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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, 2024
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 Capital 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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the consolidated financial statements of the registrant included in the filing reflect the correction of an error to previously issued consolidated financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of common stock held by non-affiliates of the Registrant, based on the closing sales price for such stock on June 28, 2024, as reported by The Nasdaq Capital Market, was approximately $21.9 million. The calculation of the aggregate market value of voting and non-voting stock excludes certain shares of the Registrant's common stock held by current executive officers, directors and stockholders that the Registrant has concluded are affiliates of the Registrant. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the Registrant or that such person is controlled by or under common control with the Registrant.

As of March 19, 2025, the Registrant had 38,339,697 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Designated portions of the Proxy Statement relating to registrant's 2025 Annual Meeting of Stockholders, which will be filed with the Securities and Exchange Commission within 120 days after the end of fiscal year 2024, are incorporated by reference into Part III of this Annual Report.

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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:

- *our expectations regarding the success of our development and commercialization strategy and our product candidates;*
- *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;*
- *any impact of pandemics, or responses to the pandemics on our business, collaborations, clinical trials or 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 (the "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 "anticipates," "believes," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "should," "will," 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 Biotherapeutics 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.

RISK FACTOR SUMMARY

Below is a summary of material factors that make an investment in our common stock speculative or risky. Importantly, this summary does not address all the risks and uncertainties that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, can be found under "Special Note Regarding Forward-Looking Statements" and Part I, Item 1A, "Risk Factors" in this Annual Report.

- 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.
- If none of our product candidates, including those in our collaborations, obtain regulatory approval and are successfully commercialized in one or more indications, or we or our collaboration partners experience significant delays in doing so, we may never generate any product revenue or become profitable.
- Our discovery and development of product candidates based on our Boltbody™ ISAC (immune-stimulating antibody conjugate) approach, as well as the BDC-3042 program based on dectin-2 agonism, are unproven, which makes it difficult to predict the time and cost of product candidate development, and we do not know whether we will be able to develop any products of commercial value, or if competing technological approaches will limit the commercial value of our product candidates or render our platform obsolete.
- We have never commercialized a product candidate and we may lack the necessary expertise, personnel and resources to successfully commercialize on our own or together with collaborators, any of our products that receive regulatory approval.
- We do not have our own manufacturing capabilities and rely on third parties to produce clinical and commercial supplies of BDC-3042, BDC-4182 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 macroeconomic uncertainties, including pandemics, labor shortages, inflation and monetary supply shifts, and potential disruptions from major geopolitical conflicts, on the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we conduct business, including our contract development and manufacturing organizations, or CDMOs, contract research organizations, or CROs, shippers and others.
- The trading price of the shares of our common stock may be volatile, and purchasers of our common stock could incur substantial losses.
- We might not be able to utilize a significant portion of our net operating loss carryforwards.

PART I

Item 1. Business.

Overview

We are a clinical-stage biopharmaceutical company developing novel immunotherapies for the treatment of cancer. Our pipeline candidates are built on our deep expertise in myeloid biology and cancer drug development. Our product candidates use pattern recognition receptors in the innate immune system to help the body recognize tumor cells for a productive anti-cancer response. Our proprietary Boltbody™ ISAC platform technology combines tumor-targeting antibodies with immune-stimulating linker-payloads. We believe this approach has the potential to create products that work with a patient's own immune system, resulting in anti-cancer efficacy with good tolerability. Having explored more than one thousand distinct linker-payloads and multiple tumor targets, we know the importance of both the linker-payload and the antibody and have developed a library of linker-payloads for use in our own development programs and in our collaborations. We believe that ISACs have the potential to transform the cancer treatment landscape in a way similar to what we've seen with antibody-drug conjugates, or ADCs. Many antibodies that target tumor antigens could be made into ISACs, providing us with future opportunities.

Our first Boltbody ISAC program was trastuzumab imbotolimod, or BDC-1001, targeting a tumor antigen known as human epidermal growth factor receptor 2 (HER2) that is common in many cancers. BDC-1001 demonstrated that the ISAC approach can safely deliver antitumor activity. However, we determined that our first-generation ISAC technology was not efficacious enough to be a commercially viable treatment option for patients in this market. As a result, in May 2024 we discontinued development of BDC-1001 as part of a strategic pipeline prioritization and restructuring plan in order to focus on BDC-3042 and our next-generation Boltbody ISAC program BDC-4182.

We are working on several Boltbody ISAC programs, both on our own and through our collaborations. BDC-4182 is a Boltbody ISAC targeting claudin 18.2 and we anticipate initiating a clinical trial in the second quarter of this year. Our collaborations broaden our pipeline and help us continue to advance our Boltbody ISAC platform technology while benefiting from our collaboration partners' resources and expertise. Our Genmab collaboration recently advanced the first program into development, and we continue research on additional programs. Our Toray collaboration continues work on an ISAC targeting Caprin-1, a novel cancer target discovered by Toray. We are also working on proprietary Boltbody ISAC programs targeting CEA and PD-L1 and will be seeking partners for those programs.

BDC-3042, our dectin-2 agonist antibody program, leverages our myeloid biology expertise to target tumor associated macrophages (TAMs). We have completed enrollment of our dose escalation study without any dose-limiting toxicities and will be reporting results from the Phase 1 study in the second quarter of 2025.

Our Pipeline

We are leveraging our myeloid biology expertise to build a robust pipeline of immuno-oncology product candidates, including multiple Boltbody ISACs and a unique agonist antibody that targets tumor-associated macrophages. In addition to these programs, we are 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 currently hold exclusive worldwide rights to all of our proprietary development programs.

BDC-3042 is an agonist antibody targeting dectin-2, an innate immune receptor found on the surface of macrophages. dectin-2 is selectively expressed in TAMs across a broad range of tumor types, including non-small cell lung, head and neck, ovarian, triple-negative breast cancer, and melanoma, among others. Most of these TAMs seem to be immunosuppressive, and agonism of dectin-2 converts them to an immunostimulatory phenotype, inducing pro-inflammatory cytokine production, enhanced phagocytosis, and antigen processing and presentation. A dectin-2 agonist antibody has the potential to convert these immunosuppressive TAMs into tumor-destructive macrophages that elicit productive anti-tumor immune responses. Anti-PD-1 therapies have been shown to upregulate the expression of dectin-2 in tumors, which provides an interesting rationale for exploring this combination. In October 2023, we dosed the first patient with BDC-3042 in the Phase 1 dose-escalation study in patients with a broad range of solid tumors. We have completed enrollment of our dose escalation study without any dose-limiting toxicities and we expect to be reporting results from the Phase 1 study in the second quarter of 2025.

BDC-4182 utilizes our next-generation Boltbody™ ISAC technology platform and targets claudin 18.2, which is overexpressed in gastric/gastroesophageal junction cancer, pancreatic cancer, and other tumor types. Selection of BDC-4182 as our clinical candidate was supported by preclinical experiments demonstrating potent anti-tumor activity in multiple preclinical models, safety and tolerability in non-human primates, and enhanced preclinical efficacy compared to cytotoxic ADCs in murine tumor models. Data on our claudin 18.2 Boltbody ISAC program were presented at the Society for Immunotherapy of Cancer's (SITC) Annual Meetings in both November of 2024 and 2023. We expect to initiate our first in human clinical trial with BDC-4182 in the second quarter 2025. We secured exclusive worldwide rights to BDC-4182 following the restructuring of the Innovent collaboration in March 2024. Innovent and its affiliates are eligible to receive commercial and sales milestone payments as well as royalties on global net sales.

We have two additional ISAC programs utilizing our next-generation Boltbody ISAC technology platform in preclinical development. One is a Boltbody ISAC targeting carcinoembryonic antigen cell adhesion molecule 5, or CEA. CEA is a well-known tumor antigen expressed in various solid tumors including, colorectal, non-small cell lung, pancreatic, and breast. CEA is upregulated on the cell surface of these cancers. CEA allows us to target these cancers, some of which are immunologically "cold." In our preclinical studies, we have observed promising in vitro and in vivo activity with notable anti-tumor activity, including complete tumor regression and immunological memory.

Our final Boltbody ISAC program targets PD-L1. Patients with tumors that are nonresponsive or become refractory to immune checkpoint blockade have few treatment options. PD-L1 is an immune checkpoint protein that can be expressed on cancer, including cancers such as lung, colorectal, and breast, and on immune cells. Expression of PD-L1 on 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 like 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 inhibitors. We believe that a PD-L1 Boltbody ISAC has the potential to overcome the limitations of current anti-PD-L1 therapies.

Our Corporate History and Team

Our company was founded in 2015 to develop and commercialize pioneering work from the Engleman Laboratory at Stanford University. We have assembled a highly qualified management team with broad experience in myeloid biology and drug development to execute our mission. Our scientific founders and 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 Astellas, Immunomedics, Jazz, Maxygen, Seagen, Roche / Genentech, and others.

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 antibody engineering and our ability to modulate TLR-agonist linker-payloads allow us to optimize the therapeutic profile of our product candidates for any target tumor antigens as part of our research and development 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 cancers that are refractory to existing therapies.

- **Develop BDC-3042, our agonist antibody targeting dectin-2.** dectin-2 represents an attractive target found in a broad range of solid tumors. BDC-3042 targets macrophages in the 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. In October 2023, we dosed the first patient with BDC-3042 in the Phase 1 dose-escalation study in patients with a broad range of solid tumors and we expect to announce results in the second quarter of 2025.
- **Develop our next-generation BDC-4182, for the treatment of patients with gastric cancer.** We are in the final stages of preparing for the first clinical trial of BDC-4182, expected to start in the second quarter of 2025. BDC-4182 is the only claudin 18.2-targeting ISAC in development. Based on our preclinical studies, we believe BDC-4182 has the potential to outperform cytotoxic ADCs. We are conducting a first-in-human dose escalation and expansion study with the normal Phase 1 goals of demonstrating safety and selecting a dose, as well as with the goal of demonstrating anti-tumor activity.
- **Selectively enter into collaborations to expand and enhance our proprietary Boltbody ISAC approach and myeloid expertise and increase the impact of our 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 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. Collaborations can also provide significant funding for our research activities. Our collaborations with Genmab and Toray are examples of this approach.
- **Continue to invest modestly in our Boltbody ISAC platform to provide future product candidates for our pipeline.** This is exemplified by our work on the CEA ISAC and the PD-L1 ISAC programs.
- **In October 2024, we successfully established a wholly-owned subsidiary in Australia, Bolt Biotherapeutics Australia PTY LTD, to expand our global footprint and better serve our research and development programs in the region.** This strategic move enhances our ability to deliver localized solutions and it aligns with Australia's tax regime, which provides certain eligible companies with tax benefits for research and development activities.

Collaboration Agreements

Joint Development and License Agreement with Toray Industries

In March 2019, we entered into a Joint Development and License Agreement, or the Toray Agreement, with Toray, to develop and commercialize a Boltbody ISAC containing a proprietary antibody owned by Toray targeting Caprin-1. Under the Toray Agreement, we exchanged co-exclusive (with each other) licenses to certain patents and know-how covering our respective technologies. 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 1 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 1 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 territories covered under the agreement, 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.

Oncology Research and Development Collaboration with Genmab A/S

In May 2021, we entered into a License and Collaboration Agreement, or the Genmab Agreement, with Genmab. Together, the companies will evaluate Genmab antibodies and bispecific antibody technologies in combination with our Boltbody ISAC technology platform, with the goal of discovering and developing next-generation bispecific ISACs for the treatment of cancer. Under this research collaboration, the companies will evaluate multiple bispecific ISAC concepts to identify up to three clinical candidates for development. Genmab will fund the research, along with the preclinical and clinical development of these candidates through initial clinical proof of concept. Under the Genmab Agreement, we received an upfront payment of $10.0 million and an equity investment of $15.0 million under a separate stock purchase agreement. Under the Genmab Agreement, we will be compensated for research and development

services at the agreed upon full-time employee rate and third-party costs through initial clinical proof of concept of the therapeutic candidates, after which both parties can exercise their respective program opt-in rights. With respect to each candidate for which a party has exercised its program opt-in rights and has exclusive global rights, the other party is eligible to receive potential development and sales-based milestone payments and tiered royalties. Bolt is eligible to receive total potential milestone payments of up to $285.0 million per therapeutic candidate exclusively developed and commercialized by Genmab, along with tiered royalties.

Oncology Research and Development Collaboration with Innovent Biologics, Inc.

In August 2021, we entered into a License and Collaboration Agreement, or the Innovent Agreement, with Innovent. Together, the companies will leverage Innovent's proprietary therapeutic antibody portfolio and antibody discovery capability against undisclosed oncology targets in combination with our Boltbody ISAC technology and myeloid biology expertise to create up to three new candidates for cancer treatments. Innovent will fund the initial research, along with the preclinical and clinical development of these candidates through initial clinical proof of concept. Under the Innovent Agreement, we received an upfront payment of $5.0 million. Under the Innovent Agreement, we will be compensated for research and development services at the agreed upon full-time employee rate and third-party costs through initial clinical proof of concept of the therapeutic candidates, after which both parties can exercise their respective license rights. The Innovent Agreement includes license options exercisable by each party to exclusively develop, manufacture and commercialize each candidate in a specific territory. With respect to each candidate for which a party has exercised its license option, the other party is eligible to receive a license option exercise fee, potential development and sales-based milestone payments and tiered royalties. In March 2024, we entered into an amended and restated agreement with Innovent that provides Bolt with worldwide rights to two ISAC programs, including BDC-4182 targeting claudin 18.2. Bolt will be assuming all future development costs for the two ISAC programs, and Innovent is eligible to receive commercial and sales milestones as well as royalties on global net sales.

License Agreements

License Agreements with Stanford University

In May 2015, we entered into a license agreement, or the Stanford Agreement, as amended, with The Board of Trustees of the Leland Stanford Junior University, or Stanford. The Stanford Agreement provides us an exclusive license to certain patents related to our proprietary Boltbody ISAC technology, to develop, manufacture, and commercialize licensed products incorporating such technology. Stanford retained the right under the Stanford Agreement, on behalf of itself and certain of its affiliates, 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.

The technology claimed by some of the patents licensed under the Stanford Agreement was developed using U.S. government funding and the license is 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 the Stanford Agreement, we are obligated to use commercially reasonable efforts to develop and commercialize licensed products and we are also required to achieve certain 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 Agreement continue until terminated. We may terminate the Stanford Agreement at any time for any reason by providing at least 30 days' written notice to Stanford. Stanford may terminate the Stanford Agreement if we breach certain provisions of such Stanford Agreement, including the payment and development and/or regulatory milestone obligations, and fail to remedy such breach within 60 days after written notice of such breach by Stanford.

Effective May 10, 2023, the Company terminated a separate license agreement with Stanford entered into in June 2018, after determining it was no longer necessary. The termination did not result in any payments due to Stanford.

Manufacturing

We do not own or operate any manufacturing facilities. We rely on third-party contract development and manufacturing organizations, or CDMOs, for production and testing of our clinical material, including the linker-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.

Competition

The biotechnology and pharmaceutical industry is 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.

To our knowledge, BDC-3042 is the only agonist antibody targeting dectin-2 in development and does not currently have any direct competition. The expression profile of dectin-2 and the safety profile that has been observed to date in dose escalation with BDC-3042 suggests that this agent could be combined with standard of care and/or other agents. In addition, dectin-2 appears to be upregulated in many different tumor types and, similar to checkpoint therapy, could have applicability to a wide range of indications with a potential market opportunity that exceeds $10 billion. There are numerous myeloid-directed therapies on the market or in development, including but not limited to those targeting CD40, CD47, Clever-1, dectin-1, LAIR1, LILRBs/ILTs, and SIRP-alpha.

To our knowledge, BDC-4182 is the only ISAC targeting claudin18.2. There are numerous claudin 18.2 targeting agents in development that utilize different therapeutic approaches, including monoclonal antibodies such as zolbetuximab, ASKB-589, FG-M108, TST001, ADCs such as ATG-022, AZD0901/CMG901, EO-3021, IBI-343, LM-302, bispecific antibodies such as ASP2138, AZD5863, givastomig, IBI-389, QLS31905 and cell therapies or CAR-Ts such as CT041, IBI-345, TAC101-CLDN18.2, Clever-1, dectin-1, LAIR1, LILRBs/ILTs, and SIRP-alpha.

Companies developing ISACs or TLR agonists could also be long-term competitors for our Boltbody ISAC platform technology. To the best of our knowledge, the only other ISAC in active clinical development is Mersana Therapeutics' XMT-2056, a HER2-targeting antibody conjugated to a STING agonist. Turning to systemically administered TLR agonists, Eikon Therapeutics is developing EIK1001, a TLR 7/8 agonist. EIK1001 is in a Phase 3 study in combination with the PD-1 inhibitor pembrolizumab in melanoma and a Phase 2 study in combination with chemotherapy and pembrolizumab in non-small cell lung cancer. In preclinical studies, Boltbody ISACs have demonstrated greater effectiveness with differentiated biology compared to unconjugated TLR or STING agonists.

Many of our potential competitors 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 our pipeline candidates and proving them 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 any drug that we may develop. Our competitors also may be more successful than us in obtaining U.S. Food and Drug Administration, or the FDA, or other regulatory approvals for their drugs more rapidly than we may obtain approval for our pipeline candidates, 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. Furthermore, 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, 2024, we have 2 issued U.S. patents, 1 issued European patent, and 1 issued Japanese patent that are solely owned by us and 4 issued U.S. patents and 5 issued foreign (Australian, Chinese, European, Japanese, and Korean) patents that we co-own with Stanford and for which Stanford has exclusively licensed its rights to us under the 2015 Stanford Agreement. In addition, as of December 31, 2025, we own or co-own with Stanford, for which Stanford has exclusively licensed its rights to us under the 2015 Stanford Agreement, approximately 202 pending patent applications in various countries (23 of which are pending in the U.S., and 7 of which are Patent Cooperation Treaty ("PCT") applications that have yet to enter the national phase in the U.S.).

More particularly, we have 1 issued U.S. patent, 1 pending U.S. nonprovisional patent application, 1 pending PCT application that has yet to enter the national phase in one or more countries, and 24 pending foreign patent applications, which we solely own, directed to BDC-3042, our novel agonistic antibody targeting an immune-activating receptor expressed on TAMs known as Dectin-2 (*CLEC6A*). The issued patent and the pending U.S. and foreign patent applications, if issued, are expected to expire between 2041 and 2044, excluding any extension of patent term that may be available. We also have 3 pending U.S. nonprovisional patent applications, 40 pending foreign patent applications, and 2 pending U.S. provisional patent applications, which we solely own, directed to BDC-4182, our next-generation Boltbody ISAC clinical candidate targeting claudin 18.2. The pending U.S. and foreign patent applications, if issued, are expected to expire between 2040 and 2045, excluding any extension of patent term that may be available.

In addition, we have 5 issued U.S. patents, 7 issued foreign patents, and 131 pending patent applications directed to ISAC technology other than BDC-3042 and BDC-4182, including 4 issued U.S. patents and 5 issued foreign patents covering our previous lead product candidate trastuzumab imbotolimod and the use thereof, which we co-own with Stanford and have exclusively licensed under the 2015 Stanford Agreement. Of these 131 pending patent applications, 1 is a U.S. provisional patent application, 6 are PCT applications that have yet to enter the national phase in one or more countries, 16 are U.S. nonprovisional patent applications, and 108 are foreign patent applications. The issued patents and the pending U.S. and foreign patent applications, if issued, are expected to expire between 2035 and 2045 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. For more information regarding our license agreement with Stanford, please see “—License 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 terms of individual issued patents extend for varying periods depending on the date of filing of the patent applications or the dates 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 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 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 the publication of discoveries in scientific or patent literature often lags 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 and European Union

In the United States, pharmaceutical products are subject to extensive regulation by the FDA under the Federal Food, Drug, and Cosmetic Act, or FDCA, the Public Health Service Act, or PHSA, and other federal and state statutes and regulations. These 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, including biological products such as our Boltbody ISAC product candidates. Our Boltbody ISACs and monoclonal antibodies are subject to approval for marketing via a Biologics License Application, or BLA. 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 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 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 Good Laboratory Practice, or GLP, requirements;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an Institutional Review Board, or 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, Good Clinical Practice, or 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 and 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 GCP 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 Risk Evaluation and Mitigation Strategy, or REMS, where applicable, and post-approval studies required by the FDA as a condition of approval.

