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

# SCHEDULE 14A

**(Rule 14a-101)**
**INFORMATION REQUIRED IN**
**PROXY STATEMENT**

## SCHEDULE 14A INFORMATION

**Proxy Statement Pursuant to Section 14(a) of the**
**Securities Exchange Act of 1934**

Filed by the Registrant ☒

Filed by a Party other than the Registrant ☐

Check the appropriate box:

☒ Preliminary Proxy Statement

☐ **Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))**

☐ Definitive Proxy Statement

☐ Definitive Additional Materials

☐ Soliciting Material under §240.14a-12

# BAUDAX BIO, INC.

(Name of Registrant as Specified In Its Charter)

(Name of Person(s) Filing Proxy Statement, if other than the Registrant)

Payment of Filing Fee (Check all boxes that apply):

☒ No fee required

☐ Fee paid previously with preliminary materials

☐ Fee computed on table in exhibit required by Item 25(b) per Exchange Act Rules 14a-6(i)(1) and 0-11

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**PRELIMINARY COPY SUBJECT TO COMPLETION DATED JULY 31, 2023**

In accordance with Rule 14a-6(d) under Regulation 14A, please be advised that Baudax Bio, Inc. intends to release definitive copies of this Proxy Statement to security holders on or about , 2023.

**490 Lapp Road**
**Malvern, PA 19355**
**(484) 395-2440**

## NOTICE OF SPECIAL MEETING OF SHAREHOLDERS
**To be held , 2023**

Notice is hereby given that a special meeting of shareholders (the "Special Meeting") of Baudax Bio, Inc. (the "Company"), will be held virtually, via live webcast at on , 2023 at a.m. Eastern Time. The purpose of the Special Meeting is the following:

1. To approve, in accordance with Nasdaq Listing Rule 5635(a), the issuance of shares of the Company's common stock, par value $0.01 per share, upon conversion of the Company's Series X Non-Voting Convertible Preferred Stock, par value $0.01 per share ("Series X Preferred Stock"), issued on June 29, 2023 (the "Conversion Proposal" or "Proposal No. 1");
2. To approve an amendment to the Amended and Restated Articles of Incorporation to effect a reverse stock split of the common stock at a ratio to be determined by the Company's Board of Directors (the "Board of Directors") within a range of one-for- (1: ) and one-for- (1: ) (or any number in between), to be effected in the sole discretion of the Board of Directors at any time within one year of the date of the Special Meeting without further approval or authorization from the Company's shareholders (the "Reverse Stock Split Proposal" or "Proposal No. 2");
3. To ratify the selection of EisnerAmper LLP ("EisnerAmper") as the Company's independent registered public accounting firm for the 2023 fiscal year (the "Auditor Proposal" or "Proposal No. 3"); and
4. To approve the adjournment or postponement of the Special Meeting, if necessary, to continue to solicit votes for Proposal Nos. 1, 2, and/or 3 (the "Adjournment Proposal" or "Proposal No. 4").

Only Company shareholders of record at the close of business on , 2023 will be entitled to vote at the Special Meeting and any adjournment or postponement thereof.

On , 2023, we announced a dividend of Series C Preferred Stock with multiple votes per share, to be issued to Company shareholders on , 2023, with the intent of increasing the likelihood of receiving sufficient votes at the Special Meeting to approve Proposal 2. Please note that the holders of this Series C Preferred Stock may only vote on Proposals 2 and 4 and their votes may only be cast in direct proportion to the final votes cast by the holders of the common stock on such proposals. As described in the accompanying proxy statement, the Series C Preferred Stock only serves to amplify the common stock voted in favor of the Reverse Stock Split Proposal.

Your vote is important. Whether or not you are able to attend the Special Meeting, it is important that your shares be represented. To ensure that your vote is recorded promptly, please vote as soon as possible, even if you plan to virtually attend the Special Meeting, by submitting your proxy via the Internet at the address listed on the proxy card or by signing, dating, and returning the proxy card.

Thank you for your ongoing support and continued interest in Baudax Bio, Inc.

By order of the Board of Directors,

Jillian Dilmore
*Corporate Controller & Corporate Secretary*
*, 2023*

**Important Notice Regarding the Availability of Proxy Materials for the Special Shareholders Meeting to Be Held on , 2023:**

This proxy statement is available to shareholders at www.proxyvote.com.

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PRELIMINARY COPY SUBJECT TO COMPLETION DATED JULY 31, 2023

**490 Lapp Road**
**Malvern, PA 19355**
**(484) 395-2440**

**PROXY STATEMENT**
**SPECIAL MEETING OF SHAREHOLDERS**
**To Be Held on , 2023**

## INFORMATION CONCERNING SOLICITATION AND VOTING

This proxy statement contains information about the Special Meeting of Shareholders (the "Special Meeting") of Baudax Bio, Inc. (the "Company," "Baudax," "we," "us," or "our"), which will be held virtually, via live webcast at on , 2023 at :00 a.m. Eastern Time. The Company's Board of Directors (the "Board of Directors" or the "Board") is using this proxy statement to solicit proxies for the Special Meeting.

All properly submitted proxies will be voted in accordance with the instructions contained in those proxies. If no instructions are specified, the proxies will be voted in accordance with the recommendation of our Board of Directors with respect to each of the matters set forth in the accompanying Notice of Special Meeting. You may revoke your proxy at any time before it is exercised at the Special Meeting by giving our corporate secretary written notice to that effect, delivering to us another signed proxy card with a later date, voting by telephone or over the internet at a later date, or virtually attending the Special Meeting and voting online during the Special Meeting.

At the Special Meeting, the Company will ask shareholders:

1. To approve, in accordance with Nasdaq Listing Rule 5635(a), the issuance of shares of the common stock, par value $0.01 per share, upon conversion of the Company's Series X Non-Voting Convertible Preferred Stock, par value $0.01 per share ("Series X Preferred Stock"), issued on June 29, 2023 (the "Conversion Proposal" or "Proposal No. 1");
2. To approve an amendment to the Amended and Restated Articles of Incorporation to effect a reverse stock split of the common stock (the "Reverse Stock Split") at a ratio to be determined by the Board of Directors within a range of one-for- (1: ) and one-for- (1: ) (or any number in between), to be effected in the sole discretion of the Board of Directors at any time within one year of the date of the Special Meeting without further approval or authorization from our shareholders (the "Reverse Stock Split Proposal" or "Proposal No. 2");
3. To ratify the selection of EisnerAmper LLP ("EisnerAmper") as the Company's independent registered public accounting firm for the 2023 fiscal year (the "Auditor Proposal" or "Proposal No. 3"); and
4. To approve the adjournment or postponement of the Special Meeting, if necessary, to continue to solicit votes for Proposal Nos. 1, 2, and/or 3 (the "Adjournment Proposal" or "Proposal No. 4" and, together with Proposal Nos. 1, 2, and 3, the "Proposals").

After careful consideration, the Board of Directors approved the Proposals being submitted to a shareholder vote, and having determined that the Proposals are advisable, fair, and in the best interests of the Company and its shareholders, recommends that shareholders vote "FOR" each of the Proposals.

Your vote is important. Whether or not you expect to virtually attend the Special Meeting, please complete, date, sign, and promptly return the accompanying proxy card in the enclosed postage-paid envelope to ensure that your shares will be represented and voted at the Special Meeting. If you hold your shares in "street name" through a broker, you should follow the procedures provided by your broker.

This proxy statement is dated , 2023 and is first being mailed to shareholders on or about , 2023.

## CAUTIONARY INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This proxy statement, and the documents incorporated by reference into this proxy statement, contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding: the Company's strategic alternatives, new development opportunities, financial position, funding for continued operations, cash reserves, projected costs, prospects, clinical trials, plans, expectations, strategies, projections and objectives of management and shareholder approval of the conversion rights of the Series X Preferred Stock. The use of words such as, but not limited to, "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "upcoming," "might," "plan," "potential," "predict," "project," "should," "target," "goal," "will," or "would" and similar words and expressions are intended to identify forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, our clinical results and other future conditions. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements. We may not actually achieve the forecasts disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Such forward-looking statements are subject to a number of material risks and uncertainties including but not limited to those set forth under the caption "Risk Factors" in this proxy statement and in the Company's most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q filed with the SEC, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the SEC. Any forward-looking statement speaks only as of the date on which it was made. Neither we, nor our affiliates, advisors or representatives, undertake any obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date hereof.

## WEBSITES

Website addresses referenced in this proxy statement are provided for convenience only, and the content on the referenced websites does not constitute a part of this proxy statement.

## OVERVIEW

## QUESTIONS AND ANSWERS ABOUT THE SPECIAL MEETING

The following section provides answers to frequently asked questions about the Special Meeting. This section, however, only provides summary information. These questions and answers may not address all issues that may be important to you as a shareholder. You should carefully read this entire proxy statement, including each of the annexes.

***Why am I receiving these materials, and who is soliciting my vote?***

We sent you this proxy statement because our Board of Directors is soliciting your proxy to vote at the Special Meeting that the Company is holding, in part, in order to seek shareholder approval on certain matters in connection with our June 2023 acquisition (the "Acquisition") of TeraImmune, Inc. ("TeraImmune") and as described in further detail herein. This proxy statement summarizes the information you need to vote at the Special Meeting. You do not need to attend the Special Meeting to vote your shares.

***When are this proxy statement and the accompanying materials scheduled to be sent to shareholders?***

On or about , 2023, we will begin mailing our proxy materials, including the Notice of the Special Meeting, this proxy statement, and the accompanying proxy card or, for shares held in street name (i.e., shares held for your account by a broker or other nominee), a voting instruction form.

***When and where will the Special Meeting take place?***

We will be hosting the Special Meeting via live webcast only. The Special Meeting will be held virtually, via live webcast at on , 2023, at :00 a.m. Eastern Time. Regardless of whether you are the "record holder" of your shares or your shares are held in street name, if you held your shares as of the close of business on , 2023, you are entitled to attend the Special Meeting. Shareholders may vote and submit questions while attending the Special Meeting online. Instructions on how to virtually attend and participate online are also available at . Information on how to vote online at the virtual Special Meeting is discussed below.

***When is the record date for the Special Meeting?***

The record date for determination of shareholders entitled to vote at the Special Meeting is the close of business on , 2023, which we refer to as the "record date."

***Who is entitled to vote at the Special Meeting?***

Only holders of record of our common stock and Series C Preferred Stock, par value $0.01 per share ("Series C Preferred Stock") as of the record date will be entitled to notice of, and to vote at, the Special Meeting or any adjournment or postponement thereof.

***How many votes can be cast by all shareholders?***

There were shares of our common stock outstanding as of the record date, all of which are entitled to vote with respect to all matters to be acted upon at the Special Meeting, and shares of Series C Preferred Stock outstanding on the record date, all of which are entitled to vote with respect to the Reverse Stock Split Proposal and the Adjournment Proposal only. Each outstanding share of common stock is entitled to one vote on each matter considered at the Special Meeting.

As previously announced, on , 2023, the Board of Directors declared a dividend of one thousandth (1/1,000th) of a share of Series C Preferred Stock, for each outstanding share of common stock, and share of common stock issuable upon conversion of our Series X Preferred Stock, par value $0.01 per share ("Series X Preferred Stock"), to shareholders of record as of the close of business on , 2023. The holders of the Series C Preferred Stock have 1,000,000 votes per whole share (i.e., 1,000 votes per one-thousandth of a share of Series C Preferred Stock) and are entitled to vote with the common stock, voting together as a single class, on the Reverse Stock Split Proposal and the Adjournment Proposal, but are not otherwise entitled to vote on the other proposals to be presented at the Special Meeting. Each share of Series C Preferred Stock redeemed pursuant to the Initial Redemption (as defined below) will have no voting power with respect to the Reverse

Stock Split Proposal or any other matter. When a holder of common stock submits a vote on the Reverse Stock Split Proposal, the corresponding number of fractional shares of Series C Preferred Stock held by such holder will be automatically voted in a mirrored fashion. For example, if a shareholder holds 10 shares of common stock (entitled to one vote per share) and votes in favor of the Reverse Stock Split Proposal, then 10,010 votes will be recorded in favor of the Reverse Stock Split Proposal, because the Series C Preferred Stock will automatically be voted in favor of the Reverse Stock Split Proposal alongside the common stock. Due to this mirrored voting structure, and since the Series X Preferred Stock is non-voting, shares of Series C Preferred Stock issued as a dividend with respect to the Series X Preferred Stock will not be able to vote such shares of Series C Preferred Stock and will be redeemed in the Initial Redemption.

All shares of Series C Preferred Stock that are not virtually present in person or by proxy at the Special Meeting as of immediately prior to the opening of the polls at the Special Meeting will be automatically redeemed (the "Initial Redemption"). Any outstanding shares of Series C Preferred Stock that have not been redeemed pursuant to the Initial Redemption will be redeemed in whole, but not in part, (i) if and when ordered by our Board or (ii) automatically upon the approval by the Company's shareholders of the Reverse Stock Split Proposal at any meeting of the shareholders held for the purpose of voting on such proposal.

We believe that the existence of the Series C Preferred Stock increases the likelihood that the Reverse Stock Split Proposal will be approved due to its amplified voting power, which may be further amplified as a result of the Initial Redemption. However, since holders of the Series C Preferred Stock have the opportunity to vote against the Reverse Stock Split Proposal, we may be unable to obtain the vote of the requisite voting power required to approve the Reverse Stock Split Proposal. In addition, if a holder of Series C Preferred Stock attends the Special Meeting virtually in person or by proxy and abstains from voting on the Reverse Stock Split Proposal, such holder's Series C Preferred Stock shall not be redeemed in the Initial Redemption, and such abstention will be treated as a vote against the Reverse Stock Split Proposal.

On the record date, there were 27,089.719 shares of Series X Preferred Stock issued and outstanding; the Series X Preferred Stock is a non-voting class and therefore is not entitled to vote on the matters being considered at the Special Meeting. In addition, any shares of Series C Preferred Stock issued as a dividend on the Series X Preferred Stock will be unable to vote such shares of Series C Preferred Stock at the Special Meeting due to the mirrored voting structure.

Of the shares of common stock issued and outstanding and entitled to vote, 1,212,185 shares of common stock were issued as consideration in our Acquisition. These 1,212,185 shares of common stock are not entitled to vote on Proposal No. 1 for purposes of the listing rules of the Nasdaq Stock Market ("Nasdaq"). The Company anticipates that these 1,212,185 shares of common stock will be voted in favor of Proposal No. 1 for purposes of adopting the proposal under Pennsylvania law. However, to comply with Nasdaq rules, the Company will instruct the judge of election to conduct a separate tabulation that subtracts 1,212,185 shares of common stock from the total number of shares voted in favor of Proposal No. 1 to determine whether that proposal has been adopted in accordance with applicable Nasdaq rules.

***How do I vote?***

If you are a shareholder of record (meaning that you hold shares in your name in the records of our transfer agent, Broadridge Corporate Issuer Solutions, Inc. ("Broadridge"), and that your shares are not held in "street name" by a bank or brokerage firm), you may vote your shares in any one of the following ways:

- *By internet.* To vote over the internet through services provided by Broadridge, please go to the following website: and follow the instructions at that site for submitting your proxy. If you vote over the internet, you do not need to complete and mail your proxy card.
- *By telephone.* To vote by telephone through services provided by Broadridge, call 1-800-690-6903, and follow the instructions provided on the proxy card that accompanies this proxy statement. If you vote by telephone, you do not need to complete and mail your proxy card.
- *By mail.* If you requested printed proxy materials, you need to complete, date, and sign the proxy card that accompanies this proxy statement and promptly mail it in the enclosed postage-prepaid envelope. You do not need to put a stamp on the enclosed envelope if you mail it from within the United States. If you are mailed or otherwise receive or obtain a proxy card, and you choose to vote by telephone or by Internet, you do not have to return your proxy card.

- *At the Special Meeting.* To vote during the Special Meeting, virtually attend the Special Meeting by visiting , where shareholders may also submit questions during the Special Meeting. The meeting starts at :00 a.m. Eastern Time. You may vote online during the Special Meeting at .

Your proxy will only be valid if you complete and return the proxy card, vote by telephone, vote over the internet before the Special Meeting, or vote online during the Special Meeting. The persons named in the proxy card will vote the shares you own in accordance with your instructions on your proxy card, in your vote by telephone, or in your vote over the internet. If you return the proxy card, vote by telephone, or vote over the internet, but do not give any instructions on a particular matter described in this proxy statement, the persons named in the proxy card will vote the shares you own in accordance with the recommendations of our Board of Directors.

