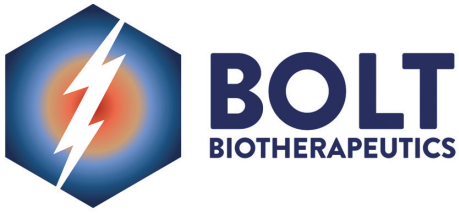

2024 Annual Meeting of Stockholders
Notice and Proxy Statement

●

2023 Annual Report on Form 10-K

900 Chesapeake Drive
Redwood City, California 94063

NOTICE OF ANNUAL MEETING OF STOCKHOLDERS
TO BE HELD ON JUNE 12, 2024
AT 11:00 A.M. PACIFIC TIME

Dear Stockholder:

You are cordially invited to attend the 2024 Annual Meeting of Stockholders of Bolt Biotherapeutics, Inc., a Delaware corporation, or the Company or Bolt Bio. The 2024 Annual Meeting of Stockholders will be held on June 12, 2024, at 11:00 a.m., Pacific Time. The 2024 Annual Meeting of Stockholders will be convened and held entirely online. You will be able to attend and participate online in the 2024 Annual Meeting of Stockholders by visiting www.proxydocs.com/BOLT, where you will be able to listen to the meeting live, submit questions, and vote.

The 2024 Annual Meeting of Stockholders is being convened to conduct the following business:

1. To elect our two nominees for Class III directors to serve until our 2027 Annual Meeting of Stockholders;
2. To ratify the selection by the audit committee of the Board of Directors of PricewaterhouseCoopers LLP as our independent registered public accounting firm for the year ending December 31, 2024; and
3. To conduct any other business properly brought before the 2024 Annual Meeting of Stockholders.

These items of business are more fully described in the Proxy Statement accompanying this Notice of Annual Meeting of Stockholders. The record date for the 2024 Annual Meeting of Stockholders is April 15, 2024. Only stockholders of record at the close of business on that date are entitled to receive notice of, and to vote at, the 2024 Annual Meeting of Stockholders or any adjournment thereof. A list of stockholders of record at the close of business on the April 15, 2024 record date will be available during the Annual Meeting at www.proxydocs.com/BOLT and electronically for the 10 days ending the day prior to the Annual Meeting to registered stockholders for any legally valid purpose related to the Annual Meeting. For access to the stockholder list, please contact us at investors@boltbio.com.

The Board of Directors recommends that you vote as follows on the matters to be presented to stockholders at the 2024 Annual Meeting of Stockholders:

1. **FOR** the election of each of our Class III director nominees named in Proposal No. 1 of the proxy statement; and
2. **FOR** the ratification of the selection by the audit committee of the Board of Directors of PricewaterhouseCoopers LLP, as the independent registered public accounting firm, as described in Proposal No. 2 of the proxy statement.

Your vote is very important. Whether or not you attend the 2024 Annual Meeting of Stockholders (by logging into www.proxydocs.com/BOLT), it is important that your shares be represented. We encourage you to read the accompanying Proxy Statement and our Annual Report on Form 10-K for the year ended December 31, 2023, and submit your proxy on the internet, by phone or by mail in accordance with the instructions in the Notice of Internet Availability of Proxy Materials. Please review the instructions on the proxy card or the information forwarded by your bank, broker or other holder of record regarding each of these voting options. If you receive more than one set of Proxy Materials or Notice of Internet Availability because your shares are registered in different names or addresses, each proxy should be signed and submitted to ensure that all of your shares will be voted. Instructions on how to attend the meeting webcast, ask questions or vote your shares online will also be included with the Notice of Internet Availability of Proxy Materials, and are provided in the Proxy Statement accompanying this Notice of Annual Meeting of Stockholders.

On behalf of the Board of Directors, thank you for your participation in this important annual process.

By Order of the Board of Directors

/s/ William P. Quinn

William P. Quinn
Chief Financial Officer and Secretary
Redwood City, California
April 26, 2024

You are cordially invited to attend the 2024 Annual Meeting of Stockholders by logging into www.proxydocs.com/BOLT and following the attendance instructions on the website. Whether or not you expect to attend the 2024 Annual Meeting of Stockholders, please vote on the internet, by phone or by mail as instructed in the Notice of Internet Availability of Proxy Materials, as promptly as possible in order to ensure your representation at the meeting. Even if you have voted by proxy prior to the meeting, you may still attend the meeting online and submit your vote prior to voting being closed at www.proxydocs.com/BOLT. Please note, however, that if you are a beneficial stockholder and hold our stock in the name of a broker, bank or other nominee and you wish to vote at the 2024 Annual Meeting of Stockholders, you must obtain a proxy issued in your name from that record holder.

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QUESTIONS AND ANSWERS ABOUT THESE PROXY MATERIALS AND VOTING PROCEDURES

Why am I receiving these materials?

We sent you a Notice of Internet Availability of Proxy Materials because the board of directors of Bolt Biotherapeutics, Inc., or the Board, is soliciting your proxy to vote at our 2024 Annual Meeting of Stockholders, or the Annual Meeting, to be held on June 12, 2024 at 11:00 a.m., Pacific Time. The meeting will be held virtually, via a live webcast at www.proxydocs.com/BOLT.

We invite you to attend the Annual Meeting to vote on the proposals described in this Proxy Statement. However, you do not need to attend the meeting to vote your shares. Instead, you may vote by proxy over the internet or by phone by following the instructions provided in the notice or, if you request printed copies of the Proxy Materials by mail, you may vote by mail.

Pursuant to the rules adopted by the Securities and Exchange Commission, or the SEC, we have elected to provide access to our Annual Meeting materials, which include this Proxy Statement and our Annual Report on Form 10-K for the year ended December 31, 2023, or the Form 10-K, over the internet in lieu of mailing printed copies. We intend to mail the Notice of Internet Availability of Proxy Materials to our stockholders of record as of April 15, 2024, or the Record Date, for the first time on or about April 26, 2024. The Notice of Internet Availability of Proxy Materials will contain instructions on how to access and review our Annual Meeting materials, how to access the live webcast of the Annual Meeting, and will also contain instructions on how to request a printed copy of the Annual Meeting materials. In addition, we have provided brokers, dealers, banks, voting trustees and their nominees, at our expense, with additional copies of our Proxy Materials and the Form 10-K so that our record holders can supply these materials to the beneficial owners of shares of our common stock as of the Record Date. The Form 10-K is also available in the "SEC Filings" section of our website at https://investors.boltbio.com/financial-information/sec-filings.

As used in this Proxy Statement, "Bolt Bio," the "Company," "we" or "us" refer to Bolt Biotherapeutics, Inc., a Delaware corporation.

Who can vote at the Annual Meeting?

Only stockholders of record at the close of business on April 15, 2024, the Record Date, will be entitled to vote at the Annual Meeting. On the Record Date, there were 38,127,740 shares of common stock outstanding and entitled to vote.

Stockholder of Record: Shares Registered in Your Name

If, on April 15, 2024, your shares were registered directly in your name with our transfer agent, Equiniti Trust Company, LLC, then you are a stockholder of record. The notice will be sent to you by mail and via the internet directly by us. As a stockholder of record, you may vote online during the live webcast of the meeting at www.proxydocs.com/BOLT, or vote by proxy. Whether or not you plan to attend the Annual Meeting online, we urge you to vote on the internet or by phone as instructed in the notice or by proxy by mail by requesting a paper copy of the Proxy Materials as instructed in the notice to ensure your vote is counted.

Beneficial Owner: Shares Registered in the Name of a Broker, Bank or Other Agent

If, on April 15, 2024, your shares were held in an account at a brokerage firm, bank or other agent, then you are the beneficial owner of shares held in "street name" and the notice is being forwarded to you by that organization. The organization holding your account is considered the stockholder of record for purposes of voting at the Annual Meeting. As a beneficial owner, you have the right to direct your broker, bank or other agent on how to vote the shares in your account. Your brokerage firm, bank or other agent will not be able to vote in the election of directors unless they have your voting instructions, so it is very important that you indicate your voting instructions to the institution holding your shares. You are also invited to attend the Annual Meeting online, as instructed in this Proxy Statement. However, since you are not the stockholder of record, you may not vote your shares online during the Annual Meeting unless you request and obtain a valid proxy from your broker, bank or other agent.

What am I voting on?

There are two matters scheduled for a vote:

- Proposal 1: To elect each of the Board's two nominees as a Class III director to serve until our 2027 Annual Meeting of Stockholders.
- Proposal 2: To ratify the selection by our audit committee of PricewaterhouseCoopers LLP as our independent registered public accounting firm for the year ending December 31, 2024.

What if another matter is properly brought before the meeting?

The Board knows of no other matters that will be presented for consideration at the Annual Meeting. If any other matters are properly brought before the meeting, it is the intention of the persons named in the accompanying proxy to vote on those matters in accordance with their best judgment.

How are Proxy Materials distributed?

Under rules adopted by the SEC, we are sending the notice to our stockholders of record and beneficial owners as of April 15, 2024. Stockholders will have the ability to access the Proxy Materials, including this Proxy Statement and our Annual Report on Form 10-K for the year ended December 31, 2023, on the internet at www.proxydocs.com/BOLT or to request a printed or electronic set of the Proxy Materials at no charge. Instructions on how to access the Proxy Materials over the internet and how to request a printed copy may be found on the notice.

In addition, any stockholder may request to receive Proxy Materials in printed form by mail or electronically by email on an ongoing basis. Choosing to receive future Proxy Materials by email will save us the cost of printing and mailing documents to stockholders and will reduce the impact of Annual Meetings on the environment. A stockholder who chooses to receive future Proxy Materials by email will receive an email prior to next year's annual meeting with instructions containing a link to those materials and a link to the proxy voting website. A stockholder's election to receive Proxy Materials by email will remain in effect until the stockholder terminates it.

How do I vote?

- For Proposal 1, you may vote "For" or "Withhold" your vote from each individual nominee.
- For Proposal 2, you may vote "For" or "Against" or abstain from voting.

Please note that by casting your vote by proxy you are authorizing the individuals listed on the proxy card to vote your shares in accordance with your instructions and in their discretion with respect to any other matter that properly comes before the Annual Meeting or any adjournments or postponements thereof.

The procedures for voting are:

Stockholder of Record: Shares Registered in Your Name

If you are a stockholder of record as of April 15, 2024, you may authorize that your shares be voted at the Annual Meeting in one of the following ways:

1. **To vote online during the Annual Meeting**, you may also vote in person virtually by attending the meeting through www.proxydocs.com/BOLT. To attend the Annual Meeting and vote your shares, you provide the control number located on your Notice or proxy card.

2. **To vote electronically prior to the Annual Meeting**, if you received the Notice or a printed copy of the Proxy Materials, follow the instructions in the Notice or on the proxy card.

3. **To vote by phone**, if you received a printed copy of the Proxy Materials, follow the instructions on the proxy card.

4. **To vote by mail**, if you received a printed copy of the Proxy Materials, complete, sign, date, and mail your proxy card in the enclosed, postage-prepaid envelope.

Beneficial Owner: Shares Registered in the Name of a Broker, Bank or Other Agent

If you hold your shares through a broker, bank or other nominee (that is, in street name), you will receive instructions from your broker, bank or nominee that you must follow in order to submit your voting instructions and have your shares voted at the Annual Meeting. If you want to vote in person virtually at the Annual Meeting, you may visit www.proxydocs.com/BOLT press the "Attend Meeting" button and follow the instructions. You may be instructed to obtain a legal proxy from your broker, bank or other nominee and to submit a copy in advance of the meeting. Further instructions will be provided to you via email.

Even if you plan to attend the Annual Meeting, we recommend that you submit your proxy or voting instructions in advance of the Annual Meeting as described above so that your vote will be counted if you later decide not to attend or are unable to attend the Annual Meeting.

How many votes do I have?

On each matter to be voted upon, you have one vote for each share of common stock you owned as of April 15, 2024.

What is the quorum requirement?

A quorum of stockholders is necessary to take any action at the meeting, other than to adjourn the meeting. The presence, online or by proxy duly authorized, of the holders of a majority of the voting power of the outstanding shares of stock entitled to vote will constitute a quorum. On April 15, 2024, there were 38,127,740 shares of common stock outstanding and entitled to vote.

Your shares will be counted toward the quorum if you submit a valid proxy or vote online at the Annual Meeting. Abstentions and broker non-votes will also be counted toward the quorum requirement. If there is no quorum, the chairman of the Annual Meeting or a majority of the votes present at the Annual Meeting may adjourn the Annual Meeting to another date.

What if I return a proxy card but do not make specific choices?

If you are a stockholder of record and you return a proxy card without marking any voting selections, your shares will be voted:

1. Proposal 1: "For" election of all two nominees for director.
2. Proposal 2: "For" the ratification of the audit committee's selection of PricewaterhouseCoopers LLP as our independent registered public accounting firm for the year ending December 31, 2024.

If any other matter is properly presented at the meeting, your proxy (one of the individuals named on your proxy card) will vote your shares using their best judgment.

If you are a beneficial owner of shares registered in the name of your broker, bank or other agent, your shares are held by your broker, bank or other agent as your nominee, or in "street name," and you will need to obtain a proxy form from the organization that holds your shares and follow the instructions included on that form regarding how to instruct the organization to vote your shares. If you do not give instructions to your broker, bank or other agent, they can vote your shares with respect to "discretionary" items but not with respect to "non-discretionary" items. Discretionary items are proposals considered routine under the rules of various national securities exchanges, and, in the absence of your voting instructions, your broker, bank or other agent may vote your shares held in street name on such proposals. Non-discretionary items are proposals considered non-routine under the rules of various national securities exchanges, and, in the absence of your voting instructions, your broker, bank or other agent may not vote your shares held in street name on such proposals and the shares will be treated as broker non-votes.

Which ballot measures are considered "routine" or "non-routine"?

Proposal 1 (the election of directors) is considered non-routine under applicable rules. A broker or other nominee cannot vote without instructions on non-routine matters, and therefore there may be broker non-votes on Proposal 1. Proposal 2 (the ratification of the selection by the audit committee of PricewaterhouseCoopers LLP, as our independent registered public accounting firm for the year ending December 31, 2024) is considered routine under applicable rules. A broker or other nominee may generally vote on routine matters, and therefore no broker non-votes are expected to exist in connection with Proposal 2.

How are votes counted?

Votes will be counted by the inspector of election appointed for the Annual Meeting, who will count:

- With respect to Proposal 1, "For" votes and "Withhold" votes, and broker non-votes.
- With respect to Proposal 2, "For" votes, "Against" votes and abstentions.

Abstentions will be counted towards the vote total for Proposal 2, and will have the same effect as "Against" votes. Abstentions will not be counted and will have no effect on the vote total for Proposal 1. Proposal 2 is considered a "routine" matter, accordingly, if you hold your shares in street name and do not provide voting instructions to your broker, bank, or other agent that holds your shares, your broker, bank, or other agent has discretionary authority to vote your shares on Proposal 2.

Who will serve as inspector of elections?

William P. Quinn, our Chief Financial Officer and Secretary, will serve as the inspector of elections.

How many votes are needed to approve each proposal?

- For Proposal 1 electing two members of the Board, our bylaws provide for a plurality voting standard for the election of directors. Under this voting standard, the two director nominees receiving the highest number of affirmative votes will be elected as Class III directors to serve until the 2027 Annual Meeting of Stockholders and until their respective successors are duly elected and qualified.
- For Proposal 2 ratifying the audit committee's selection of PricewaterhouseCoopers LLP as our independent registered public accounting firm for the year ending December 31, 2024, the proposal must receive a "For" vote from the majority of the votes cast either online or by proxy at the Annual Meeting and that are entitled to vote on the proposal, with votes cast including votes "Against" and abstentions. This is a routine proposal and therefore we do not expect any broker non-votes.

Who is paying for this proxy solicitation?

We will pay for the entire cost of soliciting proxies. In addition to the notice and the Proxy Materials, our directors and employees may also solicit proxies online, by telephone or by other means of communication. We will not pay our directors and employees any additional compensation for soliciting proxies. We may also reimburse brokerage firms, banks and other agents for the cost of forwarding the notice and any other Proxy Materials to beneficial owners.

What does it mean if I receive more than one notice?

If you receive more than one notice, your shares may be registered in more than one name or are registered in different accounts. Please vote by proxy according to each notice to ensure that all of your shares are voted.

Can I change my vote after submitting my proxy?

Yes. If you are a holder of record, you may revoke your proxy at any time before it is voted at the Annual Meeting by delivering written notice of revocation to our Secretary, by submitting a subsequently dated proxy by mail, telephone or the internet in the manner described above under "How do I vote," or by attending the Annual Meeting and voting in person virtually. Attendance at the Annual Meeting will not itself revoke an earlier submitted proxy. Your most current proxy card or telephone or internet proxy is the one that is counted.

If you hold your shares in street name, you must follow the instructions provided by your broker, bank or nominee to revoke your voting instructions, or, if you have obtained a legal proxy from your broker, bank or other nominee giving you the right to vote your shares at the Annual Meeting, by attending the Annual Meeting and voting in person virtually.

How do I attend the virtual/online Annual Meeting?

Only stockholders of record and beneficial owners of shares of our common stock as of the close of business on April 15, 2024, the Record Date, may attend and participate in the Annual Meeting, including voting and asking questions during the virtual Annual Meeting. You will not be able to attend the Annual Meeting physically in person.

In order to attend the Annual Meeting, you must visit www.proxydocs.com/BOLT. Upon entry of your control number and other required information, you will receive further instructions via email, that provides you with personalized access to attend and participate at the Annual Meeting, to vote and to submit questions during the Annual Meeting.

As part of the attendance process, you must enter the control number located on your proxy card, voting instruction form, or Notice of Internet Availability of Proxy Materials. If you are a beneficial owner of shares registered in the name of a broker, bank or other nominee, you may also need to provide the registered name on your account and the name of your broker, bank or other nominee as part of the attendance process.

On the day of the Annual Meeting, June 12, 2024, stockholders may begin to log in to the virtual-only Annual Meeting 15 minutes prior to the Annual Meeting. The Annual Meeting will begin promptly at 11:00 a.m. Pacific Time.

We will have technicians ready to assist you with any technical difficulties you may have accessing the Annual Meeting. If you encounter any difficulties accessing the virtual-only Annual Meeting platform, including any difficulties voting or submitting questions, you may call the technical support number that will be posted in your instructional email.

Submitting questions at the virtual Annual Meeting. Our virtual Annual Meeting will allow stockholders to submit questions before and during the Annual Meeting. During a designated question and answer period at the Annual Meeting, we will respond to appropriate questions submitted by stockholders. We may answer as many stockholder-submitted questions as time permits, and any questions that we are unable to address during the Annual Meeting will be answered following the meeting, with the exception of any questions that are irrelevant to the purpose of the Annual Meeting or our business or that contain inappropriate or derogatory references which are not in good taste. If we receive substantially similar questions, we will group such questions together and provide a single response to avoid repetition.

The Annual Meeting is being held virtually, so you will not be able to physically attend the meeting because there is no physical venue.

When are stockholder proposals due for next year's annual meeting?

Pursuant to Rule 14a-8 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, some stockholder proposals may be eligible for inclusion in our proxy statement for our 2025 Annual Meeting of Stockholders. Any such proposal must be submitted in writing by December 27, 2024, to our Secretary, care of Bolt Biotherapeutics, Inc., at 900 Chesapeake Drive, Redwood City, California, 94063, the address of our principal executive offices. If we change the date of our 2025 Annual Meeting of Stockholders by more than 30 days from the date of the 2024 Annual Meeting of Stockholders, the deadline shall be a reasonable time before we begin to print and send our Proxy Materials. Stockholders interested in submitting such a proposal are advised to contact knowledgeable counsel with regard to the detailed requirements of the applicable securities laws and our bylaws. The submission of a stockholder proposal does not guarantee that it will be included in our proxy statement.

Our bylaws also establish an advance notice procedure for stockholders who wish to present a proposal before an annual meeting of stockholders but do not intend for the proposal to be included in our proxy statement. Our bylaws provide that if you wish to submit a proposal that is not to be included in next year's proxy statement or nominate a director, a timely written notice of a stockholder proposal must be delivered to, or mailed and received by, our Secretary, care of Bolt Biotherapeutics, Inc., at 900 Chesapeake Drive, Redwood City, California, 94063, no earlier than February 12, 2025 and no later than the close of business on March 14, 2025, which notice must contain the information specified in our bylaws. If we change the date of our 2025 Annual Meeting of Stockholders by more than 30 days before, or more than 30 days after, the one-year anniversary of the 2024 Annual Meeting of Stockholders, then the written notice of a stockholder proposal that is not intended to be included in our proxy statement must be delivered, or mailed and received, not later than the 90th day prior to our 2025 Annual Meeting of Stockholders or, if later, the 10th day following the day on which certain public disclosure as described in our bylaws of the meeting date is made.

In addition, stockholders who intend to solicit proxies in support of director nominees other than the Company's nominees must provide notice that sets forth the information required by Rule 14a-19(b) no later than April 13, 2025.

What is "householding" and how does it affect me?

We have adopted a procedure approved by the SEC called "householding." Under this procedure, stockholders who have the same address may receive only one copy of our Form 10-K, Proxy Statement or Notice of Internet Availability of Proxy Materials, unless one or more of these stockholders notifies us that they wish to receive individual copies of such documents. This process potentially means extra convenience for stockholders and cost savings for companies.

If you are a beneficial owner of our common stock, once you receive notice from your broker, bank or other agent that they will be householding communications to your address, householding will continue until you are notified otherwise or until you revoke your consent. If, at any time, you no longer wish to participate in "householding" and would prefer to receive a separate Notice of Internet Availability of Proxy Materials, please notify your broker. Stockholders who currently receive multiple copies of the Notices of Internet Availability of Proxy Materials at their addresses and would like to request "householding" of their communications should contact their brokers. If you wish to receive a separate copy of our Form 10-K, Proxy Statement, or Notice of Internet Availability of Proxy Materials, please direct your written request to our Secretary, care of Bolt Biotherapeutics, Inc., at 900 Chesapeake Drive, Redwood City, California, 94063 or contact our Secretary at (650) 665-9295. Upon written request to us, we will promptly deliver a separate copy of our Form 10-K, Proxy Statement or Notice of Internet Availability of Proxy Materials, as applicable, to a stockholder at a shared address to which a single copy of the documents was delivered. Stockholders who currently receive multiple copies of our Form 10-K, Proxy Statement or Notice of Internet Availability of Proxy Materials at their address and would like to request householding of their communications should contact their broker, bank or other agent.

How can I find out the results of the voting at the Annual Meeting?

Preliminary voting results will be announced during the live webcast of the Annual Meeting. Final voting results will be published in a Current Report on Form 8-K that we expect to file with the SEC within four business days following the Annual Meeting. If final voting results are not available to us in time to file a Form 8-K within four business days after the meeting, we intend to file a Form 8-K to publish preliminary results and, within four business days after the final results are known to us, file an additional Form 8-K to publish the final results.

PROPOSAL 1: ELECTION OF DIRECTORS

Our Board currently consists of ten directors and is divided into three classes, designated as Class I, Class II and Class III. Under our Amended and Restated Certificate of Incorporation, our Board is authorized to assign its members in office to each class. Each class has a term of three years. There are currently three directors in Class III, Kathleen LaPorte, Richard A. Miller, M.D., and Nicole Onetto, M.D., whose terms of office are scheduled to expire at the 2024 Annual Meeting of Stockholders. Each of Ms. LaPorte and Dr. Onetto have been nominated for election at the 2024 Annual Meeting of Stockholders, at the recommendation of our Nominating and Governance Committee. Proxies cannot be voted for a greater number of persons than the number of nominees named in this proposal. Dr. Miller's term as director will expire at the 2024 Annual Meeting of Stockholders and he is not standing for re-election. Following the Annual Meeting the size of our Board will be reduced to nine directors.