The process in the European Union and other countries or jurisdictions with developed regulatory regimes is broadly comparable.

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 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 GCP, 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 Institutional Review Board (IRB) for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB 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 still 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 reflected the makeup of the United States population, 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 subjects with the target disease, usually studying an escalating single dose or multiple doses of the product candidate. The primary purpose of Phase 1 trials is to assess the metabolism, pharmacokinetics, pharmacologic action, side effect tolerability, safety of the product candidate, determine the dosing regimen(s) for subsequent investigations, and, if possible, early evidence of effectiveness.
- Phase 2 clinical trials generally involve studies in subjects with the target disease to evaluate effectiveness for a specific indication or indications. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected and possible adverse effects and safety risks are identified.
- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate clinical efficacy 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 a product.

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, subjects enrolled in Phase 1 clinical trials are cancer 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 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 recommendations as to 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 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.

In 2014, Clinical Trials Regulation 536/2014 was adopted. The new Regulation is directly applicable in all EU Member States (without national implementation) and entered into application on January 31, 2022. The new Regulation seeks to simplify and streamline the approval of clinical trials in the EU. Pursuant to the Regulation, the sponsor shall submit a single Clinical Trial Application (CTA) via the EMA's Clinical Trials Information System, or CTIS, which will cover all regulatory and ethics assessments from the member states concerned.

Any submissions made from January 31, 2023, onwards must be made through CTIS and all trials authorized pursuant to the Directive that are still ongoing on January 31, 2025, must have their details registered on CTIS. In both cases trials registered on CTIS must comply with the Regulation. Once the CTA is approved in accordance with a member state's requirements, clinical trial development may proceed. Approval and monitoring of clinical trials in the EU is, as it was under the Directive, the responsibility of individual member states, but compared to the position prior to the applicability of the Clinical Trials Regulation there is likely to be more collaboration, information-sharing, and decision-making between member states. The new Regulation also aims to streamline and simplify the rules on safety reporting and introduces enhanced transparency requirements, such as mandatory submission of a summary of the clinical trial results to a new EU Database. Clinical trials must be carried out in accordance with GCP.

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 Prescription Drug User Fee Act, or 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, or CRL. An approval letter authorizes commercial marketing of the biologic with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A CRL 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 for the FDA to reconsider the application. If a CRL is issued, the applicant may either resubmit the BLA, addressing all 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.

An application for authorization to market a product in the European Union, or one or more 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 virtue of being antibody-based biologics, fall under the centralized procedure, only this procedure will be described here. 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 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 coordination 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 to ask the applicant for clarification of anything contained within the application 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 to grant a marketing authorization. If the opinion is negative, information is given as to the grounds on which this conclusion was reached. After approval, the Rapporteur(s) continue to monitor the product throughout its life cycle.

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 antibody–drug conjugates, or 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.

Regulation (EC) 141/2000 states that a drug shall be designated as an orphan drug in the European Union 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 orphan market exclusivity, during which the EMA and European Union Member States shall not accept another marketing authorization application for the same indication for a similar medicinal product. This period of orphan market exclusivity can be reduced to six years if it no longer meets the criteria for orphan drug designation by the end of the fifth year or extended to 12 years with an agreed Pediatric Investigation Plan, or PIP.

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.

Similar conditional approval and accelerated assessment processes exist in the European Union for medicine that would fulfill an unmet medical need or therapeutic innovation. 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.

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 product lot before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each product lot to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all 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 the benefits that designation confers.

While there is no direct equivalent to the separate route for biologics, broadly equivalent requirements and controls similarly apply to the submission of pediatric testing and marketing authorization applications to the European Medicines Agency in the European Union and, post-approval, to the holding of such marketing authorizations, including conditionality.

Post-Approval Requirements

Once a BLA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA tightly 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 cGMP after approval. Biologic manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. The FDA is authorized to conduct periodic unannounced inspections at any establishment where a biologic product is manufactured to assess cGMP compliance. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality-control to maintain compliance with cGMP.

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. 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, warnings 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.

Broadly equivalent requirements, controls and sanctions similarly apply to supply, QA, manufacture, labeling, advertising, pharmacovigilance, and tracing of medicinal products as imposed by European Union laws and enforced by European Union national regulatory authorities.

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 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 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. 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. 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.

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 regulatory framework in place in the United Kingdom in relation to clinical trials is derived from the European Union's Clinical Trials Directive, as implemented into United Kingdom law. The Clinical Trials Regulation does not apply in Great Britain. It is uncertain as to what extent the United Kingdom will seek to align its regulations with the Clinical Trials Regulation, and there are already added administrative burdens as a result of Brexit for trials that take place both in the United Kingdom and the European Union, for example United Kingdom sponsored trials that also have sites in the European Union now need to have a legal representative in 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, privacy and security of health information, 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 U.S. Healthcare Laws and Regulations and Legislative Reform

U.S. Healthcare and Privacy Laws and Regulations

Healthcare providers 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, 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 U.S. 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.
- Federal civil and criminal false claims laws, such as the Federal False Claims Act, 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.
- The Health Insurance Portability and Accountability Act, or 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 or making any materially false, fictitious or fraudulent statement to a healthcare benefits program.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, which impose obligations with respect to individually identifiable health information upon covered entities (including health plans, healthcare clearinghouses and certain healthcare providers), their respective business associates and their covered subcontractors that perform services for them that involve individually identifiable health information.
- 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, as amended by the Health Care Education and Reconciliation Act, or collectively the ACA, 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 the Centers for Medicare & Medicaid Services, or CMS, information related to payments and other transfers of value provided to physicians, (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals and physician ownership and investment interests.
- 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 laws that require pharmaceutical companies to implement compliance programs, comply with certain compliance guidelines, or to track and report payments and other remuneration provided to healthcare providers; state laws that require the reporting of marketing expenditures or drug pricing,; state and local laws that require the registration of pharmaceutical sales representatives; state laws that prohibit various marketing-related activities; and other federal, state laws that govern the privacy and security of health information.

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 and oversight obligations, and the curtailment or restructuring of 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. In addition, if any physicians or 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 U.S. and state governments continue to propose and pass legislation designed to reduce the cost of healthcare. In 2010, the ACA was enacted which included changes to the coverage and reimbursement of drug products under government healthcare programs.

While there have been executive judicial and congressional challenges to the ACA, several bills affecting the implementation of certain taxes under the ACA 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 ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the ACA will be subject to judicial and congressional challenges in the future. It is unclear how such challenges and the healthcare reform measures of the Biden administration will impact the ACA.

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 until 2032 unless additional congressional action is taken. 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.

Furthermore, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. This 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, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services ("HHS") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. Further, the IRA, among other things (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. We expect that additional state and federal healthcare reform measures will be adopted in the future.

Environmental, Health and Safety Laws and Regulations

We and our third-party contractors are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the use, generation, manufacture, distribution, storage, handling, treatment, remediation and disposal of hazardous materials and wastes. Hazardous chemicals, including flammable and biological materials, are involved in certain aspects of our business, and we cannot eliminate the risk of injury or contamination from the use, generation, manufacture, distribution, storage, handling, treatment or disposal of hazardous materials and wastes. 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, 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, 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' 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 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, decisions about pricing and reimbursement vary from country to country. In certain countries, new products may be marketed after 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 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 reimbursed by their national health insurance systems to control the prices of medicinal products for human use. With pricing and reimbursement decisions taking place at the member state level, member states may approve a specific price for a product, 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 number of discounts required on pharmaceutical products. These efforts could continue as countries attempt to manage healthcare expenditures, especially in light of severe fiscal and debt crises experienced by many countries in the European Union. There can be no assurance that any country with reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products, if approved in those countries. Accordingly, reimbursement for any products in Europe may be lower, compared to the United States and may be insufficient to generate commercially reasonable revenues and profits.

The containment of healthcare costs has become a priority of foreign and domestic governments as well as private third-party payors. The pricing of drugs has 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 Resources

As of December 31, 2024, we had 52 employees, all of whom were full-time. Depending on the nature of their job, employees may have the flexibility to work remotely or out of our Redwood City office, laboratory and vivarium space. 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, diverse, and empowering environment in which our employees can grow and advance their careers. Our overall goal is to develop, expand and retain our workforce in support of our current pipeline and future business objectives. Our human resources objectives include identifying, recruiting, retaining, motivating, and integrating our existing and future employees. 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 protect the long-term interests of our stockholders. 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. We are building an environment where our employees can thrive and be inspired to make exceptional contributions towards the advancement of novel and more effective therapies for cancer patients. We also seek and support a diverse population of employees, and value the contributions of all without regard to age, race, ethnicity, gender, or sexual orientation. We recognize the value of our employees' unique backgrounds and breadth of experience in building a strong and sustainable company.

The principal purposes of our equity incentive plans are to attract, retain and motivate our employees and directors through grants of stock-based compensation awards and payments of cash-based performance bonus awards. These incentives are intended to encourage employees to perform to the best of their abilities and achieve objectives, thus contributing to our stockholder value. We also offer the 2021 Employee Stock Purchase Plan to all employees where they can purchase shares of our common stock at a discounted price. We are committed to providing a competitive and comprehensive benefits package to our employees. Our benefits package is designed to support our employees and their family's health and well-being. Our benefits include, medical, dental and vision, as well as dependent care, mental health, and other wellness benefits.

We value career development for all employees, and we provide reimbursement and time for employees to attend professional development courses ranging from technical training, competency-based workshops, and leadership development programs. Direct managers also take an active role in identifying individualized development plans to assist their employees in realizing their full potential and creating opportunities for promotions and added responsibilities that enhance the engagement and retention of our workforce. We are committed to maintaining and increasing our investment in our workforce 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. in July 2015. Our principal executive offices are located at 900 Chesapeake Drive, Redwood City, California 94063 and our telephone number is (650) 665-9295. Our corporate website address is www.boltbio.com. We make available, free of charge on our website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports, as soon as reasonably practicable after filing such reports with the SEC. Alternatively, you may access these reports at the SEC's website at www.sec.gov. Information contained on, or that can be accessed through, our website is not incorporated by reference into this Annual Report, and the inclusion of our website address is an inactive textual reference only.

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 consolidated 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.

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 BDC-3042, all of our other development programs are in preclinical development or 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, establishing collaborations, 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. For example, we discontinued development of our first Boltbody ISAC program because we determined that it was not efficacious enough to be a commercially viable treatment option for patients. 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 $63.1 million and $69.2 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $427.4 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future. It could be at least several years, if ever, before we have product revenue from 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 and other operations.

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.

We have incurred net losses and negative cash flows from operations since our inception, with an accumulated deficit of $427.4 million and anticipate continuing to incur net losses for the foreseeable future. Under our current plan, which includes income from collaboration arrangements, we believe our cash and cash equivalents and marketable securities of $70.2 million as of December 31, 2024 may be sufficient to fund our operations through mid-2026. However, due to the significant uncertainty in our plans, including the achievement of our collaboration income, we have concluded that there is substantial doubt about our ability to continue as a going concern within one year after the issuance of the consolidated financial statements.

Similarly, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of, and for the year ended, December 31, 2024, describing the existence of substantial doubt about our ability to continue as a going concern. 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. Considering all of these factors, we believe that there is substantial doubt about our ability to continue to operate as a going concern.

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, or NOL, carryforwards.

As of December 31, 2024, we had federal and state net operating loss, or NOL, carryforwards of $234.9 million and $324.0 million, respectively. The federal NOL carryforwards generated prior to 2018 and state NOL carryforwards, if not utilized, will expire beginning in 2035. We have federal NOL aggregating $230.5 million that are not subject to expiration. The NOL 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 NOL carryforwards 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 NOL carryforwards 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 NOL carryforwards are suspended or otherwise limited, such as recent California legislation limiting the usability of NOL carryforwards for tax years beginning in 2020 and before 2022.

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 NOL 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 performed a Section 382 study as of September 30, 2024 and expect approximately $2.8 million of federal research and development credits and $51.0 million of California NOL carryforwards to expire unused due to Section 382 limitations.

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 NOL 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

If none of our product candidates, including those in our collaborations, obtain regulatory approval and are successfully commercialized in one or more indications, or we or our collaboration partners experience significant delays in doing so, we may never generate any product revenue or become profitable.

We have invested most of our efforts in developing our Boltbody ISAC approach, identifying potential product candidates and conducting preclinical studies. In May 2024, we announced the discontinuation of the development of our previous lead product candidate, trastuzumab imbotolimod because we determined that it was not efficacious enough to be a commercially viable treatment option for patients. 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 product candidate development efforts and BDC-3042 is in the early stages of clinical development. We expect that a substantial portion of our efforts and expenses over the next several years will be devoted to the development of BDC-3042, BDC-4182, and our collaborations. We cannot be certain that any of our other product candidates will receive regulatory approval or will be successfully commercialized even if they receive regulatory approval. The research, testing, manufacturing, safety, efficacy, labeling, approval, sale, marketing and distribution of our product candidates are, 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, or receiving royalty payments from our collaborators. The success of our product candidates 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 discovery and development of product candidates based on our Boltbody ISAC (immune-stimulating antibody conjugate) approach, as well as the BDC-3042 program based on dectin-2 agonism, are unproven, which makes it difficult to predict the time and cost of product candidate development, 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. Our BDC-3042 program relies on agonizing dectin-2 to reprogram TAMs and is also a novel and unproven approach. BDC-3042 is in clinical development and we have not yet completed any clinical trials for any product candidate or obtained marketing approval thereafter. 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. For example, in August 2022, we announced the discontinuation of development of BDC-2034 due to off-target toxicity related to the targeting antibody. Additionally, in May 2024, we announced the discontinuation of development of our previous lead product candidate, trastuzumab imbotolimod because we determined that it was not efficacious enough to be a commercially viable treatment option for patients. 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.

We have concentrated our product research and development efforts on our novel therapeutic approach of using myeloid biology to fight cancer, and our future success depends on the successful development of our 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.

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.

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 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 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 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 any product candidate we develop, we may be unable to obtain approval of or market 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 some or all of our product candidates. 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. For example, in August 2022, we announced the discontinuation of development of BDC-2034 due to off-target toxicity related to the targeting antibody. Additionally, in May 2024, we announced the discontinuation of development of our previous lead product candidate, trastuzumab imbotolimod because we determined that it was not efficacious enough to be a commercially viable treatment option for patients.

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. 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, enrollment and recruiting suitable patients to participate in our clinical trials;
- interruptions in our business as a result of pandemics or other events outside our control, such as restrictions on travel and meetings with clinical trial sites and investigators, as well as potential disruptions in our product supply chain;
- 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 effects of a pandemic or major geopolitical developments, and associated economic conditions 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. For example, in May 2024, we announced the discontinuation of development of our previous lead product candidate, trastuzumab imbotolimod because we determined that it was not efficacious enough to be a commercially viable treatment option for patients and began prioritizing other ISAC programs, including our collaboration programs. 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 conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which reduces 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 on our own or together with collaborators, any of our products that receive regulatory approval.

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, educating adequate numbers of physicians on the benefits of 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. Other companies may develop ISACs and toll-like receptors, or TLRs, agonists that may have utility for the treatment of cancer in indications we are targeting. Additionally, companies may utilize a range of other technologies and scientific approaches including ADCs, vaccines, bispecific antibodies and receptor tyrosine kinases inhibitors. 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 our current or 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, European Union Member States 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 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 our product candidates, if any are approved, will depend on a number of factors, including, among others:

- the ability of our 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 our product candidates;
- limitations or warnings contained in the labeling approved for our 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 any of the product candidates 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 our failure to educate adequate numbers of physicians on the benefits of 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 our ability to obtain regulatory approvals of our product candidates in the United Kingdom, result in restrictions or imposition of taxes and duties for importing our product candidates into the United Kingdom or European Union, and may require us to incur additional expenses in order to develop, manufacture and commercialize our product candidates in the United Kingdom and European Union.

Following the United Kingdom's departure from the European Union, commonly referred to as Brexit, 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 became formally effective on May 1, 2021. The effects of Brexit have been and will continue to be far-reaching. In the future, Brexit may 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. For example, Great Britain is no longer covered by the centralized procedures for obtaining European Union wide marketing authorization from the EMA and a separate marketing authorization will therefore be required to market our product candidates in Great Britain.

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 further diverge from the European Union from a regulatory perspective in relation to medicinal products, tariffs could be put into place in the future. The Retained EU Law (Revocation and Reform) Act 2023, which became effective January 1, 2024 allows the Government of the United Kingdom to repeal or replace certain European Union law that was incorporated into United Kingdom law effective as of the end of the transition period, increases the likelihood of such divergence. 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.

Other European Union Member States 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 rely on third parties to produce clinical and commercial supplies of BDC-3042, BDC-4182 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. Our current third-party contract development and manufacturing organizations, or CDMOs, 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 pandemics 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 CDMOs, 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 pandemics, on the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we conduct business, including our CDMOs, 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 our 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;
- failure to deliver our products under specified storage conditions and in a timely manner; and
- other events or factors, including those resulting from geopolitical events, or responses to these events.

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 CDMOs 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 CDMOs 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 CDMOs 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.

We have established collaboration agreements with third parties to develop our current and potential future product candidates. These include our collaborations with Toray Industries, Inc., or Toray, Genmab A/S, or Genmab, and Innovent Biologics, Inc., or Innovent. We may enter into other collaboration agreements with pharmaceutical and biotechnology companies for the future development and potential commercialization of our product candidates. We will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of any product candidates we may seek to develop with them. We cannot predict the success of any collaboration that we have entered into or will enter into.

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

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

Risks Related to Regulatory Compliance

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

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act, was enacted, which includes measures that have significantly changed the way health care is financed by both governmental and private insurers. There have been executive, judicial and congressional challenges and amendments to certain aspects of the Affordable Care Act. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the Affordable Care Act will be subject to judicial or congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the second Trump administration will impact the Affordable Care Act.

In addition, other legislative changes have been proposed and adopted since the Affordable Care 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 until 2032, 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. presidential executive orders, 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. For example, the IRA, among other things (i) directs HHS to negotiate the price of certain high-expenditure, single-source biologics covered under Medicare that have been on the market for at least 11 years and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions began to take effect progressively starting in fiscal year 2023. On August 15, 2024, HHS announced the agreed upon prices for the first ten drugs that were subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare drug price negotiation program. In addition, on February 14, 2023, HHS released a report outlining three new models for testing by the Centers for Medicare & Medicaid Services Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control costs pharmaceutical and biological products.

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

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

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

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

We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, industry standards, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with privacy and data protection obligations could lead to government investigations or enforcement actions (which could include civil or criminal penalties), private litigation, reputational harm and/or adverse publicity and could negatively affect our operating results and business.

We and our collaborators and third-party providers are subject to evolving 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, proposed cybersecurity rules from the SEC, 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. If we fail to follow security regulations or 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.

For example, the California Consumer Privacy Act of 2018 (“CCPA”) applies to personal information of consumers, business representatives, and employees, and requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA provides for civil penalties of up to $7,500 per violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal data we maintain about California residents. In addition, the California Privacy Rights Act of 2020 (“CPRA”) expands the CCPA’s requirements, including by adding a new right for individuals to correct their personal information and establishing a new regulatory agency to implement and enforce the law.

Other states, such as Virginia, Colorado, Utah, and Connecticut have also passed comprehensive privacy laws, and similar laws are being considered in several other states, as well as at the federal and local levels. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the European Union’s General Data Protection Regulation (“EU GDPR”), the United Kingdom’s GDPR (“UK GDPR”), and the Personal Information Protection Act ("PIPA"), in South Korea, impose strict requirements for processing personal data. Under the EU GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros or 4% of annual global revenue, whichever

is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the United Kingdom (UK) have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA and UK's standard contractual clauses, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States.

If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

In addition to data privacy and security laws, we contractually may be subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful.

If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims); additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials.

Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of collaborators or subjects; interruptions or stoppages in our business operations (including clinical trials); interruptions or stoppages of data collection; inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

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, 2024, we have two issued U.S. patents that are solely owned by us and four issued U.S. patents and three issued foreign (Chinese Japanese, and Korean) patents that are co-owned with, and exclusively licensed to us by Stanford. Many of our patent applications that we own, co-own with Stanford, or have licensed from Stanford are U.S. provisional patent applications. A U.S. provisional patent application is not eligible to become an issued patent until, among other things, we file a 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 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 costs 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. We may 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.