***How do I vote my shares if I hold them in "street name"?***

If the shares you own are held in "street name" by a bank or brokerage firm, your bank or brokerage firm, as the record holder of your shares, is required to vote your shares according to your instructions. In order to vote your shares, you will need to follow the directions that your bank or brokerage firm provides to you. Many banks and brokerage firms solicit voting instructions over the internet or by telephone. Even if your shares are held in street name, you are welcome to attend the Special Meeting if you have a legal proxy to attend. If your shares are held in street name, you may not vote your shares online during the Special Meeting unless you obtain a "legal proxy," executed in your favor, from the holder of record (i.e., your bank or brokerage firm). If you hold your shares in street name and wish to vote online during the Special Meeting, please contact your bank or brokerage firm before the Special Meeting to obtain the necessary proxy from the holder of record. You must then submit the legal proxy to the Company by 5:00 p.m., Eastern Time, on , 2023. Legal proxies may be submitted by mail to Baudax Bio, Inc., 490 Lapp Road, Malvern, PA 19355, Attention: Corporate Secretary, telephone: (484) 395-2440.

If the beneficial owner does not provide voting instructions, banks and brokerage firms cannot vote the shares with respect to "non-routine" matters but can vote the shares with respect to "routine" matters. "Broker non-votes" occur when a beneficial owner of shares held in street name fails to provide instructions to the bank or brokerage firm holding the shares as to how to vote on matters deemed "non-routine." We believe Proposal No. 1 (Conversion Proposal), Proposal No. 2 (Reverse Stock Split Proposal), and Proposal No. 4 (the Adjournment Proposal) are each considered non-routine under applicable New York Stock Exchange rules. Thus, your broker, bank, or other nominee would not be able to vote on such non-routine matters. As noted above, if your shares are held in street name, your broker, bank, or other nominee will provide you with an instructional letter on how to vote your shares without attending the Special Meeting.

The votes of the Series C Preferred Stock on Proposal 2 will mirror the votes cast by holders of common stock, without giving effect to abstentions or broker non-votes by holders of common stock. Because the voting standard for Proposal 2 is a majority of the combined voting power of the shares of common stock and Series C Preferred Stock issued and outstanding and entitled to vote on the proposal, voting together and counted as a single class, abstentions and broker non-votes will have the effect of a vote "AGAINST" the proposal.

***How do I change my vote?***

If you are a shareholder of record, even if you complete and return a proxy card or vote by telephone or over the internet, you may change or revoke your vote at any time before your proxy is exercised by taking one of the following actions:

- send written notice to our Corporate Secretary, Jillian Dilmore, at our address above, stating that you wish to revoke your vote;
- deliver to us another signed proxy card with a later date or vote by telephone or over the internet at a later date; or
- attend the Special Meeting and vote online at the Special Meeting. Note that virtual attendance at the Special Meeting alone will not revoke your vote; you must vote online during the Special Meeting.

If you own shares in street name, your bank or brokerage firm should provide you with instructions for changing or revoking your vote.

***How is a quorum reached?***

In order for business to be conducted at the Special Meeting, a quorum must be present. A quorum consists of the holders of at least a majority of the shares of our common stock issued and outstanding and entitled to vote at the Special Meeting. Shares of Series C Preferred Stock are not counted for purposes of determining whether or not a quorum is present at the Special Meeting.

Shares of common stock present or represented by proxy (including broker non-votes and shares that are abstained or withheld or with respect to which no voting instructions are provided for one or more of the matters to be voted upon) will be counted for the purpose of determining whether a quorum exists. If a quorum is not present, the Special Meeting will be adjourned until a quorum is obtained.

***What proposals will be voted on at the Special Meeting?***

There are four proposals scheduled to be voted on at the Special Meeting:

- **Proposal No. 1** — Approval of the issuance of shares of common stock upon conversion of the Series X Preferred Stock.
- **Proposal No. 2** — Approval of the amendment of the Amended and Restated Articles of Incorporation to effect the Reverse Stock Split.
- **Proposal No. 3** — Ratification of selection of EisnerAmper LLP as the Company's independent registered public accounting firm for the 2023 fiscal year.
- **Proposal No. 4** — Approval of the adjournment or postponement of the Special Meeting, if necessary, to continue to solicit votes for Proposal Nos. 1, 2, and/or 3.

***What vote is required to approve each item at the Special Meeting?***

You may vote "for," "against," or "abstain" on each of the Proposals being presented before our shareholders. Under our Second Amended and Restated Bylaws ("Bylaws"), any proposal other than an election of directors is decided by a majority of the votes present or represented and voting on the matter, except where a larger vote is required by law or by our Amended and Restated Articles of Incorporation or our Bylaws.

- **Proposal No. 1** — The affirmative vote of the holders of shares of common stock representing a majority of the votes present or represented and voting on the matter is required for the approval of the Conversion Proposal. Broker non-votes (if any) and abstentions will not be counted as votes cast on the matter and will have no effect on the outcome of this proposal.
- **Proposal No. 2** — The affirmative vote of the holders of shares of common stock and Series C Preferred Stock, voting together as a single class, representing a majority of the voting power of the common stock and Series C Preferred Stock issued and outstanding is required for the approval of the Reverse Stock Split Proposal. Broker non-votes (if any) and abstentions will have the same effect as votes cast against the proposal.
- **Proposal No. 3** — The affirmative vote of the holders of shares of common stock representing a majority of the votes present or represented and voting on the matter is required for the approval of the Auditor Proposal. Broker non-votes (if any) and abstentions will not be counted as votes cast on the matter and will have no effect on the outcome of this proposal.
- **Proposal No. 4** — If a quorum is present at the Special Meeting, the affirmative vote of the holders of shares of common stock and Series C Preferred Stock representing a majority of the votes present or represented and voting on the matter is required for the approval of the Adjournment Proposal. If a quorum is not present at the Special Meeting, the affirmative vote of the holders of a majority of the shares of common stock present at the Special Meeting or represented by proxy is required for the approval of the Adjournment Proposal. Broker non-votes (if any) and abstentions will not be counted as votes cast on the matter and will have no effect on the outcome of this proposal.

Please refer to the discussion above under "*How many votes can be cast by all shareholders?*" for a description of the Series C Preferred Stock, which is entitled to be voted together with the common stock as a single class on the Reverse Stock Split Proposal and the Adjournment Proposal. Shares of Series C Preferred Stock that are

not present in person or by proxy as of immediately prior to the opening of the polls will be automatically redeemed in the Initial Redemption and, therefore, will not be outstanding or entitled to vote on either the Reverse Stock Split Proposal or the Adjournment Proposal and will be excluded from the calculation as to whether such proposals pass at the Special Meeting. Due to the voting power of the shares of Series C Preferred Stock that are not redeemed pursuant to the Initial Redemption on the Reverse Stock Split Proposal and the Adjournment Proposal, the holders of common stock that submit a proxy to vote their shares at the Special Meeting or virtually attend the Special Meeting will effectively have enhanced voting power on the Reverse Stock Split Proposal and the Adjournment Proposal over holders of common stock that are not represented in person or by proxy at the Special Meeting. This means that the Reverse Stock Split Proposal and the Adjournment Proposal could each be approved by the affirmative vote of the holders of less than a majority of the outstanding shares of our common stock. Assuming the minimum quorum requirement of holders representing majority of the common stock issued and outstanding and entitled to vote is met, and no other holders of shares of our common stock are present, virtually in person or by proxy at the Special Meeting, the Reverse Stock Split Proposal could be approved by holders representing only 25.1% of our outstanding common stock (along with their Series C Preferred Stock) voting to approve the Reverse Stock Split Proposal, rather than at least 50.001% of our outstanding common stock, which would be required absent the existence of the Series C Preferred Stock.

***Do I have appraisal rights?***

No. Our shareholders are not entitled to dissenters' or appraisal rights under the Pennsylvania Business Corporation Law of 1988, as amended, with respect to any of the Proposals being voted on.

***How is the vote counted?***

If you are a shareholder of record, you have the right to direct the voting of your shares by voting over the Internet, by telephone, by returning your proxy by mail, or by virtually attending the Special Meeting and voting online during the Special Meeting. In contrast, if you are a beneficial owner and your shares are held in an account at a bank or at a brokerage firm or other nominee hold, you must tell your bank, broker or other nominee how you would like your shares to be voted, which you can do by following the instructions provided to you by the bank, broker, or other nominee.

***Who will count the vote?***

The votes will be counted, tabulated, and certified by an inspector of elections appointed by the Board of Directors.

***How does the Board of Directors recommend that I vote on the Proposals?***

The Board of Directors recommends that you vote:

- **Proposal No. 1** — FOR the approval of the Conversion Proposal.
- **Proposal No. 2** — FOR the approval of the Reverse Stock Split Proposal.
- **Proposal No. 3** — FOR the approval of the Auditor Proposal.
- **Proposal No. 4** — FOR the approval of the Adjournment Proposal.

***Who is making and paying for the solicitation of proxies and how is it made?***

We are making the solicitation and will bear the costs of soliciting proxies. In addition to solicitations by mail, our directors, officers, and employees, without additional remuneration, may solicit proxies by telephone, text message, facsimile, email, personal interviews, and other means. We have engaged Campaign Management LLC to serve as our proxy solicitor to distribute our proxy materials and solicit proxies, and the estimated fee for these services is $11,500 plus additional costs for certain supplemental items if incurred, plus reimbursement for reasonable disbursements. We have requested that brokerage houses, custodians, nominees, and fiduciaries forward copies of the proxy materials to the persons for whom they hold shares and request instructions for voting the proxies. We will reimburse the brokerage houses and other persons for their reasonable out-of-pocket expenses in connection with this distribution.

***How can I know the voting results?***

We plan to announce preliminary voting results at the Special Meeting and will report the final results in a Current Report on Form 8-K to be filed with the Securities and Exchange Commission ("SEC") within four business days following the Special Meeting.

***Who can provide me with additional information and help answer my questions?***

If you would like additional copies, without charge, of this proxy statement or if you have questions about the proposals being considered at the Special Meeting, including the procedures for voting your shares, you should contact Campaign Management LLC, the Company's proxy solicitor, by telephone at 1-844-394-4517 (toll-free within North America) or 1-212-632-8422 (standard rates apply).

## RISK FACTOR SUMMARY

The following summarizes the principal factors that make an investment in the Company speculative or risky, all of which are more fully described in the Risk Factors section below. This summary should be read in conjunction with the Risk Factors section contained herein, as well as the Risk Factors sections found in our Annual Reports on Form 10-K, subsequent reports on Form 10-Q, and our other public filings, and should not be relied upon as an exhaustive summary of the material risks facing our business. The occurrence of any of these risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this proxy statement and those we may make from time to time. You should consider all of the risk factors described in our public filings when evaluating our business.

***Risks Relating to Our Financial Position and Need for Additional Capital***

- If we are unable to meet the initial listing standards of Nasdaq by November 13, 2023, or otherwise regain compliance with the listing standards of Nasdaq, our common stock may become delisted, which could have a material adverse effect on the liquidity of our common stock and our ability to raise capital.
- We are required to use reasonable best efforts to solicit shareholder approval for the conversion of our Series X Preferred Stock and if we are unable to obtain such approval by December 29, 2023, then the holders of our Series X Preferred Stock may demand cash settlement upon attempted conversions. If the holders of our Series X Preferred Stock demand this cash-settlement right, we may not have sufficient capital to funds its operations.
- There is no guarantee that the Acquisition of TeraImmune by us will increase shareholder value or that TeraImmune will be successfully integrated into our operations or achieve its desired benefits.
- Our business has incurred significant losses since our inception, and we may continue to incur significant losses for the foreseeable future. We may never achieve profitability.
- We will need to raise additional funding to advance our product candidates, which may not be available on acceptable terms, or at all. Failure to obtain capital when needed may force us to delay, limit or terminate our product development efforts or other operations.
- We may be unsuccessful in obtaining a waiver or amendment to our Credit Agreement with respect to any existing events of default thereunder. The failure to obtain such a waiver or amendment, or otherwise cure any event of default under our Credit Agreement, could allow the lender to take enforcement action against the Company or certain of its assets, including accelerating the loans and other obligations under the Credit Agreement and taking any other remedial actions permitted under the Credit Agreement or applicable law, which would have a material adverse effect on our business, financial condition and results of operations and could require us to curtail or cease operations.
- Our shareholders may experience dilution in the future.

***Risks Relating to the Business of TeraImmune***

- Our platform has never been used to develop any approved, commercially viable product.
- Our Treg-based product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, require expansion of trial size, limit their commercial potential or result in significant negative consequences.
- We currently store our T cells and research specimens at our research and development facilities and at the facilities of our clinical and/or manufacturing partners, and any damage or loss to our storage freezers and/or facilities from natural disasters or otherwise would cause delays in replacement, and our business could suffer.
- We will rely on third-party healthcare professionals to administer Tregs to patients, and our business could be harmed if these third parties administer these cells incorrectly.
- We believe we may require an updated and validated protocol for commercial-scale expansion and manufacturing of Tregs for conducting pivotal trials and for commercialization of our product candidates, if approved.
- We have not yet developed commercial-scale infrastructure for freezing and thawing large quantities of Tregs, which we believe will be required for the storage and distribution of our Tregs product candidates at commercial scale.

- Cell therapies are novel and present significant challenges.
- Public opinion and scrutiny of cell-based immunotherapy and genetic modification approaches may impact public perception of our company and Treg-based product candidates, or may adversely affect our ability to conduct our business and our business plans.
- We may rely on orphan drug status to develop and commercialize certain of our product candidates, but orphan drug designations may not confer marketing exclusivity or other expected commercial benefits and we may not be able to obtain orphan drug designations for our other product candidates.
- Because the target patient population for TI-168 and certain of our other potential product candidates is relatively small, we must achieve significant market share and maintain high per-patient prices for our products to achieve and maintain profitability.
- Cell-based therapies rely on the availability of specialty raw materials, which may not be available to us on acceptable terms or at all.

***Risks Relating to Our Intellectual Property***

- We own or license numerous pending patent applications and issued patents in the United States. If our pending patent applications fail to issue or if our issued patents are not sufficiently broad, expire or are successfully opposed, invalidated, or rendered unenforceable, our business will be adversely affected.
- The validity, scope and enforceability of any patents that cover our current or future product candidates can be challenged by third parties.
- If we are unable to maintain our licensed agreements with third parties, our business may be materially harmed.
- Third-party claims or litigation alleging infringement of patents or other proprietary rights may delay or prevent the development and commercialization of our product candidates.
- We may become involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time consuming and unsuccessful.
- We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

***Risks Relating to Ownership of Our Common Stock***

- Pursuant to the terms of the Agreement and Plan of Merger, dated June 29, 2023, by and among the Company, Bounce Merger Sub I, Inc., Bounce Merger Sub II, LLC and TeraImmune, Inc. (the "Merger Agreement"), we are required to use reasonable best efforts to recommend that our shareholders approve the conversion of all outstanding shares of our Series X Preferred Stock into shares of our common stock. We cannot guarantee that our shareholders will approve this matter, and if they fail to do so, we may be required to settle their shares of Series X Preferred Stock for cash at a price per share equal to the as-converted fair value of such shares of Series X Preferred Stock and our operations may be materially harmed.
- Our stock price could be volatile as holders of our Series X Preferred Stock become able to convert their shares to common stock and sell these shares in the open market.
- Nasdaq may delist our common stock from its exchange, which could limit your ability to make transactions in our securities and subject us to additional trading restrictions.
- Our stock price has been and may continue to be volatile, and the value of an investment in our common stock may decline.
- The issuance or sale of shares of our common stock could depress the trading price of our common stock.

***Risks Relating to the Reverse Stock Split***

- We cannot assure you that we will meet the conditions of the Staff's Hearing Decision, even if the proposed Reverse Stock Split is approved.
- We cannot assure you that the proposed Reverse Stock Split will increase the price of the common stock.
- The proposed Reverse Stock Split may decrease the liquidity of the common stock and result in higher transaction costs.

## DESCRIPTION OF THE TRANSACTIONS

***Acquisition of TeraImmune, Inc.***

On June 29, 2023 (the "Effective Date"), the Company completed its acquisition of TeraImmune, Inc. a Delaware corporation ("TeraImmune"), pursuant to the Agreement and Plan of Merger, dated June 29, 2023 (the "Merger Agreement"), by and among the Company, Bounce Merger Sub I, Inc., a Delaware corporation and wholly-owned subsidiary of the Company ("First Merger Sub"), Bounce Merger Sub II, LLC, a Delaware limited liability company and wholly-owned subsidiary of the Company ("Second Merger Sub" and, together with First Merger Sub, "Merger Subs"), and TeraImmune. In accordance with the Merger Agreement, on the Effective Date, First Merger Sub merged with and into TeraImmune (the "First Merger"), with TeraImmune being the surviving entity and a wholly-owned subsidiary of the Company. Immediately following the First Merger and as part of the same overall transaction as the First Merger, TeraImmune merged with and into Second Merger Sub (the "Second Merger" and, together with the First Merger, the "Acquisition"), with Second Merger Sub being the surviving entity of the Second Merger (the "Surviving Entity"). Following the Acquisition, the Company plans to focus on developing TI-168, a promising next-generation, autologous FVIII TCR-Treg cell therapy candidate to eliminate clotting factor VIII (FVIII) inhibitors in Hemophilia A patients. Following the Acquisition, the Company's principal executive offices will remain in Malvern, Pennsylvania.