Any vacancies on our Board resulting from death, resignation, disqualification, removal or other causes, and any newly created directorships resulting from any increase in the number of directors, shall be filled by the affirmative vote of a majority of the directors then in office, even though less than a quorum of the Board. Any director elected to fill a vacancy shall hold office for the remainder of the unexpired term in which the vacancy occurred or newly created directorship was created and until such director's successor shall have been elected and qualified.

Our bylaws provide for a plurality voting standard for the election of directors. Under this voting standard, the director nominees receiving the highest number of affirmative votes cast at the Annual Meeting are elected as directors. Shares represented by executed proxies will be voted, if authority to do so is not withheld, for the election of the three nominees named below.

If any of Ms. LaPorte and Dr. Onetto become unavailable for election as a result of an unexpected occurrence, shares that would otherwise be voted for such director will be voted for the election of a substitute nominee proposed by the Nominating and Corporate Governance Committee and nominated by the Board. Ms. LaPorte and Dr. Onetto have agreed to serve if elected. Our management has no reason to believe that any of Ms. LaPorte or Dr. Onetto will be unable to serve. If elected at the Annual Meeting, each of Ms. LaPorte or Dr. Onetto will serve until the earliest of the 2027 Annual Meeting of Stockholders, or until their respective successor is elected and qualified, or until their respective death, resignation or removal.

The following are brief biographies of Ms. LaPorte or Dr. Onetto, the nominees for director, and a discussion of their specific experience, qualifications, attributes or skills that led the Nominating and Corporate Governance Committee of the Board to recommend each of Ms. LaPorte or Dr. Onetto for director, as of the date of this Proxy Statement.

Name	Position	Age
Kathleen LaPorte	Class III Director	62
Nicole Onetto, M.D.	Class III Director	71

Kathleen LaPorte has served as a member of our Board since December 2020. Ms. LaPorte served as Chief Executive Officer of Nodality Inc. from 2015 to 2016, and as Chief Business Officer from 2014 to 2015. She currently serves as a director of 89bio, CERo Therapeutics Holdings, Inc., Q32 Bio, Precipio Diagnostics, and a private company. From 2005 to 2011, she was a Managing Director of New Leaf Ventures, a spinout from the Sprout Group. From 1993 to 2005, Ms. LaPorte served as a General Partner of the Sprout Group. Ms. LaPorte has a B.S. in Biology from Yale University and an M.B.A. from the Stanford University Graduate School of Business. We believe that Ms. LaPorte is qualified to serve on our Board due to her experience in the biotechnology and biopharmaceutical industries, her substantial professional experience, and the fact that she is a qualified financial expert.

Nicole Onetto, M.D. has served as a member of our Board since December 2021. Since June 2016, Dr. Onetto has served as an independent consultant in oncology, drug development, and translational research. She is currently on the board of directors for Basilea Pharmaceutica AG and previously served on the board at Viracta Therapeutics, Inc. (formerly Sunesis Pharmaceuticals, Inc.). Dr. Onetto received a B.A. from the University of Paris, an M.Sc. in Pharmacology from the University of Montréal, and an M.D. and a Hematology-Oncology Certificate from the University of Paris. We believe that Dr. Onetto is qualified to serve on our Board due to her extensive experience in clinical development and translational research.

THE BOARD OF DIRECTORS RECOMMENDS A VOTE "FOR" THE ELECTION OF EACH NAMED NOMINEE.

Directors Continuing in Office Until the 2025 Annual Meeting

Laura Berner has served as a member of our Board since December 2022. Since 2022, she has served as Chief Operating Officer of TRexBio, a private, venture-backed biotech company, and previously served as Chief Business Officer from 2020 to 2022. Ms. Berner served as Vice President, Head of Business Development & Investor Relations of Myovant Sciences Gmb from 2018 to 2020. Earlier in her career, she was a member of the business development team at Roche Pharma Partnering, and the transactional law group at Genentech. Ms. Berner began her career as a corporate attorney first at Ropes & Gray LLP, and later in the Office of the General Counsel at Harvard University, advising on general corporate, business development and strategic transactions. Ms. Berner earned a B.A. in Biology from Bryn Mawr College, a J.D. from Stanford Law School, and an M.B.A. from the University of Illinois Urbana-Champaign Gies College of Business. We believe that Ms. Berner is qualified to serve on our Board due to her experience in biopharma industry experience, in leadership roles spanning corporate strategy, business development, investor relations and law.

Frank D. Lee has served as a member of our Board since November 2021. Since January 2024, Mr. Lee has served as the Chief Executive Officer of Pacira Biosciences. Mr. Lee served as Chief Executive Officer of Forma Therapeutics Holdings, Inc. from March 2019 through its acquisition by Novo Nordisk in October 2022. From May 2006 to March 2019, he held various positions at Genentech, Inc., most recently as Senior Vice President, Global Product Strategy and Therapeutic Area Head for the immunology, ophthalmology and infectious diseases. Prior to joining Genentech, Inc., Mr. Lee spent approximately 13 years serving in various roles at Novartis, Janssen and Eli Lilly in engineering, manufacturing, sales/marketing and business development. He previously served on the board of directors of the Genentech Foundation. Mr. Lee received a B.S. in Chemical Engineering from Vanderbilt University and an M.B.A. in Marketing and Finance from the Wharton Graduate School of Business. We believe that Mr. Lee is qualified to serve on our Board due to his experience in shaping treatment paradigms for HER2 breast cancer patients and his commercial leadership in building innovative product strategies.

Brian O'Callaghan has served as a member of our Board since November 2021. Mr. O'Callaghan has served as the Chief Executive Officer and member of the board of directors at Deep Genomics since September 2023. Prior to joining Deep Genomics, Mr. O'Callaghan served as the Chief Executive Officer at ObsEva SA from November 2020 to May 2023, the Chief Executive Officer at Petra Pharma Corporation from May 2017 to May 2020, and as President and Chief Executive Officer at Sonrgy, Inc. from May 2015 to April 2017. Mr. O'Callaghan received an M.B.A. from the Henley School of Business at the University of Reading. We believe that Mr. O'Callaghan is qualified to serve on our Board due to his deep biotechnology and pharmaceutical experience across many therapeutic areas, leading new medicines from concept to commercialization.

Mahendra G. Shah, Ph.D. has served as a member of our Board since September 2016. Dr. Shah has served in various roles at Vivo Capital, LLC, a healthcare focused investment firm, since March 2010, and is currently serving as its Senior Fellow. Dr. Shah currently serves on the boards of directors of Verona Pharma PLC and various private companies. Dr. Shah previously served as a board member of Soleno Therapeutics, Inc., Q32 Bio (formerly Homology Medicines, Inc.), and Aadi Bioscience Inc. Dr. Shah holds a B.S. and M.S. in Pharmacy from L.M. College of Pharmacy in Gujarat, India and a Ph.D. in Pharmaceutical Sciences from St. John's University. We believe that Dr. Shah is qualified to serve on our Board due to his expertise and experience in the biopharmaceutical industry and his experience in healthcare investing.

Directors Continuing in Office Until the 2026 Annual Meeting

Randall C. Schatzman, Ph.D. has served as our Chief Executive Officer and member of the Board since July 2019. From January 2004 to March 2018, Dr. Schatzman was co-founder and served as President, Chief Executive Officer and a member of the board of directors of Alder BioPharmaceuticals, Inc., a migraine treatment biopharmaceutical company. From 1999 to 2004, Dr. Schatzman served as Senior Vice President of Discovery Research at Celltech R&D, Inc., a wholly-owned subsidiary of Celltech Group plc. From 1995 to 1999, Dr. Schatzman served as Director of Gene Discovery at Mercator Genetics Inc. From 1986 to 1995, Dr. Schatzman served as Section Leader at Roche Bioscience, previously Syntex Corp., a subsidiary of Roche Holdings Ltd. Dr. Schatzman holds a B.S. in Biochemistry from Purdue University and a Ph.D. in Molecular Pharmacology from Emory University. We believe that Dr. Schatzman is qualified to serve on our Board due to his daily insight into corporate matters as our Chief Executive Officer and his extensive background in the biotechnology industry.

Edgar G. Engleman, M.D. has been a member of our board of directors since January 2015. He is a founding member and Chief Scientific Advisor of Vivo Capital, LLC. Dr. Engleman is a Professor of Pathology and Medicine at the Stanford University School of Medicine, where he established and oversees the Stanford Blood Center, directs his immunology research team, and co-directs the Tumor Immunology and Immunotherapy Research Programs at the Stanford Cancer Institute. He is an inventor of multiple patented technologies, has authored more than 300 publications in medical and scientific journals, and trained more than 100 graduate and postgraduate students. Dr. Engleman is the lead inventor of the technology underlying a cancer immunotherapy known as Provenge (Sipulucel-T), which was shown to extend the life of patients who suffer from metastatic prostate cancer. Provenge is the first in the class of personalized immunotherapeutic agents to be FDA approved for the treatment of cancer. Dr. Engleman is the founder or cofounder of a number of biotech companies including Cetus Immune (acquired by Novartis), Genelabs (acquired by GlaxoSmithKline), Dendreon (acquired by Sanpower), and Vivo portfolio companies Medeor, Bolt, and Tranquis. He received his B.A. from Harvard College and earned his M.D. from Columbia University School of Medicine.

James I. Healy, M.D., Ph. D. has served as a member of our Board since January 2021. Dr. Healy has been a General Partner of Sofinnova Investments (formerly Sofinnova Ventures), a biotech investment firm, since June 2000. Dr. Healy currently serves as a director of ArriVent BioPharma, Inc., Natera, Inc., Y-mAbs Therapeutics, Inc. and several private companies. Previously, he served as a board member of Ascendis Pharma A/S, Amarin Corporation, Altamira Therapeutics Ltd (formerly Auris Medical Holding AG), Coherus BioSciences, Inc., PDS Biotechnology Corporation (formerly Edge Therapeutics, Inc.), NuCana PLC, and several private companies. He also previously served as a director on the Board of the National Venture Capital Association (NVCA) and the Board of the Biotechnology Industry Organization (BIO). Dr. Healy holds an M.D. and a Ph.D. in Immunology from Stanford University School of Medicine and holds a B.A. in Molecular Biology and a B.A. in Scandinavian Studies from the University of California, Berkeley. We believe Dr. Healy is qualified to serve on our Board due to his extensive experience in the biopharmaceutical industry, including as a venture capital investor and a member of the boards of directors of other biopharmaceutical companies.

Board Diversity

The Board diversity matrix, below, provides the diversity statistics for our Board. Our previous year's disclosure can be found in our definitive proxy statement filed with the SEC on April 28, 2023.

Board Diversity Matrix (As of April 26, 2024)

Total Number of Directors	10	
	Female	**Male**
Part I: Gender Identity		
Directors	3	7
Part II: Demographic Background		
African American or Black	—	—
Alaskan Native or Native American	—	—
Asian	—	2
Hispanic or Latinx	—	—
Native Hawaiian or Pacific Islander	—	—
White	3	5
Two or More Races or Ethnicities	—	—
LGBTQ+	—	
Did Not Disclose Demographic Background	—	

INFORMATION REGARDING THE BOARD OF DIRECTORS AND CORPORATE GOVERNANCE

Independence of The Board of Directors

As required under the Nasdaq Stock Market, or Nasdaq, listing standards, a majority of the members of a listed company's board of directors must qualify as "independent," as affirmatively determined by the board of directors. The Board consults with our counsel to ensure that the Board's determinations are consistent with relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in pertinent listing standards of Nasdaq, as in effect from time to time.

Consistent with these considerations, after review of all relevant identified transactions or relationships between each director, or any of his or her family members, and the Company, its senior management and its independent auditors, the Board has affirmatively determined that the following directors are independent directors within the meaning of the applicable Nasdaq listing standards: Drs. Engleman, Healy, Miller, Onetto, and Shah, Messrs. Lee and O'Callaghan, and Mses. LaPorte and Berner. In making this determination, the Board found that none of these directors or nominees for director had a material or other disqualifying relationship with the Company. Dr. Schatzman is not considered independent because he is our Chief Executive Officer.

Family Relationships

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

Board Leadership Structure

Dr. Healy has served as our lead independent director since November 2021, and in this role helps reinforce the independence of the Board as a whole. The position of lead independent director has been structured to provide additional leadership for the Board in the absence of a Board Chairperson. The lead independent director is empowered to, among other duties and responsibilities, approve agendas and meeting schedules for regular Board meetings, preside over Board meetings, preside over and establish the agendas for meetings of the independent directors, act as liaison between the Chief Executive Officer and the independent directors, approve information sent to the Board, preside over any portions of Board meetings at which the evaluation or compensation of the Chief Executive Officer is presented or discussed and, as appropriate upon request, act as a liaison to stockholders. In addition, it is the responsibility of the lead independent director to coordinate between the Board and management with regard to the determination and implementation of responses to any problematic risk management issues. As a result, we believe that the lead independent director can help ensure the effective independent functioning of the Board in its oversight responsibilities. In addition, we believe that the lead independent director is better positioned to build a consensus among directors and to serve as a conduit between the other independent directors and the Chief Executive Officer, for example, by facilitating the inclusion on meeting agendas of matters of concern to the independent directors.

Role of the Board in Risk Oversight

One of the Board's key functions is informed oversight of our risk management process. The Board does not have a standing risk management committee, but rather administers this oversight function directly through the Board as a whole, as well as through various Board standing committees that address risks inherent in their respective areas of oversight. In particular, our Board is responsible for monitoring and assessing strategic risk exposure, including a determination of the nature and level of risk appropriate for the Company. Our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The audit committee also monitors compliance with legal and regulatory requirements, in addition to oversight of the performance of our internal audit function. Audit committee responsibilities also include oversight of cybersecurity risk management, and, to that end, the committee typically meets twice annually with both IT and business personnel responsible for cybersecurity risk management and receives periodic reports from the head of cybersecurity risk management, as well as incidental reports as matters arise. Our nominating and corporate governance committee monitors the effectiveness of our Corporate Governance Guidelines, including whether they are successful in preventing illegal or improper liability-creating conduct. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking. Typically, the entire Board meets with the head of our risk management group at least annually, and the applicable Board committees meet at least annually with the employees responsible for risk management in the committees' respective areas of oversight. Both the Board as a whole and the various standing committees receive periodic reports from the head of risk management, as well as incidental reports as matters may arise. It is the responsibility of the committee chairs to report findings regarding material risk exposures to the Board as quickly as possible. The Board has delegated to the Board's lead independent director the responsibility of coordinating between the Board and management with regard to the determination and implementation of responses to any problematic risk management issues.

Hedging Policy

Under our Insider Trading Policy, our employees, directors and consultants, and their designees may not hedge their ownership of our stock, including but not limited to trading in options, puts, calls, or other derivative instruments related to our stock. Additionally, employees, directors and consultants, and their designees may not purchase our stock on margin, borrow against our stock held in a margin account, or pledge our stock as collateral for a loan.

Meetings of the Board of Directors

The Board met six times and the various committees of the Board met an aggregate of nine times during the year ended December 31, 2023. The audit committee of the Board met four times, the compensation committee of the Board met three times, and the research and development committee met two times. The nominating and corporate governance committee did not hold any meetings in 2023, but did informally caucus during 2023. All members of the Board, attended at least 75% of the aggregate number of meetings of our Board and of the committees on which they served, that were held during the period of the last fiscal year and during which they served on the Board or such committees.

Director Attendance at Annual Meeting

We invite each member of the Board to attend our annual meetings of stockholders. Three of our directors attended our 2023 annual meeting of stockholders, which was held virtually. We do not have a formal policy regarding attendance by members of the Board at our annual meetings.

Limitations of Liability and Indemnification Matters

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

- any breach of the director's duty of loyalty to the corporation or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions; or

- any transaction from which the director derived an improper personal benefit.

Such limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated certificate of incorporation authorizes us to indemnify our directors, officers, employees, and other agents to the fullest extent permitted by Delaware law. Our amended and restated bylaws provide that we are required to indemnify our directors and officers to the fullest extent permitted by Delaware law and may indemnify our other employees and agents. Our amended and restated bylaws also provide that, on satisfaction of certain conditions, we will advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. We have entered and expect to continue to enter into agreements to indemnify our directors and executive officers. With certain exceptions, these agreements provide for indemnification for related expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in connection with any action, proceeding or investigation. We believe that the amended and restated certificate of incorporation and amended and restated bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain customary directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted for directors, executive officers or persons controlling us, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

INFORMATION REGARDING COMMITTEES OF THE BOARD OF DIRECTORS

The Board of Directors

The following table sets forth certain information for our directors as of April 15, 2024:

Name	Age	Position(s)
Randall C. Schatzman, Ph.D.	69	Chief Executive Officer and Class II Director
Edgar G. Engleman, M.D.[4]	78	Founder and Class II Director
James I. Healy, M.D., Ph.D.[3]*[4]	59	Lead Independent Director and Class II Director
Laura Berner	49	Class I Director
Kathleen LaPorte[1]*	62	Class III Director
Frank D. Lee[2][3]	56	Class I Director
Richard A. Miller, M.D.[2][3][4][5]	73	Class III Director
Brian O'Callaghan[1][2]*	54	Class I Director
Nicole Onetto, M.D.[4]*	71	Class III Director
Mahendra G. Shah, Ph.D.[1][3]	79	Class I Director

(1) Member of the audit committee

(2) Member of the compensation committee

(3) Member of the nominating and corporate governance committee

(4) Member of the research and development committee

(5) Dr. Miller's term as director will expire at the 2024 Annual Meeting of Stockholders and he is not standing for re-election.

* Committee Chairperson

Composition of our Board of Directors

Our Board has established an audit committee, a compensation committee, a nominating and corporate governance committee, and a research and development committee. The composition and responsibilities of each of the committees of our Board are described below. Members serve on these committees until their resignation or until otherwise determined by our Board. Our Board may establish other committees as it deems necessary or appropriate from time to time. Each committee operates under a charter that has been approved by our board and has the composition and responsibilities described below. The charters for each committee are available at the investor relations section of our website at www.boltbio.com.

Audit Committee

Our audit committee consists of Kathleen LaPorte, Brian O'Callaghan, and Mahendra G. Shah. Our Board reviews the Nasdaq listing standards definition of independence for audit committee members on an annual basis and has determined that each member of the audit committee satisfies the independence requirements under the Nasdaq listing standards and Rule 10A-3(b)(1) of the Exchange Act. The chairperson of our audit committee is Ms. LaPorte. Our Board has determined that Ms. LaPorte is an "audit committee financial expert" within the meaning of SEC regulations, based on a qualitative assessment of Ms. LaPorte's level of knowledge and experience. Each member of our audit committee can read and understand fundamental financial statements in accordance with applicable requirements. In arriving at these determinations, our Board has examined each audit committee member's scope of experience and the nature of their employment.

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

- helping our Board oversee our corporate accounting and financial reporting processes;
- reviewing and discussing with our management the adequacy and effectiveness of our disclosure controls and procedures;
- assisting with design and implementation of our risk assessment functions;
- managing the selection, engagement, qualifications, independence and performance of a qualified firm to serve as the independent registered public accounting firm to audit our financial statements;

- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and the independent accountants, our interim and year-end operating results;
- developing procedures for employees to submit concerns anonymously about questionable accounting or audit matters;
- reviewing related person transactions;
- obtaining and reviewing a report by the independent registered public accounting firm at least annually that describes our internal quality control procedures, any material issues with such procedures and any steps taken to deal with such issues when required by applicable law;
- reviewing the adequacy and effectiveness of our information security policies and practices and the internal controls regarding information security; and
- approving or, as permitted, pre-approving, audit and permissible non-audit services to be performed by the independent registered public accounting firm.

Compensation Committee

Our compensation committee consists of Frank D. Lee, Richard A. Miller, and Brian O'Callaghan. The chairperson of our compensation committee is Mr. O'Callaghan. Our Board has determined that each member of the compensation committee is independent under the listing standards of Nasdaq, and a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act.

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

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

After taking into consideration the six factors prescribed by the SEC and Nasdaq, the compensation committee engaged Compensia Inc., for the beginning of 2023, and subsequently engaged Aon plc, or Radford, for the remainder of 2023, as compensation consultants. The compensation committee requested that Compensia and Radford:

- evaluate the efficacy of the Company's existing compensation strategy and practices in supporting and reinforcing the Company's long-term strategic goals; and
- assist in refining the Company's compensation strategy and in developing and implementing an executive compensation program to execute that strategy.

As part of its engagement, the compensation committee requested that Compensia and Radford develop a comparative group of companies and perform analyses of competitive performance and compensation levels for that group. At the request of the compensation committee, Compensia and Radford also conducted individual interviews with members of the compensation committee and senior management to learn more about the Company's business operations and strategy, key performance metrics and strategic goals, as well as the labor markets in which the Company competes. Compensia and Radford ultimately developed recommendations that were presented to the compensation committee for its consideration. Following an active dialogue with Compensia and Radford, the compensation committee approved the recommendations of Compensia and Radford.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of James I. Healy, Frank D. Lee, Richard A. Miller and Mahendra G. Shah. The chairperson of our nominating and corporate governance committee is Dr. Healy. Our Board has determined that each member of the nominating and corporate governance committee is independent under the listing standards of Nasdaq. Specific responsibilities of our nominating and corporate governance committee include:

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

Our nominating and corporate governance committee believes that candidates for director should have certain minimum qualifications, including the ability to read and understand basic financial statements, being over 21 years of age and having the highest personal integrity and ethics. The nominating and corporate governance committee also intends to consider such factors as possessing relevant expertise upon which to be able to offer advice and guidance to management, having sufficient time to devote to our affairs, demonstrated excellence in his or her field, having the ability to exercise sound business judgment and having the commitment to rigorously represent the long-term interests of our stockholders. However, the nominating and corporate governance committee retains the right to modify these qualifications from time to time. Candidates for director nominees are reviewed in the context of the current composition of our Board, our operating requirements and the long-term interests of stockholders. In conducting this assessment, the nominating and corporate governance committee typically considers diversity (including gender, racial and ethnic diversity), age, skills and such other factors as it deems appropriate, given our current needs and needs our Board, to maintain a balance of knowledge, experience and capability.

Our nominating and corporate governance committee appreciates the value of thoughtful Board refreshment, and regularly identifies and considers qualities, skills and other director attributes that would enhance the composition of our Board. In the case of incumbent directors whose terms of office are set to expire, the nominating and corporate governance committee reviews these directors' overall service to us during their terms, including the number of meetings attended, level of participation, quality of performance and any other relationships and transactions that might impair the directors' independence. In the case of new director candidates, the nominating and corporate governance committee also determines whether the nominee is independent for Nasdaq purposes, which determination is based upon applicable Nasdaq listing standards, applicable SEC rules and regulations and the advice of counsel, if necessary. The nominating and corporate governance committee conducts any appropriate and necessary inquiries into the backgrounds and qualifications of possible candidates after considering the function and needs of our Board. The nominating and corporate governance committee meets to discuss and consider the candidates' qualifications and then selects a nominee for recommendation to our Board by majority vote.