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. 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 Agreement and Genmab 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, may 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 patents issue 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 result in one or more of our owned or licensed patents 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 Member States, 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 the competitive position of 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 or similar extensions to protection provided by such patents under similar legislation in other jurisdictions, for example, in the European Union a supplementary protection certificate, or SPC, is available to extend the protection afforded to a specific product covered by a patent for maximum of five years (unless extended by six months if trials are completed in accordance with an agreed pediatric investigation plan). 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 infringe 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 macroeconomic uncertainties, including pandemics, labor shortages, inflation and monetary supply shifts, and potential disruptions from major geopolitical conflicts, on the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we conduct business, including our contract development and manufacturing organizations, or CDMOs, contract research organizations, or CROs, shippers and others.

Our business has been, and is expected to continue to be, impacted by widespread macroeconomic uncertainties, including increased inflation and interest rates, financial and credit market fluctuations, changes in economic policy, pandemics, global supply chain constraints, and recent and potential disruptions in access to bank deposits or lending commitments due to bank failures. Such macroeconomic uncertainties may continue for an extended period and have adversely impacted, and may continue to adversely impact, many aspects of our business. Our business has been, and may continue to be, impacted by pandemics and resulting economic consequences. At present, we have implemented a flexible work-from-home policy allowing employees to work from home in jobs where that is reasonable. The effects of our work-from-home policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines.

We are dependent on a global supply chain for products to be used in our clinical trials and, if approved by the regulatory authorities, for commercialization. Current macroeconomic uncertainties, including the effects of pandemics, 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-3042, which is manufactured at facilities in South Korea, or any future product candidates, could adversely affect our ability to conduct ongoing and future clinical trials of BDC-3042 and any future product candidates.

The ultimate impact of the current macroeconomic conditions remains highly uncertain and could have a material impact on our operations, and we will continue to monitor global economic conditions closely.

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

Our ability to compete in the highly competitive immuno-oncology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial and scientific 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 harm our ability to successfully implement our business strategy. In May 2024, we initiated a restructuring and reduction-in-force and appointed William Quinn as our new President and Chief Executive Officer. Management transitions may create uncertainty, divert resources and management attention, or impact public or market perception, any of which could negatively impact the company's ability to operate effectively or execute its strategies and result in an adverse impact on its business.

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. We have experienced unwanted employee attrition which we believe has been due to such competition, and we may continue to experience unwanted employee attrition in the future. 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, 2024, we had 52 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, 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 pandemics;
- 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, 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, and actions or lack of actions taken by internal personnel with access to our systems. We take steps to detect and remediate vulnerabilities, but we may not be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. These vulnerabilities may pose material risks to our business. In particular, 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 incidents relating to their computer systems could also have a material adverse effect on our business.

Actual or alleged 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. 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. Threat actors, nation-states, and nation-state-supported actors now engage, and are expected to continue to engage, in cyber-attacks, including for geopolitical reasons and in connection with military conflicts and operations. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to heightened risk of these attacks, including cyber-attacks that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services. 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. Generally, if we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms.

While we maintain cybersecurity insurance coverage that covers certain aspects of the cyber risks described above, any losses suffered by the company may not be adequately covered by insurance or other contractual rights available to us. The successful assertion of one or more large claims against us that exceed or are not covered by our insurance coverage or changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could make us unable to acquire such insurance and may have an adverse effect on our business, financial condition, and results of operations.

Risks Related to 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.

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 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, including changes in the structure of healthcare payment systems;
- 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 economic, political and market conditions and overall fluctuations in the financial markets in the United States and abroad, including as a result of pandemics and geopolitical events;
- other events or factors, including those resulting from war, incidents of terrorism, or responses to these events; 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.

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

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, increases in inflation rates and uncertainty about economic stability. For example, the COVID-19 pandemic resulted in widespread unemployment, economic slowdown and extreme volatility in the capital markets. Similarly, geopolitical conflict in Ukraine, Russia, and Israel has created volatility in the global capital markets and is expected to have further global economic consequences, including disruptions of the global supply chain and energy markets. Any such volatility and disruptions may have adverse consequences on us or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Inflation can adversely affect us by increasing our costs, including salary costs. Any significant increases in inflation and related increase in interest rates could have a material adverse effect on our business, results of operations and financial condition.

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 cease 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.

We have registered and intend to continue to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to vesting arrangements and exercise of options and, in the case of our affiliates, the restrictions of Rule 144.

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 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.

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 control over financial reporting, our ability to produce accurate consolidated 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. 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.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act , or if we are unable to maintain proper and effective internal control over financial reporting, we may not be able to produce timely and accurate consolidated 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.

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 and several state trial courts have enforced such provisions and required that suits asserting Securities Act claims be filed in federal court, there is no guarantee that courts of appeal will affirm the enforceability of such provisions and 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. 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 litigating Securities Act claims in state court, or both state and federal court, which could seriously harm our business, financial condition, results of operations, and prospects. 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.

Our failure to meet the continued listing requirements of The Nasdaq Stock Market LLC could result in a delisting of our common stock.

On July 2, 2024, we received a written notice from the Listing Qualifications Department of The Nasdaq Stock Market, LLC or Nasdaq, notifying us that on July 1, 2024, the average closing price of our common stock over the prior 30 consecutive trading days had fallen below $1.00 per share, which is the minimum average closing price required to maintain listing on the Nasdaq Global Select Market under Nasdaq Listing Rule 5450(a)(1), or the Minimum Bid Requirement. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided 180 calendar days to regain compliance with the Minimum Bid Requirement, (the "Compliance Period"), to regain compliance. As we did not regain compliance with the Minimum Bid Requirement during the Compliance Period, we applied to transfer the listing of our common stock to the Nasdaq Capital Market, as allowed under Nasdaq Listing Rule 5810(c)(3)(A), in order to qualify for an additional 180 calendar day period to regain compliance.

On January 2, 2025, we received written notice from Nasdaq notifying us that our application to transfer the listing of our common stock to The Nasdaq Capital Market was approved. The approval was based upon the Company meeting the continued listing requirement for the market value of our publicly held shares and all other Nasdaq initial listing standards, with the exception of the bid price requirement, and a written notice of our intention to cure the deficiency during the second compliance period by effecting a reverse stock split if necessary, our agreement to the conditions outlined in the Nasdaq listing requirements, and additional supporting information provided in our application.

Our common stock was transferred to The Nasdaq Capital Market on January 6, 2025, and we will be granted an additional 180 calendar days to regain compliance with the Minimum Bid Requirement. To regain compliance with the Minimum Bid Requirement, the closing bid price of our common stock must be at least $1.00 for a minimum of 10 consecutive business days at any time during this additional 180-day compliance period. If we regain compliance with the Minimum Bid Requirement, Nasdaq will provide us with written confirmation of compliance and will close the matter. If we do not regain compliance with the Minimum Bid Requirement during the additional 180-day compliance period, Nasdaq will provide written notification to us that our common stock will be delisted. In the event we receive notice that our common stock is being delisted, we would be entitled to appeal the determination to a Nasdaq Listing Qualifications Panel and request a hearing. There can be no assurance that, if the Company does appeal any delisting determination by Nasdaq to the hearings panel, such appeal would be successful.

The delisting of our common stock from Nasdaq may make it more difficult for us to raise capital on favorable terms in the future, or at all. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. Further, if our common stock were to be delisted from Nasdaq, our common stock would cease to be recognized as a covered security and we would be subject to additional regulation in each state in which we offer our securities. Moreover, there is no assurance that any actions

that we take to restore our compliance with the Nasdaq minimum bid requirement would allow our securities to be listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from falling below the Nasdaq minimum share price requirement or prevent future non-compliance with Nasdaq's listing requirements.

There can be no assurance that we will continue to meet the minimum bid price requirement, or any other requirement in the future. If we fail to meet the minimum bid price requirement, or other applicable Nasdaq listing requirements, including maintaining minimum levels of stockholders' equity or market values of our common stock, our common stock could be delisted. If our common stock were to be delisted, the liquidity of our common stock would be adversely affected, and the market price of our common stock could decrease. Additionally, if our securities are not listed on, or become delisted from, Nasdaq for any reason, and are quoted on the OTC Bulletin Board, an inter-dealer automated quotation system for equity securities that is not a national securities exchange, the liquidity and price of our securities may be more limited than if we were quoted or listed on Nasdaq or another national securities exchange. You may be unable to sell your securities unless a market can be established or sustained.

Unless our common stock continues to be listed on a national securities exchange it will become subject to the so-called "penny stock" rules that impose restrictive sales practice requirements.

If we are unable to maintain the listing of our common stock on Nasdaq or another national securities exchange, our common stock could become subject to the so-called "penny stock" rules if the shares have a market value of less than $5.00 per share. The SEC has adopted regulations that define a penny stock to include any stock that has a market price of less than $5.00 per share, subject to certain exceptions, including an exception for stock traded on a national securities exchange. The SEC regulations impose restrictive sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors. An accredited investor generally is a person whose individual annual income exceeded $200,000, or whose joint annual income with a spouse exceeded $300,000 during the past two years and who expects their annual income to exceed the applicable level during the current year, or a person with net worth in excess of $1.0 million, not including the value of the investor's principal residence and excluding mortgage debt secured by the investor's principal residence up to the estimated fair market value of the home, except that any mortgage debt incurred by the investor within 60 days prior to the date of the transaction shall not be excluded from the determination of the investor's net worth unless the mortgage debt was incurred to acquire the residence. For transactions covered by this rule, the broker-dealer must make a special suitability determination for the purchaser and must have received the purchaser's written consent to the transaction prior to sale. This means that if we are unable maintain the listing of our common stock on a national securities exchange, the ability of stockholders to sell their common stock in the secondary market could be adversely affected.

If a transaction involving a penny stock is not exempt from the SEC's rule, a broker-dealer must deliver a disclosure schedule relating to the penny stock market to each investor prior to a transaction. The broker-dealer also must disclose the commissions payable to both the broker-dealer and its registered representative, current quotations for the penny stock, and, if the broker-dealer is the sole market-maker, the broker-dealer must disclose this fact and the broker-dealer's presumed control over the market. Finally, monthly statements must be sent disclosing recent price information for the penny stock held in the customer's account and information on the limited market in penny stocks.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 1C. Cybersecurity.

Risk Management and Strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third-party hosted services, communications systems, hardware and software, and our critical data (such as information related to our product candidate development, collaboration activities and clinical trials), including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and sensitive personnel data and other personal data (collectively, "Information Systems and Data").

Our information technology department, supported by certain service providers, identifies, assesses and manages the Company's cybersecurity threats and risks. Our information technology department (led by our Director of IT

Operations and Security), identifies and assesses risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods including, for example, real-time monitoring of network events, subscribing to reports and services that identify cybersecurity threats, evaluating threats and actors reported to us, conducting scans of the threat environment, evaluating our and our industry's risk profile, coordinating with law enforcement concerning threats when appropriate, conducting (and working with third parties, as appropriate) assessments and audits for internal and external threats and vulnerabilities, and using of external intelligence feeds.

We implement and maintain various technical, physical, and organizational measures, processes, and policies, designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example, an incident detection and response plan; vulnerability management processes; risk assessments; implementation of security standards; encryption of certain data; network security controls; segregation of certain data; access controls including multi-factor authentication for certain Information Systems and Data; physical security; asset management, tracking and disposal; systems monitoring; vendor risk management program; employee training; penetration testing; and cybersecurity insurance. Our assessment and management of material risks from cybersecurity threats is integrated into the Company's overall risk management processes. For example, our information technology department presents updates on our IT environment and cybersecurity threats to the audit committee of the board of directors, which evaluates our overall enterprise risk and the effectiveness of our risk management approaches.

We use service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats. Such providers include but are not limited to legal counsel, threat intelligence service providers, cybersecurity consultants, cybersecurity software providers, managed security service providers, and penetration testing firms.

We use service providers to perform a variety of functions throughout our business, such as application providers, hosting companies, contract research organizations, contract manufacturing organizations, distributors, and supply chain resources. We have a vendor management program designed to manage cybersecurity risks associated with our use of certain of these providers. The program includes a risk assessment for certain vendors that host our Information Systems and Data. For vendors who host our critical data, we have processes designed to assess the vendor's ability to support business continuity and disaster recovery. Where appropriate, we conduct security questionnaires and a review of vendors' security. This review may include reviewing program documentation, security reports and audits, conducting security assessment calls with the vendor's security personnel, and imposing information security-related contractual obligations on the vendor. We also request data privacy assessments from certain vendors as appropriate. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our vendor management process may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider.

For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, please see the risk factor in Part 1. Item 1A, including the risk factor entitled "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."

Governance

Our board of directors addresses the Company's cybersecurity risk management as part of its general oversight function. The board of directors' audit committee is responsible for overseeing Company's cybersecurity risk management processes, including oversight of mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain Company management, including our Director of IT Operations and Security and Principal Accounting Officer.

Our Director of IT Operations and Security is responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into the Company's overall risk management strategy, reviewing security assessments and other security-related reports, and communicating key priorities to relevant personnel. For example, our Director of IT Operations and Security holds a Master of Science in information security and assurance, holds relevant certifications such as Certified Ethical Hacker, Computer Hacking Forensics Investigator, Security+ and Network+, and has worked for approximately nine years in the field of cybersecurity. Our Principal Accounting Officer is responsible for helping prepare budgets, helping prepare for cybersecurity incidents, and approving certain cybersecurity processes.

Our cybersecurity incident response and vulnerability management processes are designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including our Principal Accounting Officer. Our Principal Accounting Officer receives regular reports on the status of our cybersecurity measures, and

works with the Company's incident response team in an effort to help the Company mitigate and remediate cybersecurity incidents of which they are notified, and to assess and determine materiality for reporting purposes.

The audit committee receives periodic written and verbal reports from our Principal Accounting Officer and directly from the information technology department concerning the Company's significant cybersecurity threats and risk and the processes the Company has implemented that are intended to address them. The audit committee also receives from the Director of IT Operations and Security various written reports, summaries or presentations related to cybersecurity threats, risk, and mitigation.

Item 2. Properties.

Our headquarters are located in Redwood City, California, where we lease space in two locations totaling approximately 71,600 square feet, of which we have subleased approximately 25,583 square feet to a third party. Our lease expires in 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. We incorporate by reference into this Item our disclosures made in Note 7 to our Consolidated Financial Statements.

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". Effective January 6, 2025, our common stock was transferred to and now trades on the Nasdaq Capital Market under the same symbol. Prior to February 5, 2021, there was no public market for our common stock.

Holders of Common Stock

On March 19, 2025, there were approximately 13 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.

None.

Item 6. Reserved.

Not applicable.

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 consolidated financial statements and related notes thereto included elsewhere in this Annual Report on Form-10K for the period ended December 31, 2024. Except as otherwise indicated herein or as the context otherwise requires, references in this Annual Report on Form 10-K to "Bolt Bio," "the Company," "we," "us" and "our" refer to Bolt Biotherapeutics, Inc.

Overview

Our mission is to harness the power of the immune system to improve lives and eradicate cancer. This often means that our product candidates take new and unproven approaches to treating cancer. We believe that taking smart risks is critical to making breakthroughs. We are a clinical-stage biopharmaceutical company developing novel immunotherapies for the treatment of cancer. Our pipeline candidates are built on our deep expertise in myeloid biology and cancer drug development. Our various approaches use pattern recognition receptors expressed by the innate immune system to help the body eliminate tumor cells as part of a productive anti-cancer response. Our proprietary Boltbody™ ISAC platform technology combines tumor-targeting antibodies with immune-stimulating linker-payloads. We believe this approach has the potential to create products that work with a patient's own immune system, resulting in anti-cancer efficacy good tolerability. Having explored more than one thousand distinct linker-payloads and multiple tumor targets, we know the importance of both the linker-payload and the antibody and have developed a library of linker-payloads for use in our own development programs and in our collaborations.

BDC-3042, our dectin-2 agonist antibody program, is being developed to repolarize critical cells in the tumor microenvironment known as tumor associated macrophages (TAMs). dectin-2 agonism changes these TAMs from tumor-supportive macrophages to tumor-destructive macrophages that elicit durable anti-tumor immune responses in preclinical models. We received the Investigational New Drug Application, or IND, clearance from the FDA in July 2023. In October 2023, we dosed the first patient with BDC-3042 in the Phase 1 dose-escalation study in patients with a broad range of solid tumors. BDC-3042 has now completed the first six dose escalation cohorts without experiencing a dose-limiting toxicity.

We recently selected BDC-4182 as our next clinical candidate. BDC-4182 utilizes our next-generation Boltbody™ ISAC technology and targets the tumor-associated antigen claudin 18.2. Claudin 18.2 is a clinically validated target in oncology with zolbetuximab, a first-in-class claudin 18.2-targeted monoclonal antibody, approved in Japan, the U.S., and other countries for the treatment of patients with claudin 18.2-positive, unresectable, advanced or recurrent gastric cancer in combination with chemotherapy. Other programs targeting claudin 18.2 are in development for the treatment of gastric/gastroesophageal junction cancer, pancreatic cancer, and other tumor types. We are currently completing final preparations to initiate the first clinical trial evaluating BDC-4182 in patients. Clinical candidate selection was supported by in vitro and in vivo experiments demonstrating potent anti-tumor activity in multiple preclinical models, safety and tolerability in a non-GLP non-human primate toxicology study, and enhanced preclinical efficacy compared to cytotoxic ADCs in murine tumor models. Data on our claudin 18.2 Boltbody ISAC program was presented at the Society for Immunotherapy of Cancer's (SITC) Annual Meetings in both November of 2024 and 2023. We expect to initiate our first in human clinical trial in 2025.

In May 2024, we announced a strategic pipeline prioritization and restructuring plan pursuant to which we discontinued development of trastuzumab imbotolimod, formerly known as BDC-1001, in order to focus on our Phase 1 asset, BDC-3042, and our next generation Boltbody™ ISAC platform including new clinical candidate BDC-4182, targeting claudin 18.2 and reduce overall operating expenses. The restructuring plan reduced our workforce by approximately 50 employees, or approximately 50% of our workforce. We estimate total restructuring charges of $3.6 million, including $2.9 million in one-time termination benefits, such as severance costs and related benefits, and $0.7 million in non-cash stock-based compensation expenses. The severance payments commenced in July 2024 and will extend through July 2025.

Since our inception in January 2015, we have focused primarily on organizing and staffing our company, business planning, licensing, developing intellectual property, raising capital, developing our product candidates, and conducting preclinical studies and clinical trials. 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. 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 $242.0 million, net of underwriting discounts, commissions, and other offering expenses. In May 2021, we issued 821,045 shares of our common stock to Genmab for gross proceeds of approximately $15.0 million.

We have not recorded any revenue from product sales. To date, our only revenue has been derived from our collaborations with Toray, Genmab, and Innovent. In March 2019, we entered into the Toray Agreement to jointly develop and commercialize a Boltbody ISAC utilizing a Toray proprietary antibody. In May 2021, we entered into an oncology research and development collaboration with Genmab to evaluate Genmab antibodies and bispecific antibody engineering technologies in combination with our proprietary Boltbody ISAC technology platform, with the goal of discovering and developing next-generation bispecific ISACs for the treatment of cancer. The research collaboration will evaluate multiple bispecific ISAC product candidate concepts with the potential to identify up to three clinical candidates for development. In August 2021, we entered into an oncology research and development collaboration with Innovent to leverage Innovent's proprietary therapeutic antibody portfolio and antibody discovery capability against undisclosed oncology targets in combination with our Boltbody ISAC technology and myeloid biology expertise to create new candidates for cancer treatments. The Innovent collaboration was amended in March 2024, when we secured exclusive worldwide rights to ISAC programs utilizing specified antibodies against two tumor antigen targets. We expect our collaborations with Toray and Genmab to add additional novel ISACs to our pipeline.