TeraImmune was incorporated on April 5, 2019. Prior to the Acquisition, TeraImmune had approximately 31 stockholders. The Company has included a pro forma balance sheet reflecting the net assets acquired as if the net assets were acquired on March 31, 2023 as Annex D to this proxy statement. The estimated consideration for the Acquisition of TeraImmune was approximately $12.9 million.

Under the terms of the Merger Agreement, the Company issued to the stockholders of TeraImmune 1,212,185 shares of common stock and 27,089.719 shares of Series X Preferred Stock, which was a newly designated series of preferred stock that is intended to have economic rights equivalent to the common stock, but with limited voting rights. The rights of the Series X Preferred Stock are set forth in a Certificate of Designation of Preferences, Rights and Limitations that the Company filed with the Secretary of the Commonwealth of Pennsylvania (the "Series X Certificate of Designation") on June 30, 2023. Please see "Description of Series X Preferred Stock" under Proposal No. 1 for a complete description of the Series X Certificate of Designation and the rights of the Series X Preferred Stock.

Additionally, under the terms of the Merger Agreement, all options to purchase or acquire shares of common stock of TeraImmune, par value $0.0001 per share ("TeraImmune Common Stock") held by TeraImmune employees were assumed by the Company and converted into options to purchase shares of common stock and Series X Preferred Stock of the Company on the same terms and conditions as applied to such options immediately prior to the Mergers (but with such changes as the Company in good faith determined were necessary to reflect such assumption and conversion). At the First Effective Time (as defined below), each share of TeraImmune Common Stock outstanding immediately prior to the First Effective Time that was unvested or subject to a repurchase option or a risk of forfeiture under any applicable restricted stock purchase agreement or other similar agreement with TeraImmune (collectively, "Unvested TeraImmune Shares") was accelerated immediately prior to the effective time of the First Merger (the "First Effective Time").

Immediately following the closing of the Acquisition, on an as-converted, fully-diluted basis and excluding certain out-of-the-money warrants held by equityholders of the Company as of immediately prior to the Mergers, (i) the former stockholders of TeraImmune as of immediately prior to the Mergers owned approximately 82% of the Company's outstanding common stock and (ii) equityholders of the Company as of immediately prior to the Mergers owned approximately 18% of the Company's outstanding common stock.

Under the terms of the Merger Agreement, in connection with the closing of the Acquisition, Yong Chan Kim, Ph.D. was appointed to the Company's Board of Directors. In addition, under the terms of the Merger Agreement, if shareholder approval of the Conversion Proposal is obtained, the Company is required to use reasonable best efforts and take all necessary action so that immediately after the date on which shareholder approval of the Conversion Proposal is obtained, three individuals nominated by unanimous agreement of Gerri Henwood, the Company's President and Chief Executive Officer, and certain stockholders of TeraImmune immediately prior to the closing of the Acquisition and approved by the Nominating and Corporate Governance

Committee of the Company's Board of Directors shall be appointed to the Company's Board of Directors (provided that a sufficient number of such additional board designees shall qualify as "independent directors" to the extent necessary to ensure that the composition of the Company's Board of Directors complies with applicable SEC and Nasdaq rules).

***Conversion of Series X Preferred Stock***

Subject to shareholder approval of Proposal No. 1, each share of Series X Preferred Stock will be convertible into 1,000 shares of common stock (subject to adjustment pursuant to the Reverse Stock Split). If shareholders have not approved the conversion of the Series X Preferred Stock into common stock by December 29, 2023 (six months from the closing date of the Acquisition), then, upon any attempted conversion, holders of Series X Preferred Stock may thereafter require the Company to repurchase the Series X Preferred Stock at the then-current as-converted fair value (as such term is defined in the Series X Certificate of Designation) of the underlying common stock.

***Regulatory Approval***

No state or federal regulatory approval is required in connection with the terms of the transactions described above or under the terms of the Merger Agreement.

## BACKGROUND AND REASONS FOR THE TRANSACTIONS

In approving the Acquisition, the Board of Directors considered the pros and cons of the Acquisition versus other alternatives, including continuing to focus the Company's resources on the Company's legacy research and development pipeline, other potential business development opportunities reviewed by the Board and the opportunities and risks presented with the Acquisition in light of the Company's ongoing noncompliance with the listing standards of Nasdaq and the delisting determination made by the Nasdaq Listing Qualifications Department on June 9, 2023 (the "Delisting Determination"). In particular, the Board of Directors took into account the following events, facts and circumstances in approving the Acquisition:

- In light of the Company's limited capital resources and ongoing noncompliance with the listing standards of Nasdaq, the Board of Directors undertook an extensive process to explore strategic options intended to maximize shareholder value and bring the Company into compliance with the Nasdaq listing standards in order to permit the Company to maintain the listing of the Company's common stock on Nasdaq.
- The Board of Directors engaged financial, legal and strategic advisors to assist in the review and evaluation of strategic options, including an acquisition, merger, business combination, in-licensing, or other strategic transactions. The Board of Directors believes, after a thorough review of strategic alternatives and discussions with senior management, financial and strategic advisors and legal counsel, that the Acquisition offered the best opportunity reasonably available to the Company to preserve shareholder value and support the Company's appeal of the Delisting Determination before the Nasdaq Hearings Panel, which was scheduled for June 29, 2023. On July 24, 2023, the Nasdaq Hearings Panel notified the Company of its decision to grant the Company's request to continue its listing on Nasdaq on a conditional basis, subject to, among other things, the Company's ability to demonstrate compliance with the Nasdaq initial listing requirements by or before November 13, 2023.
- The Board of Directors believes that the structure of the Acquisition, the issuance of common stock and Series X Preferred Stock at a simultaneous sign and close of the Acquisition ("Acquisition Structure") instead of structure where our shareholders could vote to approve or disapprove of the Acquisition and the issuance of securities prior to the consummation of the Acquisition ("Traditional Structure") offered the most compelling opportunity to result in a successful appeal of the Nasdaq delisting determination and maintain the listing of the Company's common stock on Nasdaq. A Traditional Structure typically takes approximately four months to consummate and the Board of Directors believes that plan for compliance contemplated by the Acquisition Structure was more likely to obtain approval by the Nasdaq Hearings Panel at the Company's delisting appeal hearing on June 29, 2023 than a plan for compliance utilizing a Traditional Structure. Accordingly, the Board of Directors believes that if we had pursued the Traditional Structure, our plan for compliance was more likely to have been rejected by the Nasdaq Hearings Panel and the Nasdaq Hearings Panel may have been more likely to deny our appeal of the delisting action being pursued by the Nasdaq Listing Qualifications Department.
- The Board of Directors believes that, as a result of arm's length negotiations with TeraImmune, the Company and its management team negotiated the most favorable equity split for Company shareholders that TeraImmune was willing to agree to, and that the terms of the Merger Agreement include the most favorable terms to the Company in the aggregate to which TeraImmune was willing to agree.

As a result of the process to explore strategic options, in the summer of 2022, our financial advisor contacted approximately 20 companies regarding a potential transaction. The Company entered into confidentiality agreements and engaged in discussions with two such companies, but no potential transaction arose from these discussions. During the first and second quarters of 2023, members of the Company's management and its financial consultants continued reaching out to a number of potential transaction counterparties on an informal basis and entered into confidentiality agreements with five counterparties, including TeraImmune, in connection with such outreach. One of these companies, TeraImmune, executed a confidentiality agreement with the Company on June 7, 2023. After reviewing the relative merits of each of these potential strategic alternatives (taking into account speed and certainty of pursuing a transaction in light of the pending hearing before the Nasdaq Hearings Panel on June 29, 2023), and engaging in discussions with such potential counterparties,

including material discussions with three other companies, the Board of Directors determined that TeraImmune offered the greatest opportunity. Following this determination by the Company's Board of Directors, the Company's senior management and its financial, strategic and legal advisors engaged in expanded and more detailed discussions with TeraImmune.

Following the Acquisition, the Company would be better positioned to successfully appeal the delisting determination issued by the Nasdaq Listing Qualifications Department and maintain its listing on Nasdaq, providing it with enhanced opportunity to preserve shareholder value and pursue additional cash resources to fund the near-term development of the Company's legacy pipeline and the TeraImmune pipeline acquired in the Acquisition.

After giving consideration to these and other factors, the Board of Directors approved the Acquisition, which the Board of Directors believes was the best alternative reasonably available to the Company to maximize shareholder value and position the Company for long-term success.

## MATERIAL CONTRACTS ENTERED INTO AND ASSUMED IN THE ACQUISITION

***Lock-up Agreements***

Concurrently and in connection with the execution of the Merger Agreement, certain TeraImmune stockholders as of immediately prior to the Acquisition, and the directors and officers of the Company (solely in their capacity as shareholders), entered into customary lock-up agreements with the Company and TeraImmune, pursuant to which each such holder will be subject to a 180-day lock-up on the sale or transfer of shares of common stock or securities convertible into or exercisable or exchangeable for common stock held by each such holder at the closing of the Acquisition, including those shares received by TeraImmune stockholders in the Acquisition (the "Lock-up Agreements"), subject to certain customary exceptions.

The foregoing description of the Lock-up Agreements does not purport to be complete and is qualified in its entirety by reference to the form of the Lock-up Agreement, which is provided as Exhibit B to the Merger Agreement, which was filed as Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the SEC on July 5, 2023.

***Support Agreements***

In connection with the execution of the Merger Agreement, the Company and TeraImmune entered into shareholder support agreements (the "Support Agreements") with the Company's directors and officers (solely in their capacity as shareholders) as of immediately prior to the Acquisition. The Support Agreements provide that, among other things, each of the shareholders have agreed to vote or cause to be voted all of the shares of Common Stock owned by such shareholder as of the date of the Special Meeting in favor of the Conversion Proposal and the Reverse Stock Split Proposal at the Special Meeting to be held in connection therewith.

The foregoing description of the Support Agreements does not purport to be complete and is qualified in its entirety by reference to the form of the Support Agreement, which is provided as Exhibit C to the Merger Agreement, which was filed as Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the SEC on July 5, 2023.

***Forbearance Agreement***

In connection with the Acquisition, the Company entered into a Forbearance Agreement, dated as of June 29, 2023, by and among the Company, Baudax Bio N.A. LLC and Baudax Bio Limited, the lenders party thereto (the "Lenders") and Wilmington Trust, National Association (the "Forbearance Agreement"), solely in its capacity as administrative and collateral agent for the Lenders, pursuant to which the Lenders agreed to forbear their rights to exercise any rights and remedies with respect to any default under that certain Credit Agreement, dated as of May 29, 2020 (the "Credit Agreement"), resulting from the Merger, for a period of up to 30 days following the Closing. On July 30, 2023, the parties entered into Amendment No. 1 to Forbearance Agreement and Amendment No. 6 to Credit Agreement to extend such deadline until October 31, 2023 and modify certain provisions of the Credit Agreement.

The foregoing descriptions of the Forbearance Agreement and Amendment No. 1 to Forbearance Agreement and Amendment No. 6 to Credit Agreement do not purport to be complete and are qualified in their entirety by reference to the full text of the agreements, which are filed as Exhibit 10.1 to the Current Reports on Form 8-K filed with the SEC on July 5, 2023 and July 31, 2023, respectively.

***Material Agreements***

*HA FVIII TCR Agreement*

On August 5, 2019, TeraImmune entered into an exclusive worldwide license agreement (the "HA FVIII TCR Agreement") with Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. ("HJF") to utilize the licensed patent rights granted thereunder to research, design, develop, make, use, sell, distribute, exploit, improve and import the licensed products and processes covered thereby. The patent rights covered by the HA FVIII TCR Agreement include certain technologies relating to coagulation factor VIII ("FVIII") specific T cell receptors ("TCRs") or B-cell antigen receptor ("BAR") expressing Tregs, methods of producing and stabilizing FVIII specific TCR or BAR expressing Tregs, and their use in humans. HJF retains the right to grant non-exclusive licenses to the patent rights covered under the HA FVIII TCR Agreement for non-commercial and

research purposes. In addition, HJF retains the right to request that TeraImmune relinquish its exclusive rights under the HA FVIII TCR Agreement if it has not obtained U.S. Food and Drug Administration ("FDA") or other regulatory approval to a licensed product within ten years of the effective date of the HA FVIII TCR Agreement.

Pursuant to the HA FVIII TCR Agreement, TeraImmune has agreed to pay mid-single digit percent royalties on net sales (as defined therein) in jurisdictions where a valid claim with respect to the patent rights exist, and low-single digit percent royalties on net sales where no valid claim exists or where valid claims have expired. Additionally, TeraImmune agreed to pay a high-teens percentage of its non-royalty sublicense income received prior to regulatory approval of licensed product and a low-teens percentage of its non-royalty sublicense income received after regulatory approval of a licensed product, as well a minimal annual maintenance fee, which shall be credited against any royalty fees due and payable in for the calendar year relating to such maintenance fee. Further, TeraImmune is obligated to pay an aggregate of $1.3 million in milestone fees in the event such milestones are met. As of March 31, 2023, TeraImmune has paid a license royalty fee and annual royalties of $50,000 to HJF.

The HA FVIII TCR Agreement will remain in effect until the later of (a) the full end of the term or terms of certain patent rights as defined therein on a country-by-country basis or (b) 15 years from the first sale of the licensed product in a given country, whichever is longer, provided, however, that HJF may terminate the HA FVIII TCR Agreement in the event certain milestones are not met within the timeframe required by the HA FVIII TCR Agreement.

*BML Agreement*

On August 26, 2019, TeraImmune entered into the non-exclusive Biological Materials License Agreement (the "BMLA") with the National Cancer Institute ("NCI"), a part of the National Institutes of Health ("NIH"), which is part of the U.S. Government Department of Health and Human Services. Pursuant to the BMLA, TeraImmune was granted a world-wide, non-exclusive license to utilize the licensed patent rights granted thereunder to make, have made, use, sell and import autologous T cell therapy products for the treatment of Hemophilia A utilizing the pMSGV1 vector.

Pursuant to the BMLA, TeraImmune agreed to pay minimal non-refundable license, initial royalty, and annual royalty fees. Further, TeraImmune is required to pay a less than 1.0% royalty on net sales of any licensed products under the BMLA. As of March 31, 2023, TeraImmune has paid a license execution fee and annual royalties of $11,000 to NIH. The BMLA shall terminate in accordance with its terms ten years after the effective date thereof.

*HA ODN Agreement*

On June 18, 2020, TeraImmune entered into an exclusive license agreement (the "HA ODN Agreement") with the National Institute of Allergy and Infectious Diseases ("NIAID"), a part of NIH. Pursuant to the HA ODN Agreement, TeraImmune was granted a non-exclusive license to utilize the licensed patent rights granted thereunder to make, have made, use, have used, sell and have sold, offer to sell and import certain autologous T cell therapy products for the treatment of Hemophilia A for patients who have inhibitory anti-FVIII auto-antibodies in the United States.

Pursuant to the HA ODN Agreement, TeraImmune agreed to pay mid-single digit percent royalties on net sales (as defined therein) of any licensed products covered by the HA ODN Agreement. TeraImmune also agreed to a minimal non-refundable license, initial royalty, and annual royalty fees. Additionally, TeraImmune agreed to reimburse NIAID for certain patent expenses on a payment schedule that may amount in total reimbursements of up to $45,000, including expenses incurred in maintaining the patent. As of March 31, 2023, TeraImmune has reimbursed an aggregate expense of $22,000 for patent prosecution fees and paid a license royalty fee and annual royalties of $33,000 to NIAID. The HA ODN Agreement also requires the payment of up to $1.1 million in milestone payments upon the achievement of certain regulatory and commercialization milestones. The HA ODN Agreement will remain in effect until the expiration of the last to expire of certain licensed patent rights or U.S. orphan drug exclusivity, each as defined therein, provided, however, that NIAID may terminate the HA ODN Agreement in the event that certain milestones are not met within the timeframe required by the HA ODN Agreement.

*iTreg Agreement*

On November 11, 2020, TeraImmune entered into an exclusive worldwide license agreement (the "iTreg Agreement") with HJF to utilize the licensed patent rights granted thereunder to practice, research, design, develop, make, use, sell, distribute, exploit, improve and import the licensed products and processes covered thereby. The patents rights covered by the iTreg Agreement include technology related to inducable regulatory T ("iTreg") cells, methods for producing iTreg cells and their use in humans. TeraImmune agreed to take responsibility for the maintenance and prosecution of the Patent Rights (as defined therein) in consultation with HJF on all strategic global filing and prosecution decisions. HJF retains the right to grant non-exclusive licenses to the patent rights covered by the iTreg Agreement for non-commercial and research purposes. In addition, HJF retains the right to request that TeraImmune relinquish its exclusive rights under the iTreg Agreement if it has not obtained FDA or other regulatory approval to a licensed product within six years of the effective date of the iTreg Agreement.