Communications with the Board of Directors

Historically, we have not provided a formal process related to stockholder communications with our Board. Nevertheless, every effort has been made to ensure that the views of stockholders are heard by our Board or individual directors, as applicable, and that appropriate responses are provided to stockholders in a timely manner. We believe our responsiveness to stockholder communications to our Board has been excellent. Nevertheless, during the upcoming year, the nominating and corporate governance committee will give full consideration to the adoption of a formal process for stockholder communications with our Board and, if adopted, publish it promptly and post it to our website.

Research and Development Committee

Our Board has established a research and development committee; the Board has not yet adopted a charter for this committee, which to date has acted in a more informal manner. Our research and development committee consists of Edgar G. Engleman, James I. Healy, Richard A. Miller, and Nicole Onetto. The chairperson of our research and development committee is Dr. Onetto. Our research and development committee met two times during 2023.

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 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.

Process for Stockholder Nominations

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

DIRECTOR COMPENSATION

The following table sets forth information regarding the compensation earned for service on our Board during the year ended December 31, 2023. Randall C. Schatzman, Ph.D., our Chief Executive Officer, is also a member of our Board, but did not receive any additional compensation for his service as a director. Dr. Schatzman's compensation as an executive officer is set forth in "Executive Compensation-Summary Compensation Table."

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)[1][2]	Total ($)
Laura Berner	35,000	30,590	65,590
Edgar G. Engleman, M.D.[3]	40,000	30,590	70,590
James I. Healy, M.D., Ph.D.	48,000	30,590	78,590
Kathleen LaPorte	50,000	30,590	80,590
Frank D. Lee	44,000	30,590	74,590
Richard A Miller, M.D.[4]	49,000	30,590	79,590
Brian O'Callaghan	52,500	30,590	83,090
Nicole Onetto, M.D.	45,000	30,590	75,590
Mahendra G. Shah, Ph.D.[3]	46,500	30,590	77,090

(1) The amounts reported in this column do not reflect dollar amounts actually received by the non-employee director. Instead, the amounts reflect the aggregate grant date fair value of the stock options granted to the non-employee directors during 2023 under our 2021 Equity Incentive Plan, computed in accordance with ASC 718. As required by SEC rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. The amounts reported in this column reflect the accounting cost for these stock options and do not correspond to the actual economic value that may be received by the non-employee directors upon the exercise of the stock options or any sale of the underlying shares of common stock. Each non-employee director was granted a stock option to purchase 25,000 shares of common stock with an exercise price of $1.63 per share on the date of our 2023 Annual Meeting of Stockholders.

(2) As of December 31, 2023, our non-employee directors held the following option awards:

Name	Number of Option Awards
Laura Berner	87,261
Edgar G. Engleman, M.D.	75,000
James I. Healy, M.D., Ph.D.	75,000
Kathleen LaPorte	127,857
Frank D. Lee	114,071
Richard A Miller, M.D.	144,836
Brian O'Callaghan	114,071
Nicole Onetto, M.D.	112,227
Mahendra G. Shah, Ph.D.	75,000

(3) In 2023, Drs. Engleman and Shah's director compensation was paid to Vivo Capital VIII, LLC, or Vivo GP. Dr. Engleman is a voting member of Vivo GP and Dr. Shah is a managing member of Vivo PANDA, LLC, as described in the "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" section.

(4) Dr. Miller's term as director will expire at the 2024 Annual Meeting of Stockholders and he is not standing for re-election.

Non-Employee Director Compensation Policy

We adopted a non-employee director compensation policy which became effective upon the closing of our initial public offering in February 2021 and which was amended and restated in March 2022, pursuant to which our non-employee directors are eligible to receive cash and equity compensation for service on our Board and committees of our Board. Each non-employee director is entitled to receive an annual cash retainer of $35,000 for serving on our Board.

The chairperson of our Board is entitled to a cash retainer of $65,000 in lieu of the annual retainer received by other non-employee directors.

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

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

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

Each new non-employee director who joins our Board will receive an option to purchase [50,000] shares of our common stock under our 2021 Plan. The shares subject to this option will vest on a monthly basis over 36 months commencing on the grant date, subject to the non-employee director's continuous service with us on each applicable vesting date. Such newly joining director will also receive a prorated initial annual option grant consisting of an option to purchase a number of shares of our common stock determined by multiplying [25,000] by the percentage obtained by dividing the number of calendar days from the date such new director joins us to the date of the next scheduled annual stockholder meeting by the total number of calendar days scheduled to follow the date of the last annual stockholder meeting through the date of the next annual stockholder meeting. Such prorated initial annual option will vest in full on the date immediately preceding the date of next annual stockholder meeting, subject to the non-employee director's continuous service through such vesting date.

On the date of each annual meeting of our stockholders held in 2022 and 2023, each continuing non-employee director received an option to purchase 25,000 shares of our common stock under the 2021 Plan, vesting on the earlier of the one-year anniversary of the grant date or the date immediately prior to the next annual stockholder meeting date, subject to the non-employee director's continuous service with us on the applicable vesting date. Commencing with our 2024 Annual Meeting of Stockholders, on the date of each annual meeting of our stockholders, each continuing non-employee director will receive an option to purchase 22,000 shares of our common stock under the 2021 Plan, vesting on the one-year anniversary of the grant date or the date immediately prior to the next annual stockholder meeting date, subject to the non-employee director's continuous service with us on the applicable vesting date.

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

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

REPORT OF THE AUDIT COMMITTEE OF THE BOARD OF DIRECTORS

The audit committee assists the Board in its oversight of the Company's financial statements and reporting process, audit process and internal controls. The audit committee operates under a written charter adopted by the Board, which describes this and the other responsibilities of the audit committee. Management has the primary responsibility for the financial statements and the reporting process, including the systems of internal controls. Our independent registered public accounting firm is responsible for performing an independent audit of our consolidated financial statements in accordance with the auditing standards of the Public Company Accounting Oversight Board, or PCAOB, and to issue a report thereon.

The audit committee has reviewed and discussed the Company's audited financial statements with management, which has primary responsibility for the financial statements. PricewaterhouseCoopers LLP, the Company's independent registered public accounting firm for the year ended December 31, 2023, is responsible for expressing an opinion on the conformity of the Company's audited financial statements with generally accepted accounting principles. The audit committee has discussed with PricewaterhouseCoopers LLP the matters required to be discussed by the applicable requirements of the PCAOB and SEC. The audit committee has received and reviewed the written disclosures and the letter from PricewaterhouseCoopers LLP required by applicable requirements of the PCAOB regarding PricewaterhouseCoopers LLP's communications with the audit committee concerning independence, and has discussed with PricewaterhouseCoopers LLP its independence.

Based on the review and discussions referred to above, the audit committee recommended to the Board of Directors that the audited financial statements be included in the Company's 2023 Annual Report on Form 10-K for filing with the SEC. The audit committee also appointed PricewaterhouseCoopers LLP to serve as the Company's independent registered public accounting firm for the year ending December 31, 2024 and is seeking ratification of such selection by the Company's stockholders at the Annual Meeting.

AUDIT COMMITTEE

Kathleen LaPorte (Chairperson)
Brian O'Callaghan
Mahendra G. Shah, Ph.D.

April 26, 2024

The foregoing report of the audit committee of the Board of the directors does not constitute soliciting material and shall not be deemed filed, incorporated by reference into or a part of any other filing by the Company (including any future filings) under the Securities Act of 1933, as amended, or the Securities Act, or the Exchange Act, except to the extent the Company specifically incorporates such report by reference therein.

PROPOSAL 2: RATIFICATION OF SELECTION OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The audit committee of our Board has selected PricewaterhouseCoopers LLP as our independent registered public accounting firm for the year ending December 31, 2024 and has further directed that management submit the selection of our independent registered public accounting firm for ratification by the stockholders at the Annual Meeting. PricewaterhouseCoopers LLP has audited our financial statements for each of our fiscal years since the year ended December 31, 2019. Representatives of PricewaterhouseCoopers LLP are expected to be present at the virtual Annual Meeting. During the webcast, they will have an opportunity to make a statement if they so desire and will be available to respond to appropriate questions submitted online.

Neither our bylaws nor other governing documents or law require stockholder ratification of the selection of PricewaterhouseCoopers LLP as our independent registered public accounting firm. However, the audit committee is submitting the selection of PricewaterhouseCoopers LLP to the stockholders for ratification as a matter of good corporate practice. If the stockholders fail to ratify the selection, the audit committee will reconsider whether or not to retain PricewaterhouseCoopers LLP. Even if the selection is ratified, the audit committee, in its discretion, may direct the selection of a different independent registered public accounting firm at any time during the year if the audit committee determines that such a change would be in our best interests and our stockholders' best interest.

The affirmative vote of the holders of a majority of the shares of our common stock present online or represented by proxy at the Annual Meeting and entitled to cast votes on this proposal will be required to ratify the selection of PricewaterhouseCoopers LLP for the year ending December 31, 2024. Abstentions will be counted as votes cast on this proposal and will have the same effect as "Against" votes. No broker non-votes are expected to exist in connection with this proposal.

Independent Registered Public Accounting Firm Fees and Services

The following table provides information regarding the fees incurred by PricewaterhouseCoopers LLP during the years ended December 31, 2023 and 2022. The audit committee pre-approved all of the fees described below:

	Years Ended December 31,	
	2023	**2022**
Audit fees[1]	$ 895,000	$ 1,092,000
Audit-related fees	—	—
Tax fees[2]	41,200	109,500
All other fees[3]	2,000	5,400
Total fees	$ 938,200	$ 1,206,900

(1) Audit fees consist of fees professional services rendered for the annual audit of our financial statements, the review of our interim financial statements, and comfort letters, consents and assistance with and review of documents filed with the SEC.
(2) Tax fees consists of fees for services provided for tax consultation services.
(3) Consist of fees for products and services other than the services described above. All other fees for the year ended December 31, 2023 and 2022 were related to annual subscription to accounting literature and tools.

Pre-Approval Policies and Procedures

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

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

The audit committee may delegate pre-approval authority to its chairperson. The chairperson must report any pre-approval decisions to the full audit committee at its next scheduled meeting. The annual audit services, engagement terms, and fees are subject to the specific pre-approval of the audit committee. All services performed and related fees billed by PricewaterhouseCoopers LLP during 2023 and 2022 were pre-approved by the audit committee.

THE BOARD OF DIRECTORS RECOMMENDS A VOTE "FOR" PROPOSAL 2.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

PRINCIPAL STOCKHOLDERS

The following table sets forth information with respect to the beneficial ownership of our common stock as of March 28, 2024, for:

- each person or group of affiliated persons known by us to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our directors and nominees for director; and
- all of our directors and executive officers as a group.

We have determined beneficial ownership in accordance with the rules and regulations of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Except as indicated by the footnotes below, we believe, based on information furnished to us, that the persons and entities named in the table below have sole voting and sole investment power with respect to all shares that they beneficially own, subject to applicable community property laws.

Applicable percentage ownership is based on 38,127,740 shares of common stock outstanding as of March 28, 2024. In computing the number of shares beneficially owned by a person and the percentage ownership of such person, we deemed to be outstanding all shares subject to options and warrants held by the person that are currently exercisable, or exercisable within 60 days of March 28, 2024. However, except as described above, we did not deem such shares outstanding for the purpose of computing the percentage ownership of any other person.

Unless otherwise indicated, the address of each beneficial owner listed below is c/o Bolt Biotherapeutics, Inc., 900 Chesapeake Drive, Redwood City, California 94063. We believe, based on information provided to us, that each of the stockholders listed below has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

	Shares Beneficially Owned	
Name of Beneficial Owner	**Shares**	**%**
Principal Stockholders		
Tang Capital Management, LLC[1]	3,652,244	9.6
Entities affiliated with Vivo Capital[2]	3,521,291	9.2
Entities affiliated with Pivotal bioVenture Partners Fund I, L.P.[3]	3,058,419	8.0
Sofinnova Venture Partners X, L.P.[4]	2,754,437	7.2
Entities affiliated with Citadel Advisors LLC[5]	2,458,958	6.4
Directors and Executive Officers		
Randall C. Schatzman, Ph.D.[6]	2,306,458	5.7
William P. Quinn[7]	667,699	1.7
Edith A. Perez, M.D.[8]	693,595	1.8
Grant Yonehiro[9]	646,864	1.7
Edgar G. Engleman, M.D.[10]	3,343,286	8.8
Laura Berner[11]	35,872	*
James I. Healy, M.D., Ph.D.[12]	2,804,437	7.3
Kathleen LaPorte[13]	104,057	*
Frank D. Lee[14]	80,738	*
Richard A. Miller, M.D.[15]	101,410	*
Brian O'Callaghan[14]	80,738	*
Nicole Onetto, M.D.[16]	77,505	*
Mahendra G. Shah, Ph.D.[17]	1,498,286	3.9
All directors and executive officers as a group (13 persons)[18]	12,440,945	30.9

* Represents beneficial ownership of less than 1%.

(1) Based on the Schedule 13G/A filing on February 14, 2024, reporting beneficial ownership as of December 31, 2023. The Schedule 13G/A provides information only as of December 31, 2023, and, consequently, the beneficial ownership of the above-mentioned reporting person may have changed between December 31, 2023 and March 28, 2024. Tang Capital Management, LLC ("Tang Capital Management") is the general partner of Tang Capital Partners, LP ("Tang Capital Partners"), and Kevin Tang is the manager of Tang Capital Management. Tang Capital Management, Tang Capital Partners, and Kevin Tang shares voting and dispositive power over shares held by Tang Capital Management. The address for this entity is 4747 Executive Drive, Suite 210, San Diego, CA 92121.

(2) Consists of: (i) 1,821,483 shares of common stock held directly by Vivo Capital Fund VIII, L.P., of which Vivo Capital VIII, LLC ("Vivo GP") is the general partner; (ii) 251,522 shares of common stock held directly by Vivo Capital Surplus Fund VIII, L.P., of which Vivo GP is the general partner; and (iii) 1,448,286 shares of common stock held directly by Vivo PANDA Fund, L.P. ("Vivo PANDA LP"), of which Vivo PANDA, LLC ("Vivo PANDA GP") is the general partner. The voting members of Vivo GP are Michael Chang, Frank Kung, Edgar Engleman, Shan Fu, and Jack Nielsen. Dr. Engleman is a member of our board of directors. The voting members of Vivo PANDA GP are Michael Chang, Frank Kung, and Mahendra G. Shah. Dr. Shah is a member of our board of directors. The principal business address of Vivo Capital is 192 Lytton Avenue, Palo Alto, CA 94301.

(3) Consists of (i) 1,891,467 shares of common stock held directly by Pivotal bioVenture Partners Fund I G.P., L.P. ("Pivotal GP"); (ii) 1,066,952 shares of common stock held directly by NFLS Beta Limited ("NFLS"); and (iii) 100,000 shares of common stock held directly by Permwell Management Limited ("Permwell"). Pivotal GP is the general partner of Pivotal bioVenture Partners Fund I, L.P. ("Pivotal"), and Pivotal bioVenture Partners Fund I U.G.P. Ltd. (the "Ultimate General Partner") is the general partner of Pivotal GP. Based on the Schedule 13D/A filing on February 14, 2024, reporting beneficial ownership as of December 31, 2023. The Schedule 13D/A provides information only as of December 31, 2023, and, consequently, the beneficial ownership of the above-mentioned reporting person may have changed between December 31, 2023 and March 28, 2024. Ultimate General Partner is wholly-owned by Pivotal Partners Ltd ("Pivotal Partners"). Pivotal Partners is wholly-owned by Pivotal Life Sciences Holdings Limited ("Pivotal Life Sciences," and together with Pivotal, Pivotal GP, Ultimate General Partner, and Pivotal Partners, the "Pivotal Entities"). Pivotal Life Sciences is wholly owned by Nan Fung Life Sciences Holdings Limited ("Nan Fung Life Sciences"), and Nan Fung Life Sciences is wholly-owned by NF Investment Holdings Limited ("NFIHL"), which is wholly owned by Nan Fung Group Holdings Limited ("NFGHL"). Permwell is wholly-owned by NFIHL. NFLS is wholly-owned by NFLS Platform Holdings Limited ("NFLS Platform"), which is wholly-owned by Nan Fung Life Sciences. The members of the Executive Committee of NFGHL make investment decisions with respect to the securities of the Issuer held by Pivotal, Permwell, and NFLS. Kam Chung Leung, Frank Kai Shui Seto, Vincent Sai Sing Cheung, Pui Kuen Cheung, Vanessa Tih Lin Cheung, Meng Gao, Hequing Huang and Chun Wai Nelson Tang are the members of the Executive Committee of NFGHL. The address of the principal business office of each of the Pivotal Entities is 501 Second Street, Suite 200, San Francisco, California 94107. The principal business address of NFGHL and Permwell is 23rd Floor, Nan Fung Tower, 88 Connaught Road Central and 173 Des Voeux Road Central, Central, Hong Kong. The registered office address of NFIHL is Vistra Corporate Services Centre, Wickhams Cay II, Road Town, Tortola, VG1110, British Virgin Island.

(4) Consists of 2,754,437 shares of common stock held directly by Sofinnova Venture Partners X, L.P. ("SVP X"). Sofinnova Management X, L.P. ("SM X LP") is the general partner of SVP X and Sofinnova Management X-A, L.L.C. ("SM X LLC") is the general of SM X LP and each may be deemed to have sole voting, investment and dispositive power with respect to the shares held by SVP X. James I. Healy and Maha Katabi are managing members of SM X LP and may be deemed to have shared voting, investment and dispositive power over the shares owned by SVP X. Such persons disclaim beneficial ownership of such shares except to the extent of their pecuniary interest therein. Dr. Healy, a member of our board of directors, is a general partner at Sofinnova Investments, Inc. The address for SM X is 3000 Sand Hill Road, Bldg. 4, Suite 250, Menlo Park, CA 94025.

(5) Consists of (i) 2,367,482 shares of common stock held directly by Citadel Multi-Strategy Equities Master Fund Ltd. ("CM"); and (ii) 91,476 shares of common stock held directly by Citadel Securities LLC ("Citadel Securities"). Based on the Schedule 13G/A filing on February 14, 2024, reporting beneficial ownership as of December 31, 2023. The Schedule 13G/A provides information only as of December 31, 2023, and, consequently, the beneficial ownership of the above-mentioned reporting person may have changed between December 31, 2023 and March 28, 2024. Citadel Advisors LLC ("Citadel Advisors") acts as the portfolio manager of CM. Citadel Advisors Holdings LP ("CAH") is the sole member of Citadel Advisors, and Citadel GP LLC ("CGP") is the general partner of CAH. Citadel Securities Group LP ("CALC4") is the non-member manager of Citadel Securities. Citadel Securities GP LLC ("CSGP") is the general partner of CALC4. Kenneth Griffin is the President and Chief Executive Officer of CGP, and owns a controlling interest in CGP and CSGP and may be deemed to share voting and dispositive power over shares held by CM and Citadel Securities. The address for this entity is Southeast Financial Center, 200 S. Biscayne Blvd., Suite 3300, Miami, Florida 33131.

(6) Consists of: (i) 10,359 shares of common stock; and (ii) 2,296,099 shares issuable pursuant to stock options exercisable within 60 days of March 28, 2024.

(7) Consists of: (i) 36,272 shares of common stock; and (ii) 631,427 shares issuable pursuant to stock options exercisable within 60 days of March 28, 2024.

(8) Consists of: (i) 46,612 shares of common stock; and (ii) 646,983 shares issuable pursuant to stock options exercisable within 60 days of March 28, 2024.

(9) Consists of: (i) 8,918 shares of common stock; and (ii) 637,946 shares issuable pursuant to stock options exercisable within 60 days of March 28, 2024.

(10) Consists of: (i) 577,425 shares of common stock held directly by the Engleman Family Trust; (ii) 321,428 shares of common stock held directly by the Erik Nathan Engleman Irrevocable Trust dated December 6, 2012; (iii) 321,428 shares of common stock held directly by the Jason Engleman Irrevocable GST Trust dated December 06, 2012; (iv) 1,821,483 shares of common stock held directly by Vivo GP.; (v) 251,522 shares of common stock held directly by Vivo Capital Surplus Fund VIII, L.P.; and (vi) 50,000 shares issuable pursuant to stock options exercisable by Dr. Engleman within 60 days of March 28, 2024. Dr. Engleman is trustee of the Engleman Family Trust. Dr. Engleman's spouse is the trustee of the Erik Nathan Engleman Irrevocable Trust and the Jason Engleman Irrevocable GST Trust. Vivo GP is the general partner of both Vivo Capital Fund VIII, L.P. and Vivo Capital Surplus Fund VIII, L.P. The voting members of Vivo GP are Michael Chang, Frank Kung, Edgar Engleman, Shan Fu, and Jack Nielsen, and may be deemed to have shared voting and dispositive power over the shares owned by both Vivo Capital Fund VIII, L.P. and Vivo Capital Surplus Fund VIII, L.P.

(11) Consists of 35,872 shares issuable pursuant to stock options exercisable within 60 days of March 28, 2024.

(12) Consists of 2,754,437 shares of common stock held directly by SVP X; and (ii) 50,000 shares issuable pursuant to stock options exercisable by Dr. Healy within 60 days of March 28, 2024. SM X LP is the general partner of SVP X and Dr. Healy is a managing member of SM X LP. Dr. Healy disclaims beneficial ownership of such shares except to the extent of any pecuniary interest therein.

(13) Consists of: (i) 1,200 shares of common stock; and (ii) 102,857 shares issuable pursuant to stock options exercisable within 60 days of March 28, 2024.

(14) Consists of 80,738 shares issuable pursuant to stock options exercisable within 60 days of March 28, 2024.

(15) Consists of: (i) 15,602 shares of common stock; and (ii) 85,808 shares issuable pursuant to stock options exercisable within 60 days of March 28, 2024.

(16) Consists of 77,505 shares issuable pursuant to stock options exercisable within 60 days of March 28, 2024.

(17) Consists of: (i) 1,448,286 shares of common stock held directly by Vivo PANDA LP; and (ii) 50,000 shares issuable pursuant to stock options exercisable by Dr. Shah within 60 days of March 28, 2024. Dr. Shah is a managing member of Vivo PANDA GP and has shared voting and dispositive power over the shares owned by Vivo PANDA LP. Dr. Shah disclaims beneficial ownership of such shares except to the extent of any pecuniary interest therein.

(18) Consists of: (i) 7,614,972 shares of common stock directly or indirectly held by all current executive officers and directors as a group; and (ii) 4,825,973 shares of common stock issuable pursuant to options exercisable within 60 days of March 28, 2024.

EXECUTIVE OFFICERS

The following table sets forth certain information with respect to our executive officers as of April 15, 2024.

Name	Age	Position(s)
Randall C. Schatzman, Ph.D.	69	Chief Executive Officer and Director
William P. Quinn	53	Chief Financial Officer
Edith A. Perez, M.D.	67	Chief Medical Officer
Grant Yonehiro	60	Chief Business Officer

Biographical information with regard to Dr. Schatzman is presented under "Proposal No. 1—Election of Directors" in this Proxy Statement.

