In January 2021, the Company's compensation committee of the board of directors approved option grants to employees under the 2021 Plan. These options became effective upon the execution of the underwriting agreement for the Company's initial public offering. These options vest over four years and total 1,253,950 shares of common stock with an exercise price equal to the Company's initial public offering price.

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following is a description of the common stock, $0.00001 par value per share ("Common Stock") of Bolt Biotherapeutics, Inc. (the "Company," "we," "our," or "us"), which is the only security of the Company registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended. The following summary description is based on the provisions of our Amended and Restated Certificate of Incorporation (the "Certificate of Incorporation"), our Amended and Restated Bylaws, (the "Bylaws"), and the applicable provisions of the Delaware General Corporation Law (the "DGCL"). This information may not be complete in all respects and is qualified entirely by reference to the provisions of our Certificate of Incorporation and our Bylaws. Our Certificate of Incorporation and our Bylaws are filed as exhibits to our Annual Report on Form 10-K of which this exhibit is a part.

Authorized Capital Shares

Our authorized capital stock consists of 200,000,000 shares of common stock, $0.00001 par value per share, and 10,000,000 shares of preferred stock, par value $0.00001 per share. In addition, under our Certificate of Incorporation, our board of directors may, without further action by our stockholders, fix the rights, preferences, privileges and restrictions of up to an aggregate of 10,000,000 shares of preferred stock in one or more series and authorize their issuance. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences 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. As of December 31, 2020, we have no shares of preferred stock issued and outstanding. We have no present plans to issue any shares of preferred stock. For a complete description of the terms and provisions of the Company's preferred stock refer to our Certificate of Incorporation and Bylaws.

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 Certificate of Incorporation, our stockholders do 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. These provisions in our Certificate of Incorporation could discourage potential takeover attempts. See "Certificate of Incorporation and Bylaws" below.

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.

Anti-Takeover Provisions

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the DGCL, 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 Certificate of Incorporation or 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

Among other things, our Certificate of Incorporation and Bylaws:

- permit our board of directors to issue up to 10,000,000 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 is 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 requires 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 makes 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 Certificate of Incorporation provides 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 Certificate of Incorporation or our 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 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. These provisions do 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.

Corporate Opportunity Doctrine

The DGCL permits corporations to adopt provisions renouncing any interest or expectancy in certain opportunities that are presented to the corporation or its officers, directors or stockholders. Our Certificate of Incorporation, to the extent permitted by the DGCL, renounces any interest or expectancy that we have in, or right to be offered an opportunity to participate in, specified business opportunities that are from time to time presented to a member of our board of directors who is not our employee, or any partner, member, director, stockholder, employee or agent of such member, other than one of our employees. Notwithstanding the foregoing, our Certificate of Incorporation does not renounce our interest in any business opportunity that is expressly offered to a director solely in their capacity as a director.

Exchange Listing

Our common stock is listed on the Nasdaq Global Select Market under the symbol “BOLT.”

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC. The transfer agent’s address is 6201 15th Avenue, Brooklyn, New York 11219 and the telephone number is (800) 937-5449.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-252815) of Bolt Biotherapeutics, Inc. of our report dated March 31, 2021 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

San Jose, California
March 31, 2021

Exhibit 31.1

CERTIFICATIONS

I, Randall C. Schatzman, Ph.D., certify that:

1. I have reviewed this Annual Report on Form 10-K of Bolt Biotherapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2021

By: /s/ Randall C. Schatzman, Ph.D.
Randall C. Schatzman, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, William P. Quinn, certify that:

1. I have reviewed this Annual Report on Form 10-K of Bolt Biotherapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2021

By: /s/ William P. Quinn
William P. Quinn
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATIONS

In connection with the Annual Report on Form 10-K of Bolt Biotherapeutics, Inc. (the "Company") for the period ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Randall C. Schatzman, Ph.D., Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 31, 2021

By: /s/ Randall C. Schatzman, Ph.D.
Randall C. Schatzman, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Bolt Biotherapeutics, Inc. (the "Company") for the period ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, William P. Quinn, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 31, 2021

By: /s/ William P. Quinn
William P. Quinn
Chief Financial Officer
(Principal Financial Officer)