Pursuant to the iTreg Agreement, TeraImmune has agreed to pay low-single digit percent royalties to HJF on net sales (as defined therein) of any licensed product covered thereby and a low-teens percentage on its non-royalty sublicense income. TeraImmune paid a non-refundable license fee of $25,000 to HJF in December 2020. The iTreg Agreement will remain in effect until the full end of the term or terms of certain patent rights as defined therein on a country-by-country basis, provided, however, that HJF may terminate the iTreg Agreement in the event that certain milestones are not met within the timeframe required by the iTreg Agreement.

## RISK FACTORS

### Risks Relating to Our Financial Position and Need for Additional Capital

***If we are unable to meet the initial listing standards of Nasdaq by November 13, 2023, or otherwise regain compliance with the listing standards of Nasdaq, our common stock may become delisted, which could have a material adverse effect on the liquidity of our common stock and our ability to raise capital.***

The listing standards of the Nasdaq Stock Market LLC provide, among other things, that a company, in order to qualify for continued listing, must (i) maintain shareholders' equity of at least $2,500,000 pursuant to Nasdaq Listing Rule 5550(b)(1) ("Rule 5550(b)(1)") and (ii) maintain a minimum bid price of at least $1.00 per share pursuant to Nasdaq Listing Rule 5550(a)(2) ("Rule 5550(a)(2)").

On November 18, 2022, the Nasdaq Listing Qualifications Department ("Staff") informed us that we did not comply with Rule 5550(b)(1). The Staff granted our request for an extension until May 15, 2023, to comply with Rule 5550(b)(1). On May 17, 2023, we received a delist determination letter from the Staff advising us that the Staff had determined that we did not meet the terms of such extension. We requested an appeal of the Staff's determination and submitted a hearing request to the Nasdaq Hearings Panel ("Panel"), which request stayed any delisting action by the Staff at least until the hearing process concludes and any extension granted by the Panel expires.

On June 9, 2023, we received a deficiency letter from the Staff notifying us that we are not in compliance with Rule 5550(a)(2) and because we effected two reverse stock splits over the previous two-year period with a cumulative ratio of 250 shares or more to one, we are not eligible for any compliance period specified in Nasdaq Listing Rule 5810(c)(3)(A). Our noncompliance with Rule 5550(a)(2) serves as an additional basis for delisting of our securities from the Nasdaq and the Panel will consider this matter in rendering a determination regarding the our continued listing on the Nasdaq. On June 29, 2023, our hearing with the Panel was held and we submitted our plan for compliance to the Panel. On July 24, 2023, we received a letter from the Staff ("Hearing Decision") notifying us of its decision to grant our request to continue our listing on Nasdaq on a conditional basis, subject to, among other things, our ability to demonstrate compliance with the Nasdaq initial listing requirements by or before November 13, 2023. There can be no assurance that we will meet the conditions set forth by the Staff in the Hearing Decision, or that we will be able to regain compliance with such applicable Nasdaq listing requirements.

Furthermore, we believe that our acquisition of TeraImmune will, upon shareholder approval of Proposal No. 1, be considered a "change of control" transaction under Nasdaq rules. As such, the Company must meet Nasdaq's initial listing requirements. Accordingly, the Company must meet all the requirements set forth in Nasdaq Listing Rule 5505(a) and at least one of the standards set forth in Nasdaq Listing Rule 5505(b).

The listing standards of Nasdaq Listing Rule 5505(a) require the Company to have, among other things:

- a minimum bid price that is greater than or equal to $4.00 per share;
- at least 1,000,000 unrestricted publicly held shares;
- at least 300 round-lot holders, and at least 50% of such round lot holders must each hold unrestricted securities with a market value of at least $2,500;
- at least three registered and active market makers; and
- a minimum average daily trading volume of 2,000 shares over the 30 trading day period prior to listing, with trading occurring on more than half of those 30 days, unless such security is listed on Nasdaq in connection with a firm commitment underwritten public offering of at least $4 million.

The Company must also satisfy at least one of the following Nasdaq Listing Rule 5505(b) requirements:

- shareholders' equity of at least $5 million, a market value of unrestricted publicly held shares of at least $15 million, and two years of operating history;
- a market value of listed securities of at least $50 million, shareholders' equity of at least $4 million, and a market value of unrestricted publicly held shares of at least $15 million; or
- net income from continuing operations of $750,000 in the most recently completed fiscal year or in two of the three most recently completed fiscal years, shareholders' equity of at least $4 million, and a market value of unrestricted publicly held shares of at least $5 million.

There is no assurance that we will be able to meet Nasdaq's initial listing requirements or comply with the requisite Nasdaq requirements to maintain our listing of common stock on Nasdaq. If Nasdaq delists our securities from trading on its exchange and we are not able to list our securities on Nasdaq or any other national securities exchange, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our common stock;
- reduced liquidity for our common stock;
- a determination that our common stock is a "penny stock," which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for its securities;
- a limited amount of news and analyst coverage for us;
- a decreased ability to issue additional securities or obtain additional financing in the future; and
- the incurring of additional costs under state blue sky laws in connection with any sales of our securities.

If our common stock is delisted by Nasdaq, our common stock may be eligible to trade on an over-the-counter quotation system, such as the OTCQB Market, where an investor may find it more difficult to sell our stock or obtain accurate quotations as to the market value of our common stock. In the event our common stock is delisted from Nasdaq, we may not be able to list our common stock on another national securities exchange or obtain quotation on an over-the counter quotation system.

***We are required to use reasonable best efforts to solicit shareholder approval for the conversion of our Series X Preferred Stock and if we are unable to obtain such approval by December 29, 2023 (six months from the closing date of the Acquisition), then the holders of our Series X Preferred Stock may demand cash settlement upon attempted conversions. If the holders of our Series X Preferred Stock demand this cash-settlement right, we may not have sufficient capital to fund our operations.***

Pursuant to the Merger Agreement, we are required to hold a special meeting of shareholders for the purpose of obtaining shareholder approval to allow for the conversion of our Series X Preferred Stock into common stock in accordance with Nasdaq Listing Rule 5635(a). If such shareholder approval is not received, we are required to convene additional shareholder meetings every six months thereafter until such approval is obtained, which could result in substantial costs and be a distraction to management.

Moreover, if shareholders do not approve the conversion of our Series X Preferred Stock into common stock by December 29, 2023 (six months from the closing date of the Acquisition), then the holders of our Series X Preferred Stock will have the right, in lieu of the conversion of such shares of Series X Preferred Stock into common stock, to require us to repurchase their shares of Series X Preferred Stock at the then-current fair value of the underlying common stock (determined on an as-converted basis). Failure to receive shareholder approval of the Conversion Proposal within six months from the closing of the Acquisition would have a material adverse effect on our financial position, and we could be forced to seek additional funding, which may not be available on acceptable terms or at all, or reduce or eliminate certain clinical trials, programs and operating expenses, which would adversely affect our business prospects.

***There is no guarantee that the Acquisition of TeraImmune by us will increase shareholder value or that TeraImmune will be successfully integrated into our operations or achieve its desired benefits.***

On June 29, 2023, we completed the Acquisition of TeraImmune. See *"Description of the Transactions"* and *"Background and Reasons for the Transactions."* We cannot guarantee our integration efforts as a result of the Acquisition and the related transactions will not impair shareholder value or otherwise adversely affect our business. The Acquisition poses significant integration challenges between our businesses and management teams that could result in management and business disruptions, any of which could harm our results of operation, business prospects, and impair the value of such Acquisition to our shareholders.

***Our business has incurred significant losses since our inception, and we may continue to incur significant losses for the foreseeable future. We may never achieve profitability.***

Our business has incurred operating losses due to costs incurred in connection with our research and development activities, general and administrative expenses, and commercialization expenses associated with our operations. Our net losses from continuing operations for the quarters ended March 31, 2023 and 2022 were

$7.4 million and $8.2 million, respectively. As of March 31, 2023, we had an accumulated deficit of $179.5 million. We launched ANJESO, our first commercial product, in mid-2020, but we have not generated significant revenue from sales of ANJESO, and in December 2022, we announced the discontinuation of the sale of ANJESO and are evaluating commercial partnering options for the product, including divestiture. For the years ended December 31, 2022 and 2021, net product revenue was $1.3 million and $1.1 million, respectively, related to sales of ANJESO in the U.S. Our product candidate pipeline includes early-stage product candidates, including a T cell-based immunotherapy for the treatment of Hemophilia A with inhibitors, two novel neuromuscular blocking agents ("NMBs"), and a related proprietary chemical reversal agent. If our product candidates are not successfully developed and approved, we may never generate any new revenue. All of our product candidates will require the expenditure of substantial additional development time and resources before we would be able to apply for or receive regulatory approvals and begin realizing product sales. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue our development of, seek regulatory approval for, and potentially commercialize any of our product candidates, if approved, and seek to identify, assess, acquire, in-license, or develop additional product candidates. Our prior losses, combined with expected future losses, have had and will continue to have a negative effect on our shareholders' deficit and working capital.

We expect that it will be several years, if ever, before we have a commercialized product. We anticipate that our expenses will increase substantially if, and as, we:

- continue clinical development of TI-168, BX1000 and BX2000 and preclinical development of BX3000, which is currently being evaluated in preclinical studies intended to support an IND filing in the last quarter of 2023, and our other preclinical T cell-based immunotherapies;
- seek to discover and develop additional product candidates;
- seek regulatory approvals for any of our product candidates that successfully complete clinical trials;
- maintain, expand, protect, and enforce our intellectual property portfolio;
- acquire or in-license other product candidates and technologies; and
- increase our employee headcount and related expenses to support these activities.

Because of the numerous risks and uncertainties associated with pharmaceutical product development and commercialization, we are unable to predict the timing or amount of increased expenses, and when, or if, we will be able to generate revenue or achieve or maintain profitability.

***We will need to raise additional funding to advance our product candidates, which may not be available on acceptable terms, or at all. Failure to obtain capital when needed may force us to delay, limit or terminate our product development efforts or other operations.***

Developing and commercializing pharmaceutical products and cell therapies, including conducting preclinical studies and clinical trials and ramping up commercialization and manufacturing activities, is a very time-consuming, expensive, and uncertain process that takes years to complete. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct preclinical and clinical trials of, and seek regulatory and marketing approval for, our product candidates. Even if one or more of our product candidates is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate.

Our research and development expenses increased from $0.69 million for the quarter ended March 31, 2022 to $2.9 million for the quarter ended March 31, 2023. As of March 31, 2023, we had cash, and cash equivalents of $3.8 million. In April 2023, we completed a public offering of shares of common stock, together with accompanying common stock purchase warrants, and received net proceeds of approximately $3.4 million. Based on available sources, we believe our existing cash and cash equivalents will be sufficient to fund our currently anticipated operating expenses and capital expenditures requirements into the third quarter of 2023.

Attempting to secure additional financing will divert our management from our day-to-day activities, which may impair or delay our ability to develop our product candidates. Raising funds in the current economic environment may present substantial challenges, and future financing may not be available in sufficient amounts or on acceptable terms, if at all. If we are unable to raise capital when needed or on reasonable terms, we may curtail, delay or discontinue our research or development programs or wind down our business. In addition, demands on

our cash resources may change as a result of many factors currently unknown to us including, but not limited to, any unforeseen costs we may incur as a result of preclinical study or clinical trial delays due to the COVID-19 pandemic or other pandemics, epidemics or outbreaks of a contagious illness, and we may need to seek additional funds sooner than planned. If we are unable to obtain funding on a timely basis or at all, we may be required to significantly curtail or stop one or more of our research or development programs and could have a material adverse effect on our business, operating results and prospects.

***We may be unsuccessful in obtaining a waiver or amendment to our Credit Agreement with respect to any existing events of default thereunder. The failure to obtain such a waiver or amendment, or otherwise cure any event of default under our Credit Agreement, could allow the lender to take enforcement action against the Company or certain of its assets, including accelerating the loans and other obligations under the Credit Agreement and taking any other remedial actions permitted under the Credit Agreement or applicable law, which would have a material adverse effect on our business, financial condition and results of operations and could require us to curtail or cease operations.***

On May 29, 2020, we entered into that certain Credit Agreement, as amended (the "Credit Agreement") with Wilmington Trust, National Association, as administrative and collateral agent ("Agent"), and MAM Eagle Lender, LLC, as a lender ("Lender"). In connection with the Acquisition, we entered into a Forbearance Agreement, dated as of June 29, 2023, with Agent and Lender, as amended (the "Forbearance Agreement"), pursuant to which Agent and Lender agreed to forbear form exercising their rights and remedies with respect to certain events of default under the Credit Agreement until October 31, 2023.

There can be no assurance that Agent and Lender will provide us with a waiver of any events of default or agree to amend the Credit Agreement in a timely manner, or on acceptable terms, if at all to the extent any events of default have occurred and are continuing under the Credit Agreement. If we do not obtain an amendment or waiver of such events of default under the Credit Agreement, if any future events of default occur and are continuing or if the Lenders take the position that we have not complied with the terms of the Forbearance Agreement, there can be no assurance that the Lenders will not take action to collect payment of our debt or dispose of collateral securing the obligations under the Credit Agreement, which would harm our business, financial condition and results of operations and could require us to curtail or cease operations.

***Our shareholders may experience dilution in the future.***

In the future, our shareholders' percentage ownership in the company may be diluted because of equity issuances for acquisitions, capital market transactions or otherwise, including equity awards that we plan to grant to our directors, officers and employees. Such awards will have a dilutive effect on our earnings per share, which could adversely affect the market price of our common stock. From time to time, we expect to issue stock options or other share-based awards to employees under our employee benefits plans.

In addition, our Articles authorize us to issue, without the approval of our shareholders, one or more classes or series of preferred stock having such designation, powers, preferences and relative, participating, optional and other special rights, including preferences over our common stock with respect to dividends and distributions, as our board of directors may determine. The terms of one or more classes or series of preferred stock could dilute the voting power or reduce the value of our common stock. For example, we could grant the holders of preferred stock the right to elect some number of directors in all events or on the happening of specified events or the right to veto specified transactions. Similarly, the repurchase or redemption rights or liquidation preferences we could assign to holders of preferred stock could affect the residual value of the common stock.

**Risks Relating to the Business of TeraImmune**

***Our TCR T cell platform has never been used to develop any approved, commercially viable products.***

Our platform utilizing human regulatory T cells ("Tregs") for the treatment of autoimmune diseases has not yet yielded any approved commercially viable therapeutic products, and there can be no guarantee that our product development efforts using our platform will be fruitful. We could experience safety or efficacy issues in our future clinical trials which delay or prevent the further development of our Treg-based therapies, For example, our Treg-based therapies may be shown to yield a short duration of disease remission in patients with Hemophilia A, which may in turn effect the efficacy and commercial viability of our product candidates. We intend to invest in the development of our platform, and our failure to develop approved, commercially viable products would significantly limit our business and prospects and would adversely impact the market value of our common stock.

***Our TCR Treg-based product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, require expansion of trial size, limit their commercial potential or result in significant negative consequences.***

Certain of our product candidates, including TI-168, involve genetically modified T cell-based immunotherapies. Undesirable or unacceptable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the U.S. Food and Drug Administration ("FDA") or other comparable foreign regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Approved autologous cell therapies and those under development have shown frequent rates of cytokine release syndrome and neurotoxicity, and adverse events have resulted in the death of patients. Certain of our product candidates, such as TI-168, undergo genetic engineering. As these are novel technologies, errors may occur or may not present until used in humans in the clinic, and could cause adverse events. While we believe that our manufacturing process yields Tregs that have an inherent safety profile that may limit adverse events, there can be no assurance that this is the case as these are novel therapeutics.

There is no guarantee that our Treg-based product candidates will not have side effects similar to those seen in other genetically modified cell therapies or that we will be able to prevent side effects from escalating to an unsafe level for our patients. Additionally, our initial product candidate is directed at treating patients with Hemophilia A. These patients are often have co-morbidities, and we expect they will receive our product candidate after the development of inhibitors preventing the use of other treatments for Hemophilia A, and these patients may be particularly susceptible to safety and toxicity risks. Further, these side effects may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from T cell therapy may be complicated and difficult to manage, which could result in patient death or other significant issues. Additionally, it can be difficult to determine if the serious adverse or unexpected side effects were caused by the product candidate or another factor.

Our Treg-based product candidate, including TI-168, have not been tested in humans in a clinical trial and we cannot guarantee that there will not be any unexpected side effects. Although we have completed preclinical studies designed to screen for toxicity caused by unintended off-target recognition in vivo by our novel binding domains, our product candidates may still cause unintended off-target recognition in patients. Additionally, our genetically modified T cells may still bind targets other than the target antigens. If significant unexpected binding or off-target binding occurs in normal tissue, our product candidates may target and kill the normal tissue in a patient, leading to serious and potentially fatal adverse events, undesirable side effects, toxicities or other unexpected characteristics. Detection of any significant unexpected or off-target binding may halt or delay any ongoing clinical trials for our product candidates and prevent or delay regulatory approval. While we have developed a preclinical screening process to identify cross-reactivity of our product candidates, we cannot be certain that this process will identify all potential off-target tissue that our product candidates may interact with. Any unexpected or off-target binding that impacts patient safety could materially impact our ability to advance our product candidates into clinical trials and ability to proceed to marketing approval and commercialization.