William P. Quinn has served as our Chief Financial Officer since May 2020. From November 2017 to May 2020, Mr. Quinn served as Chief Financial Officer and Senior Vice President, Finance and Corporate Development, of Sunesis Pharmaceuticals, Inc. (acquired by Viracta Therapeutics, Inc.), a biopharmaceutical company. From 2011 to November 2017, Mr. Quinn served as President and Chief Executive Officer of Bullet Biotechnology, Inc., a biotechnology company. From 2003 to 2011, Mr. Quinn served in various positions at Jazz Pharmaceuticals, Inc. From 2001 to 2002, Mr. Quinn served as Chief Operating Officer and Chief Financial Officer at Novation Biosciences. From 1999 to 2001, Mr. Quinn served as Associate Partner at Mobius Venture Capital, an early-stage venture capital fund. From 2011 to 2021, Mr. Quinn served on the board of directors of A Foundation Building Strength, a non-profit dedicated to finding treatments for Nemaline Myopathy. Mr. Quinn holds a B.A. and M.A. from Stanford University and an M.B.A. from Stanford Graduate School of Business.

Edith A. Perez, M.D. has served as our Chief Medical Officer since April 2020. From 2015 to 2018, Dr. Perez served as Vice President and Head of the U.S. BioOncology Medical Unit of Genentech, Inc., a biotechnology company. From 2011 to 2015, Dr. Perez served in multiple senior leadership positions within the National Cancer Institute, including the Alliance for Clinical Trials in Oncology, Vice President and Group Vice Chair. Since 1995, Dr. Perez has held various positions at the Mayo Clinic, including Deputy Director at Large for the Mayo Clinic Cancer Center, and Supplemental Consultant in the Departments of Hematology/Oncology and Cancer Biology, Director of the Breast Cancer Translational Genomics Program and Professor of Medicine. From 2014 to 2018, Dr. Perez served as a member of the board of directors for the American Association for Cancer Research. Dr. Perez received a B.S. in Biology from the University of Puerto Rico, Rio Piedras and an M.D. from the University of Puerto Rico Medical School. Dr. Perez did her residency training in Internal Medicine at Loma Linda University and completed a Fellowship in Hematology/Oncology at the University of California at Davis. Dr. Perez is board certified in Internal Medicine, Hematology and Oncology.

Grant Yonehiro has served as our Chief Business Officer since November 2016. From February 2016 to November 2016, Mr. Yonehiro served as Interim Chief Commercial Officer at Vium, Inc., a private biotechnology company. From 2013 to January 2016, Mr. Yonehiro served as Chief Business Officer at Berkeley Lights, a public biotechnology company that merged and was acquired by Bruker. From 2009 to 2013, Mr. Yonehiro served as Chief Executive Officer and President at Perseid Therapeutics LLC, which was acquired by Astellas Pharma, Inc. in 2011. From 2003 to 2009, Mr. Yonehiro served as Chief Business Officer and Senior Vice President at Maxygen, Inc., a public biopharmaceutical company. From 1997 to 2003, Mr. Yonehiro served in various roles at GenVec, Inc., most recently serving as its Vice President, Drug Development. Mr. Yonehiro received a B.I.S. in Business, Economics and International Relations from the University of Minnesota, Twin Cities and an M.B.A. from the University of California at Berkeley.

EXECUTIVE COMPENSATION

Summary Compensation Table

The following table presents all of the compensation awarded to, earned by or paid to our named executive officers, consisting of our principal executive officer and three other most highly compensated officers serving at the end of such year, during the years ended December 31, 2023 and 2022:

Name	Year	Salary ($)	Bonus ($)	Option Awards ($)[1]	All Other Compensation ($)	Total ($)
Randall C. Schatzman, Ph.D.	2023	599,100	263,700 [2]	877,929	9,900 [4]	1,750,629
Chief Executive Officer	2022	564,100	253,845 [3]	1,406,097	11,370 [5]	2,235,412
William P. Quinn	2023	441,800	159,100 [2]	301,375	9,900 [6]	912,175
Chief Financial Officer	2022	422,775	160,655 [3]	468,699	11,130 [7]	1,063,259
Edith A. Perez, M.D.	2023	486,640	170,400 [2]	301,375	24,300 [8]	982,715
Chief Medical Officer	2022	467,920	173,130 [3]	468,699	27,270 [9]	1,137,019
Grant Yonehiro	2023	415,050	149,600 [2]	274,854	—	839,504
Chief Business Officer	2022	386,650	146,927 [3]	424,061	11,130 [10]	968,768

(1) The amounts reported in this column do not reflect dollar amounts actually received by the executive officer. Instead, the amounts reflect the aggregate grant date fair value of the stock options granted to the executive officer during 2023 or 2022, as applicable under our 2021 Equity Incentive Plan, computed in accordance with ASC 718. Assumptions used in the calculation of these amounts are included in Note 9 to our financial statements in our Form 10-K.

(2) Represents amounts earned in 2023, which will be paid in 2024. Dr. Schatzman's 2023 bonus is solely based on company performance goals, while the 2023 annual performance bonuses for the other officers are based on a combination of company performance goals and personal bonus achievements. For 2023, the compensation committee of our Board determined that the Company had achieved 80% of its corporate goals. Accordingly, Dr. Schatzman was entitled to 80% of his target bonus. The 2023 personal bonus achievement was determined to be 95% for Dr. Perez and 100% for Messrs. Quinn and Yonehiro.

(3) Represents amounts earned in 2022, which were paid in 2023. Dr. Schatzman's 2022 bonus was solely based on company performance goals, while the 2022 annual performance bonuses for the other officers were based on a combination of company performance goals and personal bonus achievements. For 2022, the compensation committee of our Board determined that the Company had achieved 90% of its corporate goals. Accordingly, Dr. Schatzman was entitled to 90% of his target bonus. The 2022 personal bonus achievement was determined to be 95% for Dr. Perez and 100% for Messrs. Quinn and Yonehiro.

(4) Dr. Schatzman received $9,900 in 401(k) match.

(5) Dr. Schatzman received $9,150 in 401(k) match and $2,220 for electronics stipend.

(6) Mr. Quinn received $9,900 in 401(k) match.

(7) Mr. Quinn received $9,150 in 401(k) match and $1,980 for electronics stipend.

(8) Dr. Perez received $9,900 in 401(k) match, $12,000 for commuting stipend and $2,400 for waiver of healthcare insurance.

(9) Dr. Perez received $9,150 in 401(k) match, $12,000 for commuting stipend, $3,720 for electronics stipend, and $2,400 for waiver of healthcare insurance.

(10) Mr. Yonehiro received $9,150 in 401(k) match and $1,980 for electronics stipend.

Outstanding Equity Awards as of December 31, 2023

The following table presents the outstanding equity incentive plan awards held by each named executive officer as of December 31, 2023:

			Option Awards			
Name	Grant Date	Vesting Commencement Date[1]	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price ($)[2]	Option Expiration Date
Randall C. Schatzman, Ph.D.	9/6/2019	7/15/2019	791,185	—	2.73	9/5/2029
	9/3/2020	9/3/2020[3]	100,000	—	4.34	9/2/2030
	9/3/2020	1/15/2021[3]	178,571	—	4.34	9/2/2030
	2/4/2021	2/4/2021[3]	340,000	—	20.00	2/3/2031
	2/18/2022	1/1/2022[4]	402,500	227,500	3.08	2/17/2032
	2/27/2023	1/1/2023[4]	222,527	505,743	1.59	2/26/2033
William P. Quinn	7/29/2020	5/4/2020[5]	135,098	17,203	2.80	7/28/2030
	9/3/2020	9/3/2020[3]	35,714	—	4.34	9/2/2030
	9/3/2020	1/15/2021[3]	42,857	—	4.34	9/2/2030
	2/4/2021	2/4/2021[3]	100,000	—	20.00	2/3/2031
	2/18/2022	1/1/2022[4]	134,167	75,833	3.08	2/17/2032
	2/27/2023	1/1/2023[4]	76,389	173,611	1.59	2/26/2033
Edith A. Perez, M.D.	7/29/2020	4/1/2020[5]	170,536	18,750	2.80	7/28/2030
	9/3/2020	9/3/2020[3]	12,142	—	4.34	9/2/2030
	9/3/2020	1/15/2021[3]	45,000	—	4.34	9/2/2030
	2/4/2021	2/4/2021[3]	100,000	—	20.00	2/3/2031
	2/18/2022	1/1/2022[4]	134,167	75,833	3.08	2/17/2032
	2/27/2023	1/1/2023[4]	76,389	173,611	1.59	2/26/2033
Grant Yonehiro	1/18/2017	11/1/2016	64,285	—	2.10	1/17/2027
	1/17/2018	11/1/2016	13,207	—	2.03	1/16/2028
	4/4/2018	2/14/2018	16,444	—	2.03	4/3/2028
	1/11/2019	7/23/2018	33,075	—	2.24	1/10/2029
	11/13/2019	7/2/2019	92,857	—	2.73	11/12/2029
	9/3/2020	9/3/2020[3]	12,142	—	4.34	9/2/2030
	9/3/2020	1/15/2021[6]	30,714	—	4.34	9/2/2030
	2/4/2021	2/4/2021[3]	100,000	—	20.00	2/3/2031
	2/18/2022	1/1/2022[4]	121,389	68,611	3.08	2/17/2032
	2/27/2023	1/1/2023[4]	69,667	158,333	1.59	2/26/2033

(1) The unvested shares underlying these options become subject to accelerated vesting as described in "Executive Compensation—Severance and Change in Control Plan" below.

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

(3) This stock option is early exercisable and, to the extent shares subject to this option are issued and unvested as of a given date, such shares will remain subject to a right of repurchase held by us. As of December 31, 2023, the named executive officer had not early exercised the option.

(4) 1/36th of the shares subject to the option vest monthly measured from the vesting commencement date.

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

(6) This option is immediately exercisable and vests monthly over a four-year period beginning upon the closing of our Series C-2 financing on January 15, 2021. As of December 31, 2023, the named executive officer had not early exercised the option.

Emerging Growth Company Status

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

Nonqualified Deferred Compensation

Our named executive officers did not participate in, or earn any benefits under, any nonqualified deferred compensation plan sponsored by us during the year ended December 31, 2023. Our Board may elect to provide our officers and other employees with nonqualified deferred compensation benefits in the future if it determines that doing so is in our best interests.

Pension and Defined Benefit Plan Retirement Benefits

Our named executive officers did not participate in, or otherwise receive any benefits under, any pension or defined benefit retirement plan sponsored by us during 2023.

Health and Welfare Benefits

All of our current named executive officers are eligible to participate in our employee benefit plans, including our medical, dental, vision, life, disability and accidental death and dismemberment insurance plans, in each case on the same basis as all of our other employees. We pay the premiums for the life, disability and accidental death and dismemberment insurance for all of our employees, including our named executive officers. We generally do not provide perquisites or personal benefits to our named executive officers.

401(k) Plan

We currently maintain a 401(k) retirement savings plan for our employees, including our named executive officers, who satisfy certain eligibility requirements. The 401(k) plan is intended to qualify as a tax-qualified plan under the Internal Revenue Code. Our named executive officers are eligible to participate in the 401(k) plan on the same basis as our other employees. The Internal Revenue Code allows eligible employees to defer a portion of their compensation, within prescribed limits, on a pre-tax basis through contributions to the 401(k) plan. We make matching contributions of up to 3% of the eligible employees' compensation to the 401(k) plan, subject to the maximum eligible salary allowable under the Internal Revenue Code.

Employment Arrangements

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

Randall C. Schatzman, Ph.D.

In June 2019, we entered into an offer letter with Dr. Schatzman, which governs the terms of his employment with us. For 2023, Dr. Schatzman was entitled to an annual base salary of $599,100 and was eligible to receive an annual performance bonus with a target amount of 55% of his annual base salary, payable based on the achievement of certain annual performance milestones or objectives as agreed by and between him and the Board on an annual basis, and subject to his continued employment through the time of payment of the bonus. For 2024, Dr. Schatzman is entitled to an annual base salary of $623,100 and is eligible to receive an annual performance bonus with a target amount of 55% of his annual base salary, payable 100% based on the achievement of certain Company performance milestones or objectives as agreed by the Board. Dr. Schatzman is also eligible to receive potential termination or change in control payments pursuant to the Severance and Change in Control Plan, or the Severance Plan, as described in "—Potential Payments upon Termination or Change in Control" below.

William P. Quinn

In April 2020, we entered into an offer letter with Mr. Quinn, which governs the terms of his employment with us. For 2023, Mr. Quinn was entitled to an annual base salary of $441,800 and was eligible to receive an annual performance bonus with a target amount of 40% of his annual base salary, based on his achievement of certain individual and company performance goals and his continued employment through the time of payment of the bonus. For 2024, Mr. Quinn is entitled to an annual base salary of $459,500 and is eligible to receive an annual performance bonus with a target amount of 40% of his annual base salary, based on his achievement of Company performance goals (50%) related to clinical, pipeline development, and financing milestones and objectives, and individual performance goals (50%). Mr. Quinn is also eligible to receive potential termination or change in control payments pursuant to the Severance Plan, as described in "—Potential Payments upon Termination or Change in Control" below.

Edith A. Perez, M.D.

In March 2020, we entered into an offer letter with Dr. Perez, which governs the terms of her employment with us. For 2023, Dr. Perez was entitled to an annual base salary of $486,640 and was eligible to receive an annual performance bonus with a target amount of 40% of her annual base salary, based on her achievement of certain individual and company performance goals and her continued employment through the time of payment of the bonus. Dr. Perez is also entitled to receive a $1,000 monthly travel allowance. For 2024, Dr. Perez is entitled to an annual base salary of $506,100 and is eligible to receive an annual performance bonus with a target amount of 40% of her annual base salary, based on her achievement of Company performance goals (50%) related to clinical, pipeline development, and financing milestones and objectives, and individual performance goals (50%). Dr. Perez is also eligible to receive potential termination or change in control payments pursuant to the Severance Plan, as described in "—Potential Payments upon Termination or Change in Control" below.

Grant Yonehiro

In October 2016, we entered into an offer letter with Mr. Yonehiro, which governs the terms of his employment with us. For 2023, Mr. Yonehiro was entitled to an annual base salary of $415,050 and was eligible to receive an annual performance bonus with a target amount of 40% of his annual base salary, based on his achievement of certain annual performance milestones, as determined by us, and subject to his continued employment through the time of payment of the bonus. For 2024, Mr. Yonehiro is entitled to an annual base salary of $431,700 and is eligible to receive an annual performance bonus with a target amount of 40% of his annual base salary, based on his achievement of Company performance goals (50%) related to clinical, pipeline development, and financing milestones and objectives, and individual performance goals (50%). Mr. Yonehiro is also eligible to receive potential termination or change in control payments pursuant to the Severance Plan, as described in "—Potential Payments upon Termination or Change in Control" below.

Potential Payments upon Termination or Change in Control

Severance and Change in Control Plan

The Severance and Change in Control Plan, or the "Severance Plan", provides severance benefits to each of our employees selected for participation in the Severance Plan, subject to execution of a participation agreement for the Severance Plan. Each of our executive officers and vice presidents, including our named executive officers, are participants in the Severance Plan. The benefits provided under the Severance Plan supersede any similar severance benefits described in a participant's offer letter or employment agreement. Participants in our Severance Plan are entitled to receive continued payment of their base salary (12 months for our Chief Executive Officer, nine months for our other executive officers and senior vice presidents, and six months for our vice presidents and all other participants so designated by our Board) upon either an involuntary termination without cause or a resignation for good reason (as each such term is defined in the Severance Plan) following such termination. In addition, each participant with a qualifying termination is also eligible for payment of continued group health plan premiums during the period of base salary continuation, a prorated bonus at the target level for the year of termination, and an additional amount equal to any then earned but unpaid performance bonus for the calendar year preceding such termination.

In the event that an involuntary termination without cause or a resignation for good reason occurs in the period commencing three months prior to and ending 12 months following a change in control, the participant will be entitled to receive a lump sum cash payment (equal to 18 of months base salary for our Chief Executive Officer, 15 months of base salary for our other executive officers, 12 months of base salary for our senior vice presidents and nine months of base salary for our vice presidents and all other participants so designated by our Board) and a lump sum cash payment in respect of such participant's target annual cash bonus (such payment at 150% of the annual target amount for our Chief Executive Officer, 125% of target for our other executive officers, 100% of target for our senior vice presidents, or 75% of target for our vice presidents and all other participants so designated by our Board). In addition, each such participant with a qualifying change in control termination is also eligible for payment of continued group health plan premiums for a period of time equal to the number of months of base salary severance that is paid in a lump sum as specified above. Also, in the event of a change in control termination, the unvested portion of any equity awards granted to any participant will fully vest and become exercisable at the later of such participant's execution of a release or the effective date of such change in control. All such severance benefits are subject to the participant signing a general release of all known and unknown claims in substantially the form provided in the Severance Plan, as well as the participant's compliance with certain post-termination restrictive covenants.

Our Chief Executive Officer is also entitled to immediate vesting acceleration of any equity awards granted to our Chief Executive Officer if the Chief Executive Officer continues to provide services to the Company through the date of such change in control.

Insider Trading and Rule 10b5-1 Trading Guidelines

We maintain an Insider Trading Policy that covers all of our directors, executive officers, employees and consultants, which sets forth restrictions and procedures related to trading in the Company's securities on the basis of material nonpublic information. Our Insider Trading Policy also describes instances where certain persons, including our directors and executive officers, must obtain prior approval before engaging in a transaction in our securities. In addition, our Insider Trading Policy sets forth restrictions for trading blackout periods applicable to covered insiders, as well as limited exceptions to such restrictions. Our Insider Trading Policy also makes clear that hedging and short positions by covered insiders in our securities is prohibited.

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or executive officer when entering into the plan, without subsequent direction from them. The director or executive officer may amend a Rule 10b5-1 plan in some circumstances and may terminate a plan at any time. The SEC recently promulgated a new rule related to the adoption and modification of Rule 10b5-1 trading plans by directors and officers of registrants, which became effective on February 27, 2023. On April 4, 2023, the Board approved the Amended and Restated Rule 10b5-1 Trading Guidelines in accordance with the new SEC rule. The Amended and Restated Rule 10b5-1 Trading Guidelines apply to our directors and executive officers and are intended to promote compliance with the new SEC rule, which requires, among other things, that any trades under a new or modified Rule 10b5-1 trading plan may not be commenced before expiration of a waiting period and that directors and executive officers may not use multiple overlapping Rule 10b5-1 trading plans except in limited circumstances. Our Amended and Restated Rule 10b5-1 Trading Guidelines permit "sell-to-cover" transactions by directors and executive officers, subject to the limitations required under the new SEC rule. The Amended and Restated Rule 10b5-1 Trading Guidelines apply to all new or modified Rule 10b5-1 trading plans adopted on or after April 4, 2023.

Incentive Compensation Recoupment Policy

We have adopted a Dodd-Frank Wall Street Reform and Consumer Protection Act-compliant compensation recoupment policy in accordance with SEC and Nasdaq requirements. Pursuant to this policy, in the event we are required to prepare an accounting restatement, we will recover any compensation received after the effective date by any current or former executive officer that is based wholly or in part upon the attainment of a financial reporting measure.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table shows certain information with respect to all of our equity compensation plans in effect as of December 31, 2023.

Plan Category	Number of securities to be issued upon exercise of outstanding stock options and rights (column a)	Weighted-average exercise price of outstanding stock options (1)	Number of securities remaining available for issuance under equity compensation plans (excluding securities reflected in column a)
Equity compensation plans approved by stockholders(2)	10,759,074	$ 4.12	1,212,323
Equity compensation plans not approved by stockholders	—	—	—
Total	10,759,074	$ 4.12	1,212,323

(1) The weighted-average exercise price does not reflect the shares that will be issued in connection with the settlement of restricted stock units (RSUs), since RSUs have no exercise price.

(2) The equity compensation plans approved by security holders are described in Note 9 to our financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2023. Includes 52,533 shares of common stock subject to outstanding RSUs.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Related Person Transaction Policy and Procedures

Our Board adopted a related person transaction policy setting forth the policies and procedures for the identification, review and approval or ratification of related person transactions. This policy covers, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and a related person were or will be participants and the amount involved exceeds $120,000, including purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness and guarantees of indebtedness. In reviewing and approving any such transactions, our audit committee will consider all relevant facts and circumstances as appropriate, such as the purpose of the transaction, the availability of other sources of comparable products or services, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction, management's recommendation with respect to the proposed related person transaction and the extent of the related person's interest in the transaction.

Certain Related Person Transactions

The following is a summary of transactions since January 1, 2022, to which we have been a participant in which the amount involved exceeded or will exceed $120,000, and in which any of our directors, executive officers or holders of more than five percent of our capital stock, or any member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest, other than compensation arrangements which are described in "Executive Compensation."

We believe the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that would be paid or received, as applicable, in arm's-length transactions.

Investor Rights Agreement

In June 2020, we entered into an amended and restated investor rights agreement, or IRA, with certain holders of our capital stock, including entities affiliated with Citadel Multi-Strategy Equities Master Fund Ltd., Pivotal bioVenture Partners LLC, Sofinnova Investments, Inc. and Vivo Capital and including certain members of, and affiliates of, our directors. The IRA provides certain holders of our common stock issued upon conversion of our preferred stock with certain registration rights, including the right to demand that we file a registration statement or request that their shares be covered by a registration statement that we are otherwise filing. Dr. Healy, a member of our Board, is affiliated with Sofinnova Investments, Inc. Drs. Engleman and Shah, members of our Board, are both affiliated with Vivo Capital. The IRA also provides these stockholders with information rights, which terminated upon the closing of our initial public offering, and a right of first refusal with regard to certain issuances of our capital stock, which did not apply to, and terminated upon, the closing of our initial public offering.

Relationship with Stanford University

In May 2015, we entered into a license agreement with Stanford University. During 2022, we made payments to Stanford of $157,700 for annual license fees and patent expense reimbursement. During 2023, we made payments to Stanford of $89,700 for annual license fees and patent expense reimbursement.

Dr. Engleman, a member of our Board, is a professor at Stanford. Dr. Engleman is a co-inventor of some of the patents that we license from Stanford. Under Stanford's policies, as a co-inventor Dr. Engleman is entitled to receive a share of any royalties that we pay to Stanford under the agreements with respect to the covered intellectual property. No royalty payments have been made to date.

Employment Arrangements

We have entered into employment agreements and offer letters with certain of our executive officers. For more information regarding these agreements with our executive officers, see "Executive Compensation-Employment Arrangements."

Equity Grants

We have granted options to certain of our directors and executive officers. For more information regarding the options granted to our directors and named executive officers, see "Executive Compensation" and "Director Compensation".

Indemnification

We provide indemnification for our directors and officers so that they will be free from undue concern about personal liability in connection with their service to the Company. Our amended and restated certificate of incorporation contains provisions limiting the liability of directors, and our amended and restated bylaws provides that we will indemnify each of our directors and officers to the fullest extent permitted under Delaware law. Our amended and restated certificate of incorporation and amended and restated bylaws also provide our Board with discretion to indemnify our employees and other agents when determined appropriate by the board.

In addition, we have entered into an indemnification agreement with each of our directors, executive officers and certain employees, which requires us to indemnify them. For more information regarding these agreements, see "Information Regarding the Board of Directors and Corporate Governance —Limitations of Liability and Indemnification Matters."

Policies and Procedures for Related Person Transactions

Our Board has adopted a related person transaction policy setting forth the policies and procedures for the identification, review and approval or ratification of related person transactions. This policy covers, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and a related person were or will be participants and the amount involved exceeds $120,000, including purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness and guarantees of indebtedness. In reviewing and approving any such transactions, our audit committee will consider all relevant facts and circumstances as appropriate, such as the purpose of the transaction, the availability of other sources of comparable products or services, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction, management's recommendation with respect to the proposed related person transaction and the extent of the related person's interest in the transaction.