In October 2024, we established a wholly-owned subsidiary in Australia, Bolt Biotherapeutics Australia PTY LTD, to expand our global footprint and better serve our research and development programs in the region. We expect this strategic move to enhance our ability to deliver localized solutions, strengthen partnerships, and accelerate growth in the Australian life sciences market, which offers a supportive environment for research and development initiatives, including a tax regime that provides certain eligible companies with tax benefits.

We have incurred operating losses since our inception. Our net losses were $63.1 million and $69.2 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $427.4 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 as we:

- conduct our ongoing and planned clinical trials;
- continue our research and development programs;
- continue 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 year-to-year, depending on the timing of our planned clinical trials and preclinical studies, and our expenditures on other research and development activities.

Business Conditions and Macroeconomic Factors

Macroeconomic factors, such as increased inflation and interest rates, financial and credit market fluctuations, changes in economic policy, global supply chain constraints, and recent and potential disruptions in access to bank deposits due to bank failures, have had, and we believe will continue to have, an impact on our business and results of operations. Similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

The effects of a pandemic or major geopolitical developments, and associated economic conditions, remain difficult to predict due to numerous uncertainties. We believe that the direct and indirect impacts of these business conditions and macroeconomic factors are difficult to isolate or quantify. See Item 1A, Risk Factors, and the Special Note Regarding Forward-Looking Statements elsewhere in this Annual Report for additional details. We will continue to closely monitor and evaluate the nature and extent of these macroeconomic factors on our business, consolidated results of operations, and financial condition.

Components of Results of Operations

Revenue

To date, our only revenue has been collaboration revenue derived from our collaborations with Toray, Genmab, and Innovent. 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 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, which were converted into shares of our common stock upon the completion of our IPO in February 2021. 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 as compensation 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. The research plan and program development continue to be reevaluated by both parties and the outcome of this reevaluation may impact the scope and timing of our performance obligation to Toray.

In May 2021, we entered into an oncology research and development collaboration with Genmab to evaluate Genmab antibodies and bispecific antibody engineering technologies in combination with our proprietary Boltbody ISAC technology platform, with the goal of discovering and developing next-generation bispecific ISACs for the treatment of cancer. The research collaboration will evaluate multiple bispecific ISAC concepts to identify up to three clinical candidates for development. Genmab will fund the research, along with the preclinical and clinical development of these candidates through initial clinical proof of concept. Under the Genmab Agreement, we received an upfront payment of $10.0 million and in conjunction with the collaboration, Genmab purchased 821,045 shares of our common stock for $15.0 million. We evaluated the collaboration together with Genmab's purchase of our common stock and allocated $1.4 million from the stock purchase proceeds, together with the $10.0 million upfront payment, to deferred revenue. We recognize this deferred revenue, together with payments received from Genmab for compensation 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 Genmab.

In August 2021, we entered into an oncology research and development collaboration with Innovent, or the Original Innovent Agreement, to leverage Innovent's proprietary therapeutic antibody portfolio and antibody discovery capability against undisclosed oncology targets in combination with our Boltbody ISAC technology and myeloid biology expertise to create new candidates for cancer treatments. Under the Original Innovent Agreement, the Company received an upfront payment of $5.0 million. We allocated the entire $5.0 million upfront payment to deferred revenue, which we recognized together with other payments received from Innovent as collaboration revenue over time as we fulfilled our performance obligation to Innovent. The Innovent agreement, as amended in March 2024, or the Amended Innovent Agreement, no longer meets the criteria under ASC 606. $2.5 million of deferred revenue allocated to the unsatisfied performance obligation as of the contract modification date was recognized as revenue in the three months ended March 31, 2024.

We expect that any collaboration revenue we generate from our current collaborations, and from any future collaboration partners, will fluctuate in the future as a result of the timing and outcome of development activities and the timing and amount paid, 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:

- costs related to manufacturing our product candidates for clinical trials and preclinical studies, including fees paid to third-party CDMOs;
- salaries, payroll taxes, employee benefits and stock-based compensation charges for those individuals involved in research and development efforts;
- external research and development expenses, including lab materials and supplies and payments to CROs, investigative sites, and consultants to conduct our clinical trials and preclinical and non-clinical studies; 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 CROs and consultants in connection with our clinical and preclinical studies and costs related to manufacturing materials for our studies. Since our inception and through December 31, 2024, the majority of our third-party expenses were related to the research and development of trastuzumab imbotolimod, BDC-3042, and other product candidates. With the exception of costs incurred to satisfy our performance obligations under our collaboration agreements, 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 as these costs are associated with 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 expect to continue to incur 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. 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, and 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 of 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 to continue to incur general and administrative expenses for the foreseeable future to support our ongoing research and development activities and the costs of operating as a public company. These costs will likely include 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.

Restructuring Charges

Restructuring charges consist of one-time termination benefits such as severance costs and related benefits and stock-based compensation charges associated with a reduction-in-force.

Impairment Charges

Impairment charges consist of one-time impairment loss associated with an impairment evaluation to assess the impact on the carrying value of our long-lived assets.

Other Income, Net

Interest Income, Net

Interest income consists of interest income from our marketable securities investments.

Other Income

Other income in 2024 consists of the one-time payment received from Innovent under the Amended Innovent Agreement.

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023

	Years Ended December 31,		
	2024	2023	Change
	(In thousands)		
Collaboration revenue	$ 7,690	$ 7,876	$ (186)
Operating expenses:			
Research and development	57,469	61,542	(4,073)
General and administrative	18,457	22,530	(4,073)
Restructuring charges	3,343	—	3,343
Impairment charges	1,469	—	1,469
Total operating expenses	80,738	84,072	(3,334)
Loss from operations	(73,048)	(76,196)	3,148
Other income (expense), net:			
Interest income, net	5,255	6,999	(1,744)
Other income (expense), net	4,675	—	4,675
Total other income (expense), net	9,930	6,999	2,931
Net loss	(63,118)	(69,197)	6,079
Net unrealized gain (loss) on marketable securities	60	956	(896)
Comprehensive loss	$ (63,058)	$ (68,241)	$ 5,183

Collaboration Revenue

Revenue was $7.7 million and $7.9 million for the years ended December 31, 2024 and 2023, respectively. The increase in revenue in the comparative periods was mainly due to revenue recognized under the Amended Innovent Agreement, as we satisfied our performance obligation to Innovent. The increase was also due to continued progress in our other collaborations as we fulfill our performance obligations to our collaboration partners.

Research and Development Expenses

Research and development expenses decreased by $4.0 million from $61.5 million in 2023 to $57.5 million in 2024. The decrease was due to $4.1 million in lower personnel-related expenses due to a decrease in headcount related to the reduction in workforce, a decrease of $0.9 million in facilities expenses, $0.8 million in lower research and development lab supplies and contract services expense, and a decrease of $0.4 million in consulting expenses, offset by $1.3 million in higher clinical expenses related to the advancement of trastuzumab imbotolimod clinical trial into Phase 2 in both monotherapy and in combination with nivolumab and $1.0 million in higher manufacturing expenses related to more raw materials purchased and the timing of batch production of our product candidates.

General and Administrative Expenses

General and administrative expenses decreased by $4.0 million from $22.5 million in 2023 to $18.5 million in 2024. The decrease was due to $3.5 million decrease in salary, bonus and related expenses as a result of the restructuring plan, a decrease of $1.5 million in lower consulting, professional services, marketing expenses, and public relations expenses primarily related to a decrease in legal expenses, offset by $0.9 million in higher facility expenses.

Restructuring Charges

Restructuring charges were $3.3 million in 2024, consisting of $2.9 million of one-time termination benefits such as severance costs and related benefits and $0.7 million of non-cash stock-based compensation expense as a result of a restructuring plan. There were no restructuring charges in 2023.

Impairment Charges

Impairment charges were $1.5 million in 2024. On August 7, 2020, the Company executed a non-cancellable lease agreement (the "Chesapeake Master Lease"), which consist of an existing lease and additional space, for its corporate office, laboratory and vivarium space in Redwood City, California. In December 2024, we initiated efforts to sublease part of our Chesapeake Master Lease, which represented a change in circumstances and constituted a triggering event. In response, we performed an impairment evaluation to assess the impact on the carrying value of our long-lived assets. Based on this evaluation, we determined that an impairment charge was required and recognized an impairment loss. There were no impairment charges in 2023.

Other Income, Net

Interest Income, Net

Interest income was $5.3 million in 2024 and $7.0 million in 2023, respectively. The interest income, net was primarily comprised of interest income from marketable securities.

Other Income

Other income was $4.7 million in 2024 and zero in 2023. The other income in 2024 was due to the one-time payment received from Innovent under the Amended Innovent Agreement.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred net losses, $63.1 million and $69.2 million in 2024 and 2023, respectively, and negative cash flows from operations since our inception, with an accumulated deficit of $427.4 million and anticipate continuing to incur net losses for the foreseeable future. Under our current plan, which includes income from collaboration arrangements, we believe our cash and cash equivalents and marketable securities of $70.2 million as of December 31, 2024 may be sufficient to fund our operations through mid-2026. However, due to the significant uncertainty in our plans, including the achievement of our collaboration income, we have concluded that there is substantial doubt about our ability to continue as a going concern within one year after the issuance of the consolidated financial statements.

We evaluated our current cash position, historical results, forecasted cash flows and plans with regard to liquidity. Our investment policy prioritizes preservation of principal and availability of cash to meet cash flow requirements, and maximizing total net returns after satisfying the first two conditions. Our policy only allows for investments in fixed-income instruments such as corporate bonds and government securities. We believe we will meet longer-term expected future cash requirements and obligations through a combination of cash flows from operating activities, available cash balances, and equity or debt financings or other capital sources, including potential collaborations, licenses, and other similar arrangements, however, there can be no assurance the additional sources will be available at favorable terms or at all.

Shelf Registration and At-The-Market Equity Offering

On March 30, 2022, we filed a shelf registration statement on Form S-3, or the Registration Statement. Pursuant to the Registration Statement, we may offer and sell securities having an aggregate public offering price of up to $250.0 million. In connection with the filing of the Registration Statement, we also entered into a sales agreement with TD Cowen, or Cowen, as sales agent or principal, pursuant to which we may issue and sell shares of our common stock for an aggregate offering price of up to $75.0 million under an at-the-market offering program, or the ATM. Pursuant to the ATM, we will pay Cowen a commission rate equal to 3.0% of the gross proceeds from the sale of any shares of common

stock. We are not obligated to make any sales of shares of our common stock under the ATM. As of December 31, 2024, no shares of our common stock have been sold under the ATM.

Summary Cash Flows

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

	Years Ended December 31,	
	2024	2023
	(In thousands)	
Net cash (used in) provided by:		
Operating activities	$ (61,289)	$ (69,525)
Investing activities	57,576	71,038
Financing activities	108	253
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (3,605)	$ 1,766

Operating Activities

Net cash used in operating activities was $61.3 million and $69.5 million for 2024 and 2023, respectively. Net cash used in operating activities for 2024 was due to our net loss of $63.1 million, adjusted for $10.3 million of non-cash charges and a $8.4 million change in operating assets and liabilities. The non-cash charges were comprised of $7.4 million for stock-based compensation, $2.3 million of non-cash lease-related expense, and $1.8 million for depreciation and amortization expense, partially offset by $2.6 million for accretion of discount on marketable securities and $0.1 million gain on sale of property and equipment. The change in net operating assets was primarily due to a $4.7 million decrease in deferred revenue, a $4.9 million decrease in our accounts payable and accrued expenses, $1.4 million decrease in operating lease liabilities, offset by a $2.6 million increase in our prepaid expense and other assets. Net cash used in operating activities for 2023 was due to our net loss of $69.2 million, adjusted for $9.5 million of non-cash charges and a $9.9 million change in operating assets and liabilities. The non-cash charges were comprised of $9.2 million for stock-based compensation, $3.0 million of non-cash lease-related expense, and $1.9 million for depreciation and amortization expense, offset by $4.5 million for accretion of discount on marketable securities. The change in net operating assets was due to a $3.6 million decrease in deferred revenue related to our collaboration agreements, a $3.4 million decrease in our accounts payable and accrued expenses, a $2.4 million decrease in operating lease liabilities, offset by a $0.5 million increase in our prepaid expense and other assets.

Investing Activities

Net cash provided by investing activities was $57.6 million and $71.0 million in 2024 and 2023, respectively. The net cash provided by investing activities in 2024 was due to $146.3 million in maturities of marketable securities, offset by $88.9 million in purchases of marketable securities. The net cash provided by investing activities for the same period in 2023 was due to $236.2 million maturities of marketable securities, offset by $165.0 million in purchases of marketable securities and $0.2 million in purchases of property and equipment.

Financing Activities

Net cash provided by financing activities was $0.1 million and $0.3 million for 2024 and 2023, respectively. The net cash provided by financing activities for 2024 was due to net proceeds from the issuance of common stock from our employee stock purchase plan. The net cash provided by financing activities for the same period in 2023 was due to the net proceeds from the issuance of common stock from our employee stock purchase plan and exercise of stock options.

Funding Requirements

Based upon our current operating plans, which includes assumptions regarding collaboration revenue and sublease income, we believe that our existing cash, cash equivalents and marketable securities should be sufficient to fund our operations only through mid-2026. As a result of the risks inherent in budgeting for early-stage drug development, we have concluded that there is substantial doubt about our ability to continue as a going concern.

See Note 2 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information on our assessment. Similarly, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements, as of and for the year ended, December 31, 2024, describing the existence of substantial doubt about our ability to continue as a going concern.

We will need to raise additional capital to continue the advancement of our programs. In the near term, our primary uses of cash will be to fund the completion of key milestones for clinical programs and to fund our operations, including research and development activities and employee salaries. This includes significant costs relating to clinical trials and manufacturing our product candidates. Our uses of cash in the long term will be similar as we advance our research and development activities and pay employee salaries. Most pharmaceutical products require larger clinical trials as development progresses, and we expect our funding requirements to grow with the advancement of our programs. Our long-term funding requirements will depend on many factors, which are uncertain but include our portfolio prioritization decisions and the success of our collaborations. In turn, our ability to raise additional capital through equity or partnering will depend on the general economic environment in which we operate and our ability to achieve key milestones. 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;
- the type, number, scope, results, costs, and timing of 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 equity or debt financings or other capital sources, including potential collaborations, licenses, the sale of future royalties, and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements 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

Collaboration Agreements

Joint Development and License Agreement with Toray Industries

In March 2019, we entered into a Joint Development and License Agreement, or the Toray Agreement, with Toray Industries, Inc., or Toray, to develop and commercialize a Boltbody ISAC containing a proprietary antibody owned by Toray. Under the Toray Agreement, we exchanged co-exclusive (with each other) licenses to certain patents and know-how covering our respective technologies. 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 1 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 1 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 territories covered under the agreement, unless either party elects to opt out of its co-funding obligations or reduce them by half, which election can be made on a region-by-region basis. The research plan and program development continue to be reevaluated by both parties and the outcome of this reevaluation may impact the scope and timing of the collaboration.

Oncology Research and Development Collaboration with Genmab A/S

In May 2021, we entered into a License and Collaboration Agreement, or the Genmab Agreement, with Genmab A/S, or Genmab. Together, the companies will evaluate Genmab antibodies and bispecific antibody technologies in combination with our Boltbody ISAC technology platform, with the goal of discovering and developing next-generation bispecific ISACs for the treatment of cancer. Under this research collaboration, the companies will evaluate multiple bispecific ISAC concepts to identify up to three clinical candidates for development. Genmab will fund the research, along with the preclinical and clinical development of these candidates through initial clinical proof of concept. Under the Genmab Agreement, we received an upfront payment of $10.0 million and an equity investment of $15.0 million under a separate stock purchase agreement. Under the Genmab Agreement, we will be compensated for research and development services at the agreed upon full-time employee rate and third-party costs through initial clinical proof of concept of the therapeutic candidates, after which both parties can exercise their respective program opt-in rights. With respect to each candidate for which a party has exercised its program opt-in rights and has exclusive global rights, the other party is eligible to receive potential development and sales-based milestone payments and tiered royalties. Bolt is eligible to receive total potential milestone payments of up to $285.0 million per therapeutic candidate exclusively developed and commercialized by Genmab, along with tiered royalties.

Oncology Research and Development Collaboration with Innovent Biologics, Inc.

In August 2021, we entered into a License and Collaboration Agreement, or the Innovent Agreement, with Innovent Biologics, Inc., or Innovent. Under the Innovent Agreement, the companies will leverage Innovent's proprietary therapeutic antibody portfolio and antibody discovery capability against undisclosed oncology targets in combination with our Boltbody ISAC technology and myeloid biology expertise to create up to three new candidates for cancer treatments with the potential to provide significant benefit to patients. Innovent will fund the initial research, along with the preclinical and clinical development of these candidates through initial clinical proof of concept. Under the Innovent Agreement, we received an upfront payment of $5.0 million. Under the Innovent Agreement, we will be compensated for research and development services at the agreed upon full-time employee rate and third-party costs through initial clinical proof of concept of the therapeutic candidates, after which both parties can exercise their respective license rights. The Innovent Agreement includes license options exercisable by each party to exclusively develop, manufacture and commercialize each candidate in a specific territory. With respect to each candidate for which a party has exercised its license option, the other party is eligible to receive a license option exercise fee, potential development and sales-based milestone payments, and tiered royalties. In March 2024, we entered into an amended and restated agreement with Innovent that provides Bolt with worldwide rights to two ISAC programs. Bolt will be assuming all future development costs for the two ISAC programs, and Innovent is eligible to receive commercial and sales milestones as well as royalties on global net sales.

License Agreements

License Agreements with Stanford University

In May 2015, we entered into a license agreement with Stanford, pursuant to which Stanford granted us an exclusive license to certain inventions. 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 the license 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 the license 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 the license 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 the license agreement, we will reimburse Stanford's patent expenses, including reasonable costs incurred in assisting us with prosecuting and maintaining licensed patents.

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these consolidated 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 consolidated 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 consolidated 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 consolidated financial statements.

Revenue Recognition

For all periods presented, we recognized revenue in accordance with the provisions of Accounting Standard Codification Topic 606, *Revenue from Contract with Customers,* or ASC 606. In accordance with ASC 606, when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. 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. For combined performance obligation that is satisfied over time, collaboration revenue is recognized over time proportionate to the costs 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. In some agreements, we receive compensation for the research and development services performed, which may be billed in the quarter ahead of performance and are trued up on the subsequent quarter's invoice following the work performed, or billed based on actual hours incurred. The cumulative effect of revisions to estimated hours to complete our performance obligation will be recorded in the period in which changes are identified and amounts can be reasonably estimated. 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 consolidated 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. Our accrual is dependent, in part, upon the receipt of timely and accurate reporting from CROs and other third-party vendors. Variations in the assumptions used to estimate accruals including, but not limited to, the number of patients enrolled, the rate of patient enrollment and the actual services performed, may vary from our estimates, resulting in adjustments to clinical trial expenses in future periods. Changes in these estimates that result in material changes to our accruals could materially affect our financial condition and results of operations. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

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 consolidated 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 2024 and 2023.

In 2024 and 2023, stock-based compensation expense related to stock options was $7.4 million and $9.2 million, respectively. As of December 31, 2024, the unrecognized stock-based compensation expense related to stock options was $2.8 million and is expected to be recognized as expense over a weighted-average period of approximately 1.28 years.

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 consolidated 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 (NOL) and Research and Development Carryforwards and Other Income Tax Information

As of December 31, 2024, we had federal and state net operating loss, or NOL, carryforwards of $234.9 million and $324.0 million, respectively. The federal NOL carryforwards generated prior to 2018 and state NOL carryforwards, if not utilized, will expire beginning in 2035. Federal NOL carryforwards aggregating $230.5 million are not subject to expiration.The NOL carryforwards subject to expiration could expire unused and be unavailable to offset future income tax liabilities. The federal NOL carryforwards 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, 2024, we also had federal and state research credit carryforwards of $11.5 million and $6.5 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 file tax returns in the U.S. and California. We are not currently under examination in any of these jurisdictions and all its tax years remain effectively open to examination due to NOL carryforwards.

We have performed a Section 382 study as of September 30, 2023 and expect approximately $2.8 million of federal research and development credits and $51.0 million of California NOL carryforward to expire unused due to Section 382 limitations. 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.

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

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

Item 8. Consolidated Financial Statements and Supplementary Data.