If serious adverse events or undesirable side effects arise, we could be required to suspend, delay, or halt our planned clinical trials and regulatory authorities could deny approval or require us to limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Undesirable side effects could also result in an expansion in the size of our clinical trials, increasing the expected costs and timeline of our clinical trials. Side effects that are observed during the trial, whether treatment related or not, could also affect patient recruitment for future trials or the ability of enrolled patients to complete the trial or result in potential product liability claims.

Further, if serious adverse events or undesirable side effects are identified during development or after approval and are determined to be attributed to any of our product candidates, we may be required to develop risk evaluation and mitigation strategies to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry.

Any of these occurrences may harm our business, financial condition and prospects significantly.

***We currently store our T cells and research specimens at our research and development facilities and at the facilities of our clinical and/or manufacturing partners, and any damage or loss to our storage freezers and/or facilities from natural disasters or otherwise would cause delays in replacement, and our business could suffer.***

Specimens are stored in our freezers at our research and development facilities. If these cells are damaged, including by the loss or malfunction of our freezers or our back-up power systems, as well as by damage from fire or other natural disasters, our development program could be delayed or terminated and our business could suffer. Loss of a significant supply would require manufacturing of additional vector which could cause us to incur significant additional expenses and liability.

***We will rely on third-party healthcare professionals to administer our T cell-based product candidates to patients, and our business could be harmed if these third parties administer these cells incorrectly.***

We will rely on the expertise of physicians, nurses and other associated medical personnel to administer our T cell-based product candidates to clinical trial patients. If these medical personnel are not properly trained to administer, or do not properly administer, our product candidates, the therapeutic effect of our product candidates may be diminished or the patient may suffer injury.

In addition, third-party medical personnel will have to be trained on proper methodology for thawing Tregs received from us. If this thawing is not performed correctly, the cells may become damaged and/or the patient may suffer injury. While we intend to provide training materials and other resources to these third-party medical personnel, the thawing of Tregs will occur outside our supervision and may not be administered properly. If, due to a third-party error, people believe that Tregs are ineffective or harmful, the desire to use Tregs may decline, which would negatively impact our business, reputation and prospects. We may also face significant liability even though we may not be responsible for the actions of these third parties.

***We believe we may require an updated and validated protocol for commercial-scale expansion and manufacturing of our product candidates for conducting pivotal trials and for commercialization of our product candidates, if approved.***

Future clinical trials that we conduct, as well as any potential commercialization of our product candidates when approved, will depend on the reliability, safety and efficacy of our protocols for manufacturing our product candidates at scale. Our efforts to scale up production of our product candidates in anticipation of future clinical trials or commercialization may reveal, an inability to overcome biology or may otherwise encounter challenges, including scrutiny from regulatory authorities. To the extent we encounter any such difficulties, our ability to conduct additional clinical trials or to scale for commercialization will be hindered or prevented, which would have an adverse effect on our business.

***We have not yet developed commercial-scale infrastructure for freezing and thawing large quantities of Tregs, which we believe will be required for the storage and distribution of our T cell-based product candidates at commercial scale.***

We have not demonstrated that Tregs can be frozen and thawed in large commercial-scale quantities without damage, in a cost-efficient manner and without degradation over long periods of time. We may encounter difficulties not only in developing freezing and thawing, but also in obtaining the necessary regulatory approvals for using such in treatment. If we cannot adequately demonstrate similarity of our frozen product to the unfrozen form to the satisfaction of the FDA, we could face substantial delays in our regulatory approvals. If we are unable to freeze Tregs for shipping purposes, our ability to promote adoption and standardization of our products, as well as achieve economies of scale by centralizing our production facility, will be limited. Even if we are able to successfully freeze and thaw Tregs in large quantities, we will still need to develop a cost-effective and reliable distribution and logistics network, which we may be unable to accomplish. For these and other reasons, we may not be able to commercialize Tregs on a large scale or in a cost-effective manner.

***Cell therapies are novel and present significant challenges.***

T cell-based product candidates represent a relatively new field for treatment of autoimmune disorders. Advancing this novel and personalized therapy creates significant challenges, including:

- obtaining regulatory approval, as the FDA and other regulatory authorities have limited experience with commercial development of cell therapies for autoimmune diseases;

- sourcing clinical and, if approved, commercial supplies for the materials used to manufacture and process our product candidates;
- developing a consistent and reliable process, while limiting contamination risks, for engineering and manufacturing T cells ex vivo and infusing the engineered cells into the patient;
- educating medical personnel regarding the potential safety benefits, as well as the challenges, of incorporating our product candidates into their treatment regimens;
- establishing sales and marketing capabilities upon obtaining any regulatory approval to gain market acceptance of a novel therapy; and
- the availability of coverage and adequate reimbursement from third-party payors for our novel and personalized therapy.

***Public opinion and scrutiny of cell-based immunotherapy and genetic modification approaches may impact public perception of our company and T cell-based product candidates, or may adversely affect our ability to conduct our business and our business plans.***

Our T cell-based product candidates utilize a relatively novel technology involving the genetic modification of human cells and utilization of those modified cells in humans. Public perception may be influenced by negative claims about our platform, or that of competitor's products and/or programs such as claims that cell-based immunotherapy is unsafe, unethical, expensive or immoral and, consequently, our approach may not gain the acceptance of the public or the medical community. Negative public reaction to cell-based immunotherapy in general and a recent increase in patient deaths and clinical holds by other companies could result in greater government regulation and stricter labeling requirements of cell-based immunotherapy products, including any of our product candidates, and could cause a decrease in the demand for any products we may develop. Negative public attitudes may adversely impact our ability to enroll patients in clinical trials. Moreover, our success will depend upon physicians specializing in the treatment of those diseases that our product candidates target prescribing, and their patients being willing to receive, treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments they are already familiar with and for which greater clinical data may be available. More restrictive government regulations or negative public opinion could have an adverse effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop. Adverse events in our clinical trials, even if not ultimately attributable to our product candidates, and the resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our potential product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates.

***We may rely on orphan drug status to develop and commercialize certain of our product candidates, but orphan drug designations may not confer marketing exclusivity or other expected commercial benefits and we may not be able to obtain orphan drug designations for our other product candidates.***

We may rely on orphan drug exclusivity for product candidates that we may develop. Orphan drug status confers seven years of marketing exclusivity in the United States under the Federal Food, Drug, and Cosmetic Act ("FDCA"), and up to ten years of marketing exclusivity in Europe for a particular product in a specified indication, subject to certain conditions. However, we may be unable to obtain orphan drug designations for any of our product candidates that we are currently developing or may pursue. Even if we do obtain orphan drug designations and are the first to obtain marketing approval of our product candidates for the applicable indications, we will not be able to rely on these designations to exclude other companies from manufacturing or selling biological products using the same principal molecular structural features for the same indication beyond these timeframes. Furthermore, any marketing exclusivity in Europe can be reduced from ten years to six years if the initial designation criteria have significantly changed since the market authorization of the orphan product.

For any product candidate for which we may be granted orphan drug designation in a particular indication, it is possible that another company also holding orphan drug designation for the same product candidate will receive marketing approval for the same indication before we do. If that were to happen, our applications for that indication may not be approved until the competing company's period of exclusivity expires. Even if we are the first to obtain marketing authorization for an orphan drug indication in the United States, there are circumstances

under which a competing product may be approved for the same indication during the seven-year period of marketing exclusivity, such as if the later product is shown to be clinically superior to our orphan product, or if the later product is deemed a different product than ours. Further, the seven-year marketing exclusivity would not prevent competitors from obtaining approval of the same product candidate as ours for indications other than those in which we have been granted orphan drug designation, or for the use of other types of products in the same indications as our orphan product.

***Because the target patient population for TI-168 and certain of our other potential product candidates is relatively small, we must achieve significant market share and maintain high per-patient prices for our products to achieve and maintain profitability.***

Certain of our Treg-based product candidates, including TI-168, target diseases with relatively small patient populations. As a result, our per-patient prices must be relatively high in order to recover our development and manufacturing costs and achieve and maintain profitability. In addition, because the number of potential patients in each disease population is small, it is not only important to find patients who begin therapy to achieve significant market penetration of the product, but we also need to be able to maintain these patients on therapy for an extended period of time. Due to the expected costs of treatment for our Treg-based product candidates, we may be unable to maintain or obtain sufficient market share at a price high enough to justify our product development efforts and manufacturing expenses.

***Cell-based therapies rely on the availability of specialty raw materials, which may not be available to us on acceptable terms or at all.***

Our Treg-based product candidates require many specialty raw materials, some of which are manufactured by small companies with limited resources and experience to support a commercial therapeutic, or to deliver raw materials to our specifications. The suppliers may be ill-equipped to support the manufacturing of our product candidates, especially in non-routine circumstances like an FDA inspection or medical crisis, such as widespread contamination. We generally do not have dedicated supply contracts with many of our suppliers, and we may not be able to contract with them on acceptable terms, or at all. Further, some of our suppliers may not be able to scale-up as we move to clinical trials or commercialization. Accordingly, we may experience delays in receiving, or fail to secure entirely, key raw materials to support clinical or commercial manufacturing. Certain raw materials also require third-party testing, and some of the testing service companies may not have capacity or be able to conduct the testing that we request.

We also face competition for supplies from other Treg-focused companies. Such competition may make it difficult for us to secure raw materials or the testing of such materials on commercially reasonable terms or in a timely manner.

Some raw materials are currently available from a single supplier, or a small number of suppliers. We cannot be sure that these suppliers will remain in business or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose. In addition, the lead time needed to establish a relationship with a new supplier can be lengthy, and we may experience delays in meeting demand in the event we must switch to a new supplier. The time and effort to qualify a new supplier, including to meet any regulatory requirements for such qualification, could result in additional costs, diversion of resources or reduced manufacturing yields, any of which would negatively impact our operating results. Further, we may be unable to enter into agreements with a new supplier on commercially reasonable terms, which could have a material adverse impact on our business.

**Risks Relating to Our Intellectual Property**

***We own or license numerous pending patent applications and issued patents in the United States. If our pending patent applications fail to issue or if our issued patents are not sufficiently broad, expire or are successfully opposed, invalidated, or rendered unenforceable, our business will be adversely affected.***

Our commercial success will depend in part on obtaining and maintaining patent protection for our product candidates, as well as successfully defending our current and future patents against third-party challenges. To protect our proprietary technology, we intend to rely on patents, and we may also rely on other intellectual property protections, including trade secrets, nondisclosure agreements and confidentiality provisions.

There can be no assurance that our pending patent applications will result in issued patents. The patent applications that we have filed and have not yet been granted may fail to result in issued patents in the United

States or foreign countries. Even if the patents do successfully issue, third parties may challenge the patents or the inventorship thereof, which can lead to an issued patent being found invalid, unenforceable or can otherwise alter the ownership of the patents.

The issuance of any patent is not a certainty. Unless and until our pending applications issue, their protective scope is impossible to determine. It is impossible to predict whether or how many of these applications will result in issued patents and patents that issue may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of patent exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which may limit our ability to prevent others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. In addition, upon expiration of a patent, we may be limited in our ability to prevent others from using or commercializing subject matter covered by the expired patents. 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. The patent position of biotechnology and pharmaceutical companies, including us, generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. 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 the first filing, or in some cases at all. Therefore, we cannot know with certainty whether we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. In addition, we may not be aware of particular prior art publications that may have an impact on patentability or enforceability. Further, the examination process may require us or our licensors to narrow the claims for our pending patent applications due to, for example, such prior art publications, which may limit the scope of patent protection that may be obtained if these applications issue. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Furthermore, our pending applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we own or have licensed from third parties may be challenged in the courts or patent offices in the U.S. and abroad. Such challenges may result in the loss of patent protection, the narrowing of claims in such patents, and/or the invalidity or unenforceability of such patents, 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 for our technology and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of patents or narrow the scope of patent protection.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. The Leahy Smith America Invents Act (the “Leahy Smith Act”) enacted in September 2011, brought significant changes to the U.S. patent system. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The United States Patent Office continues to develop and implement 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 became effective on March 16, 2013. The Leahy Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patent, all of which could have a material adverse effect on our business and financial condition.

We exclusively license from Cornell University issued patents in the U.S. and other major foreign markets directed to BX1000 that expire in 2027, subject to any applicable disclaimer or extension, along with a pending PCT application directed to certain methods of using BX1000 that, if issued, would expire in 2041, subject to any applicable disclaimer or extension. We also exclusively license from Cornell University issued patents in the U.S. and other major foreign markets directed to BX2000 that expire in 2033, subject to any applicable disclaimer or extension, along with a pending PCT application directed to certain methods of using BX2000 that, if issued, would expire in 2041, subject to any applicable disclaimer or extension. We exclusively license from

the National Institutes of Health ("NIH") issued U.S. patents covering methods of producing a population of cells having stable, regulatory T cells and cell culture compositions containing isolated human regulatory T cells, antibodies and an oligonucleotide that expire in 2033 subject to any applicable disclaimer or extensions. We also exclusively license from Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. ("HJF") issued patents in the U.S. and a pending European patent application relating to methods of producing and stabilizing T cell populations enriched for regulatory T cells and cell culture compositions that expire in 2034 subject to any applicable disclaimer or extension. We also exclusively license from HJF a family of pending U.S. and foreign patent applications directed to immunosuppressive induced regulatory T cells and methods of producing these cells which if issued would expire in 2041 subject to any applicable disclaimer or extensions. With respect to intranasal dexmedetomidine, we own issued patents in the U.S. and certain major foreign markets that expire in 2032, subject to any disclaimers or extensions.

***If we are unable to obtain and maintain trade secret or patent protection for any of our current product candidates and future product candidates or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.***

We rely, and will continue to rely, upon a combination of patents, trademarks, trade secret protection and confidentiality agreements with employees, consultants, collaborators, advisors and other third parties to protect the intellectual property related to our brand, current and future drug development programs and product candidates. Our success depends in large part on our ability to obtain and maintain patent protection in the U.S. and other countries with respect to our current product candidates and any future product candidates and their uses. We seek to protect our proprietary position by filing patent applications in the U.S. and abroad in the licensed territory related to our current and future drug development programs and product candidates, successfully defending our intellectual property rights against third-party challenges and successfully enforcing our intellectual property rights to prevent third-party infringement. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We may choose not to seek patent protection for certain innovations or products and may choose not to pursue patent protection in certain jurisdictions and under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope and, in any event, any patent protection we obtain may be limited. We generally apply for patents in those countries in the licensed territory where we intend to make, have made, use, offer for sale or sell products and where we assess the risk of infringement to justify the cost of seeking patent protection. However, we do not seek protection in all countries where we intend to sell products and we may not accurately predict all the countries where patent protection would ultimately be desirable. If we fail to timely file a patent application in any such country or major market, we may be precluded from doing so at a later date. We may also make statements to regulatory authorities during the regulatory approval process that may be inconsistent with positions that have been taken during prosecution of our patents, which may result in such patents being narrowed, invalidated or held unenforceable.

The patent applications that we in-license in the U.S. or in other foreign countries may fail to result in issued patents with claims that protect our product candidates or result in patents that are narrowed, invalidated or held unenforceable following challenge in certain jurisdictions. We cannot guarantee any current or future patents will provide us with any meaningful protection or competitive advantage. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application or be used to invalidate an issued patent. The examination process may require us to narrow our claims, which may limit the scope of any patent protection we obtain. Even if patents do successfully issue based on our patent applications and even if such patents cover our product candidates, uses of our product candidates or other aspects related to our product candidates, third parties may challenge their validity, ownership, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable or circumvented, any of which could limit our ability to prevent competitors and other third parties from developing and marketing similar products or limit the length of terms of patent protection we may have for our product candidates, if approved, and technologies. Other companies may also design around our patents. Third parties may have blocking patents that could prevent us from marketing our product candidates, if approved, or practicing our own patented technology. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate while under patent protection could be reduced. If any of our patents expire or are challenged, invalidated, circumvented or

otherwise limited by third parties prior to the commercialization of our product candidates and if we do not own or have exclusive rights to other enforceable patents protecting our product candidates, competitors and other third parties could market products that are substantially similar to ours and our business would suffer.

If the patent applications we hold or have in-licensed with respect to our development programs and our product candidates fail to issue, if their breadth or strength of protection is threatened or if they fail to provide meaningful exclusivity for our product candidate, TI-168, it could dissuade companies from collaborating with us to develop our product candidates and threaten our ability to commercialize future drugs. Any such outcome could have an adverse effect on our business. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such application.