HOUSEHOLDING OF PROXY MATERIALS

The SEC has adopted rules that permit companies and intermediaries (e.g., brokers) to satisfy the delivery requirements for Notices of Internet Availability of Proxy Materials or other Annual Meeting materials with respect to two or more stockholders sharing the same address by delivering a single Notice of Internet Availability of Proxy Materials or other Annual Meeting materials addressed to those stockholders. This process, which is commonly referred to as "householding," potentially means extra convenience for shareholders and cost savings for companies.

This year, a number of brokers with account holders who are Bolt Biotherapeutics, Inc. stockholders will be "householding" our Proxy Materials. A single Notice of Internet Availability of Proxy Materials will be delivered to multiple shareholders sharing an address unless contrary instructions have been received from the affected stockholders. Once you have received notice from your broker that they will be "householding" communications to your address, "householding" will continue until you are notified otherwise or until you revoke your consent. If, at any time, you no longer wish to participate in "householding" and would prefer to receive a separate Notice of Internet Availability of Proxy Materials, please notify your broker or contact Bolt Biotherapeutics, Inc. Direct your written request to our Secretary, care of Bolt Biotherapeutics, Inc., at 900 Chesapeake Drive, Redwood City, California, 94063 or contact our Secretary at (650) 665-9295. Stockholders who currently receive multiple copies of the Notices of Internet Availability of Proxy Materials at their addresses and would like to request "householding" of their communications should contact their brokers.

OTHER MATTERS

The Board knows of no other matters that will be presented for consideration at the Annual Meeting. If any other matters are properly brought before the meeting, it is the intention of the persons named in the accompanying proxy to vote on such matters in accordance with their best judgment.

By Order of the Board of Directors
/s/ William P. Quinn
Chief Financial Officer and Secretary
Redwood City, California
April 26, 2024

ADDITIONAL INFORMATION

Our Form 10-K has been posted on our corporate website at https://investors.boltbio.com/financial-information/sec-filings and at www.proxydocs.com/BOLT. For stockholders receiving a Notice of Internet Availability of Proxy Materials, instructions on how to request a printed copy of our Proxy Materials and Form 10-K are included in the Notice of Internet Availability. Stockholders receiving a printed copy of this Proxy Statement have also received a copy of our Form 10-K. We will provide, without charge, a copy of our Form 10-K for the year ended December 31, 2023 (including the financial statements but excluding the exhibits thereto) upon the written request of any stockholder or beneficial owner of our common stock. Requests should be directed to our Secretary the following address:

Bolt Biotherapeutics, Inc.
900 Chesapeake Drive
Redwood City, CA 94063

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, 2023
OR

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

For the transition period from to
Commission File Number 001-39988

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

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

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

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

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

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

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

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

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

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

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

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

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

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

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued 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 o□cers 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 30, 2023, as reported by The Nasdaq Global Select Market, was approximately $32.1 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 14, 2024, the Registrant had 38,127,740 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Designated portions of the Proxy Statement relating to registrant's 2024 Annual Meeting of Stockholders, which will be filed with the Securities and Exchange Commission within 120 days after the end of fiscal year 2023, 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.
- We face concentrated risk in our dependence on the success of our lead product candidate, trastuzumab imbotolimod, formerly known as BDC-1001, which is in clinical development and which has not completed a pivotal trial. If we do not obtain regulatory approval for and successfully commercialize our lead product candidate in one or more indications or we experience significant delays in doing so, or if we are unable to advance our other product candidates through preclinical and clinical development, obtain regulatory approval for and successfully commercialize our other product candidates in one or more indications, or we experience significant delays in doing so, we may never generate any revenue or become profitable.
- Our 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 trastuzumab imbotolimod, BDC-3042, 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 various approaches 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 hundred 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.

Our first Boltbody ISAC program is trastuzumab imbotolimod, formerly known as BDC-1001, targeting a tumor antigen known as human epidermal growth factor receptor 2 (HER2) that is often found in cancers such as breast and gastroesophageal cancer. In 2023, trastuzumab imbotolimod completed the Phase 1 stage of clinical development and advanced into a Phase 2 program that includes four different HER2-positive solid tumor types: breast cancer, gastroesophageal cancer, colorectal cancer, and endometrial cancer. In September 2023, the U.S. Food and Drug Administration, or FDA, granted trastuzumab imbotolimod Orphan Drug Designation for the treatment of gastric cancer, including gastroesophageal junction cancer. In the Phase 2 program we are evaluating trastuzumab imbotolimod as a single agent and in combination with the HER2-targeting antibody pertuzumab, and we also have the ability to add cohorts to evaluate trastuzumab imbotolimod in combination with the PD-1 inhibitor nivolumab.

Our expertise in myeloid cell biology also forms the foundation for additional, innovative immuno-oncology approaches that complement our Boltbody ISAC platform. For example, 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 results in these TAMs changing from tumor-supportive macrophages into 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 three dose escalation cohorts without experiencing a dose-limiting toxicity.

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.

Our lead product candidate, trastuzumab imbotolimod, is currently in clinical development for the treatment of patients with HER2-positive solid tumors, including breast, colorectal, endometrial, and gastroesophageal cancer. In September 2023, the U.S. Food and Drug Administration, or FDA, granted trastuzumab imbotolimod Orphan Drug Designation for the treatment of gastric cancer, including gastroesophageal junction cancer. We have two clinical collaboration and supply agreements to study trastuzumab imbotolimod in combination with other drugs. One is with Bristol-Myers Squibb, or BMS, for nivolumab, a leading PD-1 checkpoint inhibitor, and the other is with F. Hoffmann-La Roche Ltd, or Roche, for pertuzumab, a HER2-targeting monoclonal antibody. HER2, or human epidermal growth factor receptor 2, is a protein expressed by the HER2 gene that is also known as ERBB2 and is expressed in a wide range of tumors beyond the four mentioned above. Trastuzumab imbotolimod is a Boltbody ISAC comprising the HER2-targeting biosimilar of trastuzumab conjugated to one of our proprietary TLR7/8 agonists to augment the potential anti-tumor response. Preliminary clinical data demonstrate that trastuzumab imbotolimod is well tolerated at dose levels up to 20 mg/kg administered intravenously every week and leads to changes in key biomarkers in the tumor and plasma consistent with our proposed mechanism of action. Monotherapy activity has been seen in the form of partial and complete responses and long-term disease stabilization across several different HER2-expressing tumors, and we have also seen partial responses and stable disease in combination with the PD-1 inhibitor nivolumab. In August 2023 we announced that the first patients had been dosed in a Phase 2 study exploring efficacy in HER2-positive colorectal, endometrial, and gastroesophageal cancers. In December 2023, we dosed the first patient in the Phase 2 clinical trial investigating trastuzumab imbotolimod in metastatic breast cancer after treatment with Enhertu®, as a single agent and in combination with the HER2-targeting antibody pertuzumab. A second 2-arm Phase 2 study is designed to explore combination with nivolumab only after demonstration of monotherapy activity.

Our second program, 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, and melanoma, among others. We demonstrated that stimulation with our agonist antibody has anti-tumor activity in preclinical models. We developed a lead agonist antibody that binds to Dectin-2 and activates human TAMs. Activated TAMs produce TNFα, IL-6, IL-1β, CCL3, and other cytokines and chemokines. We completed the IND-enabling activities for BDC-3042 and received 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.

Our third program is a proprietary next-generation ISAC program in preclinical development against an undisclosed target.

We entered into our first collaboration in March 2019 with Toray Industries, Inc., or Toray, 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 A/S, or 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. In August 2021, we entered into an oncology research and development collaboration with Innovent Biologics, Inc., or Innovent, to leverage Innovent's proprietary therapeutic antibody portfolio and antibody discovery capability against undisclosed oncology targets in combination with our advanced ISAC technology and myeloid biology expertise to create new candidates for cancer treatments. The Innovent collaboration was amended in March 2024, when we secured global rights to two Boltbody ISAC programs. We expect our collaborations to add additional novel ISACs to our pipeline.

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 Alder, Astellas, Jazz, Roche / Genentech, and others. Together, our team has a proven track record in the discovery, development, and commercialization of numerous approved therapeutics such as Alecensa, Cytovene, Evenity, Gazyva, Herceptin, Kadcyla, Polivy, Perjeta, Rituxan, Tecentriq, Valcyte, Venclexta, and Vyepti while at other companies.

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 linker-payloads allow us to optimize the therapeutic profile of our product candidates for any tumor antigen as part of our research and discovery efforts to produce durable anti-tumor responses. We believe that our approach is applicable to a broad spectrum of tumor-associated antigens expressed on cancers, including cancers that are refractory to existing therapies.
- **Advance the development of our lead Boltbody ISAC product candidate, trastuzumab imbotolimod, for the treatment of patients with HER2-positive cancers.** Trastuzumab imbotolimod is currently in Phase 2 clinical trials for the treatment of patients with certain HER2-positive solid tumors. Based on promising data from our Phase 1 dose-escalation trial, we believe trastuzumab imbotolimod has the potential to be effective both as a monotherapy and in combination with existing therapies for patients with HER2-positive solid tumors. While approved HER2-targeting agents are important and effective treatment options for patients with HER2-positive solid tumors, many patients do not respond to these therapies, develop tumor progression after initial response or are not eligible for current HER2-targeting therapies. These sizable patient populations do not have adequate treatment options. Therefore, we intend to rapidly advance development of trastuzumab imbotolimod across multiple HER2-positive cancers, including breast, colorectal, endometrial, and gastroesophageal cancers.
- **Advance 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.
- **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 are examples of this approach.
- **Continue to invest in our myeloid expertise and Boltbody ISAC approach to explore the full potential of our targeted immunotherapies for the treatment of cancer.** Our expertise, rigor, and data-driven approach may lead to additional research and discovery programs that are complementary or independent of our Boltbody ISAC approach and our growing library of innate immune stimulators.

Trastuzumab Imbotolimod (formerly known as BDC-1001)

Overview

Our lead product candidate, trastuzumab imbotolimod, is currently in clinical development for the treatment of patients with HER2-positive solid tumors. Trastuzumab imbotolimod provides a compelling example of the potential of Boltbody ISACs to address unmet medical needs in solid tumors. Trastuzumab imbotolimod is delivered systemically and acts locally by targeting HER2-expressing tumors and related metastatic disease, triggering their destruction by the innate and adaptive immune systems. Trastuzumab imbotolimod consists of a biosimilar of the humanized monoclonal antibody trastuzumab that is chemically conjugated to one of our proprietary TLR7/8 agonists via a non-cleavable linker.

Preclinical Data

We have conducted extensive *in vitro* and *in vivo* experiments over the course of developing trastuzumab imbotolimod. Detailed results can be reviewed in our posters and publications, including *Ackerman SE, et al. Nature Cancer. 2021; 2:18-33.* Key findings from our preclinical studies include:

- Delivery of an intact, active Boltbody ISAC targeting an antigen on tumors is required to maximize anti-tumor activity. If the ISAC components are administered together without conjugation or if ISAC does not bind to the tumor, or the ISAC is missing an active Fc domain or an active immune stimulant, then it will not work as well and the extent of tumor elimination will be compromised. Research results include several models where a HER2 antibody alone does not provide sufficient tumor reduction, but a HER2 ISAC does.

- Using a cell-impermeable linker-payload conjugated with a stable, non-cleavable linker minimizes safety concerns.
- Changes in biomarker activity are concentrated in the tumor, with levels of cytokines and chemokines in the tumor generally ranging from 3-10 times the levels seen in the plasma.
- An increase in proinflammatory cytokines and chemokines, and an increase in immune cell infiltrate into the tumor, can be seen prior to anti-tumor activity.
- Once the immune system has been trained by the HER2 ISAC to eliminate tumors, it will reject a rechallenge from the same tumor cell line, even when the HER2 target antigen is no longer present. This demonstrates epitope spreading and durable immune protection.
- Data supporting the combination of a HER2 ISAC with the HER2-targeting antibody pertuzumab was presented at SITC in December 2023. This combination improves efficacy in three ways:
    - Enhances anti-tumor activity
    - Enables anti-tumor activity at lower doses
    - Produces anti-tumor activity against tumors with lower HER2 expression

Overview of HER2 Indications and Treatment Paradigms

HER2 is a proto-oncogene that encodes a transmembrane protein involved in signal transduction pathways that promote cell growth and differentiation. HER2 protein overexpression and gene amplification have been documented across multiple cancers, including breast, gastric, bladder, lung, esophageal, colorectal, endometrial, ovarian, salivary gland, pancreatic, cervical, and other cancers. Prevalence of HER2-overexpressing or -amplified tumors varies across indications. Targeting HER2 with antibodies and small molecule tyrosine kinase inhibitors in combination with chemotherapy has had a major impact on patients with HER2-positive breast and gastric cancer, but there remains a significant unmet medical need on an individual and global patient basis. Our trastuzumab imbotolimod program seeks to improve therapeutic outcomes for patients with HER2-positive tumors starting with four tumor types: 1) HER2-positive breast cancer refractory to Enhertu®, 2) HER2-positive gastroesophageal cancer refractory to existing anti-HER2 therapies, 3) HER2-positive colorectal cancer refractory to existing anti-HER2 therapies, and 4) HER2-positive endometrial cancer refractory to approved therapies. In addition, we have interest in potentially exploring other tumor types in the future, such as cases with HER2-low expression, in both monotherapy and various combination strategies. Our plans also envision trials in earlier stages of cancer, such as the neoadjuvant, post-neoadjuvant, and adjuvant settings.

HER2-targeting agents have been approved for patients with HER2-positive breast, gastric, and colorectal cancers, and HER2-low breast cancer, with HER2-positivity based on protein overexpression or gene amplification. Trastuzumab and trastuzumab-deruxtecan are approved for both HER2-positive breast and gastric cancer; tucatinib is approved for HER2-positive breast and colorectal cancer; and trastuzumab-deruxtecan is also approved for HER2-low breast cancer. Additional approved HER2-targeting agents for HER2-positive breast cancer include the following: pertuzumab, trastuzumab emtansine, trastuzumab-hyaluronidase-oysk, lapatinib, neratinib, margetuximab, and tucatinib. There are no approved HER2 therapies for HER2-positive endometrial cancer.

According to Globe Life Sciences research, the 2023 annual incidence of patients with breast cancer in the United States and in France, Germany, Italy, Spain and the UK (currently known as 4EU & UK) was estimated to be approximately 591,370 patients in the aggregate. Of these, approximately 118,274 patients had tumors that were HER2-positive. In addition, the 2023 annual incidence of patients with colorectal cancer, endometrial cancer and gastroesophageal cancer was estimated to be 404,291, 114,330 and 123,161 respectively. Of these, approximately 24,257, 31,441 and 13,548, respectively, had tumors that were HER2-positive.

Clinical Development Overview

We are currently conducting a Phase 2 trial of trastuzumab imbotolimod administered as a single agent or in combination with nivolumab, a PD-1 checkpoint inhibitor. We have completed a monotherapy dose-escalation and a nivolumab combination dose-escalation. This trial is evaluating safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary anti-tumor activity in patients with HER2-expressing solid tumors. All patients in our study have metastatic disease and disease progression after multiple prior therapies. In August 2023 we announced that the first patients had been dosed in the Phase 2 clinical trial to evaluate safety and anti-tumor activity in HER2-positive colorectal, endometrial, and gastroesophageal tumors.

Monotherapy

- *Monotherapy dose-escalation to evaluate safety and determine a recommended Phase 2 dose, or RP2D (completed).*
- *Monotherapy dose expansion to evaluate safety and preliminary responses in HER2-positive colorectal, endometrial, and gastroesophageal tumors (ongoing).*

Combination with Checkpoint Inhibitor

- *Combination dose-escalation with nivolumab (PD-1 checkpoint inhibitor) to evaluate safety and determine the RP2D of trastuzumab imbotolimod in combination with nivolumab (completed).*
- *Combination therapy with nivolumab to evaluate safety and preliminary responses in predefined tumor types. Part 4 will proceed only after demonstrating anti-tumor activity in Part 3 (future possibility).*

We are also currently conducting a two-cohort Phase 2 trial evaluating trastuzumab imbotolimod administered as a single agent or in combination with pertuzumab, a HER2-targeting monoclonal antibody. This trial will evaluate safety, tolerability, pharmacokinetics, pharmacodynamics and anti-tumor activity in patients with HER2-positive breast cancer. All patients in this study must have disease progression after treatment with Enhertu®. In December 2023 we announced that the first patient had been dosed in this trial.

Phase 1 Trial Results

We completed our Phase 1 dose-escalation study of trastuzumab imbotolimod in early 2023. Trastuzumab imbotolimod was well tolerated at all doses tested, through the highest dose of 20 mg/kg weekly, and produced anti-tumor activity, including multiple partial responses, across a diverse set of solid tumor types. The dose-escalation trial enrolled more than 100 patients with 16 different types of HER2-expressing solid tumors. All patients enrolled in the study had evidence of tumor progression after standard of care, and a majority of the patients were heavily pre-treated. We saw promising signs of clinical activity as a single agent and in combination with nivolumab. We have selected 20 mg/kg dosed every other week as the RP2D and are proceeding with Phase 2 clinical trials.

Our latest clinical data update was made at the European Society for Medical Oncology (ESMO) Congress in October 2023. The Phase 1 dose-escalation trial administered trastuzumab imbotolimod to 131 patients with 16 different HER2-expressing solid tumor types across 18 dose levels in two arms, as monotherapy and in combination with nivolumab. At enrollment, all patients entered in the study had evidence of tumor progression following prior standard of care treatments, and a majority of the patients were heavily pre-treated. At the RP2D, one CR was observed in the monotherapy arm in a patient with salivary gland cancer and three PRs were observed; one in the monotherapy arm in a patient with biliary tract cancer and two in the combination arm in patients with colorectal and ovarian cancer. The response rate at the RP2D was 29% in evaluable patients with HER2-positive tumors, both in monotherapy (2/7, 29%) and in combination with nivolumab (2/7, 29%). At the RP2D, among evaluable patients with HER2-positive tumors, 43% (3/7) in the monotherapy arm and 57% (4/7) in the combination arm experienced at least 24 weeks of disease control, and 57% (4/7) in the monotherapy arm and 86% (6/7) in the combination arm achieved tumor shrinkage.

Trastuzumab imbotolimod continues to be well tolerated at all dose levels and schedules as both monotherapy and in combination with nivolumab with no increase in toxicity in combination with trastuzumab imbotolimod. The most frequent drug-related treatment-emergent adverse events (TEAEs) were grade 1 or 2 infusion-related reactions, which were observed in 29.8% of subjects. The only other drug-related TEAE seen in more than 10% of subjects was grade 1 or 2 fatigue, which was observed in 11.5% of subjects. Grade 3 or higher treatment-related TEAEs were seen in ten subjects (7.6%), with only one grade 4 and no grade 5 drug-related TEAEs. Pharmacodynamic responses in both plasma and tissue were consistent with the mechanism of action for an ISAC. Statistically significant upregulation of TLR signaling pathway, macrophage function, antigen processing, and T cell-inflamed gene signatures was observed in the patients with clinical benefit versus those without clinical benefit. Increases in innate immunity signatures were observed in patients in the every-other week dosing cohorts, but not in the weekly dosing cohorts. The once-weekly dosing cohorts experienced higher rates of adverse events versus every-two-week dosing, including: grade 3 or higher trastuzumab imbotolimod-related TEAEs (10.0% versus 2.6%), grade 3 or higher LVEF decreases (7.5% versus 2.6%), and infusion-related reactions (40.0% versus 28.2%), providing further support for the selection of 20 mg/kg dosed every other week as the RP2D.

BDC-3042

In addition to the Boltbody ISAC platform, our expertise in myeloid biology and immuno-oncology led us to discover Dectin-2 as a novel oncology target expressed by tumor-associated macrophages (TAMs). We have demonstrated that agonism of Dectin-2 with the natural ligand mediates tumor regression in syngeneic mouse models, and that this effect disappears when Dectin-2 is blocked. Dectin-2 agonism causes TAMs to increase production of cytokines and chemokines such as TNFα, IL-6, IL-1β, and CCL3.

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 in phenotype, and agonism of Dectin-2 mediates 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 differentially upregulate expression of Dectin-2 within tumors, which provides an interesting rationale for exploring this combination.

We discovered a number of potent agonist antibodies targeting Dectin-2 and lead optimization resulted in a lead candidate with an engineered Fc domain which we are developing. Our preclinical work has demonstrated that this antibody can potently activate human macrophages, eliciting production of proinflammatory cytokines and chemokines including TNFα, IL-6, IL-1β, and CCL3. In ex-vivo experiments, we also demonstrated induction of significant cytokines and chemokines from primary human tumor samples which included a mix of tumor cells and immune cell infiltrate. We have also demonstrated that stimulation with our agonist antibody has better anti-tumor activity than pembrolizumab in humanized mice bearing MDA-MB-231 tumors, which endogenously express PD-L1.

We received IND clearance for BDC-3042 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. We have completed the first three dose cohorts without observing any dose-limiting toxicities, and continue to explore higher doses in this Phase 1 study.

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. 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. 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.

Oncology Clinical Trial Collaboration and Supply Agreement with Bristol-Myers Squibb

In September 2021, we entered into a clinical collaboration and supply agreement, or the BMS Agreement, with BMS to study trastuzumab imbotolimod in combination with BMS's PD-1 checkpoint inhibitor nivolumab, for the treatment of HER2-expressing solid tumors. Under the BMS Agreement, BMS granted us a non-exclusive, non-transferable, royalty-free license (with a right to sublicense) under its intellectual property to use nivolumab in a clinical trial for a combination therapy of nivolumab and our proprietary compound, trastuzumab imbotolimod, and has agreed to supply nivolumab at no cost to us and we will sponsor, fund and conduct the initial Phase 1/2 clinical trial in accordance with an agreed-upon protocol. Both parties will own the study data produced in the clinical trial, other than study data related solely to nivolumab, which will belong solely to BMS, or study data related solely to trastuzumab imbotolimod, which will belong solely to us. The parties may conduct additional clinical trials on the combined therapy which may be sponsored and funded by one party, or jointly funded. We initiated the clinical trial evaluating the combination of nivolumab and trastuzumab imbotolimod in the fourth quarter of 2021.

Clinical Supply Agreement with F. Hoffmann-La Roche Ltd

In September 2022, we entered into a clinical supply agreement, or the Roche Agreement, with Roche to study trastuzumab imbotolimod in combination with Roche's pertuzumab (Perjeta®), a compound approved for the treatment of HER2-positive breast cancer. Under the Roche Agreement, Roche granted us a non-exclusive, non-sublicensable, royalty-free license under its intellectual property to use pertuzumab in a clinical trial for a combination therapy of pertuzumab and our proprietary compound, trastuzumab imbotolimod, and has agreed to supply pertuzumab at no cost to us and we will sponsor, fund and conduct the initial Phase 2 clinical trial in accordance with an agreed-upon protocol. Both parties will own the study data produced in the clinical trial, other than study data related solely to pertuzumab, which will belong solely to Roche, or study data related solely to trastuzumab imbotolimod, which will belong solely to us. The parties may conduct additional clinical trials on the combined therapy which may be sponsored and funded by one party, or jointly funded. We are currently in a Phase 2 trial evaluating the combination of pertuzumab and trastuzumab imbotolimod.