BOLT BIOTHERAPEUTICS, INC.
INDEX TO CONSOLIDATED 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 2024 consolidated financial statements of Bolt Biotherapeutics, Inc. and its subsidiary and the 2023 financial statements of Bolt Biotherapeutics, Inc. (collectively referred to as the "Company"), which comprise the balance sheets as of December 31, 2024 and 2023, and the related statements of operations and comprehensive loss, of stockholders' equity 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, 2024 and 2023, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt About the Company's Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has incurred net losses and negative cash flows from operations since inception, has an accumulated deficit and anticipates continuing to incur net operating losses and negative cash flows from operations for the foreseeable future that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP
San Jose, California
March 24, 2025

We have served as the Company's auditor since 2019.

BOLT BIOTHERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share amounts)

	December 31,	
	2024	2023
Assets		
Current assets:		
Cash and cash equivalents	$ 7,205	$ 10,810
Short-term investments	40,118	91,379
Restricted cash	784	—
Prepaid expenses and other current assets	2,707	3,519
Total current assets	50,814	105,708
Property and equipment, net	3,139	4,957
Operating lease right-of-use assets	21,756	19,120
Restricted cash, non-current	981	1,765
Long-term investments	22,880	26,413
Other assets	62	1,821
Total assets	$ 99,632	$ 159,784
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,507	$ 2,987
Accrued expenses and other current liabilities	9,083	12,486
Deferred revenue	3,015	2,201
Operating lease liabilities	2,251	2,782
Total current liabilities	15,856	20,456
Operating lease liabilities, net of current portion	22,958	17,437
Deferred revenue, non-current	3,620	9,107
Other long-term liabilities	—	43
Total liabilities	42,434	47,043
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Common stock, $0.00001 par value; 200,000,000 shares authorized at December 31, 2024 and 2023; 38,339,697 and 38,114,606 shares issued and outstanding at December 31, 2024 and 2023, respectively	—	—
Additional paid-in capital	484,504	476,989
Accumulated other comprehensive gain	97	37
Accumulated deficit	(427,403)	(364,285)
Total stockholders' equity	57,198	112,741
Total liabilities and stockholders' equity	$ 99,632	$ 159,784

See accompanying notes to the consolidated financial statements.

BOLT BIOTHERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share amounts)

	Years Ended December 31,	
	2024	2023
Collaboration revenue	$ 7,690	$ 7,876
Operating expenses:		
Research and development	57,469	61,542
General and administrative	18,457	22,530
Restructuring charges	3,343	—
Impairment charges	1,469	—
Total operating expense	80,738	84,072
Loss from operations	(73,048)	(76,196)
Other income (expense), net:		
Interest income, net	5,255	6,999
Other income, net	4,675	—
Total other income, net	9,930	6,999
Net loss	(63,118)	(69,197)
Net unrealized gain on marketable securities	60	956
Comprehensive loss	$ (63,058)	$ (68,241)
Net loss per share, basic and diluted	$ (1.65)	$ (1.83)
Weighted-average shares outstanding, basic and diluted	38,183,931	37,811,984

See accompanying notes to the consolidated financial statements.

BOLT BIOTHERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share amounts)

	Common Shares	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2022	**37,797,902**	$ —	**$ 467,513**	**$ (919)**	**$ (295,088)**	**$ 171,506**
Issuance of common stock upon vesting of restricted stock units	58,034	—	—	—	—	—
Issuance of common stock under employee stock purchase plan	254,169	—	247	—	—	247
Issuance of common stock upon exercise of stock options	4,501	—	6	—	—	6
Stock-based compensation	—	—	9,223	—	—	9,223
Unrealized gain on available-for-sale investments	—	—	—	956	—	956
Net loss	—	—	—	—	(69,197)	(69,197)
Balance at December 31, 2023	**38,114,606**	**$ —**	**$ 476,989**	**$ 37**	**$ (364,285)**	**$ 112,741**
Issuance of common stock upon vesting of restricted stock units	41,713	—	—	—	—	—
Issuance of common stock under employee stock purchase plan	183,378	—	108	—	—	108
Stock-based compensation	—	—	7,407	—	—	7,407
Unrealized gain on available-for-sale investments	—	—	—	60	—	60
Net loss	—	—	—	—	(63,118)	(63,118)
Balance at December 31, 2024	**38,339,697**	**$ —**	**$ 484,504**	**$ 97**	**$ (427,403)**	**$ 57,198**

See accompanying notes to the consolidated financial statements.

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

	Years Ended December 31,	
	2024	2023
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (63,118)	$ (69,197)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,781	1,854
Stock-based compensation expense	7,407	9,223
Accretion of discount on marketable securities	(2,615)	(4,493)
Gain on sale of fixed assets	(70)	—
Asset impairment	1,469	—
Non-cash lease expense	2,297	2,952
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	2,571	(454)
Accounts payable and accrued expenses	(4,883)	(3,413)
Operating lease liabilities, net	(1,412)	(2,392)
Deferred revenue	(4,673)	(3,606)
Other long-term liabilities	(43)	1
Net cash used in operating activities	(61,289)	(69,525)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(41)	(206)
Proceeds from sales of property and equipment	148	—
Purchases of marketable securities	(88,855)	(164,988)
Maturities of marketable securities	146,324	236,232
Net cash provided by investing activities	57,576	71,038
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	108	253
Net cash provided by financing activities	108	253
NET (DECREASE) INCREASE IN CASH	(3,605)	1,766
Cash, cash equivalents and restricted cash at beginning of year	12,575	10,809
Cash, cash equivalents and restricted cash at end of period	$ 8,970	$ 12,575
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 7,205	$ 10,810
Restricted cash	1,765	1,765
Total cash, cash equivalents and restricted cash	$ 8,970	$ 12,575
Supplemental schedule of non-cash investing and financing activities:		
Purchases of property and equipment included in accounts payable and accrued liabilities	$ —	$ 152
Right of use assets obtained in exchange for operating lease obligations	$ 6,402	$ —

See accompanying notes to the consolidated financial statements.

BOLT BIOTHERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Description of the Business

Bolt Biotherapeutics, Inc. (the "Company") is a clinical-stage biopharmaceutical company developing novel immunotherapies for the treatment of cancer. The Company's pipeline candidates are built on the Company's deep expertise in myeloid biology and cancer drug development, uniting the targeting precision of antibodies with the power of the innate and adaptive immune system to reprogram the tumor microenvironment for a productive anti-cancer response.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). The financial statements for the fiscal year ended December 31, 2024 are consolidated and include the accounts of the Company and its subsidiary. The financial statements for the fiscal year ended December 31, 2023 were not consolidated and only reflect the accounts of the Company. Certain reclassifications on the statement of cash flows have been made to prior period amounts to conform to current period presentation.

Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, Bolt Biotherapeutics Australia PTY LTD (which are referred to herein, collectively, as the Company where context requires). The Company did not hold any assets or generate revenue during and as of the year ended December 31, 2024. All intercompany balances and transactions have been eliminated on consolidation.

Out-of-Period Adjustment

On August 7, 2020, the Company executed a non-cancellable lease agreement (the "Chesapeake Master Lease") for its corporate office, laboratory and vivarium space in Redwood City, California. During the year ended December 31, 2024, the Company recorded an out-of-period adjustment related to an error in lease accounting that occurred in fiscal year 2020 and which was identified during the close process in December 2024. This adjustment corrected an understatement of operating lease right-of-use asset of $6.4 million and an understatement of operating lease liabilities of $6.8 million as of December 31, 2024. Additionally, this adjustment resulted in a cumulative impact of $0.4 million in total rent expense, of which $0.3 million is related to research and development expense and $0.1 million is related to general and administrative expense, recorded in the year ended December 31, 2024 which related to prior periods. The Company assessed the materiality of this adjustment on the previously issued annual financial statements in accordance with SEC Staff Accounting Bulletin No. 99. The Company concluded that the out-of-period adjustments were not material to the annual financial statements for the year ended December 31, 2024 or to the previously reported annual or interim periods for the years ended December 31, 2023.

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, delay or inability to obtain chemical or biological intermediates from such suppliers required for the synthesis of the Company's product candidates, 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.

Global economic and business activities continue to face widespread macroeconomic uncertainties, including pandemics, labor shortages, inflation and monetary supply shifts, recession risks and potential disruptions from major geopolitical conflicts. The Company continues to actively monitor the impact of these macroeconomic factors on its financial condition, liquidity, operations, and workforce. The extent of the impact of these factors on the Company's operational and financial performance, including its ability to execute its business strategies and initiatives in the

expected time frame, will depend on future developments, which are uncertain and cannot be predicted; however, any continued or renewed disruption resulting from these factors could negatively impact the Company's business.

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.

Liquidity and Going Concern

The Company has incurred net losses and negative cash flows from operations since its inception, has an accumulated deficit of $427.4 million and anticipates continuing to incur net losses for the foreseeable future. Under the Company's current plan, which includes income from collaboration arrangements, management believes its cash and cash equivalents and marketable securities of $70.2 million as of December 31, 2024 may be sufficient to fund the Company's operations through mid-2026. However, due to the significant uncertainty in its plans, including the achievement of its collaboration income, the Company has concluded that there is substantial doubt about its ability to continue as a going concern within one year after the issuance of the consolidated financial statements.

As a result, the Company will be required to raise additional capital by partnering, selling equity, or other means. There can be no assurance as to whether partnering efforts will be successful or whether additional financing will be available on terms acceptable to the Company, if at all. If sufficient funds on acceptable terms are not available when needed, it would have a negative impact on the Company's financial condition and could force the Company to delay, limit, reduce, or terminate product development or future commercialization efforts or grant rights to develop and market product candidates that the Company would otherwise plan to develop and market itself.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The accompanying consolidated financial statements do not reflect any adjustments relating to the recoverability and reclassifications of assets and liabilities that might be necessary if the Company is unable to continue as a going concern.

The Company will need to raise additional capital to continue the advancement of its programs. In the near term, the Company's primary uses of cash will be to fund the completion of key milestones for clinical programs and to fund its operations, including research and development activities and employee salaries. This includes significant costs relating to clinical trials and manufacture of the Company's product candidates. The Company's uses of cash in the long term will be similar as the Company advances its research and development activities and pays employee salaries. Most pharmaceutical products require larger clinical trials as development progresses, and the Company expects its funding requirements to grow with the advancement of its programs. The Company's long-term funding requirements will depend on many factors, which are uncertain but include its portfolio prioritization decisions and the success of its collaborations. In turn, the Company's ability to raise additional capital through equity or partnering will depend on the general economic environment in which it operates and its ability to achieve key milestones.

Use of Estimates

The preparation of the consolidated 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 consolidated 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, stock-based compensation, restructuring costs, long-lived assets impairment assessment, and accrued 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.

Reclassification

Certain amounts in the accompanying consolidated financial statements were reclassified to conform to the current presentation.

Restructuring Charges

Restructuring charges consist primarily of employee severance costs and related benefits. Liabilities for costs associated

with a restructuring activity are recognized when the liability is incurred and are measured at fair value. For one-time employee terminations benefits, the Company recognizes the liability in full on the communication date when future services are not required or amortizes the liability ratably over the service period, if required. The fair value of termination benefits reflects the Company's estimate of expected utilization of certain Company-funded post-employment benefits. One-time termination benefits include severance, continuation of health insurance coverage for certain employees, and other company funded benefits.

Long-lived Assets Impairment Assessment

Long-lived assets, including operating lease assets, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The recoverability of assets to be held and used is measured by a comparison of the carrying amount of the asset group to future net cash flows estimated by the Company to be generated by such assets. If such asset group is considered to be impaired, the impairment to be recognized is the amount by which the carrying amount of the asset group exceeds the fair value of the asset group. Any impairment loss is allocated to the long-lived assets of the group on a pro rata basis using the relative carrying amounts of those assets, except that the carrying amount of an individual asset cannot be reduced below its fair value.

Factors that may indicate potential impairment and trigger an impairment test include, but are not limited to, general macroeconomic conditions, conditions specific to the industry and market, an adverse change in legal factors and business climate or operational performance of the business.

Calculating the fair value of a reporting unit, an asset group and an individual asset involves significant estimates and assumptions. These estimates and assumptions include, among others, projected future cash flows, risk-adjusted discount rates, future economic and market conditions, and the determination of appropriate market comparables. Changes in these factors and assumptions used can materially affect the amount of impairment loss recognized in the period the asset was considered impaired.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash, cash equivalents and marketable securities. At December 31, 2024 and 2023, most of the Company's funds were invested with a registered investment manager and custodied at one financial institution, with operating cash kept at a separate financial institution, and account balances may at times exceed federally insured limits. Management believes that the Company is not subject to unusual or significant credit risk beyond the normal credit risk associated with commercial banking relationships.

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, 2024 and 2023, cash and cash equivalents consisted primarily of bank deposits and money market funds which were unrestricted as to withdrawal or use.

Allowance for Credit Losses

For available-for-sale securities in an unrealized loss position, the Company first assesses whether it intends to sell, or if it is more likely than not that the Company will be required to sell, the security before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the security's amortized cost basis is written down to fair value through earnings. For available-for-sale securities that do not meet the aforementioned criteria, the Company evaluates whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, the Company considers the severity of the impairment, any changes in interest rates, market conditions, changes to the underlying credit ratings and forecasted recovery, among other factors. The credit-related portion of unrealized losses, and any subsequent improvements, are recorded in interest income through an allowance account. Any impairment that has not been recorded through an allowance for credit losses is included in other comprehensive income (loss) on the statements of operations and comprehensive loss.

The Company elected the practical expedient to exclude the applicable accrued interest from both the fair value and amortized costs basis of its available-for-sale securities for purposes of identifying and measuring an impairment. Accrued interest receivable on available-for-sale securities is recorded within cash and cash equivalents on the Company's balance sheets. The Company's accounting policy is to not measure an allowance for credit loss for accrued

interest receivable and to write-off any uncollectible accrued interest receivable as a reversal of interest income in a timely manner, which the Company considers to be in the period in which it determines the accrued interest will not be collected by the Company.

Marketable Securities

The Company classifies its marketable securities as available-for-sale and records such assets at estimated fair value in the balance sheets, with unrealized gains and non-credit related 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. The Company classifies marketable securities with remaining maturities greater than three months but less than one year as short-term investments, and those with remaining maturities greater than one year are classified as long-term investments. The Company invests its excess cash balances primarily in corporate debt securities. 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, 2024 and 2023, the Company had short-term and 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) and corporate credit card program.

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.

Cloud Computing Arrangements

The Company incurs costs to implement cloud computing arrangements hosted by third party vendors. Costs incurred to implement cloud computing service arrangements are capitalized when incurred during the application development phase, and recognized as prepaid and other assets and other non-current assets on the balance sheet. Implementation costs are subsequently amortized over the expected term of the related cloud service. The carrying value of cloud computing implementation costs are tested for impairment when an event or circumstance indicates that the asset might be impaired. Changes in cloud computing arrangement implementation costs are classified within operating activities in the statements of cash flows. The Company does not consider cloud computing agreements to be material to its consolidated financial statements.

Revenue Recognition

Under Accounting Standard Codification Topic 606, *Revenue from Contract with Customers* ("ASC 606"), the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the following steps are performed: (i) identification of a contract to provide goods or services to a customer; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration, if any; (iv) where a contract contains multiple performance obligations, the Company must allocate the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when (or as) each performance obligation is satisfied.

The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer.

At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

As part of the accounting for these arrangements, the Company develops assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company uses key assumptions to determine the stand-alone selling price, which may include development timelines, reimbursement rates for personnel costs, discount rates, and probabilities of technical and regulatory success. The Company evaluates each performance obligation and determines if it is satisfied over time. In addition, variable consideration must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.

The Company constrains the estimates of variable consideration such that it is probable that a significant reversal of previously recognized revenue will not occur in future reporting periods. When determining if variable consideration should be constrained, management considers whether there are factors outside the Company's control that increase the likelihood of a significant reversal of previously recognized revenue and revenue-related amounts in future reporting periods. These estimates are re-assessed each reporting period as necessary depending on the facts and circumstances of each contract.

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"), Genmab A/S ("Genmab"), and Innovent Biologics, Inc. ("Innovent"), 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. Cash and cash equivalents, restricted cash, marketable debt securities, accounts payable, accrued expenses and other current liabilities are reported at their respective fair values in our balance sheets. The carrying amount of the remaining financial instruments approximate fair value due to their short-term nature. Refer to Note 3 for the methodologies and assumptions used in valuing financial instruments.

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 Accounting Standard Codification Topic 842, *Leases* ("ASC 842"). 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.

At the commencement date of a lease, the Company recognizes lease liabilities which represent its obligation to make lease payments, and right-of-use assets ("ROU assets") which represent its right to use the underlying asset during the lease term. The lease liability is measured at the present value of lease payments over the lease term. As the Company's leases typically do not provide an implicit rate, the Company uses an incremental borrowing rate based on the information available at the lease commencement date. The ROU asset is measured at cost, which includes the initial measurement of the lease liability and initial direct costs incurred by the Company and excludes lease incentives. ROU assets are recorded in operating lease ROU assets and lease liabilities are recorded in operating lease liabilities, current and noncurrent in the balance sheets.

Lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Operating lease expense is recognized on a straight-line basis over the lease term. The Company does not recognize lease liabilities and ROU assets for short-term leases with terms of twelve months or less.

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 grant date fair value is utilized for restricted stock awards and the fair value of each stock option grant is estimated on the date of grant using the Black-Scholes 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.

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 potentially dilutive securities. Basic and diluted net loss per share is presented in conformity with the two-class method required for participating securities. The Company 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 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 marketable securities. The Company incurred a net unrealized gain on marketable securities of $0.1 million and a net unrealized loss $1.0 million during the years ended December 31, 2024 and 2023, respectively.

Segment Reporting

Operating segments are defined as components of an entity where discrete financial information is evaluated regularly by the chief operating decision maker ("CODM") in deciding how to allocate resources and in assessing performance. The Company's Chief Executive Officer is its CODM. The Company's CODM reviews financial information presented on a consolidated basis for the purposes of making operating decisions, allocating resources and evaluating financial performance. As such, the Company has determined that it operates in one operating and one reportable segment. The Company's long-lived assets are entirely based in the United States.

Recently Adopted Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-07 Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures ("ASU 2023-07"), which requires entities to disclose incremental segment information on an annual and interim basis. ASU 2023-07 requires entities with a single reportable segment to provide all the disclosures required by the amendments in ASU 2023-07 and all existing segment disclosures in Segment Reporting (Topic 280). ASU 2023-07 is effective for annual periods on January 1, 2024, and interim periods beginning on January 1, 2025. The ASU does not change how a public entity identifies its operating segments, aggregates them, or applies the quantitative thresholds to determine its reportable segments. The Company adopted the new standard effective December 31, 2024. As a result, the Company has enhanced its segment disclosures to include the presentation of net loss by segment and the disclosure of our chief operating decision-maker. The adoption of this ASU affects only the Company's disclosures, with no impact on its financial condition and results of operations. Refer to Note 13 for further detail.

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.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures (“ASU 2023-09”). ASU 2023-09 requires enhanced annual disclosures regarding the rate reconciliation and income taxes paid information. ASU 2023-09 is effective for annual periods on January 1, 2025 and may be adopted on a prospective or retrospective basis. Early adoption is permitted. The Company is evaluating the impact of this guidance on its consolidated financial statements and related disclosures.

In March 2024, the FASB issued ASU 2024-02, Codification Improvements ("ASU 2024-02"). This ASU aims to improve and simplify the language and structure of the Codification by removing references to Concepts Statements. This amendment is effective for periods beginning after December 15, 2024. The Company does not expect the adoption of ASU 2024-02 to have a material impact on its consolidated financial statements and related disclosures.

In November 2024, the FASB issued ASU 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40) ("ASU 2024-03"). This ASU requires more detailed information about specified categories of expenses (purchases of inventory, employee compensation, depreciation, amortization, and depletion) included in certain expense captions presented on the face of the income statement. This ASU is effective for fiscal years beginning after December 15, 2026, and for interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The amendments may be applied either (1) prospectively to consolidated financial statements issued for reporting periods after the effective date of this ASU or (2) retrospectively to all prior periods presented in the consolidated financial statements. The Company is evaluating the impact of this guidance on its consolidated 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 years ended December 31, 2024 and 2023, financial assets measured on a recurring basis consist of cash invested in money market accounts, short-term investments, and long-term investments. The fair value of short and long-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.