The patent position of biotechnology and pharmaceutical companies is generally highly uncertain, involves complex legal, scientific and factual questions, and has in recent years been the subject of much litigation. The standards that the U.S. Patent and Trademark Office ("USPTO") and its foreign counterparts use to grant patents are not always applied predictably or uniformly. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions.

Patent reform legislation in the U.S. could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. For example, the Leahy Smith Act was signed into law in 2011 and includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. 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 party review, and derivation proceedings. After March 2013, under the Leahy Smith Act, the U.S. transitioned to a first inventor to file system in which, assuming that the other statutory requirements 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.

Publications of discoveries in scientific literature often lag behind the actual discoveries and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not until a patent issues. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect current product candidates or any future product candidates, in whole or in part, or which effectively prevent others from commercializing competitive products. Changes in either the patent laws or interpretation of the patent laws in the U.S. and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in opposition, derivation, reexamination inter partes review, post-grant review or interference proceedings challenging our owned or licensed patent rights. 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 current product candidates or any future product candidates 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. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current product candidates or any future product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices, both in the U.S. and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical products or limit the duration of the patent protection of our products. Moreover, patents have a limited lifespan. In the U.S., 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. In certain instances, the patent term may be

adjusted to add additional days to compensate for delays incurred by the USPTO in issuing the patent. Also, the patent term may be extended for a period of time to compensate for at least a portion of the time a product candidate was undergoing FDA regulatory review. However, the life of a patent, and the protection it affords, is limited. Without patent protection for current product candidates or any future product candidates, we may be open to competition from generic versions of such products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

Filing, prosecuting and defending patents on current product candidates or any future product candidates in all countries throughout the world would be prohibitively expensive and even in countries where we have sought protection for our intellectual property, such protection may be less extensive than that provided in the U.S. The requirements for patentability may differ in certain countries, particularly developing countries and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some foreign countries do not protect patent rights to the same extent as federal laws in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S. or from selling or importing products made using our inventions in certain jurisdictions. Competitors may exploit our inventions in jurisdictions where we have not obtained patent protection to develop their own products and may also export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the U.S. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

We do not have patent rights in certain foreign countries in which a market may exist. Moreover, in foreign jurisdictions where we may obtain patent rights, proceedings to enforce such rights 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. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, 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, could put 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. Thus, we may not be able to stop a competitor from marketing and selling in foreign countries products and services that are the same as or similar to our products and services and our competitive position in the international market would be harmed.

Many countries, including E.U. countries have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. 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.

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

Patents have a limited lifespan. In the U.S., 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. In certain instances, the patent term may be adjusted to add additional days to compensate for delays incurred by the USPTO in issuing the patent. Also, the patent term may be extended for a period of time to compensate for at least a portion of the time a product candidate was undergoing FDA regulatory review. However, 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, we may be open to competition from competitive products, including generics or biosimilars. Given the amount

of time required for the development, testing and regulatory review of any new product candidate, patents protecting such candidates might expire before or shortly after such candidates are commercialized. 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.

***If we are not able to obtain patent term extension in the U.S. under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity for our current product candidates or future product candidates that we may identify, our business may be harmed.***

Our commercial success will largely depend on our ability to obtain and maintain patent and other intellectual property rights in the U.S. and other countries with respect to our proprietary technology, product candidates and our target indications. Our issued patents directed to our various product and product candidates expire between 2024 to 2041. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after such candidates begin to be commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents.

Depending upon the timing, duration and specifics of FDA marketing approval of our current product candidates or other product candidates that we may identify, one of the U.S. patents covering each of such product candidates or the use thereof may be eligible for up to five years of patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"). The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA approved product as compensation for the patent term lost during the FDA premarket regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension also may be available in certain foreign countries, including the E.U., upon regulatory approval of our product candidates, based on similar legislation. Nevertheless, we may not be granted patent term extension either in the U.S. or in any foreign country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request.

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 will have the right to exclusively market our product may be shortened and our competitors may obtain approval to market competing products sooner and our revenue could be reduced, possibly materially.

It is possible that we will not obtain patent term extension under the Hatch-Waxman Act for a U.S. patent covering our current product candidates or other product candidates that we may identify even where that patent is eligible for patent term extension or if we obtain such an extension, it may be for a shorter period than we had sought. Further, for patents we may later in-license or jointly own, we may not have the right to control patent prosecution, including filing with the USPTO a petition for patent term extension under the Hatch-Waxman Act. Thus, if one of these patents was eligible for patent term extension under the Hatch-Waxman Act, we might not be able to control whether a petition to obtain a patent term extension would be filed or obtained from the USPTO.

***Generic competitors can challenge the U.S. patents protecting our product candidates by filing an ANDA or 505(b)(2) NDA for a generic or a modified version of our product candidates or seek abbreviated approval for biological products that are biosimilar to or interchangeable with biologic product candidates and negatively affect our competitive position.***

Separate and apart from the protection provided under the U.S. patent laws, drug candidates may be subject to the provisions of the Hatch-Waxman Act, which may provide drug candidates with either a three- or five-year period of marketing exclusivity following receipt of FDA approval. The Hatch-Waxman Act prohibits the FDA from accepting the filing of an abbreviated new drug application ("ANDA") (for a generic product) or a new drug application ("NDA") under Section 505(b)(2) of the FDCA ("Section 505(b)(2) NDA") (for a modified version of the product) for three years for active drug ingredients previously approved by the FDA or for five years for active drug ingredients not previously approved by the FDA.

There is an exception, however, for newly approved molecules that allows competitors to challenge a patent beginning four years into the five-year exclusivity period by alleging that one or more of the patents listed in the FDA's list of approved drug products are invalid, unenforceable and/or not infringed and submitting an ANDA for a generic version of a drug candidate. This patent challenge is commonly known as a Paragraph IV certification. If we have an Orange Book listed patent and a third party submits a Paragraph IV certification to the FDA, a notice of the Paragraph IV certification must also be sent to us once the third party's ANDA is accepted for filing by the FDA. We may then initiate a patent infringement lawsuit within 45 days of receipt of the notice and we will be entitled to a 30 month stay running from the end of the 5-year new chemical entity ("NCE") exclusivity period. If we do not file a patent infringement lawsuit within the required 45-day period, the third party's ANDA or 505(b)(2) NDA will not be subject to the 30-month stay and the FDA could approve the ANDA or 505(b)(2) NDA after expiration of any applicable marketing exclusivity, such as the 5-year NCE exclusivity period or 3-year clinical investigation exclusivity. Within the past several years, the generic industry has aggressively pursued approvals of generic versions of innovator drugs at the earliest possible point in time.

If a generic company is able to successfully challenge the patents covering drug candidates or design around our patents and obtain FDA approval for an ANDA or 505(b)(2) NDA, the generic company may choose to launch a generic or modified version of our drug candidate. Any launch of a generic or modified version of our drug candidates prior to the expiration of patent protection will have a material adverse effect on our revenues and our results of operations.

Our product candidates for which we intend to seek approval as a biological product may face competition sooner than anticipated. In the U.S., the Biologics Price Competition and Innovation Act ("BPCIA") created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. New biologics, TI-168, may be entitled to regulatory exclusivity under the BPCIA. The BPCIA grants new biologics 12 years of FDA-granted exclusivity from the date of FDA's licensure of the biologic. Further, under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. During the period of exclusivity, however, another company may still market a competing version of the reference product if the FDA approves a full Biologics License Application ("BLA") for the competing product containing the sponsor's own clinical data from adequate and well controlled clinical trials to demonstrate the safety, purity and potency of their product. After the expiration of the exclusivity period, the FDA can approve a biosimilar product through an abbreviated approval process. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty.

For biologics subject to approval by the FDA via a BLA, TI-168, the BPCIA provides a mechanism for one or more third parties to seek FDA approval to manufacture or sell a biosimilar or interchangeable versions of brand name biological products. Due to the large size and complexity of biological products as compared to small molecules, a biosimilar must be "highly similar" to the reference product with "no clinically meaningful differences between the two." The BPCIA, requires a formal pre-litigation process which includes the exchange of information between a biosimilar applicant and a reference biologic sponsor that includes the identification of relevant patents and each parties' basis for infringement and invalidity. After the exchange of this information, we may then initiate a lawsuit within 30 days to defend the patents identified in the exchange. If the biosimilar applicant successfully challenges the asserted patent claims it could result in the invalidation of or render unenforceable some or all of the relevant patent claims or result in a finding of non-infringement. Such litigation or other proceedings to enforce or defend intellectual property rights are often very complex in nature, may be very expensive and time-consuming, may divert our management's attention from our core business and may result in unfavorable results that could limit our ability to prevent third parties from competing with TI-168 or any future product candidates.

We believe that TI-168 should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

***Outside of the United States we cannot be certain that any country's patent or trademark office will not implement new rules that could seriously affect how we draft, file, prosecute and maintain patents, trademarks and patent and trademark applications.***

We cannot be certain that the patent or trademark offices of countries outside the United States will not implement new rules that increase costs for drafting, filing, prosecuting and maintaining patents, trademarks and patent and trademark applications or that any such new rules will not restrict our ability to file for patent or trademark protection. For example, we may elect not to seek patent protection in some jurisdictions or for some drug candidates in order to save costs. We may be forced to abandon or return the rights to specific patents due to a lack of financial resources.

For example, following the result of a referendum in 2016, the U.K. left the EU on January 31, 2020, commonly referred to as Brexit. The impact of the withdrawal of the U.K. from the EU will not be known for some time, which could lead to a period of uncertainty relating to our ability to obtain and maintain patents and trademarks in the U.K. In 2012, the European Patent Package ("EU Patent Package") regulations were passed with the goal of providing for a single pan-European Unitary Patent, and a new European Unified Patent Court ("UPC") for litigation of European patents. It is possible that implementation of the EU Patent Package will occur in the first half of 2023. If the EU Patent Package is ratified and in effect, all European patents, including those issued prior to ratification, would by default automatically fall under the jurisdiction of the UPC and allow for the possibility of obtaining pan-European injunctions. Under the EU Patent Package as currently proposed, once the UPC is established, patent holders are permitted to "opt out" of the UPC on a patent-by-patent basis during an initial seven year period after the EU Patent Package is ratified. Owners of traditional European patent applications who receive notice of grant after the EU Patent Package is ratified could either accept a Unitary Patent or validate the patent nationally and file an opt-out demand. The EU Patent Package may increase the uncertainties and costs surrounding the enforcement or defense of our issued European patents and pending applications. The full impact on future European patent filing strategy and the enforcement or defense of our issued European patents in member states and/or the UPC is not known.

***The validity, scope and enforceability of any patents that cover our current or future product candidates can be challenged by third parties.***

As an alternate path to FDA approval, particularly for modifications to drug products previously approved by the FDA, an applicant may submit a Section 505(b)(2) NDA. Section 505(b)(2) was enacted as part of the Hatch-Waxman Act and it permits approval of applications other than those for duplicate products and permits reliance for such approvals on literature or on the FDA's findings of safety and effectiveness of an approved drug product. To the extent that a Section 505(b)(2) NDA relies on clinical trials conducted for a previously approved drug product or the FDA's prior findings of safety and effectiveness for a previously approved drug product, the Section 505(b)(2) applicant must submit patent certifications in its application with respect to any patents for the reference product that are listed in the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book. Specifically, the applicant must certify for each listed patent that, in relevant part, (1) the required patent information has not been filed; (2) the listed patent has expired; (3) the listed patent has not expired but will expire on a particular date and approval is not sought until after patent expiration; or (4) the listed patent is invalid, unenforceable or will not be infringed by the proposed new product. A certification that the new product will not infringe the previously approved product's listed patent or that such patent is invalid or unenforceable is known as a Paragraph IV certification. If the applicant does not challenge one or more listed patents through a Paragraph IV certification, the FDA will not approve the Section 505(b)(2) NDA until all the listed patents claiming the referenced product have expired. Further, the FDA will also not approve a Section 505(b)(2) NDA until any non-patent exclusivity, such as, for example, five-year exclusivity for obtaining approval of a new chemical entity, three-year exclusivity for an approval based on new clinical trials, or pediatric exclusivity, listed in the Orange Book for the reference product, has expired. If the Section 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the owner of the reference product and relevant patent holders within 20 days after the Section 505(b)(2) NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement suit against the Section 505(b)(2) applicant. Under the FDCA, the filing of a patent infringement lawsuit within 45 days of receipt of the notification regarding a Paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA for 30 months, beginning on the date the patent holder receives notice, or until the patent expires or a court deems the patent unenforceable, invalid or not infringed, whichever is earlier. Even if a patent infringement claim is not

brought within the 45-day period, a patent infringement claim may be brought under traditional patent law, but it does not invoke the 30-month stay. Moreover, in cases where a Section 505(b)(2) application containing a Paragraph IV certification is submitted after the fourth year of a previously approved drug's five-year exclusivity period, and the patent holder brings suit within 45 days of notice of certification, the 30-month period is automatically extended to prevent approval of the Section 505(b)(2) application until the date that is seven and one-half years after approval of the previously approved reference product. The court also has the ability to shorten or lengthen either the 30-month or the seven and one-half year period if either party is found not to be reasonably cooperating in expediting the litigation. Thus, the Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its product only to be subject to significant delay and patent litigation before its product may be commercialized. Alternatively, if the NDA applicant or relevant patent holder does not file a patent infringement lawsuit within the specified 45-day period, the FDA may approve the Section 505(b)(2) application at any time, assuming the application is otherwise approvable.

For biologics subject to approval by the FDA via a BLA, such as TI-168, the BPCIA provides a mechanism for one or more third parties to seek FDA approval to manufacture or sell a biosimilar or interchangeable versions of brand name biological products. Due to the large size and complexity of biological products as compared to small molecules, a biosimilar must be "highly similar" to the reference product with "no clinically meaningful differences between the two." The BPCIA, requires a formal pre-litigation process which includes the exchange of information between a biosimilar applicant and a reference biologic sponsor that includes the identification of relevant patents and each parties' basis for infringement and invalidity. After the exchange of this information, we may then initiate a lawsuit within 30 days to defend the patents identified in the exchange. If the biosimilar applicant successfully challenges the asserted patent claims it could result in the invalidation of or render unenforceable some or all of the relevant patent claims or result in a finding of non-infringement. Such litigation or other proceedings to enforce or defend intellectual property rights are often very complex in nature, may be very expensive and time-consuming, may divert our management's attention from our core business and may result in unfavorable results that could limit our ability to prevent third parties from competing with TI-168 or any future product candidates.

***If we are unable to maintain our licensed agreements with third parties, our business may be materially harmed.***

We have licensed certain intellectual property rights, including certain intellectual property rights covering our product candidates, from Cornell University, NIH and HJF. We are dependent on the Cornell University, NIH and HJF agreements for the development, manufacture and commercialization of our product candidates. If, for any reason, our licenses with Cornell University, NIH and/or HJF are terminated or we otherwise lose those rights, it could adversely affect our business. The Cornell University, NIH and HJF license agreements impose, and any future collaboration agreements or license agreements we enter into are likely to impose, various development, commercialization, funding, milestone payment, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and Cornell University, NIH and HJF, as the licensors, may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology or having to negotiate new or reinstated licenses on less favorable terms or enable a competitor to gain access to the licensed technology. Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our third-party relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us as well as our partners; and
- the priority of invention of patented technology.

In addition, the agreement under which we currently license intellectual property from NIH and HJF is complex, and certain provisions in the agreement may be susceptible to multiple interpretations. The resolution of any contract

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

***Obtaining and maintaining our 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 for noncompliance with these requirements.***

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and fee payment during the life of a patent. 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 noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, nonpayment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our current product candidates or any of our future product candidates, our competitors might be able to enter the market earlier than anticipated, which would have an adverse effect on our business.

***We may need to license intellectual property from third parties and such licenses may not be available or may not be available on commercially reasonable terms.***

A third party may hold intellectual property, including patent rights that are important or necessary to the development of any of our product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our current product candidates or any future product candidates, in which case we would be required to obtain a license from these third parties on commercially reasonable terms. Such a license may not be available, or it may not be available on commercially reasonable terms. Our business would be harmed if we are not able to obtain such a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology.

The risks described elsewhere pertaining to our intellectual property rights also apply to the intellectual property rights that we in-license and any failure by us or our licensors to obtain, maintain, defend and enforce these rights could have an adverse effect on our business. In some cases, we may not have control over the prosecution, maintenance or enforcement of the patents that we license and may not have sufficient ability to provide input into the patent prosecution, maintenance and defense process with respect to such patents and our licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain, defend and enforce the licensed patents.

***Third-party claims or litigation alleging infringement of patents or other proprietary rights may delay or prevent the development and commercialization of our product candidates.***

Our commercial success depends in part on our ability to operate while avoiding infringement and other violations of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. There is a substantial amount of litigation, both within and outside the U.S., involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation and administrative law proceedings, inter partes review and post grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. Our competitors in both the U.S. and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for or obtain, patents that will prevent, limit or otherwise

interfere with our ability to make, use and sell, if approved, our product candidate. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization.