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 product 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 product 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 product 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 CMOs 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.

Manufacturing Agreement with Piramal

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

Supply Agreement with EirGenix

In January 2022, we entered into an amended and restated supply agreement with EirGenix, Inc., or the Amended Supply Agreement, which amends the original supply agreement with EirGenix, Inc., or EirGenix, dated March 10, 2019, pursuant to which EirGenix agreed to supply to us, on a non-exclusive basis, bulk drug substance of EG12014, its monoclonal antibody being developed as a biosimilar of trastuzumab, which we use in the manufacture of trastuzumab imbotolimod. In addition, EirGenix provides us access to its regulatory data package and services to facilitate our development and commercialization efforts and we are required to make milestone payments to EirGenix up to an aggregate of $2.0 million based upon achievement of certain trastuzumab imbotolimod regulatory milestones and pay for the supply of EG12014. The agreement will remain in effect as long as we, or any of our affiliates or licensees, continue to pursue the development or commercialization of any HER2 Boltbody ISAC, unless earlier terminated. We may terminate the agreement if EirGenix fails to supply sufficient quantities of EG12014 or if EirGenix does not obtain regulatory approval for EG12014 as a standalone biosimilar product. We may also terminate the EirGenix Agreement upon prior written notice to EirGenix. EirGenix may terminate the agreement if we do not actively develop a HER2 Boltbody ISAC for more than two years. In addition, either party may terminate the agreement for the other party's uncured material breach or insolvency.

Competition

The biotechnology and pharmaceutical 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.

Oncology therapeutics on the market and in development range from traditional cancer therapies, including chemotherapy, to new therapies that harness the body's own immune system to fight cancer. A significant part of the immune response to cancer involves myeloid cells, including macrophages, dendritic cells, neutrophils, monocytes and granulocytes, all of which dynamically regulate tumor growth and progression. There are several therapies targeting myeloid cells on the market or in development. We view companies developing ISACs, especially ISACs with TLR7 agonist, TLR8 agonist or dual TLR7/8 agonist payloads, as the closest competitors for our lead program, trastuzumab imbotolimod. To the best of our knowledge, the only other ISAC in active clinical development that we are aware of is Mersana Therapeutics' XMT-2056. In January 2023, Mersana's XMT-2056 started a Phase 1 trial in subjects with HER2-expressing breast, gastric, colorectal and non-small-cell lung cancers. The trial was placed on clinical hold from March to October 2023 and resumed after lowering the starting dose. We do not consider any company developing unconjugated TLR agonists or unconjugated STING agonists to be direct competitors given that our Boltbody ISAC approach has demonstrated greater effectiveness with differentiated biology and a favorable safety profile as compared to unconjugated TLR or STING agonists that are typically administered intratumorally or have significant toxicities when administered systemically.

We are initially developing trastuzumab imbotolimod for the treatment of HER2-positive cancers. HER2 is a well-known and validated oncology target and there are marketed therapies and others in development addressing this target. Marketed therapies include Roche's Herceptin, Perjeta, Kadcyla and Phesgo (fixed-dose combination of Herceptin/Perjeta), Novartis' Tykerb, Puma Biotechnology's Nerlynx, Seagen's Tukysa, MacroGenics' Margenza, as well as Daiichi Sankyo and AstraZeneca's Enhertu®. We are aware of several therapies in development for patients with HER2-positive tumors including Jazz Pharmaceuticals and Zymework's zanidatamab and Zymework's ZW49, Pfizer and RemeGen's disitamab vedotin, Byondis' trastuzumab duocarmazine (also known as SYD985) Merus' MCLA-128, and Ambrx/Johnson&Johnson's ARX788.

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 trastuzumab imbotolimod and our other pipeline candidates that prove to be more effective or safer than competing products in our target indications. We could see a reduction or elimination of our commercial opportunity if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than trastuzumab imbotolimod or any other 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 trastuzumab imbotolimod or our other drugs, which could result in our competitors establishing a strong market position before we are able to enter the market.

Intellectual Property

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

Regardless of the coverage we seek under our existing patent applications, there is always a risk that an alteration to the product or process may provide sufficient basis for a competitor to avoid infringement claims. In addition, the coverage claimed in a patent application can be significantly reduced before a patent is issued and courts can reinterpret patent scope after issuance. Moreover, many jurisdictions, including the United States, permit third parties to challenge issued patents in administrative proceedings, which may result in further narrowing or even cancellation of patent claims. 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, 2023, we have 2 issued U.S. patents and 1 issued European patent that are solely owned by us and 4 issued U.S. patents and 3 issued foreign (Chinese, 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, 2023, we own or co-own with Stanford, for which Stanford has exclusively licensed its rights to us under the 2015 Stanford Agreement, approximately 259 pending patent applications in various countries (32 of which are pending in the U.S., and 8 of which are Patent Cooperation Treaty ("PCT") applications that have yet to enter the national phase in the U.S.).

In particular, the 4 issued U.S. patents and 3 issued foreign patents that we co-own with Stanford and for which Stanford has exclusively licensed its rights to us under the 2015 Stanford Agreement contain claims to our lead product candidate trastuzumab imbotolimod and/or the use thereof and will expire between 2037 and 2040. We have 16 pending patent applications, including 2 pending U.S. nonprovisional patent applications and 14 pending foreign patent applications, which contain claims to our lead product candidate trastuzumab imbotolimod and which we co-own with Stanford and for which Stanford has exclusively licensed its rights to us under the 2015 Stanford Agreement. These issued patents and pending patent applications, if issued, are expected to expire between 2037 and 2040, excluding any extension of patent term that may be available. We also have 8 pending patent applications, including 1 pending U.S. nonprovisional patent application, 1 pending PCT application that has yet to enter the national phase in the U.S., and 6 pending foreign patent applications, which we solely own, directed to the clinical use of our lead product candidate trastuzumab imbotolimod, as well as 1 European patent, which we solely own, directed to a method of preparing immunoconjugates, which could be utilized to prepare our lead product candidate trastuzumab imbotolimod or other Boltbody ISACs. These pending patent applications, if issued, are expected to expire between 2038 and 2043, excluding any extension of patent term that may be available.

In addition, we have 2 issued U.S. patents and 235 pending patent applications directed to potential products and methods other than our lead product candidate trastuzumab imbotolimod and the use thereof, including 221 pending patent applications that are solely owned by us, 13 pending patent applications that we co-own with Stanford and have exclusively licensed under the 2015 Stanford Agreement, and 1 pending patent application that is co-owned with Innovent. Of these 235 pending patent applications, 4 are U.S. provisional patent applications, 8 are PCT applications that have yet to enter the national phase in one or more countries, 25 are U.S. nonprovisional patent applications, and 198 are foreign patent applications. These pending patent applications, if issued, are expected to expire between 2035 and 2044 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. For two years from 1 January 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, may adopt decisions taken by the European Commission on the approval of new marketing authorizations through the centralized procedure, and the MHRA will have regard to marketing authorizations approved in a country in the European Economic Area (although in both cases a marketing authorization will only be granted if any Great Britain-specific requirements are met). Various national procedures are now available to place a drug on the market in the United Kingdom, Great Britain, or Northern Ireland, with the main national procedure having a maximum timeframe of 150 days (excluding time taken to provide any further information or data required). The data exclusivity periods in the United Kingdom are currently in line with those in the European Union, but the Trade and Cooperation Agreement provides that the periods for both data and market exclusivity are to be determined by domestic law, and so there could be divergence in the future.

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, 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 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 and foreign 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 and foreign 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, 2023, we had 100 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 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 trastuzumab imbotolimod and 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 and conducting research, preclinical studies and clinical trials. Our approach to the discovery and development of product candidates based on our Boltbody ISAC approach is unproven, and we do not know whether we will be able to develop any product candidates that succeed in clinical development or products of commercial value. As an organization, we have not yet completed any clinical trials, obtained regulatory approvals, manufactured a commercial-scale product (or arranged for a third party to do so on our behalf), or conducted sales and marketing activities necessary for successful product commercialization. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing biopharmaceutical products.

Since inception in 2015, we have not generated any product revenue and have incurred significant operating losses. Our net losses were $69.2 million and $88.1 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $364.3 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 a commercialized drug. The net losses we incur may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if, and as, we:

- continue to advance our research and preclinical and clinical development of our product candidates;
- expand and initiate further clinical trials for our product candidates;
- seek to identify additional product candidates;
- seek marketing approvals for our product candidates that successfully complete clinical trials, if any;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- maintain, expand, protect and enforce our intellectual property portfolio and obtain licenses to third-party intellectual property;
- attract, hire and retain additional administrative, clinical, regulatory and scientific personnel;
- enter into third-party relationships for clinical trials, manufacturing and supply; and
- incur additional legal, accounting and other expenses in operating our business, including the additional costs associated with operating as a public company.

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

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

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

Identifying and developing potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and begin selling any approved products. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our ongoing and planned preclinical studies, initiate additional clinical trials for our product candidates and seek regulatory approval for our current product candidates and any future product candidates we may develop. Our expenses could increase beyond our current expectations if the FDA requires us to perform clinical trials and other studies in addition to those that we currently anticipate. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or terminate our research and development programs or future commercialization efforts.

As of December 31, 2023, we had cash, cash equivalents and marketable securities of $128.6 million. Based upon our current operating plan and assumptions, we believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operations for at least the next 12 months following the issuance date of this Annual Report on Form 10-K. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. Changes may occur beyond our control that would cause us to consume our available capital before that time, including changes in and progress of our development activities and changes in regulation. Our future capital requirements will depend on many factors, including:

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

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

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

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

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

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

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

As of December 31, 2023, we had federal and state net operating loss, or NOL, carryforwards of $205.7 million and $278.5 million, respectively. The federal NOLs include $4.4 million that may be used to offset up to 100% of future taxable income and will begin to expire in 2035, unless previously utilized, and $201.3 million that are not subject to expiration. The net operating loss carryforwards subject to expiration could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Cuts and Jobs Act, or the Tax Act, as modified by the Coronavirus Aid, Relief and Economic Security Act, or CARES Act, federal net operating losses incurred in taxable years beginning after December 31, 2017 and in future taxable years may be carried forward indefinitely, but the deductibility of such federal net operating losses in taxable years beginning after December 31, 2020 is limited. There is variation in how states will respond to the Tax Act and CARES Act. In addition, for state income tax purposes, there may be periods during which the use of NOLs is suspended or otherwise limited, such as recent California legislation limiting the usability of NOLs for tax years beginning in 2020 and before 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 net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. The completion of our initial public offering, together with private placements and other transactions that have occurred since our inception, may trigger such an ownership change pursuant to Section 382. We have 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 net operating losses 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 net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

Risks Related to the Development of Our Product Candidates

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

We do not have any products that have received regulatory approval and may never be able to develop marketable product candidates. We are very early in our development efforts. Trastuzumab imbotolimod, our lead product candidate, and BDC-3042 are in the early stages of clinical development, and are our only product candidates to have advanced beyond preclinical studies. We have invested most of our efforts in developing our Boltbody ISAC approach, identifying potential product candidates and conducting preclinical studies. We expect that a substantial portion of our efforts and expenses over the next several years will be devoted to the development of trastuzumab imbotolimod in our ongoing and planned clinical trials in HER2-positive solid tumors including breast, colorectal, endometrial, and gastroesophageal. As a result, our business currently depends heavily on the successful development, regulatory approval and, if approved, commercialization of trastuzumab imbotolimod in one or more of these indications. We cannot be certain that trastuzumab imbotolimod will receive regulatory approval or will be successfully commercialized even if it receives regulatory approval. The research, testing, manufacturing, safety, efficacy, labeling, approval, sale, marketing and distribution of trastuzumab imbotolimod is, and will remain, subject to comprehensive regulation by the FDA and similar foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through preclinical studies and clinical trials that the product candidate is safe and effective for use in each target indication. Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. Failure to obtain regulatory approval for our product candidates will prevent us from commercializing and marketing our product candidates. The success of trastuzumab imbotolimod and any other 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. While our lead product candidate, trastuzumab imbotolimod, and BDC-3042 are in clinical development and we have not yet completed any clinical trials for any product candidate or in obtaining 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. 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 lead product candidate, trastuzumab imbotolimod, and other product candidates. There can be no assurance that any development problems we experience in the future related to our novel therapy will not cause significant delays or unanticipated costs, or that such development problems can be efficiently solved. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all.

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 are developing trastuzumab imbotolimod as a combination therapy in addition to a single agent therapy. For example, we have clinical supply agreements with BMS to study trastuzumab imbotolimod with nivolumab and with Roche to study trastuzumab imbotolimod with pertuzumab. Also, we may develop future product candidates for use in combination with one or more currently approved cancer therapies. Even if any product candidate we develop was to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other drugs or for indications other than cancer. This could result in our own products being removed from the market or being less successful commercially.

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

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

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

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

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

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

The risk of failure for our product candidates is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval. To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans for use in each target indication. Clinical testing is expensive and can take many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. For example, in August 2022, we announced the discontinuation of development of BDC-2034 due to off-target toxicity related to the targeting antibody.

In addition, the results of preclinical studies and earlier clinical trials may not be predictive of the results of later-stage preclinical studies or clinical trials. The results generated to date in preclinical studies or clinical trials for our product candidates do not ensure that later preclinical studies or clinical trials will demonstrate similar results. We have limited clinical data for any of our product candidates. Product candidates in later stages of clinical trials, although we have none at this stage as of yet, may fail to show the desired safety and efficacy traits despite having progressed through preclinical and earlier stage clinical trials. For example, the favorable results of our ongoing trial of trastuzumab imbotolimod in patients with HER2-expressing solid tumors may not be predictive of similar results in subsequent trials. In later-stage clinical trials, we will likely be subject to more rigorous statistical analyses than in completed earlier stage clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in later-stage clinical trials due to adverse safety profiles or lack of efficacy, notwithstanding promising results in earlier trials, and we cannot be certain that we will not face similar setbacks. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the dosing regimen and other clinical trial protocols, and the rate of dropout among clinical trial participants. If we fail to produce positive results in our planned preclinical studies or clinical trials of any of our product candidates, the development timeline and regulatory approval and commercialization prospects for our product candidates, and, correspondingly, our business and financial prospects, would be materially and adversely affected.

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

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

- delays in reaching a consensus with regulatory authorities on trial design;
- delays in reaching agreement or failing to agree on acceptable terms with prospective CROs and clinical trial sites;
- delays in opening sites, 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 August 2022, we announced that we were winding down spending on BDC-2034, pausing other early-stage research programs, and 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. We are aware that Mersana is developing a HER2-targeting ISAC, and other companies may develop ISACs and toll-like receptor, or TLR, agonists that may have utility for the treatment of HER2-positive cancers and other indications we are targeting. With respect to trastuzumab imbotolimod, there are numerous companies developing and marketing therapies focused on HER2-expressing cancers that utilize a range of other technologies and scientific approaches including ADCs, vaccines, bispecific antibodies and receptor tyrosine kinases inhibitors. Several of these companies have approved therapies, including AstraZeneca, Daiichi Sankyo, Novartis, Puma Biotechnology, and Roche, and many others have therapies in clinical development, including Ambrx/Johnson&Johnson, Byondis, Merus, and Zymeworks, . 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 trastuzumab imbotolimod and our other current and future product candidates receive marketing approval, whether as a single agent or in combination with other therapies, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current approved immunotherapies, and other cancer treatments like chemotherapy and radiation therapy, are well established in the medical community, and doctors may continue to rely on these therapies. If any of our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may never become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- the ability to offer our products, if approved, for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- sufficient third-party coverage or reimbursement, including of combination therapies;
- the willingness of patients to pay all, or a portion of, out-of-pocket costs associated with our products in the absence of sufficient third-party coverage and adequate reimbursement;
- adoption of a companion diagnostic or complementary diagnostic; and
- the prevalence and severity of any side effects.

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

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

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

- pricing and cost effectiveness;
- the effectiveness of our sales and marketing strategies;
- our ability to increase awareness of our product candidates through marketing efforts;
- our ability to obtain sufficient third-party coverage and adequate reimbursement; and
- the likelihood that the FDA may impose additional requirements that limit the promotion, advertising, distribution or sales of our product candidates.

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

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

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

Even if we obtain regulatory approval for any of our product candidates, they will be subject to extensive and ongoing regulatory requirements for manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, sampling and record-keeping. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practices, or cGMP, regulations and GCPs, for any clinical trials that we conduct post-approval, all of which may result in significant expense and limit our ability to commercialize such products. In addition, any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. For example, prescription drugs may be promoted only for the approved indications in accordance with the approved label. However, physicians may, in their independent medical judgment, prescribe legally available products for off-label uses. The FDA does not regulate the behavior of physicians in their choice of treatments, but the FDA does restrict manufacturer's communications on the subject of off-label use of their products. Companies may only share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. The FDA may also require a REMS as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability. Moreover, if there are changes in the application of legislation or regulatory policies, or if problems are discovered with a product or our manufacture of a product, or if we or one of our distributors, licensees or co-marketers fails to comply with regulatory requirements, the regulators could take various actions. These include:

- issuing warning or untitled letters;
- seeking an injunction or imposing civil or criminal penalties or monetary fines;
- suspension or imposition of restrictions on operations, including product manufacturing;
- seizure or detention of products, refusal to permit the import or export of products or request that we initiate a product recall;

- suspension or withdrawal of our marketing authorizations;
- suspension of any ongoing clinical trials;
- refusal to approve pending applications or supplements to applications submitted by us; or
- requiring us to conduct additional clinical trials, change our product labeling or submit additional applications for marketing authorization.

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

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

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

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

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

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or 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.

The United Kingdom held a referendum on June 23, 2016, in which a majority voted for the United Kingdom's withdrawal from the European Union, commonly referred to as Brexit. As a result of this vote, the United Kingdom left the European Union on January 31, 2020. Following a transition period, 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. Since a significant proportion of the regulatory framework in the United Kingdom applicable to our business and our product candidates was derived from European Union directives and regulations, Brexit has had, and will continue to have, a material impact upon the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the United Kingdom and in the European Union (given that certain development activities relating to our products take place in the United Kingdom). 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 trastuzumab imbotolimod, BDC-3042, and our other current and future product candidates.

We have limited experience in drug formulation and manufacturing and do not own or operate, and we do not expect to own or operate facilities for drug manufacturing, storage, distribution or testing. We have entered into supply agreements with Piramal Healthcare UK Ltd, or Piramal, to manufacture drug substance and drug product and EirGenix, Inc., pursuant to which we agreed to purchase monoclonal antibodies, including a biosimilar of trastuzumab, for our Boltbody ISAC trastuzumab imbotolimod. We have entered into supply agreements with Samsung Biologics Co., Ltd., or SBL, to manufacture monoclonal antibodies for our BDC-3042 program. Our current third-party CMOs may be unable or unwilling to supply us with sufficient clinical and commercial grade quantities of our clinical materials due to production shortages or other supply interruptions resulting from 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 CMOs, we could experience delays in our development efforts as we locate and qualify new manufacturers. Under such circumstances, we may be required to receive drug substance for use on a purchase order basis, and as such, there can be no assurance that we actually receive sufficient quantities. See also the risk factor titled "Our business, operations and clinical development plans and timelines and supply chain could be adversely affected by the effects of health epidemics, including pandemics, on the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we conduct business, including our CMOs, CROs, shippers and others."

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

- inability to meet our product specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and quality issues, including related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for additional scale-up;
- failure of the manufacturer to comply with cGMP and similar foreign standards;
- inability to negotiate manufacturing agreements with third parties on commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on a limited number of sources, and in some cases, single sources for components, such that if we are unable to secure a sufficient supply of these drug components, we will be unable to manufacture and sell trastuzumab imbotolimod or other product candidates in a timely fashion, in sufficient quantities or under acceptable terms;
- lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier or the issuance of a FDA Form 483 notice or warning letter;
- carrier disruptions or increased costs that are beyond our control;
- 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 CMOs are or may be engaged with other companies to supply and manufacture materials or products for such companies, which also exposes our suppliers and manufacturers to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may also affect the regulatory clearance of a contract supplier's or manufacturer's facility. If the FDA or a comparable foreign regulatory agency does not approve these facilities for the supply or manufacture of our product candidates, or if it withdraws its approval in the future, we may need to find alternative supply or manufacturing facilities, which would negatively impact our ability to develop, obtain regulatory approval of or market our product candidates, if approved.

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

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

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

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

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

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

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

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

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

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, Innovent Biologics, Inc., or Innovent, Bristol-Myers Squibb Company, or BMS, and F. Hoffmann-La Roche Ltd, or Roche. 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 to certain aspects of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the Affordable Care Act such as removing penalties, starting January 1, 2019, for not complying with the Affordable Care Act's "individual mandate" to carry health insurance. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act 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 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 Biden 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, 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, or 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 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 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. 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, 2023, 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, including trastuzumab imbotolimod. For example, in May 2015 and June 2018 we entered into license agreements with Stanford under which we are granted rights to intellectual property that are necessary to the development and commercialization of trastuzumab imbotolimod or are otherwise important to our business. We may also need to obtain additional licenses to advance the development and commercialization of our current product candidates and other product candidates we may develop. It is possible that we may be unable to obtain any additional licenses at a reasonable cost or on reasonable terms, or at all, or such licenses may be non-exclusive. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly.

Our existing license agreements with Stanford impose, and we expect that future license agreements will impose, upon us various development, regulatory and/or commercial diligence obligations, obligations to make milestone or royalty payments or to share revenues and other obligations. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy-related event, the licensor may have the right to terminate the license, and if they exercise that right we would not be able to develop, market, or otherwise commercialize our technology and product candidates covered by the license, which in the case of our 2015 license agreement with Stanford includes trastuzumab imbotolimod. 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 trastuzumab imbotolimod, which is currently manufactured at facilities in the United Kingdom and the United States, 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 trastuzumab imbotolimod, 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 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 seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval for and commercialize our product candidates.

Competition to hire qualified personnel in our industry is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. This competitive situation has become exacerbated by the increase in employee resignations currently taking place throughout the United States, in part as a result of pandemics, which is commonly referred to as the "great resignation." 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, 2023, we had 100 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.

Additionally, the holders of an aggregate of 5,841,050 shares of our common stock, or their transferees, have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If we were to register the resale of these shares, they could be freely sold in the public market without limitation. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

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

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

- provide for a classified board of directors whose members serve staggered terms;
- authorize our board of directors to issue, without further action by the stockholders, shares of undesignated preferred stock with terms, rights and preferences determined by our board of directors that may be senior to our common stock;

- require that any action 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 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 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.

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, Senior Director of IT, and Chief Financial Officer.

Our Director of IT Operations and Security and Senior Director of IT are 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 Senior Director of IT has 25 years of IT management experience at various public biotechnology companies. Our Chief Financial 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 Chief Financial Officer. Our Chief Financial 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 Chief Financial 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 or the Senior Director of IT, 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 13,743 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.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

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

Holders of Common Stock

On March 14, 2024, there were approximately 17 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 financial statements and related notes thereto included elsewhere in this Annual Report on Form-10K for the period ended December 31, 2023. 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

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 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 good tolerability. Having explored more than one hundred 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.