There were no transfers in or out of Level 3 fair value measurements during the years ended December 31, 2024 and 2023.

Marketable securities, all of which are classified as available-for-sale securities, consisted of the following at December 31, 2024 and 2023 (in thousands):

	December 31, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Asset-backed securities	$ 19,998	$ 46	$ (10)	$ 20,034
U.S. treasury securities	14,346	18	—	14,364
Commercial paper	2,079	3	—	2,082
Corporate debt securities	26,478	46	(6)	26,518
Total	$ 62,901	$ 113	$ (16)	$ 62,998

	December 31, 2023			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Asset-backed securities	$ 17,347	$ 10	$ (15)	$ 17,342
U.S. treasury securities	43,924	34	(11)	43,947
Other government agency securities	13,371	—	(15)	13,356
Commercial paper	20,351	4	(10)	20,345
Corporate debt securities	22,763	41	(2)	22,802
Total	$ 117,756	$ 89	$ (53)	$ 117,792

As of December 31, 2024, the unrealized losses for available-for-sale investments were primarily due to changes in interest rates and not due to increased credit risks associated with specific securities. The contractual terms of those investments do not permit the issuer to settle the securities at a price less than the amortized cost bases of the investments. The Company does not currently intend to sell the investments. As of December 31, 2024, no allowance for credit losses was recorded and the Company did not recognize any impairment losses related to investments.

The tables below show the gross unrealized losses and fair value of the Company's available-for-sale securities with unrealized losses that are not deemed to have credit losses (in thousands), aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position at December 31, 2024 and 2023, respectively:

	December 31, 2024					
	Less Than 12 Months		More Than 12 Months		Total	
	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses
Asset-backed securities	$ 2,000	$ —	$ 18,034	$ (10)	$ 20,034	$ (10)
U.S. treasury securities	10,382	—	3,982	—	14,364	—
Commercial paper	2,082	—	—	—	2,082	—
Corporate debt securities	14,710	—	11,808	(6)	26,518	(6)
Total	$ 29,174	$ —	$ 33,824	$ (16)	$ 62,998	$ (16)

	December 31, 2023					
	Less Than 12 Months		More Than 12 Months		Total	
	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses
Asset-backed securities	$ 4,686	$ —	$ 12,656	$ (15)	$ 17,342	$ (15)
U.S. treasury securities	34,104	—	9,843	(11)	43,947	(11)
Other government agency securities	2,477	(1)	10,879	(14)	13,356	(15)
Commercial paper	20,345	(10)	—	—	20,345	(10)
Corporate debt securities	9,566	(1)	13,236	(1)	22,802	(2)
Total	$ 71,178	$ (12)	$ 46,614	$ (41)	$ 117,792	$ (53)

Accrued interest receivable on available-for-sale securities were $0.3 million and $0.3 million at December 31, 2024 and 2023, respectively, which are recorded in cash and cash equivalents line item on the Company's balance sheets. The Company has not written off any accrued interest receivables for the years ended December 31, 2024 and 2023.

At December 31, 2024 and 2023, the fair values of the Company’s assets, which are measured at fair value on a recurring basis, were determined using the following inputs (in thousands):

	December 31, 2024			
	Total	(Level 1)	(Level 2)	(Level 3)
Money market funds	$ 5,620	$ 5,620	$ —	$ —
Asset-backed securities	20,034	—	20,034	—
U.S. treasury securities	14,364	12,379	1,985	—
Commercial paper	2,082	—	2,082	—
Corporate debt securities	26,518	—	26,518	—
Total	$ 68,618	$ 17,999	$ 50,619	$ —

	December 31, 2023			
	Total	(Level 1)	(Level 2)	(Level 3)
Money market funds	$ 8,641	$ 8,641	—	$ —
Asset-backed securities	17,342	—	17,342	—
U.S. treasury securities	43,947	33,001	10,946	—
Other government agency securities	13,356	—	13,356	—
Commercial paper	20,345	—	20,345	—
Corporate debt securities	22,802	—	22,802	—
Total	$ 126,433	$ 41,642	$ 84,791	$ —

4. License and Equity Agreement

License and Equity Agreement with Related Party

In May 2015, the Company entered into a license agreement (as amended, the "Stanford Agreement"), with The Board of Trustees of the Leland Stanford Junior University ("Stanford"). The Stanford Agreement provides the Company exclusive licenses to certain inventions. As consideration, the Company issued Stanford shares of its common stock and a limited right to purchase equity in future financing. Dr. Edgar G. 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 Company's Series A financing in September 2016. Additionally, the Company is required by the Stanford Agreement 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 the Stanford Agreement to pay Stanford tiered royalties on the Company's and its sublicensees' net sales of licensed products, if any, at 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 the Stanford Agreement with respect to the covered intellectual property. In May 2024, Dr. Engleman resigned from the board of directors of the Company. No royalty payments have been made to date.

Effective May 10, 2023, the Company terminated a separate license agreement with Stanford entered into in June 2018, after determining it was no longer necessary. The termination did not result in any payments due to Stanford.

5. Balance Sheet Components

Property and Equipment, net

Property and equipment, net, consist of the following (in thousands):

	December 31,	
	2024	2023
Laboratory equipment	$ 9,745	$ 10,038
Office equipment	386	386
Leasehold improvements	286	285
Total property and equipment	10,417	10,709
Less accumulated depreciation and amortization	(7,278)	(5,752)
Total	$ 3,139	$ 4,957

Depreciation expense related to property and equipment was $1.8 million and $1.9 million for the years ended December 31, 2024 and 2023, respectively.

Prepaids and Other Current Assets and Other Non-current Assets

Prepaids and other current assets and other non-current assets, consist of the following (in thousands):

	December 31,	
	2024	2023
Prepaids and other current assets:		
Cloud computing arrangement implementation costs	$ 55	$ 178
Prepaid software	501	725
Prepaid rent	532	181
Other receivables, net	1,165	1,527
Other prepaids and other current assets	454	908
Prepaids and other current assets	2,707	3,519
Other non-current assets		
Cloud computing arrangement implementation costs - non-current	51	371
Other non-current assets	11	1,450
Other non-current assets	62	1,821

As of December 31, 2024 and 2023, cloud computing arrangement implementation costs consisted of deferred costs of

zero and $0.6 million, respectively, and associated accumulated amortization of $0.4 million and $30,000, respectively.

Accrued Expenses and Other Current Liabilities

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

	December 31,	
	2024	2023
Accrued research and development	$ 3,761	$ 6,092
Accrued compensation	4,203	5,820
Accrued restructuring charges	739	—
Accrued other	380	574
Total	$ 9,083	$ 12,486

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 Agreement") with Toray Industries, Inc. ("Toray") to jointly develop and commercialize a Boltbody™ immune-stimulating antibody conjugate ("ISAC") containing Toray's proprietary antibody to treat cancer. The Company determined that the Toray Agreement is a contract with a customer and should be accounted for under ASC 606. In conjunction with the Toray 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. 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 Agreement and included in the total consideration for collaboration revenue. In February 2021, in connection with the Company's initial public offering ("IPO"), all outstanding shares of Series T convertible preferred stock were converted into shares of the Company's common stock.

In the Toray Agreement, the Company has identified one bundled performance obligation which includes the license rights, research and development services and services associated with participation on a joint steering committee. The transaction price includes the $1.5 million allocated from the Series T convertible preferred stock and $1.8 million of estimated variable consideration related to compensation for research and development services at the agreed upon full-time employee rate and third-party costs. 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. 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. 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. As of December 31, 2024, receivables of $7,500 related to research and development services performed under the Toray Agreement were recorded as part of the prepaid expenses and other current assets line item on the Company's consolidated balance sheet. There were no receivables as of December 31, 2023. 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. As of December 31, 2024, contract liabilities totaling $0.9 million at period-end were recorded in deferred revenue with $0.4 million in current liabilities and $0.5 million in non-current liabilities on the balance sheet based on the forecasted periods of performance. As of December 31, 2023, contract liabilities totaling $1.5 million at period-end were recorded in deferred revenue with $0.5 million in current liabilities and $1.0 million in non-current liabilities on the balance sheet based on the forecasted periods of performance.

The Company following table presents changes in the contract liability (in thousands):

Balance at December 31, 2023	$ 1,502
Addition—amount billed or accrued for research and development services	317
Revenue recognized	(914)
Balance at December 31, 2024	$ 905

The Company recorded $0.9 million and zero revenue during the years ended December 31, 2024 and 2023, respectively. The Toray Agreement includes both fixed and variable considerations. Under the Toray Agreement, the Company will be compensated for early-stage development and manufacturing activities based on agreed full-time equivalent rates and actual out of pocket costs through the completion of the first Phase 1 clinical trial for the collaboration product and Toray is entitled to reimbursement for 50% of such development costs from the Company's share of revenues collected from the sale or licensing of collaboration products. Although the legal term of the agreement is until collaboration products are no longer sold in the territories covered under the agreement, the parties have present enforceable rights and obligations through the end of the first Phase 1 clinical trial, after which both parties can opt out of continued development under the agreement. As such, the accounting term of the Toray Agreement is considered to terminate upon completion of the first Phase 1 clinical trial. After the conclusion of the first Phase 1 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 territories covered under the agreement, 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 territories covered under the agreement as a whole. Such optional additional items will be accounted for as contract modifications when development advances past certain milestones and the parties both exercise their opt-in rights.

Oncology Research and Development Collaboration with Genmab A/S

In May 2021, the Company entered into a License and Collaboration Agreement (the "Genmab Agreement") with Genmab A/S ("Genmab"). Together, the companies will evaluate Genmab antibodies and bispecific antibody engineering technologies in combination with the Company's ISAC technology platform, with the goal of discovering and developing next-generation bispecific ISACs for the treatment of cancer. Under this research collaboration, the companies will evaluate multiple bispecific ISAC concepts to identify up to three clinical candidates for development. Genmab will fund the research, along with the preclinical and clinical development of these candidates through initial clinical proof of concept. Under the Genmab Agreement, the Company received an upfront payment of $10.0 million. The Company determined that the Genmab Agreement is a contract with a customer and should be accounted for under ASC 606. In conjunction with the Genmab Agreement, the Company entered into a stock purchase agreement (the "Genmab SPA") for the issuance of 821,045 shares of the Company's common stock to Genmab for a total purchase price of $15.0 million. These contracts have been evaluated together and the consideration in excess of the fair value of the common stock of $1.4 million has been allocated to the Genmab Agreement and included in the total consideration for collaboration revenue.

In the Genmab Agreement, the Company has identified one bundled performance obligation that includes the license rights, research and development services and services associated with participation on a joint research committee. The transaction price includes the $10.0 million upfront payment, the $1.4 million allocated from the Genmab SPA, and $17.7 million of estimated variable consideration related to compensation for research and development services at the agreed upon full-time employee rate and third-party costs. 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. Compensation for the research and development services are billed in the quarter based on actual hours incurred to satisfy the performance obligation. 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. As of December 31, 2024 and December 31, 2023, receivables of $0.8 million and $0.6 million, respectively, related to research and development services performed under the Genmab Agreement were recorded as part of the prepaid expenses and other current assets line item on the balance sheet. 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. As of December 31, 2024, contract liabilities totaling $5.7 million were recorded in deferred revenue with $2.6 million in current liabilities and $3.1 million in non-current liabilities on the balance sheet based on the forecasted periods of performance. As of December 31, 2023, contract liabilities totaling $6.7 million were recorded in deferred revenue with $1.0 million in current liabilities and $5.7 million in non-current liabilities on the balance sheet based on the forecasted periods of performance.

As part of the Company's ongoing collaboration with Genmab, the Company has reassessed the related variable consideration. In alignment with the Company's latest forecast and strategic objectives, Genmab has agreed to take on an increased share of the activities originally planned as joint efforts, further optimizing resource allocation and enhancing operational efficiency. As a result, the Company's variable consideration has been significantly reduced, impacting the recognized revenue for the period. The Company's previously recognized revenue is not subject to reversal; however, the Company has adjusted its forward-looking revenue projections accordingly. While this resulted in no recognized revenue in the three-month period ending December 31, 2024, the Company will continue to make progress on the Genmab collaboration agreement and expects to recognize revenue in future periods as its performance obligations are satisfied. The Company remains committed to executing on this agreement and will continue to reassess its revenue recognition estimates as new information becomes available.

The following table presents changes in the Company's contract liability (in thousands):

Balance at December 31, 2022	$	8,498
Addition—amount billed for research and development services		1,896
Revenue recognized		(3,730)
Balance at December 31, 2023		6,664
Addition—amount billed for research and development services		2,369
Revenue recognized		(3,303)
Balance at December 31, 2024	$	5,730

The Company recorded $3.3 million and $3.7 million in revenue earned during the years ended December 31, 2024 and 2023, based on services performed under the Genmab Agreement during the period. Under the Genmab Agreement, the Company will be compensated for research and development services at the agreed upon full-time employee rate and third-party costs through initial clinical proof of concept of the therapeutic candidates, which also represents the period of time both parties have enforceable rights and obligations. As such, the accounting term of the Genmab Agreement was considered to terminate upon completion of the initial clinical proof of concept of the therapeutic candidates, after which Genmab has the option to develop and commercialize up to three therapeutic candidates and the Company has the option to participate in development and commercialization of one candidate. The Genmab Agreement includes optional additional items which will be accounted for as contract modifications after initial clinical proof of concept of the therapeutic candidates. With respect to each candidate for which a party has exercised its program opt-in rights and has exclusive global rights, the other party is eligible to receive potential development and sales-based milestone payments and tiered royalties, subject to certain customary reductions, the amount of all such considerations will vary based on the market potential of the applicable territory for which such party has exercised its program opt-in rights. Under the Genmab Agreement, the Company is eligible to receive total potential milestone payments of up to $125.0 million in development milestones and $160.0 million in sale milestones per therapeutic candidate exclusively developed and commercialized by Genmab, along with tiered royalties at rates from a single-digit to mid-teens percentage based on net sales of each therapeutic candidate. However, given the current phase of development of therapeutic candidates under the Genmab Agreement, the Company cannot estimate the probability or timing of achieving these milestones, and, therefore, has excluded all milestone and royalty payments from the transaction prices of the agreement.

Oncology Research and Development Collaboration with Innovent Biologics, Inc.

In March 2024, the Company entered into an amended and restated license and collaboration agreement with Innovent Biologics, Inc. (the "Amended Innovent Agreement"), which amends the original license and collaboration agreement with Innovent Biologics, Inc. ("Innovent") dated August 25, 2021 (the "Original Innovent Agreement"). Under the Original Innovent Agreement, the Company and Innovent leveraged Innovent's proprietary therapeutic antibody portfolio and antibody discovery capability against undisclosed oncology targets in combination with the Company's Boltbody ISAC technology and myeloid biology expertise to create new candidates for cancer treatments. Innovent funded the initial research, along with the preclinical development of these candidates through the contract modification date. Under the Original Innovent Agreement, the Company received an upfront payment of $5.0 million and was compensated for research and development services at the agreed upon full-time employee rate and third-party costs.

As part of the Amended Innovent Agreement, Innovent paid the Company a one-time payment of $4.7 million to be relieved from certain future funding and developmental obligations under the Original Innovent Agreement. Additionally, the Company secured exclusive worldwide rights to ISAC programs utilizing specified antibodies against two tumor antigen targets and assumed all future development and commercialization costs for any such ISAC program. Under the Amended Innovent Agreement, the Company has the right, but not the obligation, to further develop and commercialize the ISAC programs. Innovent and its affiliates are eligible to receive total potential milestones payments of up to $112.7 million, as well as royalties in low single digits on global net sales. The Company determined that the Amended Innovent Agreement no longer meets the criteria under ASC 606. Therefore, $2.5 million of deferred revenue allocated to the unsatisfied performance obligation as of the contract modification date, was recognized as revenue and the $4.7 million one-time payment received was recognized as other income on the consolidated statement of operations and comprehensive loss in the first quarter of 2024.

The following table presents changes in the Company's contract liability (in thousands):

Balance at December 31, 2022	$	4,957
Addition—amount billed for research and development services		2,330
Revenue recognized		(4,145)
Balance at December 31, 2023		3,142
Addition—amount billed for research and development services		331
Revenue recognized		(3,473)
Balance at December 31, 2024	$	—

The Company recorded $3.4 million and $4.1 million in revenue earned during the years ended December 31, 2024 and 2023, based on services performed the performance obligation under the Innovent collaboration during the periods.

7. Commitments and Contingencies

Leases

The Company has operating leases for its corporate office, laboratory and vivarium space in Redwood City, California. On August 7, 2020, the Company executed a non-cancellable lease agreement for 71,646 square feet of space (the "Chesapeake Master Lease"), which consist of 25,956 square feet under an existing lease and 45,690 square feet of additional space, for its corporate office, laboratory and vivarium space in Redwood City, California. The Chesapeake Master Lease has an initial term of ten years from the commencement date, with an option to extend the lease for an additional 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 was paid directly by the landlord to various vendors. Upon execution of the non-cancellable lease agreement, the Company took control of 10,000 square feet of space, which was subleased as further described below. The remaining 35,690 square feet of additional office, laboratory and vivarium space commenced in June 2021.

The sublease agreement, to sublease 10,500 square feet, commenced in June 2021 and expired on July 31, 2023. In August 2022, the second sublease agreement was amended to expand the subleased premises to 11,655 square feet in the first year and further increase to 13,743 square feet in the second year. In addition, the expiration date of the second sublease was also amended to the expiration date of the Chesapeake Master Lease. The subtenant has an early termination option with an effective date no earlier than September 30, 2024, after which either the Company or the sublessee have the right to terminate the sublease prior to the expiration date by providing at least fifteen months written notice to the other party. The subtenant does not have an option to extend the sublease term. Rent for the second sublease is subject to scheduled annual increases and the subtenant is responsible for certain operating expenses and taxes throughout the term under the sublease agreement. Sublease income was approximately $0.8 million and $0.8 million for each of the years ended December 31, 2024 and 2023.

At December 31, 2024 and 2023, finance right-of-use leases were used to finance capital equipment such as printers or ozone generators, and are immaterial.

The weighted-average remaining lease term and discount rate related to the Company's lease liabilities as of December 31, 2024 were 6.4 years and 11.9%, 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, 2023 were 6.7 years and 11.1%, 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.

Cash required as security for our operation leases is secured by a letter of credit on behalf of the lessor in the amount of approximately $1.6 million and is recorded as restricted cash on the balance sheet as of December 31, 2024 and 2023.

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

	Years Ended December 31,	
	2024	2023
Total operating lease cost	$ 4,922	$ 4,480

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

	Years Ended December 31,	
	2024	2023
Operating cash flows from operating leases	$ 4,886	$ 4,726

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, 2024 (in thousands):

	Operating Leases	Sublease Income
2025	$ 5,122	$ 979
2026	5,399	248
2027	5,584	—
2028	5,775	—
2029	5,974	—
Thereafter	8,789	—
Total lease payments	36,643	1,227
Less interest	(11,434)	—
Total	$ 25,209	$ 1,227

Impairment

In June 2024, the Company conducted an impairment assessment following its May 2024 announcement and restructuring plan. As part of this evaluation, the Company assessed whether these events constituted a triggering event that could impact the carrying value of its long-lived assets. The Company concluded that a triggering event had occurred but determined that no impairment charge was necessary.

In December 2024, the Company both abandoned a portion of its Chesapeake Master Lease and initiated efforts to sublease this space, which indicated the carrying amount may not be recoverable and constituted a triggering event under ASC 360 for this asset group. In performing the impairment assessment, the Company utilized the income approach using a discounted cash flow methodology to estimate fair values of its right-of-use assets.

The carrying value of the asset grouping was compared to its estimated fair value. The analysis measured the undiscounted cash flows over the remaining lease term, by utilizing key market based assumptions such as rent, lease terms, lease up costs, and a discount rate. It also considered current market lease rates and applied a discount rate of 8.0%. These represented Level 3 nonrecurring fair value measurements. Based on these analyses, the Company recognized pre-tax long-lived asset impairment charges of $1.5 million on the right-of-use assets, disclosed as a separate line item on the consolidated income statement, during the year ended December 31, 2024.