There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents or until such patents expire. Similarly, if any third-party patent was to be held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

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

Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers, cause product shipment delays or prohibit us from manufacturing, importing, marketing or otherwise commercializing our product candidates or any future product candidates. Any uncertainties resulting from the initiation and continuation of any litigation could have an adverse effect on our ability to raise additional funds or otherwise have an adverse effect on our business, results of operation, financial condition or cash flows.

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. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, which could have an adverse effect on the price of shares of our common stock. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of shares of our common stock. The occurrence of any of these events may have an adverse effect on our business, results of operation, financial condition or cash flows.

We cannot provide any assurances that third-party patents do not exist which might be enforced against our product candidates or any future product candidates, resulting in either an injunction prohibiting our sales or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third parties.

***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 or any future 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 application in the U.S. and abroad that is or may be relevant to or necessary for the commercialization of our product candidates or any future product candidates in any jurisdiction. Patent applications in the U.S. and elsewhere are not published until 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. In addition, 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 U.S. remain confidential until patents issue. Therefore, patent applications covering our product candidates or any future product candidates could have been filed by others 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 any future product candidates, including the use thereof, provided such pending patent applications result in issued patents, our ability to develop and market our product candidates or any future product candidates can be adversely affected in jurisdictions where such patents issue.

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 candidate, if approved. We may incorrectly determine that our applicable product candidate is 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 U.S. or abroad that we consider relevant may be incorrect, and our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates or any future product candidates, if approved.

If we fail to identify and correctly interpret 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, we may be temporarily or permanently prohibited from commercializing any of our products that are held to be infringing. We might, if possible, also be forced to redesign products 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.

***We may become involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time consuming and unsuccessful.***

Competitors may infringe or otherwise violate our patents, the patents of our licensors or misappropriate or violate our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement or misappropriation proceeding, a court may decide that a patent or trade secret of ours or our licensors is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. The standards that courts use to interpret patents are not always applied predictably or uniformly and can change, particularly as new technologies develop. As a result, we cannot predict with certainty how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court. Further, even if we prevail against an infringer in U.S. district court, there is always the risk that the infringer will file an appeal and the district court judgment will be overturned at the appeals court and/or that an adverse decision will be issued by the appeals court relating to the validity or enforceability of our patents.

An adverse result in any litigation or defense proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly in a manner insufficient to achieve our business objectives or could put our

patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the U.S., 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 lack of written description or statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO or made a materially misleading statement during prosecution.

Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, inter partes review, or post-grant review, or oppositions or similar proceedings outside the U.S., in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. For patents and patent applications that we may in-license, we may have a limited right or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current product candidates or any future product candidates. Such a loss of patent protection could harm our business.

We may not be able to detect or prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the U.S. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail and even if successful, may result in substantial costs and distract our management and other employees.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. 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. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of shares of our common stock.

***Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.***

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our shareholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

***Changes in the patent laws or trade secret laws in the U.S. or other countries or jurisdictions could diminish the value of patents and trade secrets in general, thereby impairing our ability to protect current product candidates or any of our future product candidates.***

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents and trade secrets relating to our product candidates and any future product candidates. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent or trade secret laws or interpretation of the such laws in the U.S. or USPTO rules and regulations could increase the uncertainties and costs.

In addition, the U.S. federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act of 1980 (the "Bayh-Dole Act"). Under the Bayh-Dole Act, the federal government retains a “nonexclusive, nontransferable, irrevocable, paid-up license” for its own benefit. The Bayh-Dole Act also provides federal agencies with “march-in rights.” March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a “nonexclusive, partially exclusive or exclusive license” to a “responsible applicant or applicants.” If the patent owner refuses to do so, the government may grant the license itself.

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. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents and trade secrets could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future or the protection of our trade secrets.

Similarly, changes in patent law and regulations and trade secret laws in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces such laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. We cannot predict future changes in the interpretation of patent and trade secret laws or changes to patent or trade secret laws that might be enacted into law by U.S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications and trade secrets and our ability to obtain additional patent protection in the future.

***If we are unable to protect the confidentiality of our trade secrets and other proprietary information, including as a result of our reliance on third parties, our business and competitive position could be harmed.***

In addition to seeking patents for our product candidate, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. Despite these efforts and the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information due to our reliance on third parties, 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. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

Monitoring unauthorized uses and disclosures of our intellectual property is difficult and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any 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 U.S. are less willing or unwilling to protect trade secrets. Further, our key employees, consultants, suppliers or other individuals with access to our proprietary technology and know-how may incorporate that technology and know-how into projects and inventions developed independently or with third parties. As a result, disputes may arise regarding the ownership of the proprietary rights to such technology or know-how and any such dispute may not be resolved in our favor. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them or those to whom they communicate it from using that technology or information to compete with us. If any of our trade secrets or other proprietary information were to be disclosed to or independently developed by a competitor, our competitive position could be harmed.

We may be subject to claims that our licensors, employees, consultants, independent contractors or we have wrongfully used or disclosed confidential information of their former employers or other third parties.

We do and may employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our licensors, competitors or potential competitors. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, consultants, collaborators, independent contractors and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us and to not use the knowhow or confidential information of their former employer or other third parties, we may be subject to claims that we or our employees, consultants, collaborators or independent contractors have inadvertently or otherwise used or disclosed know-how or confidential information of their former employers or other third parties. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could result in customers

seeking other sources for the technology, or in ceasing from doing business with us. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or our product candidate. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition.

***We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.***

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, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidate. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership of our owned or in-licensed patents, trade secrets or other intellectual property. In addition, 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 develops 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 or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable personnel or intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidate. Even if we and our licensors are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have an adverse effect on 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 and have an adverse effect on the success of our business. 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 an adverse effect on the price of shares 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. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials and internal research programs or in-license needed technology or any future product candidates. 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 or any future product candidates, if approved.

***We may not be successful in obtaining necessary intellectual property rights to future products through acquisitions and in-licenses.***

We may seek to acquire or in-license additional product candidates or technologies to grow our product offerings and intellectual property portfolio. However, we may be unable to acquire or in-license intellectual property rights relating to, or necessary for, any such product candidates from third parties on commercially reasonable terms or at all. In that event, we may be unable to develop or commercialize such product candidates or technology. We may also be unable to identify product candidates or technology that we believe are an appropriate strategic fit for our company and protect intellectual property relating to, or necessary for, such product candidates and technology.

The in-licensing and acquisition of third-party intellectual property rights for product candidates is a competitive area and a number of more established companies are also pursuing strategies to in-license or acquire third-party intellectual property rights for products that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. If we are unable to successfully obtain rights to additional technologies or products, our business, financial condition, results of operations and prospects for growth could suffer.

In addition, we expect that competition for the in-licensing or acquisition of third-party intellectual property rights for product candidates and technologies that are attractive to us may increase in the future, which may mean fewer suitable opportunities for us as well as higher acquisition or licensing costs. We may be unable to in-license or acquire the third-party intellectual property rights for product candidates or technology on terms that would allow us to make an appropriate return on our investment.

***Intellectual property rights do not necessarily address all potential threats to our competitive advantage.***

Once granted, patents may remain open to invalidity challenges including opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such granted patent. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus challenged or may lose the allowed or granted claims altogether.

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

- others may be able to make formulations or compositions that are the same as or similar to our current product candidates or future product candidates but that are not covered by the claims of the patents that we own or have licensed;
- others may be able to make a product that is similar to our product candidates and not covered by the patents that we exclusively licensed and have the right to enforce;
- we, our licensor or any collaborators might not have been the first to make or reduce to practice the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed;
- we, our licensor or any collaborators might not have been the first to file patent applications covering certain of our or our licensor's inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing or misappropriating our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- patents that we own or have exclusively licensed may not provide us with any competitive advantage or may be held invalid or unenforceable as a result of legal challenges;
- our competitors might conduct research and development activities in the U.S. and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and 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;
- third parties performing manufacturing or testing for us using our product candidates or technologies could use the intellectual property of others without obtaining a proper license;

- parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights over that intellectual property;
- we may not develop or in-license additional proprietary technologies that are patentable;
- we may not be able to obtain and maintain necessary licenses on commercially reasonable terms or at all; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, our business, financial condition, results of operations and business prospects could be adversely affected.

**Risks Relating to Ownership of Our Common Stock**

***Pursuant to the terms of the Merger Agreement, we are required to use reasonable best efforts to recommend that our shareholders approve the conversion of all outstanding shares of our Series X Preferred Stock into shares of our common stock. We cannot guarantee that our shareholders will approve this matter, and if they fail to do so, we may be required to settle their shares of Series X Preferred Stock for cash at a price per share equal to the as-converted fair value and our operations may be materially harmed.***

Under the terms of the Merger Agreement, we agreed to use reasonable best efforts to call and hold a meeting of our shareholders to obtain the requisite approval for the conversion of all outstanding shares of Series X Preferred Stock issued in the Acquisition into shares of our common stock, as required by the Nasdaq listing rules, within 90 days after the date of the Merger Agreement and, if such approval is not obtained at that meeting, to seek to obtain such approval at an annual or special shareholders meeting to be held at least every six months thereafter until such approval is obtained, which would be time-consuming and costly.

Additionally, if our shareholders do not timely approve the conversion of our Series X Preferred Stock, then the holders of our Series X Preferred Stock may be entitled to require us to redeem their shares of Series X Preferred Stock for cash at a price per share equal to the then-current as-converted fair value (as such term is defined in the Series X Certificate of Designation) of the Series X Preferred Stock. As described in the Series X Certificate of Designation, the fair value of the Series X Preferred Stock is the last reported closing stock price of our Common Stock on Nasdaq on the trading day immediately prior to the date on which the notice of conversion is delivered. If we are forced to redeem a significant amount of shares of Series X Preferred Stock for cash as described above, such cash settlement could materially affect our results of operations, including raising a substantial doubt about our ability to continue as a going concern.

***Our stock price could be volatile as holders of our Series X Preferred Stock become able to convert their shares to common stock and sell these shares in the open market.***

Our stock price could be volatile as holders of our Series X Preferred Stock become able to convert their shares to common stock and sell these shares in the open market. As of the record date, we had approximately shares of common stock issued and outstanding and 27,089,719 shares of common stock potentially issuable upon conversion of all issued and outstanding shares of Series X Preferred Stock. If the shareholders approve the Conversion Proposal and shares of Preferred Stock are converted into common stock, as such shares of common stock become eligible for resale in the open market, our stock may experience higher volatility. If a significant number of shareholders seek to sell their shares upon becoming eligible to do so, our stock price may decline.

***Nasdaq may delist our common stock from its exchange, which could limit your ability to make transactions in our securities and subject us to additional trading restrictions.***

If our common stock is delisted from Nasdaq, our common stock would likely then trade only in the over-the-counter market. If our common stock were to trade on the over-the-counter market, selling our common stock could be more difficult because smaller quantities of shares would likely be bought and sold, transactions could be delayed, and we could face significant material adverse consequences, including: a limited availability of market quotations for our securities; reduced liquidity with respect to our securities; a determination that our shares are a "penny stock," which will require brokers trading in our securities to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for our securities; a reduced amount of news and analyst coverage for our Company; and a decreased ability to issue additional securities or obtain additional financing in the future. These

factors could result in lower prices and larger spreads in the bid and ask prices for our common stock and would substantially impair our ability to raise additional funds and could result in a loss of institutional investor interest and fewer development opportunities for us.

In addition to the foregoing, if our common stock is delisted from Nasdaq and it trades on the over-the-counter market, the application of the "penny stock" rules could adversely affect the market price of our common stock and increase the transaction costs to sell those shares. The SEC has adopted regulations which generally define a "penny stock" as an equity security that has a market price of less than $5.00 per share, subject to specific exemptions. If our common stock is delisted from Nasdaq and it trades on the over-the-counter market at a price of less than $5.00 per share, our common stock would be considered a penny stock. The SEC's penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document that provides information about penny stocks and the risks in the penny stock market. The broker-dealer must also provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and the salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer's account. In addition, the penny stock rules generally require that before a transaction in a penny stock occurs, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's agreement to the transaction. If applicable in the future, these rules may restrict the ability of brokers-dealers to sell our common stock and may affect the ability of investors to sell their shares, until our common stock no longer is considered a penny stock.

***Some provisions of our charter documents and Pennsylvania law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our shareholders and may prevent attempts by our shareholders to replace or remove our current management.***

Provisions in our Second Amended and Restated Articles of Incorporation, as amended ("Articles"), and Second Amended and Restated Bylaws ("Bylaws") could make it more difficult for a third-party to acquire us or increase the cost of acquiring us, even if doing so would benefit our shareholders, or remove our current management. These include provisions that:

- divide our board of directors into three classes with staggered three-year terms;
- provide that a special meeting of shareholders may be called only by a majority of our board of directors, the chairman of our board of directors or our chief executive officer or president;
- establish advance notice procedures with respect to shareholder proposals to be brought before a shareholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of director;
- provide that certain provisions of the Articles may only be amended with the affirmative vote of 66 2/3% of the holders of the outstanding shares of capital stock;
- provide that shareholders may only act at a duly organized meeting; and
- provide that members of our board of directors may be removed from office by our shareholders only for cause by the affirmative vote of 75% of the total voting power of all shares entitled to vote generally in the election of directors.

These provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management by making it more difficult for shareholders to replace members of our board of directors, who are responsible for appointing the members of our management. Because we are incorporated in Pennsylvania, we are governed by the provisions of the Pennsylvania Business Corporation Law of 1988, as amended ("PBCL"), which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our shareholders. Under Pennsylvania law, a corporation may not, in general, engage in a business combination with any holder of 20% or more of its capital stock unless the holder has held the stock for five years or, among other things, the board of directors has approved the transaction. Any provision of our Articles or Bylaws or Pennsylvania law that has the effect of delaying or deterring a change in control could limit the opportunity for our shareholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock.

***Our Articles designate the state and federal courts located within the County of Philadelphia in the Commonwealth of Pennsylvania as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our shareholders, which could discourage lawsuits against us and our directors and officers.***

Our Articles provide that, unless we consent in writing to the selection of an alternative forum, a state or federal court located within the County of Philadelphia in the Commonwealth of Pennsylvania will be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of our company, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees or our shareholders, (iii) any action asserting a claim arising pursuant to any provision of PBCL, or (iv) any action asserting a claim peculiar to the relationships among or between our company and our officers, directors and shareholders. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our Articles described above. This choice of forum provision may limit a shareholder's ability to bring a claim in a judicial forum that it finds favorable for the types of claims listed above, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provision contained in our Bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, operating results and financial condition.

***Our stock price has been and may continue to be volatile, and the value of an investment in our common stock may decline.***

An active, liquid and orderly market for our common stock may not be sustained, which could depress the trading price of our common stock or cause it to continue to be highly volatile or subject to wide fluctuations. In the last 52 weeks, our common stock has traded as low as $0.5190 per share. Some of the factors that could negatively affect our share price or result in fluctuations in the price or trading volume of our common stock include, among other things:

- the commencement, enrollment, or results of our current and future preclinical studies and clinical trials, and the results of trials of our competitors or those of other companies in our market sector;
- regulatory approval of our product candidates, or limitations to specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- manufacturing, supply or distribution delays or shortages;
- our ability to identify and successfully acquire or in-license new product candidates on acceptable terms;
- FDA, state or international regulatory actions, including actions on regulatory applications any of our product candidates;
- legislative or regulatory changes;
- judicial pronouncements interpreting laws and regulations;
- changes in government programs;
- announcements of new products, services or technologies, commercial relationships, acquisitions or other events by us or our competitors;
- market conditions in the pharmaceutical and biotechnology sectors;
- fluctuations in stock market prices and trading volumes of similar companies;
- the volatility of capital markets and other adverse macroeconomic factors, including due to inflationary pressures, interest rate and currency rate fluctuations, economic slowdown or recession, banking instability, geopolitical tensions or the outbreak of hostilities or war;
- changes in accounting principles;
- litigation or public concern about the safety of our product candidates or similar product candidates;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant shareholders;
- our ability to obtain additional financing to advance our development operations;
- our announcement of financing transactions, including debt, convertible notes, warrant exchanges, etc.;
- our ability to regain and maintain compliance with the listing standard of Nasdaq;

- the continued negative effects of the COVID-19 pandemic on the global economy; and
- actions by institutional shareholders.

These broad market and industry factors may decrease the market price of our common stock, regardless of our actual operating performance. The stock market in general has from time-to-time experienced extreme price and volume fluctuations, including recently. In addition, in the past, following periods of volatility in the overall market and decreases in the market price of a company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

***The issuance or sale of shares of our common stock could depress the trading price of our common stock.***

If (i) we issue additional shares of our common stock or rights to acquire shares of our common stock in other future transactions, (ii) any of our existing shareholders sells a substantial amount of our common stock, or (iii) the market perceives that such issuances or sales may occur, then the trading price of our common stock may significantly decrease. In addition, our issuance of additional shares of common stock will dilute the ownership interests of our existing common shareholders.