Our first Boltbody ISAC program is trastuzumab imbotolimod, formerly known as BDC-1001, targeting a tumor antigen known as human epidermal growth factor receptor 2 (HER2) that is often found in cancers such as breast and gastroesophageal cancer. In 2023, trastuzumab imbotolimod completed the Phase 1 stage of clinical development and advanced into a Phase 2 program that includes four different HER2-positive solid tumor types: breast cancer, gastroesophageal cancer, colorectal cancer, and endometrial cancer. In September 2023, the U.S. Food and Drug Administration, or FDA, granted trastuzumab imbotolimod Orphan Drug Designation for the treatment of gastric cancer, including gastroesophageal junction cancer. In the Phase 2 program we are evaluating trastuzumab imbotolimod as a single agent and in combination with the HER2-targeting antibody pertuzumab, and we also have the ability to add cohorts to evaluate trastuzumab imbotolimod in combination with the PD-1 inhibitor nivolumab.

Our expertise in myeloid cell biology also forms the foundation for additional, innovative immuno-oncology approaches that complement our Boltbody ISAC platform. For example,BDC-3042, our Dectin-2 agonist antibody program. BDC-3042 is being developed to repolarize critical cells in the tumor microenvironment known as tumor-associated macrophages (TAMs). Dectin-2 agonism results in these TAMs changing from tumor-supportive macrophages into 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 three dose escalation cohorts without experiencing a dose-limiting toxicity.

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 global rights to two Boltbody ISAC programs. We expect our collaborations with Toray and Genmab to add additional novel ISACs to our pipeline.

In September 2021, we entered into a clinical collaboration and supply agreement with BMS to study trastuzumab imbotolimod in combination with BMS's nivolumab, a leading PD-1 checkpoint inhibitor, for the treatment of patients with HER2-expressing solid tumors. Under the BMS Agreement, BMS will be providing nivolumab at no cost to us and we will sponsor, fund, and conduct the initial Phase 1/2 clinical trial in accordance with an agreed-upon protocol. We initiated the clinical trial evaluating the combination of nivolumab and trastuzumab imbotolimod in the fourth quarter of 2021. In September 2022, we entered into a clinical supply agreement, or the Roche Agreement, with Roche to study trastuzumab imbotolimod in combination with Roche's pertuzumab (Perjeta®), a compound approved for the treatment of HER2-positive breast cancer. Under the Roche Agreement, Roche will be providing pertuzumab at no cost to us and we will sponsor, fund, and conduct an initial Phase 2 clinical trial in accordance with an agreed-upon protocol. The original Phase 1/2 clinical trial will move into Phase 2 dose expansions in three separate cohorts evaluating colorectal, endometrial, and gastroesophageal cancers. Following demonstration of monotherapy anti-tumor activity in an indication, a separate cohort will be initiated to evaluate trastuzumab imbotolimod in combination with nivolumab in that indication. In addition, a randomized two-arm Phase 2 clinical trial will investigate trastuzumab imbotolimod as monotherapy and in combination with pertuzumab in patients with HER2-positive metastatic breast cancer.

We have incurred operating losses since our inception. Our net losses were $69.2 million and $88.1 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $364.3 million. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future, and we further expect our expenses will increase substantially as we:

- conduct our ongoing and planned clinical trials;
- continue our research and development programs;
- expand our clinical, regulatory, quality and manufacturing capabilities;
- seek regulatory approvals for our product candidates; and
- operate as a public company.

Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending 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 initial public offering 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 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 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, the Company received an upfront payment of $5.0 million. We allocated the entire $5.0 million upfront payment to deferred revenue, which we recognize together with other payments received from Innovent as collaboration revenue over time as we fulfill our performance obligation to Innovent. The Innovent collaboration was amended in March 2024, when we secured global rights to two Boltbody ISAC programs.

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 results 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, 2023, 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. In February 2022, we early terminated the lease agreement for our former headquarters facility, which would have expired in January 2023. We received approximately $0.2 million in returned deposits, and extinguished operating lease assets and liabilities of approximately $0.4 million.

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.

Other Income, Net

Interest Income, Net

Interest income consists of interest on our cash, cash equivalents, and short-term investments.

Results of Operations

Comparison of the Years Ended December 31, 2023 and 2022

	Years Ended December 31,		
	2023	2022	Change
	(In thousands)		
Collaboration revenue	$ 7,876	$ 5,729	$ 2,147
Operating expenses:			
Research and development	61,542	73,123	(11,581)
General and administrative	22,530	22,927	(397)
Total operating expense	84,072	96,050	(11,978)
Loss from operations	(76,196)	(90,321)	14,125
Other income, net	—	—	
Interest income	6,999	2,223	4,776
Total other income, net	6,999	2,223	4,776
Net loss	(69,197)	(88,098)	18,901
Net unrealized loss on marketable securities	956	(598)	1,554
Comprehensive loss	$ (68,241)	$ (88,696)	$ 20,455

Collaboration Revenue

Revenue was $7.9 million and $5.7 million for the years ended December 31, 2023 and 2022, respectively. The increase in revenue in the comparative periods was due to continued progress in our collaborations with Genmab and Innovent as we fulfill our performance obligations to our collaboration partners. We expect to continue to provide services to further our collaborations with our partners.

Research and Development Expenses

Research and development expenses decreased by $11.6 million from $73.1 million in 2022 to $61.5 million in 2023. The decrease was due to $10.6 million in lower manufacturing expenses related to fewer raw materials purchased and the timing of batch production of our product candidates and $2.2 million in lower research and development lab supplies and contract services expense, offset by $0.7 million in higher personnel-related expenses due to an increase in headcount and $0.6

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.

General and Administrative Expenses

General and administrative expenses decreased by $0.4 million from $22.9 million in 2022 to $22.5 million in 2023. The decrease was due to $1.4 million in lower consulting and professional services expenses and $0.9 million in lower facility-related expenses, offset by $1.3 million in higher personnel-related expenses due to an increase in headcount and $0.5 million higher software licensing expenses.

Other Income, Net

Other Income, Net

Interest income increased by $4.8 million from $2.2 million in 2022 to $7.0 million in 2023. The increase was due to higher interest income from higher yields on our marketable securities.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred net losses and negative cash flows from operations since our inception and anticipate we will continue to incur net losses for the foreseeable future. As of December 31, 2023, we had an accumulated deficit of $364.3 million. Our net loss was $69.2 million and $88.1 million in 2023 and 2022, respectively, and we expect to incur additional losses in the future. We evaluated our current cash position, historical results, forecasted cash flows and plans with regard to liquidity.

We believe that our current cash, cash equivalents and marketable securities balances as of December 31, 2023 will be sufficient to meet our cash needs for at least 12 months following the issuance date of this Annual Report on Form 10-K. 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.

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

	Years Ended December 31,	
	2023	2022
	(In thousands)	
Net cash provided by (used in):		
Operating activities	$ (69,525)	$ (76,504)
Investing activities	71,038	57,862
Financing activities	253	503
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 1,766	$ (18,139)

Operating Activities

Net cash used in operating activities was $69.5 million and $76.5 million for 2023 and 2022, respectively. 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 collaboration agreements, a $3.4 million decrease in our accounts payable and accrued expenses, a $2.4 million decrease in operating lease liabilities, and a $0.5 million increase in our prepaid expense and other assets. Net cash used in operating activities for 2022 was due to our net loss of $88.1 million, adjusted for $14.7 million of non-cash charges and a $3.1 million change in operating assets and liabilities. The non-cash charges were comprised of $9.6 million for stock-based compensation, $3.2 million of non-cash lease related expense, $1.7 million for depreciation and amortization expense, and $0.2 million for accretion of discount on marketable securities. The change in net operating assets was due to a $2.6 million decrease in operating lease liabilities, a $2.2 million decrease in deferred revenue related to our collaboration agreements, and an $0.9 million increase in our prepaid expense and other assets, offset by a $2.8 million increase in our accounts payable and accrued expenses.

Investing Activities

Net cash provided by investing activities was $71.0 million and $57.9 million in 2023 and 2022, respectively. The net cash provided by investing activities in 2023 was due to $236.2 million maturity of marketable securities, offset by $165.0 million in purchases of marketable securities and $0.2 million in purchases of property and equipment. Net cash provided by investing activities in 2022 was due to $240.5 million maturity of marketable securities, offset by $180.7 million in purchases of marketable securities and $2.0 million in purchases of property and equipment.

Financing Activities

Net cash provided by financing activities was $0.3 million and $0.5 million for 2023 and 2022, respectively. The net cash provided by financing activities for 2023 was due to net proceeds from the issuance of common stock from the 2021 Employee Stock Purchase Program and exercise of stock options. Net cash provided by financing activities for 2022 was from the issuance of common stock from the 2021 Employee Stock Purchase Program and exercise of stock options.

Funding Requirements

Based upon our current operating plans, we believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operations for at least the next 12 months following the issuance date of this Annual Report on Form 10-K. The Company will need to raise additional capital to continue the advancement of its programs. In the near term, our primary uses of cash will be to fund the completion of key milestones for trastuzumab imbotolimod and BDC-3042 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

Contract Supply Agreement

In January 2022, we entered into an amended and restated supply agreement with EirGenix, Inc., which amends the original supply agreement with EirGenix, Inc., or EirGenix, dated March 10, 2019, pursuant to which EirGenix agreed to supply to us, on a non-exclusive basis, bulk drug substance of EG12014, its monoclonal antibody being developed as a biosimilar of trastuzumab, which we use in the manufacture of trastuzumab imbotolimod. In addition, EirGenix provides us access to its regulatory data package and services to facilitate our development and commercialization efforts and we are required to make milestone payments to EirGenix up to an aggregate of $2.0 million based upon achievement of certain trastuzumab imbotolimod regulatory milestones and pay for the supply of EG12014. The agreement will remain in effect as long as we, or any of our affiliates or licensees, continue to pursue the development or commercialization of any HER2 Boltbody ISAC, unless earlier terminated. We may terminate the agreement if EirGenix fails to supply sufficient quantities of EG12014 or if EirGenix does not obtain regulatory approval for EG12014 as a standalone biosimilar product. We may also terminate the EirGenix Agreement upon prior written notice to EirGenix. EirGenix may terminate the agreement if we do not actively develop a HER2 Boltbody ISAC for more than two years. In addition, either party may terminate the agreement for the other party's uncured material breach or insolvency.

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.

Oncology Clinical Trial Collaboration and Supply Agreement with Bristol-Myers Squibb

In September 2021, we entered into a clinical collaboration and supply agreement, or the BMS Agreement, with Bristol-Myers Squibb Company, or BMS, to study trastuzumab imbotolimod in combination with BMS's PD-1 checkpoint inhibitor nivolumab, for the treatment of HER2-expressing solid tumors. Under the BMS Agreement, BMS granted us a non-exclusive, non-transferable, royalty-free license (with a right to sublicense) under its intellectual property to use nivolumab in a clinical trial for a combination therapy of nivolumab and our proprietary compound, trastuzumab imbotolimod, and has agreed to supply nivolumab at no cost to us and we will sponsor, fund and conduct the initial Phase 1/2 clinical trial in accordance with an agreed-upon protocol. Both parties will own the study data produced in the clinical trial, other than study data related solely to nivolumab, which will belong solely to BMS, or study data related solely to trastuzumab imbotolimod, which will belong solely to us. The parties may conduct additional clinical trials on the combined therapy which may be sponsored and funded by one party, or jointly funded. We initiated the clinical trial evaluating the combination of nivolumab and trastuzumab imbotolimod in the fourth quarter of 2021.

Clinical Supply Agreement with F. Hoffmann-La Roche Ltd

In September 2022, we entered into a clinical supply agreement, or the Roche Agreement, with Roche to study trastuzumab imbotolimod in combination with Roche's pertuzumab (Perjeta®), a compound approved for the treatment of HER2-positive breast cancer. Under the Roche Agreement, Roche granted us a non-exclusive, non-sublicenseable, royalty-free license under its intellectual property to use pertuzumab in a clinical trial for a combination therapy of pertuzumab and our proprietary compound, trastuzumab imbotolimod, and has agreed to supply pertuzumab at no cost to us and we will sponsor, fund and conduct the initial Phase 2 clinical trial in accordance with an agreed-upon protocol. Both parties will own the study data produced in the clinical trial, other than study data related solely to pertuzumab, which will belong solely to Roche, or study data related solely to trastuzumab imbotolimod, which will belong solely to us. The parties may conduct additional clinical trials on the combined therapy which may be sponsored and funded by one party, or jointly funded. We are currently in a Phase 2 trial evaluating the combination of pertuzumab and trastuzumab imbotolimod.

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.

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.

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our financial statements and accompanying notes. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. While our significant accounting policies are described in more detail in Note 2 to our financial statements included elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies and estimates to be most critical to the preparation of our financial statements.

Revenue Recognition

For all periods presented, we recognized revenue in accordance with the provisions of 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 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 9 to our financial statements included elsewhere in this Annual Report on Form 10-K for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options granted in 2023 and 2022.

In 2023 and 2022, stock-based compensation expense related to stock options was $9.2 million and $9.6 million, respectively. As of December 31, 2023, the unrecognized stock-based compensation expense related to stock options was $9.7 million and is expected to be recognized as expense over a weighted-average period of approximately 1.8 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 financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

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

As of December 31, 2023, we had federal and state NOL carryforwards of $205.7 million and $278.5 million, respectively. The federal NOLs include $4.4 million that may be used to offset up to 100% of future taxable income and will begin to expire in 2035 unless previously utilized and $201.3 million that are not subject to expiration. The net operating loss carryforwards subject to expiration could expire unused and be unavailable to offset future income tax liabilities. The federal NOLs not subject to expiration are available to offset up to 80% of taxable income each year indefinitely. The state NOL carryforwards will begin to expire in 2035, unless previously utilized. As of December 31, 2023, we also had federal and state research credit carryforwards of $9.4 million and $5.6 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 net operating loss 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 net operating losses 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. Financial Statements and Supplementary Data.

BOLT BIOTHERAPEUTICS, INC.
INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Bolt Biotherapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Bolt Biotherapeutics, Inc. (the "Company") as of December 31, 2023 and 2022, 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, 2023 and 2022, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our audits of these financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the 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.

Emphasis of Matter

As discussed in Note 2 to the financial statements, the Company will need to raise additional capital to continue the advancement of its programs.

/s/ PricewaterhouseCoopers LLP
San Jose, California
March 21, 2024

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

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

	December 31,	
	2023	**2022**
Assets		
Current assets:		
Cash and cash equivalents	$ 10,810	$ 9,244
Short-term investments	91,379	159,644
Prepaid expenses and other current assets	3,519	3,858
Total current assets	105,708	172,746
Property and equipment, net	4,957	6,453
Operating lease right-of-use assets	19,120	22,072
Restricted cash	1,765	1,565
Long-term investments	26,413	23,943
Other assets	1,821	1,028
Total assets	$ 159,784	$ 227,807
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,987	$ 3,594
Accrued expenses and other current liabilities	12,486	15,140
Deferred revenue	2,201	1,993
Operating lease liabilities	2,782	2,391
Total current liabilities	20,456	23,118
Operating lease liabilities, net of current portion	17,437	20,220
Deferred revenue, non-current	9,107	12,921
Other long-term liabilities	43	42
Total liabilities	47,043	56,301
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.00001 par value, authorized shares—10,000,000 shares authorized at December 31, 2023 and 2022; zero shares issued and outstanding at December 31, 2023 and 2022	—	—
Common stock, $0.00001 par value; 200,000,000 shares authorized at December 31, 2023 and 2022; 38,114,606 and 37,797,902 shares issued and outstanding at December 31, 2023 and 2022, respectively	1	—
Additional paid-in capital	476,988	467,513
Accumulated other comprehensive gain (loss)	37	(919)
Accumulated deficit	(364,285)	(295,088)
Total stockholders' equity	112,741	171,506
Total liabilities, convertible preferred stock, and stockholders' equity	$ 159,784	$ 227,807

See accompanying notes to the financial statements.

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

	Years Ended December 31,	
	2023	2022
Collaboration revenue	$ 7,876	$ 5,729
Operating expenses:		
Research and development	61,542	73,123
General and administrative	22,530	22,927
Total operating expense	84,072	96,050
Loss from operations	(76,196)	(90,321)
Other income, net		
Interest income	6,999	2,223
Total other income, net	6,999	2,223
Net loss	(69,197)	(88,098)
Net unrealized gain (loss) on marketable securities	956	(598)
Comprehensive loss	$ (68,241)	(88,696)
Net loss per share, basic and diluted	$ (1.83)	$ (2.36)
Weighted-average shares outstanding, basic and diluted	37,811,984	37,358,425

See accompanying notes to the financial statements.

BOLT BIOTHERAPEUTICS, INC.
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, 2021	**37,399,694**	**$ —**	**$ 457,430**	**$ (321)**	**$ (206,990)**	**$ 250,119**
Issuance of common stock upon vesting of restricted stock units	80,533	—	—	—	—	—
Issuance of common stock under employee stock purchase plan	258,488	—	368	—	—	368
Issuance of common stock upon exercise of stock options	59,187	—	135	—	—	135
Vesting of early exercised options	—	—	4	—	—	4
Stock-based compensation	—	—	9,576	—	—	9,576
Unrealized loss on available-for-sale investments	—	—	—	(598)	—	(598)
Net loss	—	—	—	—	(88,098)	(88,098)
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	1	246	—	—	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**	**$ 1**	**$ 476,988**	**$ 37**	**$ (364,285)**	**$ 112,741**

See accompanying notes to the financial statements.

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

	Years Ended December 31,	
	2023	**2022**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (69,197)	$ (88,098)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,854	1,666
Stock-based compensation expense	9,223	9,576
Accretion of premium/discount on short-term investments	(4,493)	184
Non-cash lease expense	2,952	3,225
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(454)	(903)
Accounts payable and accrued expenses	(3,413)	2,768
Operating lease liabilities	(2,392)	(2,596)
Deferred revenue	(3,606)	(2,162)
Other long-term liabilities	1	(164)
Net cash used in operating activities	(69,525)	(76,504)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(206)	(1,953)
Purchases of marketable securities	(164,988)	(180,704)
Maturities of marketable securities	236,232	240,519
Net cash provided by investing activities	71,038	57,862
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	253	503
Net cash provided by financing activities	253	503
NET INCREASE (DECREASE) IN CASH	1,766	(18,139)
Cash, cash equivalents and restricted cash at beginning of year	10,809	28,948
Cash, cash equivalents and restricted cash at end of period	$ 12,575	$ 10,809
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 10,810	$ 9,244
Restricted cash	1,765	1,565
Total cash, cash equivalents and restricted cash	$ 12,575	$ 10,809
Supplemental schedule of non-cash investing and financing activities:		
Purchases of property and equipment included in accounts payable and accrued liabilities	$ 152	$ 8
Deferred offering costs in accounts payable and accrued liabilities	$ 102	$ 102
Right of use assets obtained in exchange for operating lease obligations	$ —	$ 852

See accompanying notes to the financial statements.

BOLT BIOTHERAPEUTICS, INC.
NOTES TO 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. The Company's various approaches use pattern recognition receptors in the innate immune system to help the body recognize tumor cells for a productive anti-cancer response.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). Certain reclassifications on the statement of cash flows have been made to prior period amounts to conform to current period presentation.

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, 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

The Company has incurred net losses and negative cash flows from operations since our inception and anticipates to continue to incur net losses for the foreseeable future. As of December 31, 2023, the Company had cash and cash equivalents and marketable securities of $128.6 million and an accumulated deficit of $364.3 million. Based upon the Company's current operating plans, the Company believes that its existing cash, cash equivalents and marketable securities will be sufficient to fund its operations for at least the next 12 months following the issuance date of this Annual Report on Form 10-K. 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 trastuzumab imbotolimod, formerly known as BDC-1001, and BDC-3042 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 financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. On an ongoing basis, the Company evaluates its estimates and assumptions, including those related to revenue recognition, stock-based compensation 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.

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, 2023 and 2022, 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, 2023 and 2022, 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, 2023 and 2022, the Company had $1.8 million and $1.6 million, respectively, of long-term restricted cash deposited with a financial institution. The restricted cash is held in separate bank accounts to support letter of credit agreements related to the Company's facility leases which expire in 2025 and 2031 (see Note 7) and corporate credit card program in 2023.

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.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, primarily comprised of property and equipment, for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparison of the carrying amount to the estimated undiscounted future cash flows, which the assets or asset groups are expected to generate. If such assets are considered to be impaired, the impairment to be recognized at the amount by which the carrying amount of the assets or asset groups exceeds the estimated fair value of the assets or asset groups. There have been no such impairments of long-lived assets during the periods presented.

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.

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 as the convertible preferred stock is considered a participating security because it participates in dividends with common stock. The Company also considers the shares issued upon the early exercise of stock options subject to repurchase to be participating securities because holders of such shares have non-forfeitable dividend rights in the event a dividend is paid on common stock. The holders of all series of convertible preferred stock and the holders of early exercised shares subject to repurchase do not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to common stockholders. Because the Company has reported a net loss for all periods presented, diluted net loss per share is the same as basic net loss per share for all periods presented as potentially dilutive securities were anti-dilutive.

Comprehensive Loss

Comprehensive loss includes all changes in equity (net assets) during a period from non-owner sources, including unrealized gains and losses on marketable securities. The Company incurred a net unrealized gain on marketable securities of $1.0 million and a net unrealized loss $0.6 million during the years ended December 31, 2023 and 2022, respectively.

Segment Reporting

The Company has one operating segment. Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker, which is the Company's Chief Executive Officer, in making decisions regarding resource allocation and assessing performance.

Recent Accounting Standards

From time to time, new accounting standards are issued by the Financial Accounting Standards Board (the "FASB"), or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on the Company's financial position or results of operations upon adoption.

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments- Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, and subsequent amendments to the initial guidance under ASU 2018-19, ASU 2019-04, ASU 2019-05, ASU 2020-03, and ASU 2020-02. The standard changes how entities will measure credit losses for most financial assets and certain other instruments that are not measured at fair value through net income. Financial assets measured at amortized cost will be presented at the net amount expected to be collected by using an allowance for credit losses. The Company adopted ASU 2016-13 as of January 1, 2023. The adoption of ASU 2016-13 did not have a material impact on the Company's financial position or results of operations.

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 beginning after December 15, 2024 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 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, 2023 and 2022, 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-term 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. Financial liabilities measured at fair value on a recurring basis include the convertible preferred stock purchase right liability described below.

There were no transfers within the hierarchy during the years ended December 31, 2023 and 2022.

Marketable securities, all of which are classified as available-for-sale securities, consisted of the following at December 31, 2023 and 2022 (in thousands):

	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

	December 31, 2022			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Asset backed securities	$ 12,754	$ 11	$ (99)	$ 12,666
U.S. treasury securities	54,747	1	(517)	54,231
Other government agency securities	5,009	—	(29)	4,980
Commercial paper	56,170	—	—	56,170
Corporate debt securities	55,827	—	(287)	55,540
Total	$ 184,507	$ 12	$ (932)	$ 183,587

As of December 31, 2023, 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 and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost bases, which may be at the time of maturity. As of December 31, 2023, 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, 2023 and 2022, respectively:

	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)

	December 31, 2022					
	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	$ 3,180	$ (5)	$ 9,485	$ (94)	$ 12,665	$ (99)
U.S. treasury securities	14,723	(28)	39,508	(489)	54,231	(517)
Other government agency securities	—	—	4,980	(29)	4,980	(29)
Corporate debt securities	6,977	(32)	48,563	(255)	55,540	(287)
Total	$ 24,880	$ (65)	$ 102,536	$ (867)	$ 127,416	$ (932)

Accrued interest receivable on available-for-sale securities were $0.3 million and $0.5 million at December 31, 2023 and 2022, 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, 2023 and 2022.