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, 2024, the Company did not have any material indemnification claims that were probable or reasonably possible and consequently had not recorded related liabilities.

Other Commitments

The Company enters into agreements in the normal course of business, including with contract research organizations for clinical trials, contract manufacturing organizations for certain manufacturing services, and vendors for preclinical studies and other services and products for operating purposes, which are generally cancelable upon written notice.

Legal Proceedings

From time to time, we might be subject to various legal proceedings relating to claims arising out of our operations. The outcome of litigation is inherently uncertain. If one or more legal matters were resolved against us in a reporting period for amounts above management's expectations, our business, results of operations, financial position and cash flows for that reporting period could be materially adversely affected. Except as described below, we are not currently involved in any material legal proceedings, the ultimate disposition of which could have a material adverse effect on our operations, financial condition or cash flows.

Securities Class Action

On July 2, 2024, a securities class action complaint was filed against the Company and certain of its directors and executive officers (collectively, the "Defendants") in the United States District Court for the Northern District of California, captioned Nesterenko v. Bolt Biotherapeutics, Inc. et al., Case No. 3:24-cv-03985, purportedly on behalf of a class of individuals who purchased or otherwise acquired the Company's common stock between February 5, 2021 and May 14, 2024. The complaint alleged that Defendants made false and/or misleading statements in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended. The complaint sought unspecified monetary damages and other relief. On October 3, 2024, the court appointed a lead plaintiff, appointed lead plaintiff's counsel, and ordered the parties to submit a proposed briefing schedule for the filing of an amended complaint and the Company's response thereto, which the parties submitted on October 23, 2024. On January 17, 2025, the lead plaintiff voluntarily dismissed the case, bringing the legal proceedings to a close.

8. Restructuring

On May 14, 2024, the Company announced a strategic pipeline prioritization and restructuring plan pursuant to which it discontinued developing trastuzumab imbotolimod in order to focus on the Company's Phase 1 asset, BDC-3042, a dectin-2 agonist antibody, and the Company's next generation ISAC platform including new clinical candidate, BDC-4182, targeting claudin 18.2, and reduced overall operating expenses. The restructuring plan reduced the Company's workforce by approximately 50%. The Company recorded a total restructuring charge of $3.6 million, which consists of $2.9 million of one-time termination benefits such as severance costs and related benefits and $0.7 million of non-cash stock-based compensation expense. Cash payments of $1.9 million were made during the year ended December 31, 2024. As of December 31, 2024, $0.7 million of one-time termination benefits remain payable and are recorded within the accrued expenses and other current liabilities line item on the Company's consolidated balance sheet. Severance payments commenced in July 2024 and will extend through July 2025. The following table provides details on the Company's restructuring and other charges (in thousands):

Liability balance, June 30, 2024	$	2,900
Adjustments in the period		(221)
Cash payments		(1,940)
Balance at December 31, 2024	$	739

In June 2024, the Company assessed whether the restructuring plan constituted a triggering event indicating potential impairment of its long-lived assets, including operating lease right-of-use assets and property and equipment. Based on this evaluation, the Company determined that while impairment indicators were present, no impairment charge was necessary at that time.

9. Common Stock

Shelf Registration and At-The-Market Equity Offering

On March 30, 2022, the Company filed a shelf registration statement on Form S-3 (the "Registration Statement"). Pursuant to the Registration Statement, the Company may offer and sell securities having an aggregate public offering price of up to $250.0 million. In connection with the filing of the Registration Statement, the Company also entered into a sales agreement with Cowen and Company, LLC ("Cowen"), as sales agent or principal, pursuant to which the Company may issue and sell shares of its common stock for an aggregate offering price of up to $75.0 million under an at-the-market (the "ATM") offering program. Pursuant to the ATM, the Company will pay Cowen a commission rate equal to 3.0% of the gross proceeds from the sale of any shares of common stock. The Company is not obligated to make any sales of shares of its common stock under the ATM. As of December 31, 2024, no shares of the Company's common stock have been sold under this ATM.

Common Stock Reserved for Future Issuance

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

	December 31, 2024
Common stock options issued and outstanding	11,423,193
Common stock restricted stock awards issued and outstanding	—
Common stock available for future issuance under the 2021 Plan	1,838,033
Common stock available for future issuance under the ESPP	771,661
Total	14,032,887

10. Stock-Based Compensation

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 (the "2021 Plan") and the Company's stockholders approved the 2021 Plan. The 2021 Plan authorized issuance of up to 8,075,000 shares of common stock and it became effective upon the execution of the underwriting agreement for the Company's IPO. In addition, the number of shares of common stock reserved for issuance under the 2021 Plan automatically increases on the first day of January of each calendar year that commences after the 2021 Plan became effective and continuing through and including January 1, 2031, in an amount equal to 5% of the total number of shares of the Company's common stock outstanding on December 31, or a lesser number of shares determined by the Company's board of directors or compensation committee. As a result, common stock reserved for issuance under the 2021 Plan was increased by 1,905,730 shares on January 1, 2024. In connection with the workforce reduction described in Note 8 "Restructuring", the Company entered into consulting agreements with certain officers of the Company, pursuant to which a total of 1,615,713 stock options previously granted to the officers were canceled on July 15, 2024.

In addition, in January 2021, the Company's board of directors and stockholders adopted the 2021 Employee Stock Purchase Plan (the "ESPP"). The ESPP authorized issuance of up to 420,000 shares of common stock and it became effective upon the execution of the underwriting agreement for the Company's IPO. The ESPP permits participants to purchase common stock through payroll deductions of up to 15% of their eligible compensation. Employees purchase shares of common stock at a price per share equal to 85% of the lower of the fair market value at the start or end of six-month purchase periods within the two-year offering period. In addition, the number of shares of common stock reserved for issuance under the ESPP automatically increases on January 1 of each calendar year that commences after the ESPP became effective and continuing through and including January 1, 2031, by the lesser of (1) 1% of the total number of shares of the Company's common stock outstanding on December 31 of the preceding calendar year, (2) 840,000 shares, and (3) a number of shares determined by the Company's board of directors. As a result, common stock reserved for issuance under the ESPP was increased by 381,146 shares on January 1, 2024. During the years ended December 31, 2024 and 2023, 183,378 and 254,169 shares were issued under the ESPP, respectively.

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 would commence vesting upon the closing of the Series C-2 financing and 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 financing milestone was achieved during January 2021. Accordingly, the Company recognized stock-based compensation expenses related to the Performance Awards of approximately $35,000 and $0.1 million for the years ended December 31, 2024 and 2023, respectively. The weighted-average grant date fair value of the Performance Awards was $3.24 per share.

The following table summarizes the stock option activity during the year ended December 31, 2024:

	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, 2023	10,706,541	$ 4.12	7.7		$ 12
Granted	4,849,434	$ 0.96		$ 0.76	
Exercised	—	$ —			
Canceled/forfeited	(4,132,782)	$ 4.89			
Outstanding at December 31, 2024	11,423,193	$ 2.50	5.7		$ —
Exercisable at December 31, 2024	6,380,591	$ 3.56	4.8		$ —
Vested or expected to vest at December 31, 2024	11,423,193	$ 2.50	5.7		$ —

The intrinsic value of options exercised was zero and $2,000 during the year ended December 31, 2024 and 2023, respectively. The fair value of options vested was $1.1 million and $2.1 million during the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, there was approximately $2.8 million of unrecognized stock-based compensation related to unvested stock options, which the Company expects to recognize over a weighted-average period of 1.28 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,	
	2024	2023
Expected volatility	98-105 %	92-94 %
Risk-free interest rate	3.7-4.7 %	3.5-4.9 %
Expected option life (in years)	5.2-6.1	5.2-6.1
Expected dividend yield	0.0 %	0.0 %
Fair value per share of common stock	$0.56-$1.27	$0.98-$1.90

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, which use the midpoint between the vesting date and the expiration date of each option.

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– The fair value of the Company's common stock is determined by the closing price, on the date of grant, of its common stock, which is traded on the Nasdaq Capital Market.

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,	
	2024	2023
Research and development	$ 3,152	$ 3,702
General and administrative	4,255	5,521
Total	$ 7,407	$ 9,223

Restricted Stock Units

In December 2021, the Company issued 336,000 restricted stock units under the 2021 Plan at a grant date fair value of $4.51 per share. These restricted stock units vested in equal quarterly installments over three years, subject to the employee's continued employment with, or services to, the Company on each vesting date. Each restricted stock unit represents the right to receive one share of the Company's common stock when and if the applicable vesting conditions are satisfied.

The following table summarizes the activity of the restricted stock units during the year ended December 31, 2024:

	RSU Outstanding	Weighted-average Grant Date Fair Value
Outstanding at December 31, 2023	52,533	$ 4.51
Granted	—	
Vested	(41,713)	$ 4.51
Canceled/forfeited	(10,820)	$ 4.51
Outstanding at December 31, 2024	—	$ —

As of December 31, 2024, total unrecognized stock-based compensation expense relating to unvested restricted stock units was zero and the weighted-average remaining vesting period was zero years.

As of December 31, 2024, all restricted stock awards were vested and none were outstanding.

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,	
	2024	2023
Numerator:		
Net loss	$ (63,118)	$ (69,197)
Denominator:		
Weighted average common shares outstanding	38,210,589	37,904,318
Weighted average common stock outstanding subject to repurchase related to unvested early exercised stock options and restricted stock awards	(26,658)	(92,334)
Weighted average common shares outstanding - basic and diluted	38,183,931	37,811,984
Net loss per share attributable to common stockholders, basic and diluted	$ (1.65)	$ (1.83)

Potentially dilutive shares to be issued under the ESPP as of December 31, 2024 and 2023 were not included in the calculation of diluted net loss per share because they would be anti-dilutive and were immaterial. In addition, potential 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):

	Years Ended December 31,	
	2024	2023
Common stock options issued and outstanding	11,423,193	10,706,541
Common stock outstanding subject to repurchase related to unvested early exercised stock options and restricted stock awards	—	52,533
Total	11,423,193	10,759,074

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. 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. Beginning in 2021, the Company makes matching contributions of up to 3% of the eligible employees' compensation to the 401(k) plan. During the years ended December 31, 2024 and 2023, the Company made contributions to the 401(k) plan of $0.5 million and $0.6 million, respectively.

13. Segment Reporting

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the chief operating decision maker (CODM), in deciding how to allocate resources to an individual segment and in assessing performance. The Company's CODM is its chief executive officer. Based on the information used by the CODM to allocate resources, the Company has determined it operates in one segment. The Company's operating segment generates revenue from its development agreement with Toray, Genmab, and Innovent, as described in Note 6.

The CODM assesses performance for the Company's operating segment and decides how to allocate resources based on the Company's cash runway and Net Loss that also is reported on the Consolidated Statements of Operations and Comprehensive Loss Income as Net Loss. Net loss is used to monitor budget versus actual results. The measure of segment assets is reported on the balance sheets as total assets.

As of December 31, 2024 and 2023, all of the Company's property and equipment was maintained in the United States.

For the year ended December 31, 2024 and 2023, all of the Company's revenue was generated and incurred in the United States.

Please refer to the consolidated financial statements for further information related to these measures of segment performance. In addition, research and development and general and administrative expenses are significant segment expenses regularly provided to the CODM with the following categories:

	Years Ended December 31,	
	2024	2023
	(In thousands)	
Significant Segment Expenses:		
Personnel related costs	23,936	29,537
Research and development expenses	14,346	14,576
Clinical trial expenses	11,285	10,048
General and administrative expenses	16,686	18,836
Stock-based compensation expense	7,407	9,223
Other segment expenses (Note A)	2,266	1,852
Total segment expenses	75,926	84,072
Restructuring charges	3,343	—
Impairment charges	1,469	—
Total operating expenses	80,738	84,072

(Note A) Other segment expense include depreciation expense and other miscellaneous expenses.

14. Income Taxes

The Company has not recorded any income tax expense for the years ended December 31, 2024 and 2023.

A reconciliation of the Company's effective tax rate and federal statutory tax rate is summarized as follows (in thousands):

	Years Ended December 31,	
	2024	2023
Income tax benefit at statutory rates	$ (13,255)	$ (14,531)
Permanent items	32	35
Valuation allowance	12,832	14,957
Stock-based compensation	1,830	1,367
Research and development tax credits	(1,439)	(1,828)
Provision for income taxes	$ —	$ —

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 our deferred tax assets for federal and state income taxes are as follows (in thousands):

	December 31,	
	2024	2023
Deferred tax assets:		
Net operating loss carryforward	$ 53,485	$ 47,331
Research tax credits	11,353	9,465
Capitalized research and development expenses	27,436	21,848
Lease liability	7,137	5,736
Stock-based compensation	2,256	2,645
Reserves and accruals	1,585	2,493
Intangible assets	127	145
Total deferred tax assets	103,379	89,663
Less valuation allowance	(96,870)	(83,680)
Net deferred tax assets	6,509	5,983
Deferred tax liabilities:		
Right-of-use assets	(6,159)	(5,424)
Property and equipment	(311)	(461)
Prepaid assets	(39)	(98)
Total deferred tax assets	(6,509)	(5,983)
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, 2024 and 2023 due to historical losses and uncertainty surrounding the use of such assets. The valuation allowance increased by $13.2 million between December 31, 2024 and December 31, 2023 primarily due to the generation of operating losses.

As of December 31, 2024, the Company has net operating loss, or NOL, carryforwards for federal and state income tax purposes of $234.9 million and $324.0 million, respectively. The federal NOL carryforwards generated prior to 2018 and state NOL carryforwards, if not utilized, will expire beginning in 2035. Federal NOL carryforwards aggregating $230.5 million are not subject to expiration.

The Company has research credit carryforwards for federal and state income tax purposes of approximately $11.5 million and $6.5 million, respectively, as of December 31, 2024. 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 NOL and credit carryforwards may be subject to annual limitations due to the change in ownership provisions of the Internal Revenue Code of 1986 and similar state provisions. The annual limitation may result in the expiration of NOL and credit carryforwards before utilization. The Company has performed a Section 382 study as of September 30, 2023 and expects approximately $2.8 million of federal research and development tax credits and $51.0 million of California NOL carryforwards to expire unused due to Section 382 limitations.

The Company files tax returns in the United States, California and various states. 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 NOL 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,	
	2024	2023
Balance at beginning of period	$ 18,748	$ 13,819
Decrease related to prior year positions	—	(375)
Increase related to current year positions	5,084	5,304
Balance at end of period	$ 23,832	$ 18,748

During the years ended December 31, 2024 and 2023, no interest or penalties were required to be recognized relating for unrecognized tax benefits. 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 accrued liability and an increase to income tax expense.

15. Subsequent Events

New Sublease

On March 10, 2025, the Company entered into a new sublease agreement under its Chesapeake Master Lease in Redwood City, California to sublease 11,773 square feet. The Company's sublease term expires thirty-six months from the commencement date, with an option for renewal. The fixed lease payment will be approximately $44,000 per month. The subtenant is responsible for certain operating expenses and taxes throughout the term under the sublease agreement.

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

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized, and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to provide reasonable assurance that information required to be disclosed in our reports filed or submitted under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure. Based on his evaluation as of December 31, 2024, the Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were effective at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, 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.

Management under the supervision of and with the participation of the Chief Executive Officer and Chief Financial Officer, has assessed the effectiveness of our internal control over financial reporting as of December 31, 2024. In making its assessment of internal control over financial reporting, management used the criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2024.

This Annual Report does not include an audit report of the Company's independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to audit by our independent registered public accounting firm pursuant to rules of the Securities and Exchange Commission that permit us to provide only management's report in this Annual Report on Form 10-K. In addition, because we are an "emerging growth company" defined in the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting for so long as we are an emerging growth company.

Changes in Internal Control over Financial Reporting

There were no material changes in our internal control over financial reporting in the three months ended December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

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 Nasdaq 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.

The remaining information required by this Item, which will be set forth in our definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after our fiscal year ended December 31, 2024 under the captions “Proposal 1: Election of Directors”, “Executive Officers” and “Information Regarding the Board of Directors and Corporate Governance – Insider Trading Policy”, is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this Item will be set forth in our definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after our fiscal year ended December 31, 2024 under the captions “Executive Compensation”, “Compensation Committee Interlocks and Insider Participation” and “Director Compensation” and is incorporated herein by reference.

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

The information required by this Item will be set forth in our definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after our fiscal year ended December 31, 2024 under the caption “Security Ownership of Certain Beneficial Owners and Management” and is incorporated herein by reference.

Information regarding our equity compensation plans required by this item will be set forth in our definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after our fiscal year ended December 31, 2024 under the caption "Equity Compensation Plan Information," and is incorporated by reference.

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

The information required by this Item will be set forth in our definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after our fiscal year ended December 31, 2024 under the captions and “Information Regarding the Board of Directors and Corporate Governance – Independence of the Board of Directors” and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this Item will be set forth in our definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after our fiscal year ended December 31, 2024 under the caption “Ratification of Selection of Independent Registered Public Accounting Firm” and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Consolidated Financial Statement Schedules.

(a)(1) The consolidated 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) Consolidated 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.	10-K	001-39988	4.3	3/31/2021	
10.1+	2015 Equity Incentive Plan, as amended.	S-1/A	333-252136	10.2	2/1/2021	
10.2+	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	
10.3+	2021 Equity Incentive Plan.	S-1/A	333-252136	10.4	2/1/2021	
10.4+	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	
10.5+	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	
10.6+	2021 Employee Stock Purchase Plan.	S-1/A	333-252136	10.7	2/1/2021	
10.7	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	
10.8	Form of Warrant to Purchase Common Stock.	S-1	333-252136	10.9	1/15/2021	

Exhibit Number	Description of Exhibit	Form	File No.	Exhibit	Filing Date	Filed Herewith
10.9+	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	
10.10+	Consulting Agreement by and between the Registrant and Randall C. Schatzman, dated May 13, 2024	8-K	001-39988	10.11	5/14/2024	
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 Edith Perez, dated March 16, 2020.	S-1	333-252136	10.13	1/15/2021	
10.13+	Consulting Agreement by and between the Registrant and Edith Perez, dated May 13, 2024	8-K	001-39988	10.12	5/14/2024	
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	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	
10.16	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	
10.17	Sales Agreement, by and between the Registrant and Cowen and Company, LLC dated March 30, 2022.	S-3	333-263994	1.2	3/30/2022	
10.18+	Amended and Restated Severance and Change in Control Plan.	10-K	001-39988	10.24	3/29/2023	
10.19	First Amendment to Britannia Seaport Centre Lease by and between the Registrant and HCP LS Redwood City, LLC, dated November 7, 2022.	10-K	001-39988	10.25	3/29/2023	
19.1	Insider Trading Policy					X
21.1	Subsidiaries of the Registrant					X
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

Exhibit Number	Description of Exhibit	Form	File No.	Exhibit	Filing Date	Filed Herewith
31.1	Certification of Principal Executive Officer and 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 and 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
97.1+	Incentive Compensation Recoupment Policy.	10-K	001-39988	97.1	3/21/2024	
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					X
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)					X

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

Portions of this exhibit have been omitted as the Registrant has determined that the omitted information (i) is not material and (ii) would likely cause competitive harm to the Registrant if publicly disclosed.

* 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 24, 2025

BOLT BIOTHERAPEUTICS, INC.

By: /s/ William P. Quinn
William P. Quinn
President, Chief Executive Officer and Chief Financial Officer (Principal Executive and Financial Officer)

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints William P. Quinn 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/ William P. Quinn William P. Quinn	President, Chief Executive Officer and Chief Financial Officer *(Principal Executive and Financial Officer)*	March 24, 2025
/s/ Sarah Nemec Sarah Nemec	Senior Vice President, Finance *(Principal Accounting Officer)*	March 24, 2025
/s/ Brian O'Callaghan Brian O'Callaghan	Chairman	March 24, 2025
/s/ Laura Berner Laura Berner	Director	March 24, 2025
/s/ Kathleen LaPorte Kathleen LaPorte	Director	March 24, 2025
/s/ Jakob Dupont, M.D. Jakob Dupont, M.D.	Director	March 24, 2025
/s/ Nicole Onetto, M.D. Nicole Onetto, M.D.	Director	March 24, 2025

BOLT BIOTHERAPEUTICS, INC.