At December 31, 2023 and 2022, the fair values of the Company’s assets and liabilities, which are measured at fair value on a recurring basis, were determined using the following inputs (in thousands):

	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	$ —

	December 31, 2022			
	Total	(Level 1)	(Level 2)	(Level 3)
Money market funds	$ 6,885	$ 6,885	$ —	$ —
Asset backed securities	12,666	—	12,666	—
U.S. treasury securities	54,231	54,231	—	—
Other government agency securities	4,980	—	4,980	—
Commercial paper	56,170	—	56,170	—
Corporate debt securities	55,540	—	55,540	—
Total	$ 190,472	$ 61,116	$ 129,356	$ —

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. 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,	
	2023	2022
Laboratory equipment	$ 10,038	$ 9,738
Office equipment	386	358
Leasehold improvements	285	272
Total property and equipment	10,709	10,368
Less accumulated depreciation and amortization	(5,752)	(3,915)
Total	$ 4,957	$ 6,453

Depreciation expense related to property and equipment was $1.9 million and $1.7 million for the years ended December 31, 2023 and 2022, 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,	
	2023	2022
Prepaids and other current assets:		
Cloud computing arrangement implementation costs	$ 178	$ —
Other prepaids and other current assets	3,341	3,858
Prepaids and other current assets	3,519	3,858
Other non-current assets		
Cloud computing arrangement implementation costs - non-current	371	—
Other non-current assets	1,450	1,028
Other non-current assets	1,821	1,028

As of December 31, 2023 and 2022, cloud computing arrangement implementation costs consisted of deferred costs of $0.6 million and zero, respectively, and associated accumulated amortization of $30,000 and zero, respectively.

Accrued Expenses and Other Current Liabilities

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

	December 31,	
	2023	2022
Accrued research and development	$ 6,092	$ 9,373
Accrued compensation	5,820	4,804
Accrued other	574	963
Total	$ 12,486	$ 15,140

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 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. 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, 2023, and 2022, contract liability totaling $1.5 million at each 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 recorded zero revenue during the years ended December 31, 2023 and 2022. The Toray Agreement includes both fixed and variable consideration. 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 incurred through the completion of the first Phase 1 clinical trial for the lead product candidate 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 was 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 which 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. 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 $31.0 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, 2023, receivables of $0.6 million 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, 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.

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

Balance at December 31, 2021	$	10,574
Addition—amount billed for research and development services		2,166
Revenue recognized		(4,242)
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

The Company recorded $3.7 million and $4.2 million in revenue earned during the years ended December 31, 2023 and 2022, 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 is considered to terminate upon completion of the initial clinical proof of concept of the therapeutic candidates, after which both parties can exercise their respective program opt-in rights. 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, have excluded all milestone and royalty payments from the transaction prices of the agreement.

Oncology Research and Development Collaboration with Innovent Biologics, Inc.

In August 2021, the Company entered into a License and Collaboration Agreement (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 the Company's advanced 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, the Company received an upfront payment of $5.0 million. The Company determined that the Innovent Agreement is a contract with a customer and should be accounted for under ASC 606. In conjunction with the Innovent Agreement, the Company entered into a stock purchase agreement with Innovent (the "Innovent SPA") which contains both a put option and call option allowing Innovent and the Company to respectively initiate a market value purchase and sale of the Company's common stock, for an aggregate investment of up to $10.0 million by Innovent, subject to certain share price limitations. The Innovent Agreement and Innovent SPA have been evaluated together and since the options may be exercised at market value by either party, no consideration from the Innovent SPA has been allocated to the Innovent Agreement and included in the total consideration for collaboration revenue. Both options expired unexercised on May 25, 2022.

In the Innovent 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 $5.0 million upfront payment and up to $8.0 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, 2023, receivables of $0.7 million related to research and development services performed under the Innovent 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, 2023, contract liabilities totaling $3.1 million were recorded in deferred revenue with $0.6 million in current liabilities and $2.5 million in non-current liabilities on the balance sheet based on the forecasted periods of performance.

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

Balance at December 31, 2021	$	5,000
Addition—amount billed for research and development services		1,444
Revenue recognized		(1,487)
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

The Company recorded $4.1 million and $1.5 million in revenue earned during the years ended December 31, 2023 and 2022, based on services performed under the Innovent Agreement during the period. Under the Innovent 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 Innovent Agreement is considered to terminate upon completion of the 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, which will be accounted for as contract modifications after the initial clinical proof of concept of the therapeutic candidates and the parties have exercised their respective license options with respect to each candidate. 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, 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 license option. Under the Innovent Agreement, the Company is eligible to receive up to $28.5 million in potential license option exercise fee, $111.5 million in development milestone payment, $297.5 million in sales-based milestone payments, and tiered royalties at rates from a mid-single digit to low-teens percentage based on net sales, subject to certain customary reductions, for therapeutic candidates exclusively developed and commercialized by Innovent in specific territories. However, given the current phase of development of therapeutic candidates under the Innovent Agreement, the Company cannot estimate the probability or timing of achieving these milestones, and, therefore, have excluded all license option exercise fee, milestone and royalty payments from the transaction prices of the agreement.

Oncology Clinical Trial Collaboration and Supply Agreement with Bristol-Myers Squibb

In September 2021, the Company entered into a clinical collaboration and supply agreement with Bristol-Myers Squibb Company ("BMS") to study trastuzumab imbotolimod in combination with BMS's PD-1 checkpoint inhibitor nivolumab, for the treatment of HER2-expressing solid tumors (the "BMS Agreement"). Under the BMS Agreement, BMS granted the Company a non-exclusive, non-transferable, royalty-free license (with a right to sublicense) under its intellectual property to use nivolumab in a clinical trial for a combination therapy of nivolumab and the Company's proprietary compound, trastuzumab imbotolimod, and has agreed to supply nivolumab at no cost to the Company and the Company will sponsor, fund and conduct the initial Phase 1/2 clinical trial in accordance with an agreed-upon protocol. Both parties will own the study data produced in the clinical trial, other than study data related solely to nivolumab, which will belong solely to BMS, or study data related solely to trastuzumab imbotolimod, which will belong solely to the Company. The parties may conduct additional clinical trials on the combined therapy which may be sponsored and funded by one party, or jointly funded. Given the terms of the BMS Agreement, the Company has concluded that it is not within the scope of ASC 808 or ASC 606. Any relevant costs arising from the clinical trial will be expensed as incurred and recorded in research and development expenses. The Company initiated the clinical trial for the combination therapy of nivolumab and trastuzumab imbotolimod in the fourth quarter of 2021.

Clinical Supply Agreement with F. Hoffmann-La Roche Ltd

In September 2022, the Company entered into a clinical supply agreement with Roche to study trastuzumab imbotolimod in combination with Roche's pertuzumab (Perjeta®), a compound approved for the treatment of HER2-positive breast cancer (the "Roche Agreement"). Under the Roche Agreement, Roche granted the Company a non-exclusive, non-sublicenseable, royalty-free license under its intellectual property to use pertuzumab in a clinical trial for a combination therapy of pertuzumab and the Company's proprietary compound, trastuzumab imbotolimod, and has agreed to supply pertuzumab at no cost to the Company. The Company will sponsor, fund and conduct the initial Phase 2 clinical trial in accordance with an agreed-upon protocol. Both parties will own the study data produced in the clinical trial, other than study data related solely to pertuzumab, which will belong solely to Roche, or study data related solely to trastuzumab imbotolimod, which will belong solely to the Company. The parties may conduct additional clinical trials on the combined therapy which may be sponsored and funded by one party, or jointly funded. Given the terms of the Roche Agreement, the Company has concluded that it is not within the scope of ASC 808 or ASC 606. Any relevant costs arising from the clinical trial will be expensed as incurred and recorded in research and development expenses.

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.

In connection with the execution of the Chesapeake Master Lease, the Company entered into two operating lease agreements to sublease portions of the premises to two unrelated third parties. The first sublease agreement, to sublease 10,000 square feet, commenced in August 2020 and expired on August 31, 2022. The second 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 the early termination date no earlier than September 30, 2024, and no 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 under the two sublease agreements was approximately $0.8 million for each of the years ended December 31, 2023 and 2022.

At December 31, 2023 and 2022, we have no leases accounted for as finance right-of-use lease.

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 weighted-average remaining lease term and discount rate related to the Company's lease liabilities as of December 31, 2022 were 7.4 years and 11.0%, 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, 2023 and 2022.

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

	Years Ended December 31,	
	2023	2022
Total operating lease cost	$ 4,480	$ 4,346

Supplemental cash flow information related to cash paid for amounts included in the measurement of lease liabilities was as follows (in thousands):

	Years Ended December 31,	
	2023	2022
Operating cash flows from operating leases	$ 4,726	$ 4,660

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, 2023 (in thousands):

	Operating Leases	Sublease Income
2024	$ 4,886	$ 540
2025	4,340	—
2026	3,484	—
2027	3,602	—
2028	3,724	—
Thereafter	9,514	—
Total lease payments	29,550	540
Less interest	(9,331)	—
Total	$ 20,219	540

Supply Agreement

The Company has entered into a supply agreement with a contract manufacturer pursuant to which the Company may be required to pay milestone payments upon the achievement of specified regulatory milestones. The agreement is cancellable by the Company upon delivering the appropriate prior written notice. At December 31, 2023, potential future milestone payments under this agreement were up to $2.0 million.

Guarantees and Indemnifications

In the normal course of business, the Company enters into agreements that contain a variety of representations and provide for general indemnification. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. As of December 31, 2023, the Company does not have any material indemnification claims that were probable or reasonably possible and consequently has 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

The Company is subject to claims and assessments from time to time in the ordinary course of business but is not aware of any such matters, individually or in the aggregate, that will have a material adverse effect on the Company's financial position, results of operations or cash flows.

8. 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, 2023, no shares of the Company's common stock have been sold under the ATM.

Common Stock Reserved for Future Issuance

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

	December 31, 2023
Common stock options issued and outstanding	10,706,541
Common stock restricted stock awards issued and outstanding	52,533
Common stock available for future issuance under the 2021 Plan	638,430
Common stock available for future issuance under the ESPP	573,893
Total	11,971,397

9. 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 stock awards granted under the 2021 Plan vest at the rate specified in the stock option agreement and shall have terms no more than ten years from the date of grant. The terms and conditions governing the stock awards under the 2021 Plan are at the sole discretion of the board of directors. In addition, the number of shares of common stock reserved for issuance under the 2021 Plan will automatically increase on the first day of January 1 of each calendar year that commences after the 2021 Plan becomes effective and continuing through and including January 1, 2031, in an amount equal to 5% of the total number of shares of 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 1,889,895 shares and 1,869,984 shares on January 1, 2023 and 2022, respectively.

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 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 the 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 will automatically increase on January 1 of each calendar year that commences after the ESPP becomes effective and continuing through and including January 1, 2031, by the lesser of (1) 1% of the total number of shares of 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 377,979 shares on January 1, 2023. During the year ended December 31, 2023, 254,169 shares were issued under the ESPP.

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 $0.1 million and $0.3 million for the years ended December 31, 2023 and 2022, 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, 2023:

	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, 2022	7,225,635	$ 5.55	8.0		$ —
Granted	4,095,780	$ 1.46		$ 1.11	
Exercised	(4,501)	$ 1.39			
Canceled/forfeited	(610,373)	$ 3.32			
Outstanding at December 31, 2023	10,706,541	$ 4.12	7.7		$ 12
Exercisable at December 31, 2023	6,189,313	$ 4.82	7.0		$ —
Vested or expected to vest at December 31, 2023	10,706,541	$ 4.12	7.7		$ 12

The intrinsic value of options exercised was $2,000 and $45,000 during the year ended December 31, 2023 and 2022, respectively. The fair value of options vested was $2.1 million and $7.9 million during the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, there was approximately $9.7 million of unrecognized stock-based compensation related to unvested stock options, which the Company expects to recognize over a weighted-average period of 1.8 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,	
	2023	2022
Expected volatility	92-94 %	88-93 %
Risk-free interest rate	3.5-4.9 %	1.7-4.3 %
Expected option life (in years)	5.2-6.1	5.0-6.1
Expected dividend yield	0.0 %	0.0 %
Fair value per share of common stock	$0.77-$1.47	$0.98-$2.75

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–Determining the best estimated fair value of the Company's common stock required significant judgment and management considered several factors, including the Company's stage of development, equity market conditions affecting comparable public companies, significant milestones and progress of research and development efforts.

Stock-Based Compensation Expense

The following table summarizes the components of stock-based compensation expense recognized in the Company's statement of operations and comprehensive loss (in thousands):

	Years Ended December 31,	
	2023	2022
Research and development	$ 3,702	$ 4,109
General and administrative	5,521	5,467
Total	$ 9,223	$ 9,576

Restricted Stock Awards

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 awards vest 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 award 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 awards during the year ended December 31, 2023:

	RSU Outstanding	Weighted-average Grant Date Fair Value
Outstanding at December 31, 2022	121,867	$ 4.51
Granted	—	
Vested	(58,034)	$ 4.51
Canceled/forfeited	(11,300)	$ 4.51
Outstanding at December 31, 2023	52,533	$ 4.51

As of December 31, 2023, total unrecognized stock-based compensation expense relating to unvested restricted stock awards was $0.2 million and the weighted-average remaining vesting period was 1.0 years.

The aggregate intrinsic value of restricted stock award is calculated as the closing price per share of the Company's common stock on the last trading day of the fiscal period, multiplied by the number of restricted stock awards expected to vest as of December 31, 2023. As of December 31, 2023, the aggregate intrinsic value of restricted stock awards was $59,000.

10. 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,	
	2023	2022
Numerator:		
Net loss	$ (69,197)	$ (88,098)
Denominator:		
Weighted average common shares outstanding	37,904,318	37,574,757
Common stock outstanding subject to repurchase related to unvested early exercised stock options and restricted stock awards	(92,334)	(216,332)
Weighted average common shares outstanding - basic and diluted	37,811,984	37,358,425
Net loss per share attributable to common stockholders, basic and diluted	$ (1.83)	$ (2.36)

Potentially dilutive securities not included in the calculation of diluted net loss per share because to do so would be anti-dilutive are as follows (in common stock equivalent shares):

	Years Ended December 31,	
	2023	2022
Common stock options issued and outstanding	10,706,541	7,225,635
Common stock outstanding subject to repurchase related to unvested early exercised stock options and restricted stock awards	52,533	121,867
Total	10,759,074	7,347,502

11. 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, 2023 and 2022, the Company made contributions to the 401(k) plan of $0.6 million and $0.5 million, respectively.

12. Income Taxes

The Company recorded a current state tax provision of zero related to state minimum taxes for each of the years ended December 31, 2023 and 2022, which is recorded in general and administrative expenses in the accompanying statement of operations and comprehensive loss.

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

	Years Ended December 31,	
	2023	2022
Income tax benefit at statutory rates	$ (14,531)	$ (18,501)
Permanent items	35	5
Valuation allowance	14,957	16,920
Stock-based compensation	1,367	1,307
Research and development tax credits	(1,828)	269
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,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforward	$ 47,331	$ 42,564
Research tax credits	9,465	6,928
Capitalized research and development expenses	21,848	13,250
Lease liability	5,736	6,600
Stock-based compensation	2,645	1,953
Reserves and accruals	2,493	3,787
Intangible assets	145	168
Total deferred tax assets	89,663	75,250
Less valuation allowance	(83,680)	(68,192)
Net deferred tax assets	5,983	7,058
Deferred tax liabilities:		
Right-of-use assets	(5,424)	(6,443)
Property and equipment	(461)	(472)
Prepaid assets	(98)	(143)
Total deferred tax assets	(5,983)	(7,058)
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, 2023 and 2022 due to historical losses and uncertainty surrounding the use of such assets. The valuation allowance increased by $15.5 million between December 31, 2023 and December 31, 2022 primarily due to the generation of operating losses.

As of December 31, 2023, the Company has net operating loss carryforwards for federal and state income tax purposes of $205.7 million and $278.5 million, respectively. The federal net operating loss carryforwards generated prior to 2018 and state net operating loss carryforwards, if not utilized, will expire beginning in 2035. Federal net operating losses aggregating $201.3 million are not subject to expiration.

The Company has research credit carryforwards for federal and state income tax purposes of approximately $9.4 million and $5.6 million, respectively, as of December 31, 2023. The federal credits begin to expire in 2038 and the state credits can be carried forward indefinitely.

Utilization of some of the federal and state net operating loss and credit carryforwards may be subject to annual limitations due to the change in ownership provisions of the Internal Revenue Code of 1986 and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits 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 net operating losses 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 net operating loss carryforwards.

The Company recognizes a tax benefit from uncertain tax positions when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits. Due to the existence of the full valuation allowance, future changes in unrecognized tax benefits will not impact the Company’s effective tax rate. The Company does not foresee material changes to its liability for uncertain tax benefits within the next 12 months.

The following table summarizes the activity in the Company's gross unrecognized tax benefits (in thousands):

	Years Ended December 31,	
	2023	2022
Balance at beginning of period	$ 13,819	$ 12,659
Decrease related to prior year positions	(375)	(5,054)
Increase related to current year positions	5,304	6,214
Balance at end of period	$ 18,748	$ 13,819

During the years ended December 31, 2023 and 2022, 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.

On June 29, 2020, California Governor Newsom signed to law the state's budget package which included Assembly Bill 85 (AB 85). AB 85 contained two major tax changes: (1) it suspends the usage of net operating losses (NOLs) for certain taxpayers; and (2) it limits certain business tax credits for tax years 2020, 2021, and 2022. Senate Bill 113 (SB 113), which Gov. Newsom signed into law Feb. 9, 2022, contains important California tax law changes, including reinstatement of 2022 business tax credits and net operating loss (NOL) deductions limited by AB 85. The Company is in a taxable loss position in 2023 and 2022 and thus the bill has no impact on the financial statements.

13. Subsequent Events

The Company signed an Amended and Restated Collaboration Agreement with Innovent in March 2024 (the "Amended Innovent Agreement"). Under the Amended Innovent Agreement, the Company receives worldwide rights to two ISAC programs and will be assuming all future development costs for the two ISAC programs. Innovent will manufacture the first cGMP batch of antibody and make a one-time payment to the Company of $4.7 million. Innovent is eligible to receive sales milestones payments and royalties on global net sales.

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 their evaluation as of December 31, 2023, 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 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 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 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, 2023. 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, 2023.

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, 2023 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 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, 2023 under the captions "Proposal 1: Election of Directors" and "Executive Officers" and 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, 2023 under the captions "Executive Compensation", "Compensation Committee Interlocks and Insider Participation" and "Compensation of Non-Employee Board Members" 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, 2023 under the caption "Security Ownership of Certain Beneficial Owners and Management" and is incorporated herein 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, 2023 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, 2023 under the caption "Ratification of Selection of Independent Registered Public Accounting Firm" and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

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

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

(a)(3) **Exhibits**

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

Exhibit Number	Description of Exhibit	Form	File No.	Exhibit	Filing Date	Filed Herewith
3.1	Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect.	8-K	001-39988	3.1	2/9/2021	
3.2	Amended and Restated Bylaws of the Registrant, as currently in effect.	S-1	333-252136	3.4	1/15/2021	
4.1	Reference is made to Exhibits 3.1 and 3.2.					
4.2	Form of common stock certificate of the Registrant.	S-1	333-252136	4.1	1/15/2021	
4.3	Description of Securities.	10-K	001-39988	4.3	3/31/2021	
10.1	Amended and Restated Investor Rights Agreement, dated June 26, 2020, by and among the Registrant and the investors listed on Schedule A thereto.	S-1	333-252136	10.1	1/15/2021	
10.2+	2015 Equity Incentive Plan, as amended.	S-1/A	333-252136	10.2	2/1/2021	
10.3+	Forms of Option Agreement, Stock Option Grant Notice and Notice of Exercise under the 2015 Equity Incentive Plan.	S-1	333-252136	10.3	1/15/2021	
10.4+	2021 Equity Incentive Plan.	S-1/A	333-252136	10.4	2/1/2021	
10.5+	Forms of Option Agreement, Stock Option Grant Notice and Notice of Exercise under the 2021 Equity Incentive Plan.	S-1/A	333-252136	10.5	2/1/2021	
10.6+	Forms of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the 2021 Equity Incentive Plan.	S-1/A	333-252136	10.6	2/1/2021	
10.7+	2021 Employee Stock Purchase Plan.	S-1/A	333-252136	10.7	2/1/2021	
10.8	Form of Indemnification Agreement, by and between the Registrant and each of its directors and executive officers.	S-1	333-252136	10.8	1/15/2021	
10.9	Form of Warrant to Purchase Common Stock.	S-1	333-252136	10.9	1/15/2021	

Exhibit Number	Description of Exhibit	Form	File No.	Exhibit	Filing Date	Filed Herewith
10.10+	Offer of Employment by and between the Registrant and Randall C. Schatzman, dated June 10, 2019.	S-1	333-252136	10.10	1/15/2021	
10.11+	Offer Letter by and between the Registrant and William Quinn, dated April 14, 2020.	S-1	333-252136	10.11	1/15/2021	
10.12+	Offer Letter by and between the Registrant and Edith Perez, dated March 16, 2020.	S-1	333-252136	10.13	1/15/2021	
10.13+	Offer Letter by and between the Registrant and Grant Yonehiro, dated October 26, 2016.	S-1	333-252136	10.14	1/15/2021	
10.14	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	
10.15#	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	
10.16#	Master Services Agreement by and between the Registrant and Piramal Healthcare UK Ltd, dated June 26, 2018.	S-1	333-252136	10.23	1/15/2021	
10.17#	Amended and Restated Supply Agreement between the Registrant and EirGenix, Inc., dated January 25, 2022.	10-Q	001-39988	10.1	5/12/2022	
10.18	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	
10.19#	Clarification Letter dated April 27, 2022 between the Registrant and EirGenix, Inc.	10-Q	001-39988	10.1	8/10/2022	
10.20+	Amended and Restated Severance and Change in Control Plan.	10-K	001-39988	10.24	3/29/2023	
10.21	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	
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 Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
97.1+	Incentive Compensation Recoupment Policy.					X
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 21, 2024

BOLT BIOTHERAPEUTICS, INC.

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

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Randall C. Schatzman, Ph.D. and William P. Quinn, and each of them, as his or her true and lawful attorneys-in-fact and agents, each with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or either of them, or their or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ Randall C. Schatzman, Ph.D. Randall C. Schatzman, Ph.D.	Chief Executive Officer and Director *(Principal Executive Officer)*	March 21, 2024
/s/ William P. Quinn William P. Quinn	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 21, 2024
/s/ Laura Berner Laura Berner	Director	March 21, 2024
/s/ Edgar G. Engleman, M.D. Edgar G. Engleman, M.D	Director	March 21, 2024
/s/ James I. Healy, M.D James I. Healy, M.D.	Director	March 21, 2024
/s/ Kathleen LaPorte Kathleen LaPorte	Director	March 21, 2024
/s/ Frank D. Lee Frank D. Lee	Director	March 21, 2024
/s/ Richard A. Miller, M.D. Richard A. Miller, M.D.	Director	March 21, 2024
/s/ Brian O'Callaghan Brian O'Callaghan	Director	March 21, 2024
/s/ Nicole Onetto, M.D. Nicole Onetto, M.D.	Director	March 21, 2024
/s/ Mahendra G. Shah, Ph.D. Mahendra G. Shah, Ph.D.	Director	March 21, 2024

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