INSIDER TRADING POLICY

APPROVED BY THE BOARD OF DIRECTORS

JANUARY 14, 2021

INTRODUCTION

This policy determines acceptable transactions in the securities of Bolt Biotherapeutics, Inc. (the "***Company***" or "***Bolt***") by our employees, directors and consultants. During the course of your employment, directorship or consultancy with the Company, you may receive important information that is not yet publicly available ("***inside information***"), about the Company or about other publicly-traded companies with which the Company has business dealings. Because of your access to this inside information, you may be in a position to profit financially by buying or selling, or in some other way dealing, in the Company's stock, or stock of another publicly-traded company, or to disclose such information to a third party who does so profit (a "***tippee***").

INSIDER TRADING POLICY

Securities Transactions

Use of inside information by someone for personal gain, or to pass on, or "tip," the inside information to someone who uses it for personal gain, is illegal, regardless of the quantity of shares, and is therefore prohibited. You can be held liable both for your own transactions and for transactions effected by a tippee, or even a tippee of a tippee. Furthermore, it is important that the appearance of insider trading in securities be avoided. The only exception is that transactions directly with the Company, *e.g.,* option exercises for cash or purchases under the Company's employee stock purchase plan, are permitted. However, the subsequent sale (including the sale of shares in a cashless exercise program) or other disposition of such stock is fully subject to these restrictions.

Inside Information

As a practical matter, it is sometimes difficult to determine whether you possess inside information. The key to determining whether nonpublic information you possess about a public company is inside information is whether dissemination of the information would likely affect the market price of the company's stock or would likely be considered important, or "material," by investors who are considering trading in that company's stock. Certainly, if the information makes you want to trade, it would probably have the same effect on others. Remember, both positive and negative information can be material. If you possess inside information, you may not trade in a company's stock, advise anyone else to do so or communicate the information to anyone else until you know that the information has been publicly disseminated. This policy also applies to all family members and other household members of those covered by this policy and all companies controlled by those covered by this policy. You may never recommend to another person that he or she buy, hold or sell our stock. This means that in some circumstances, you may have to forego a proposed transaction in a company's securities even if you planned to execute the transaction prior to learning of the inside information and even though you believe you may suffer an economic loss or sacrifice an anticipated profit by waiting. "***Trading***" includes engaging in short sales, transactions in put or call options, hedging transactions and other inherently speculative transactions.

You may not participate in “chat rooms” or other electronic discussion groups or contribute to blogs, bulletin boards or social media forums on the Internet concerning the activities of Bolt or other companies with which Bolt does business, even if you do so anonymously, unless doing so is part of your job responsibilities and you have explicit authorization from the Company’s Chief Financial Officer.

Although by no means an all-inclusive list, information about the following items may be considered to be inside information until it is publicly disseminated:

- financial results or forecasts;
- major new products or processes;
- acquisitions or dispositions of assets, divisions, companies, etc.;
- events regarding our securities (e.g., defaults on senior securities, calls of securities for redemption, repurchase plans, stock splits, public or private equity/debt offerings, declaration of stock splits or changes in our dividend policies or amounts);
- major contract awards or cancellations;
- scientific, clinical or regulatory results;
- top management or control changes;
- possible tender offers or proxy fights;
- significant writeoffs;
- actual or threatened major litigation, SEC or other investigations, or a major development in or the resolution of any such litigation or investigation;
- impending bankruptcy;
- gain or loss of a significant license agreement or other contracts with customers or suppliers;
- pricing changes or discount policies;
- corporate partner relationships;
- communications with government agencies; and
- notice of issuance of patents, the acquisition of other material intellectual property rights or other significant intellectual property developments.

For information to be considered publicly disseminated, it must be widely disclosed through a press release or SEC filing, and a sufficient amount of time must have passed to allow the information to be fully disclosed. Generally speaking, information will be considered publicly disseminated after two full trading days have elapsed since the date of public disclosure of the information. For example, if an announcement of inside information of which you were aware was made prior to trading on Wednesday, then you may execute a transaction in the Company’s securities on Friday.

STOCK TRADING BY DIRECTORS, EMPLOYEES AND CONSULTANTS

We require that all directors, employees and consultants limit their transactions in the Company's stock to defined time periods following public dissemination of quarterly and annual financial results and notify, and receive approval from, the Company's Chief Financial Officer prior to engaging in transactions in the Company's stock and observe other restrictions designed to minimize the risk of apparent or actual insider trading.

Covered Insiders

The provisions outlined in this stock trading policy apply to all directors, employees and consultants of the Company. Generally, any entities or family members or others whose trading activities are controlled or influenced by any of such persons should be considered to be subject to the same restrictions.

Window Period

Generally, except as set forth in this policy, all directors, employees and consultants may buy or sell securities of the Company at any time other than during a blackout period (as defined below). From time to time, the Company's Chief Executive Officer and/or Chief Financial Officer may require that directors, employees and consultants suspend trading in the Company's securities because there exists undisclosed information that would make trades by directors, employees and consultants inappropriate. The period during which trading is suspended is referred to in this policy as a "***blackout period***." It is important to note that the fact that the Company is in a blackout period should be considered inside information. An employee or director who believes that special circumstances require him or her to trade during a blackout period should consult with the Company's Chief Financial Officer. Permission to trade during a blackout period will be granted only where the circumstances are extenuating and there appears to be no significant risk that the trade may subsequently be questioned.

Exceptions to Window Period

ESPP/Option Exercises. Employees who are eligible to do so may purchase stock under the Company's Employee Stock Purchase Plan ("***ESPP***") on periodic designated dates in accordance with the ESPP without restriction to any particular period. Directors, employees and consultants may exercise options for cash granted under the Company's stock option plans without restriction to any particular period. However, the subsequent sale of the stock (including sales of stock in a cashless exercise) acquired upon the exercise of options or pursuant to the ESPP is subject to all provisions of this policy.

10b5-1 Automatic Trading Programs. In addition, purchases or sales of the Company's securities made pursuant to, and in compliance with, a written plan established by a director or executive officer or other member of management that meets the requirements of Rule 10b5-1 under the Securities Exchange Act of 1934, as amended (the "***Exchange Act***") (a "***Trading Plan***") may be made without restriction to any particular period provided that (i) the Trading Plan was established in good faith, in compliance with the requirements of Rule 10b5-1, at the time when such individual was not in possession of inside information about the Company and the Company had not imposed any trading blackout period, (ii) the Trading Plan was reviewed by the Company prior to establishment, solely to confirm compliance with this policy and the securities laws. The Company must be notified of the establishment of any such Trading Plan, any amendments to such Trading Plan and the termination of such Trading Plan.

Pre-Clearance and Advance Notice of Transactions

In addition to the requirements of above, directors and executive officers may not engage in any transaction in the Company's securities, including any purchase or sale in the open market, loan, pledge,

hedge or other transfer of beneficial ownership. Officers and directors must first obtain pre-clearance of the transaction from the Company's Chief Financial Officer (the "***Clearing Officer***") at least two business days in advance of the proposed transaction. The Clearing Officer will then determine whether the transaction may proceed and, if so, will direct the Compliance Coordinator (as identified in the Company's Section 16 Compliance Program) to assist in complying with the reporting requirements under Section 16(a) of the Exchange Act, if any. Pre-cleared transactions not completed within five business days shall require new pre-clearance under the provisions of this paragraph. The Company may, at its discretion, shorten such period of time.

Advance notice of gifts or an intent to exercise an outstanding stock option shall be given to a Clearing Officer. To the extent possible, advance notice of upcoming transactions to be effected pursuant to an established Trading Plan shall also be given to a Clearing Officer. Upon completion of any transaction, the directors, employees or consultants must immediately notify the Compliance Coordinator and any other individuals identified in Section 3 of the Company's Section 16 Compliance Program so that the Company may assist in any Section 16 reporting obligations.

Prohibition of Speculative or Short-term Trading

No director, employee or consultant to Bolt may engage in short sales, transactions in put or call options, hedging transactions, margin accounts, pledges, or other inherently speculative transactions with respect to the Company's stock at any time.

Short-Swing Trading/Control Stock/Section 16 Reports

Officers and directors subject to the reporting obligations under Section 16 of the Exchange Act should take care not to violate the prohibition on short-swing trading (Section 16(b) of the Exchange Act) and the restrictions on sales by control persons (Rule 144 under the Securities Act of 1933, as amended), and should file all appropriate Section 16(a) reports (Forms 3, 4 and 5), which are enumerated and described in the Company's Section 16 Compliance Program, and any notices of sale required by Rule 144.

DURATION OF POLICY'S APPLICABILITY

This policy continues to apply to your transactions in the Company's stock or the stock of other public companies engaged in business transactions with the Company even after your employment, directorship or consultancy with the Company has terminated. If you are in possession of inside information when your relationship with the Company concludes, you may not trade in the Company's stock or the stock of such other company until the information has been publicly disseminated or is no longer material.

PENALTIES

Anyone who effects transactions in the Company's stock or the stock of other public companies engaged in business transactions with the Company (or provides information to enable others to do so) on the basis of inside information is subject to both civil liability and criminal penalties, as well as disciplinary action by the Company. An employee, director or consultant who has questions about this policy should contact his or her own attorney or the Company's Chief Financial Officer in person, via email or by telephone. Contact information for our Chief Financial Officer can be found in the Company's directory, which is freely accessible on the Company's Corporate Intranet. Please also see Frequently Asked Questions attached hereto as **EXHIBIT A**.

EXHIBIT A

FREQUENTLY ASKED QUESTIONS

1. What is insider trading?

A: Insider trading is the buying or selling of stocks, bonds, futures, or other securities by someone in possession of material, nonpublic information. Insider trading also includes trading in options (puts and calls) the price of which is linked to the underlying price of a company's stock. It does not matter how many shares you buy or sell, or whether it has an effect on the stock price – if you have material, nonpublic information and you trade, you have broken the law.

2. Why is insider trading illegal?

A: If company insiders are able to use their confidential knowledge to their financial advantage, other investors would not have confidence in the fairness and integrity of the marketplace. Requiring those who have such information to disclose (the information to the public) or abstain (from trading) ensures an even playing field.

3. What is material, nonpublic information?

A: Information is material if it would influence a reasonable investor to buy or sell a stock, bond or other security. This could mean many things – financial results, potential mergers, major contracts, etc. Information is nonpublic if it has not yet been released and disseminated to the public.

4. Who can be guilty of insider trading?

A: Anyone who buys or sells a security while in possession of material, nonpublic information. It does not matter if you are not an executive officer or director, or even if you do not work at Bolt– if you know something material about the value of a security that not everyone else does, regardless of who you are, you can be found guilty of insider trading.

5. Does Bolt have an insider trading policy?

A: Yes.

6. What if I work in a foreign office?

A: There is no difference. The policy and law applies to you. Because our common stock trades on a United States securities exchange, the insider trading laws of the U.S. apply. The U.S. Securities and Exchange Commission (the SEC) (a U.S. government agency in charge of investor protection) and the Financial Industry Regulatory Authority (FINRA) (a private regulator that oversees U.S. exchanges) routinely investigate trading in a company's securities conducted by internationally-based individuals and firms. In addition, as a Bolt employee, our policies apply to you no matter where in the world you work.

7. What if I don't buy or sell anything, but I tell someone else the information and they buy or sell?

A: That is called "tipping." You are the "tipper" and the other person is called the "tippee". If the tippee buys or sells based on that material, nonpublic information, you might still be guilty of insider trading. In fact, if you tell family members who tell others and those people then trade on the information, those family members might be guilty of insider trading too. As a result, you may not discuss material, non-public information about Bolt with anyone outside Bolt, including spouses, family members, friends,

or business associates. This includes anonymous discussion on the Internet about Bolt or companies with which Bolt does business.

8. What if I don't tell them the information itself, I just tell them whether they should buy or sell?

A: That is still tipping, and you can still be found guilty of insider trading. According to our policies, you may never recommend to another person that they buy, hold or sell our common stock or any derivative security related to our common stock.

9. What are the penalties if I trade on inside information, or tip off someone else?

A: Anyone found liable in a civil case for trading on inside information may need to pay the U.S. government an amount equal to any profit made or any loss avoided and may also face a penalty of up to three times this amount. Persons found liable for tipping inside information, even if they did not trade themselves, may face a penalty of up to three times the amount of any profit gained or loss avoided by everyone in the chain of tippees. In addition, anyone convicted of criminal insider trading can face prison terms and additional fines.

10. What is "loss avoided"?

A: If you sell a common stock or a related derivative security before the negative news is publicly announced, and as a result of the announcement the stock price declines, you have avoided the loss caused by the negative news.

11. Am I restricted from trading securities of any companies except Bolt (for example a customer or competitor of Bolt)?

A: Yes. U.S. insider trading laws restrict everyone from trading in a company's securities based on material nonpublic information about that company, regardless of whether the person is directly connected with that company. Therefore, if you obtain material nonpublic information about another company, you should not trade in that company's securities. You should be particularly conscious of this restriction if, through your position at Bolt, you sometimes obtain sensitive, material information about other companies and their business dealings with Bolt.

12. So if I do not trade Bolt securities when I have material nonpublic information, and I don't "tip" other people, I am in the clear, right?

A: Not necessarily. Even if you do not violate U.S. law, you may still violate our policies. Our policies are stricter than the law requires, so that we and our employees can avoid even the appearance of wrongdoing. Therefore, please review the entire policy carefully.

13. If I am aware of new product or service developments that have not been announced to the public, do I possess material non-public information?

A: In most circumstances, Bolt does not consider new product and service developments to be material information that would require the closing of the trading window with respect to those individuals that are aware of these developments. However, there are circumstances where a new product or service in development or issues with respect to current or past products or services could be so significant that it constitutes material non-public information. In these circumstances, you will be notified by email if the trading window is closed for you.

14. So when can I buy or sell my Bolt securities?

A: According to our policies, if you have material, nonpublic information, you may not buy or sell our common stock until the third trading day after that information is released or announced to the public. At that point, the information is considered public. **Even if you do not have material, nonpublic information, you may not trade in our common stock during any trading "blackout" period**. (A list of current blackout periods can be obtained from the Company's Chief Financial Officer and additional trading blackout periods may be announced by email.)

15. If I have an open order to buy or sell Bolt securities on the date the trading window closes, my broker will cancel the open order and won't execute the trade, right?

A: No. If you have any open orders at the time the trading window closes, it is your responsibility to cancel these orders with your broker. If you have an open order and it executes after the trading window closes, it is a violation of our insider trading policy and may also be a violation of the insider trading laws.

16. Am I allowed to trade derivative securities of Bolt? Or, short Bolt common stock?

A: No. Under our policies, you may not trade in derivative securities related to our common stock, which includes, but is not limited to publicly-traded call and put options. In addition, under our policies, you may not engage in short selling of our common stock at any time. "Derivative securities" are securities other than common stock that are speculative in nature because they permit a person to leverage his or her investment using a relatively small amount of money. Examples of derivative securities include (but are not limited to) "put options" and "call options". These are different from employee stock options, which are not derivative securities**.**

"Short selling" is profiting when you expect the price of the stock to decline, and includes transactions in which you borrow stock from a broker, sell it, and eventually buy it back on the market to return the borrowed shares to the broker. Profit is made through the expectation that the stock price will decrease during the period of borrowing.

17. Why does Bolt prohibit trading in derivative securities and short selling?

A: Many companies with volatile stock prices have adopted such policies because of the temptation it represents to try to benefit from a relatively low cost method of trading on short-term swings in stock prices (without actually holding the underlying common stock) and encourages speculative trading. For this reason, we have decided to prohibit employees from such trading. As we are dedicated to building stockholder value, short selling our common stock is adverse to our stated values and would not be received well by our stockholders.

18. Can I purchase Bolt securities on margin or hold them in a margin account?

A: Under our policies, you may not purchase our common stock on margin or hold it in a margin account at any time. "Purchasing on margin" is the use of borrowed money from a brokerage firm to purchase our securities. Holding our securities in a margin account includes holding the securities in an account in which the shares can be sold to pay a loan to the brokerage firm.

19. Why does Bolt prohibit me from purchasing Bolt securities on margin or holding them in a margin account?

A: Margin loans are subject to a margin call whether or not you possess insider information at the time of the call. If your margin call were called at a time when you had insider information and you could not or did not supply other collateral, you and Bolt could be subject to litigation based on your insider

trading activities: the sale of the stock (through the margin call) when you possessed material nonpublic information. The sale would be attributed to you even though the lender made the ultimate determination to sell. The U.S. Securities and Exchange Commission takes the view that you made the determination to not supply the additional collateral and you are therefore responsible for the sale.

20. Can I exercise stock options during a trading blackout period or when I possess material nonpublic information?

A: Yes. You may exercise the option and receive shares, but you may not sell the shares (even to pay the exercise price or any taxes due) or otherwise settle the option during a trading blackout period or any time that you have material, nonpublic information. Also note that if you choose to exercise and hold the shares, you will be responsible at that time for any taxes due.

21. Am I subject to the trading blackout period if I am no longer an employee of Bolt?

A: It depends. If your employment with Bolt ends on a day that the trading window is closed, you will be subject to the trading blackout period then in effect. If your employment with Bolt ends on a day that the trading window is open, you will not be subject to the next trading blackout period. However, even if you are not subject to our trading blackout period after you leave Bolt, you should not trade in Bolt securities if you possess material non-public information. That restriction stays with you as long as the information you possess is material and not released by Bolt.

22. Can I gift stock while I possess material nonpublic information or during a trading blackout period?

A: Because of the potential for the appearance of impropriety, you may not make gifts, whether to charities, to a trust or otherwise, of our common stock when you possess material nonpublic information or during a trading blackout period.

23. What if I purchased publicly-traded options or other derivative securities before I became a Bolt employee (or contractor or consultant)?

A: The same rules apply as for employee stock options. You may exercise the publicly-traded options at any time, but you may not sell such securities during a trading blackout period or at any time that you have material, nonpublic information. When you become a Bolt employee, you must report to our Chief Financial Officer that you hold such publicly traded options or other derivative securities.

24. May I own shares of a mutual fund that invests in Bolt?

A: Yes.

25. Are mutual fund shares holding Bolt subject to the trading blackout periods?

A: No. You may trade in mutual funds holding our common stock at any time.

26. May I use a "routine trading program" or "10b5-1 plan"?

A: Yes, subject to the requirements discussed in our Insider Trading and Trading Window Policy. A routine trading program, also known as a 10b5-1 plan, allows you to set up a highly structured program with your stock broker through which you specify ahead of time the date, price, and amount of securities to be traded. If you wish to create a 10b5-1 plan, you must contact our Chief Financial Officer for approval in person, via email or by telephone. Contact information for our Chief Financial Officer can be found in the Company's directory, which is freely accessible on the Company's Corporate Intranet.

27. What happens if I violate our insider trading policy?

A: Violation of our policies may result in severe personnel action, including a memo to your personnel file and up to and including termination of your employment or other relationship with Bolt. In addition, you may be subject to criminal and civil enforcement actions by the government.

28. Who should I contact if I have questions about our insider trading policy?

A: You should contact our Chief Financial Officer.

BOLT BIOTHERAPEUTICS, INC.

The following is a list of subsidiaries of the Company as of December 31, 2024, omitting some subsidiaries which, considered in the aggregate, would not constitute a significant subsidiary.

SUBSIDIARY **(Name under which subsidiary does business)**	**STATE OR OTHER JURISDICTION OF CORPORATION OR ORGANIZATION**
Bolt Biotherapeutics Australia PTY LTD	Australia

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-252815, 333-263987, 333-270938, and 333-278141) and Form S-3 (No. 333-263994) of Bolt Biotherapeutics, Inc. of our report dated March 24, 2025 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
San Jose, California
March 24, 2025

Exhibit 31.1

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) 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

d) 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 24, 2025

By: /s/ William P. Quinn
William P. Quinn
President, Chief Executive Officer and Chief Financial Officer
(Principal Executive and 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, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, William P. Quinn, President, Chief Executive Officer and 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 24, 2025

By: /s/ William P. Quinn
William P. Quinn
President, Chief Executive Officer and Chief Financial Officer
(Principal Executive and Financial Officer)