***We do not expect to pay any cash dividends for the foreseeable future.***

We do not anticipate that we will pay any cash dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our operations. Our ability to pay cash dividends is currently restricted by the terms of our credit facility with MAM Eagle Lender, LLC. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not purchase our common stock.

**Risks Relating to the Reverse Stock Split**

***We cannot assure you that we will meet the conditions of the Staff's Hearing Decision, even if the proposed Reverse Stock Split is approved.***

On July 24, 2023, we received the Hearing Decision from the Staff notifying us of its decision to grant our request to continue our listing on Nasdaq on a conditional basis, subject to, among other things, our ability to demonstrate compliance with the Nasdaq initial listing requirements by or before November 13, 2023. There can be no assurance that we will meet the conditions set forth by the Staff in the Hearing Decision or be able to comply with the Nasdaq initial listing requirements by November 13, 2023, or maintain compliance with other Nasdaq listing requirements, even if the Reverse Stock Split Proposal is approved by our shareholders. Further, even if the Reverse Stock Split Proposal is approved by our shareholders, there is uncertainty as to whether Pennsylvania courts would find the use of our Series C Preferred Stock to approve the Reverse Stock Split Proposal to be sufficient under Pennsylvania Law. The use of super-voting preferred stock, such as the Series C Preferred Stock, to approve an amendment to a company's articles of incorporation has not been validated by a Pennsylvania court to date and has been neither specifically prohibited by, nor provided for, in applicable statutes. If we are required to appeal any notification of delisting in the future, and such appeal is denied or if we fail to regain compliance with Nasdaq's continued listing standards during any future period granted by Nasdaq, our common stock will become subject to delisting from Nasdaq.

***We cannot assure you that the proposed Reverse Stock Split will increase the price of the common stock.***

We expect that the Reverse Stock Split will increase the market price of the common stock. However, the effect of the Reverse Stock Split on the market price of the common stock cannot be predicted with any certainty, and the history of reverse stock splits for other companies in our industry is varied, particularly since some investors may view a reverse stock split negatively. It is possible that the per share price of the common stock after the Reverse Stock Split will not increase in the same proportion as the reduction in the number of outstanding shares of common stock following the Reverse Stock Split, and the Reverse Stock Split may not result in a per share price that would attract investors who do not trade in lower priced stocks. In addition, we cannot assure you that the common stock will be more attractive to investors. Even if we implement the Reverse Stock Split, the market price of the common stock may decrease due to factors unrelated to the Reverse Stock Split, including our future

performance. If the Reverse Stock Split is consummated and the trading price of our common stock declines, the percentage decline as an absolute number and as a percentage of our overall market capitalization may be greater than would occur in the absence of the Reverse Stock Split.

***The proposed Reverse Stock Split may decrease the liquidity of the common stock and result in higher transaction costs.***

The liquidity of the common stock may be negatively impacted by the Reverse Stock Split, given the reduced number of shares that would be outstanding after the Reverse Stock Split, particularly if the stock price does not increase as a result of the Reverse Stock Split. In addition, if the Reverse Stock Split is implemented, it may increase the number of our shareholders who own "odd lots" of fewer than 100 shares of common stock, which may be more difficult to sell. Brokerage commissions and other costs of transactions in odd lots are generally higher than the costs of transactions of more than 100 shares or of even multiples of 100 shares of common stock. Accordingly, the Reverse Stock Split may not achieve the desired results of increasing marketability of the common stock as described above.

## DESCRIPTION OF BUSINESS OF BAUDAX BIO, INC.

***Company Overview***

We are a pharmaceutical and cell therapy company primarily focused on innovative products for acute care and related settings and the treatment of autoimmune disorders. We believe that we can bring valuable therapeutic options for patients, prescribers and payers to the acute care and related markets.

We hold exclusive global rights to two new molecular entities, which are centrally acting Neuromuscular Blocking Agents ("NMBs") BX1000, an intermediate duration of action NMB that recently completed a Phase II clinical trial, and BX2000, an ultra-short acting NMB currently undergoing a Phase I clinical trial. A proprietary blockade reversal agent, BX3000, is currently being evaluated in preclinical studies intended to support an investigational new drug ("IND") filing in the last quarter of 2023. BX3000 is an agent that is expected to rapidly reverse BX1000 and BX2000 blockade. All three agents are licensed from Cornell University. We believe these agents, when an NMB and BX3000 are administered in succession, allow for a rapid onset of centrally acting neuromuscular blockade, followed by a rapid reversal of the neuromuscular blockade with BX3000. These novel agents have the potential to meaningfully reduce time to onset and reversal of blockade and improve the reliability of onset and offset of neuromuscular blockade. The combination of the blocking agent, and the reversal agent can potentially reduce time in operating rooms resulting in potential clinical and cost advantages, as well as valuable cost savings for hospitals and ambulatory surgical centers and has the potential for an improved clinical profile in terms of safety compared to other NMBs and reversal agents.

In mid-2020, we launched our first commercial product, ANJESO, in the United States. ANJESO was the first and only 24-hour, intravenous ("IV") analgesia agent. ANJESO is a cyclooxygenase-2 ("COX-2"), preferential, non-steroidal anti-inflammatory ("NSAID") for the management of moderate to severe pain, which could be administered alone or in combination with other non-NSAID analgesics. We discontinued commercial sales of ANJESO in December 2022 and further withdrew the NDA in March 2023.

In June 2023, we acquired TeraImmune, Inc. ("TeraImmune"), a privately-held biotechnology company focused on discovery and development of novel immune cell therapies using human regulatory T cells ("Tregs") for autoimmune diseases. Treg therapies are designed to act as a targeted therapeutic that focuses on known pathological antibodies to suppress inflammatory responses. Tregs help to maintain homeostasis by regulating autoimmune and inflammatory responses. We believe that Tregs can address a significant unmet need in the treatment of autoimmune diseases such as Hemophilia A and multiple sclerosis. We have in-licensed a patent family covering methods of producing T cell populations enriched for regulatory T cells and cell culture compositions from U.S. Department of Health and Human Services, as represented by National Institute of Allergy and Infectious Diseases of the National Institutes of Health under an exclusive, sublicensable royalty-bearing license. We exclusively license 2 issued U.S. patents covering methods of producing a population of cells having stable, regulatory T cells and cell culture compositions containing isolated human regulatory T cells, antibodies and an oligonucleotide that expire in 2033 subject to any applicable disclaimer or extensions.

Tregs are designed to recognize and target certain cells through the engagement of target-specific receptors by peptide antigens presented on the surface of the target cell by the major histocompatibility complex. Our proprietary and patented technology platform consists of two approaches: (1) TREGable™, which involves the isolation of natural Tregs, and (2) TREGing™, which involves engineering effector T ("Teff") cells into antigen-specific Tregs. Each approach is intended to recognize and attack pathogens while avoiding an attack on healthy cells and tissues. The lead product candidate we acquired in the acquisition with TeraImmune, TI-168, is being developed for the treatment of Hemophilia A with inhibitors, which received IND clearance in 2022. We have in-licensed 2 patent families relating to TI-168, nucleic acids constructs encoding T cell receptors, methods of producing TI-168, immunosuppressive induced regulatory T cells and methods of producing these cells from the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. ("HJF") under two worldwide, exclusive, sublicensable royalty-bearing licenses. We exclusively license 2 issued patents in the U.S. and a pending European patent application relating to methods of producing and stabilizing T cell populations enriched for regulatory T cells and cell culture compositions that expire in 2034 subject to any applicable disclaimer or extension. We also exclusively license a family of pending U.S. and foreign patent applications directed to immunosuppressive induced regulatory T cells and methods of producing these cells which if issued would expire in 2041 subject to any applicable disclaimer or extensions.

***Our Strategy***

We believe that we can bring valuable therapeutic options for patients, prescribers and payers to the hospital, acute care and other markets. We believe we can create value for our shareholders through the development, and potential approval and commercialization of our NMB and NMB reversal agents, TI-168 for treatment of the Hemophilia A, as well as our other pipeline product candidates we develop for the treatment of autoimmune disorders utilizing Treg-based therapies. In addition to our pipeline, we continue to evaluate acquisition and in-licensing opportunities, especially those that can contribute revenue and cash flow.

Our near-term goals include:

- *Leveraging our development experience to progress our NMB blockade and reversal productcandidates, as well as TI-168.* Our clinical stage product pipeline includes proprietary NMB blockade product candidates for use in anesthesia, BX1000 and BX2000, as well as an NMB reversal agent currently in preclinical studies, BX3000, which is currently being evaluated in preclinical studies intended to support an IND filing in the last quarter of 2023. We believe the concurrent development of a blocking agents and reversal agent used safely in the same patient, once certain stand alone and initial combination information is available, will allow our programs to provide clinical, financial, and temporal advantages to patients. In addition, we intend to leverage our drug development expertise to commence a Phase 1/2a clinical trial of TI-168 for treatment of the Hemophilia A, and continue to develop TI-168 and other product candidates for the treatment of autoimmune disorders. We believe such programs can also proceed in a cost effective manner. Further, we believe we will be able to leverage the data we generate from our TI-168 clinical trials for the further expansion of our Treg-based therapy platform, enabling us to expand our target indications and product candidates. Our overall goal is to leverage our drug development expertise to safely develop these product candidates.
- *Further characterize commercial opportunity for the NMB related franchise with additional market studies with more data from clinical trials to add to the target product profile(s).*
- *Pursuing the license or acquisition of additional products and product candidates.* We are seeking in-license or acquisition opportunities to add commercial or near-commercial products and product candidates to our portfolio. We have the experience of establishing reimbursement and other functions for the commercialization of a product in the United States and we believe we can utilize this infrastructure for the successful commercialization of acquired assets or licensed products.

***Products and Pipeline***

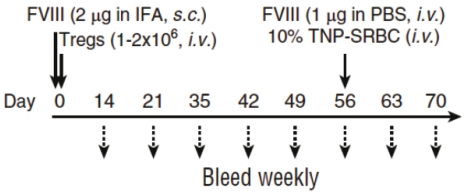
*Clinical Development*

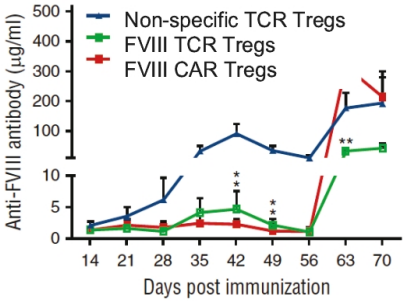
As discussed above, we are currently developing TI-168 for the treatment of Hemophilia A with inhibitors while concurrently continuing to progress the development of our existing NMB portfolio, each of which is discussed in greater detail below.

*TI-168*

Our lead Treg-based product candidate, TI-168, is being developed for the treatment of Hemophilia A with inhibitors. Hemophilia A is significant bleeding disorder characterized by impaired clotting as a result of deficiencies in the production or coagulation factor VIII (“FVIII”). Hemophilia A is an orphan disease that is lifelong and with limited treatment options. Approximately 30% of Hemophilia A patients develop inhibitors to FVIII, which can add complexity to its treatment regimen, and increase costs significantly. Inhibitors have historically been contraindicated with gene therapy, further limiting treatment options. The current standard of care for patients with FVIII inhibitors includes immune tolerance induction (“ITI”), along with the use of Emicizumab and bypass agents. We believe ITI therapy has important limitations, including that a significant portion of the patient population does not respond to ITI (up to 60%), recurrence can occur in a significant number of patients (up to 29%), the therapy can be expensive with respect to both time and resources, and may render a patient ineligible for gene therapy. We believe that TI-168, subject to U.S. Food and Drug Administration (“FDA”) approval and commercialization, may provide Hemophilia A patients with the ability to avoid the potentially prohibitive cost, inconvenience, efficacy concerns and other limitations of ITI. Further, we believe that patients with FVIII tolerance that receive TI-168 will be potential candidates for gene therapy.

TI-168 is an autologous FVIII TCR-Treg cell therapy for the treatment of Hemophilia A patients with refractory inhibitors, which is designed to replace ITI treatments. Preclinical studies have shown that FVIII TCR-Tregs showed FVIII-specific immunosuppressive efficacy, with TCRs outperforming chimeric antigen receptor ("CAR") Tregs. As illustrated in the images below, in a preclinical study, hemophilic mice were subcutaneously immunized for FVIII, and four hours thereafter, infused with either a TCR Treg, CAR Treg or nonspecific Treg. Over the course of the study, the nonspecific Treg could not effectively control the development of anti-FVIII antibodies, while the anti-FVIII antibody response was effectively suppressed by both the TCR and CAR Tregs over a period of approximately 8 weeks. Further, rechallenge with FVIII at day 56 resulted in a much higher loss of tolerance for the CAR Treg group, while the TCR Treg group's loss of tolerance remained significantly lower. We believe that FVIII TCR Tregs may provide a therapeutic option in controlling anti-FVIII antibody formation in refractory Hemophilia A patients, and have the potential to perform better than CAR Treg therapies.




We plan to initiate a Phase 1/2a clinical trial of TI-168 for the treatment of Hemophilia A with inhibitors, with proof of concept data expected on the first 3 patients within the next 12-15 months. We are actively engaging in the Institutional Review Board ("IRB") clinical trial site process. We intend to seek orphan drug designation in the United States for TI-168 for the treatment of Hemophilia A.

*BX1000*

We completed a Phase I study in 2021 for BX1000 which evaluated its safety profile when administered with Total Intravenous Anesthesia, as well as the dose response of neuromuscular blockade. We completed a dose-escalation study evaluating BX1000 in a total of 58 healthy volunteers who had already undergone endotracheal intubation while under general anesthesia. After intubation, subjects received a single IV bolus dose of BX1000 and were monitored for neuromuscular blockade and for any changes in vital signs or the presence of adverse events. BX1000 dose-escalations were continued until prespecified effects were observed. Doses of BX1000, up to 0.4 mg/kg, were well tolerated in this study of healthy volunteer subjects. Muscle paralysis was rapidly achieved along with complete spontaneous recovery. Neuromuscular blocking parameters were observed to increase in depth and duration of blockade while the time to onset of blockade was reduced with increasing doses of BX1000. Pharmacokinetic exposures increased with increasing study doses while elimination of the study compound remained rapid. Evaluation of electrocardiogram data using concentration-QTc modeling did not identify a risk of QTc prolongation within the studied dosing range. We engaged with the FDA regarding the design for the Phase II study in patients undergoing elective hernia and similar abdominal surgical procedures utilizing total intravenous anesthesia, in the fall of 2022, and initiated enrollment in the study in the fourth quarter of 2022. In January 2023, we announced the positive outcome of the interim analysis of the randomized, double blind, active controlled clinical Phase II trial, which compared three doses of BX1000 to a standard dose of rocuronium. The interim analysis was performed without breaking the study blind and was based on the first 20 of the 80 total patients being enrolled to the 4 study arms. The primary efficacy endpoint was the proportion of patients meeting criteria for Good or Excellent intubating conditions using a standardized scale. Additionally, the study is evaluating the safety and tolerability of BX1000 as compared to rocuronium in this patient population.

The Top-line results for the Phase II clinical trial for BX1000 showed that BX1000 met the primary endpoint of readiness for intubation (evaluated as "Good" or "Excellent" - Viby-Mogensen 1996) at 60 seconds for all

three dose levels of BX1000 compared to the active-control, rocuronium. Study treatments were generally well tolerated, with no occurrence of severe or serious adverse events. The frequency and severity of adverse events was similar across all four dose groups, and no notable events were aggregated in any one dose group.

*BX2000*

We filed an IND for BX2000 in 2020 in order to conduct a first-in-human clinical trial. We conducted an additional toxicology study requested by the FDA in 2021 and in March 2022, FDA notified us that we could proceed with initiation of a first in human, Phase I dose-escalation study in healthy volunteers.

In June of 2022, we announced the completion of dosing of the first cohort of the Phase I dose escalation study for BX2000, which we believe to be a rapid onset, ultra-short acting NMB agent, in healthy volunteers. The study is investigating single, ascending doses of BX2000 administered in a single, intravenous bolus injection compared to placebo. The study is comprised of up to 10 dosing cohorts and each cohort will enroll 8 patients. The study will evaluate the effect of BX2000 on safety, including heart rate, blood pressure, corrected QT interval, pharmacokinetics, and the time course of the neuromuscular blocking profile. Subjects will be monitored at an inpatient facility for 24 hours following administration of BX2000. There are also follow up visits on Day 8 and additional follow ups will take place approximately 2 and 4 weeks after dosing to evaluate the continued safety of study participants.

Enrollment began in the second quarter of 2022 and cohort 2 completed, as planned, in the fourth quarter of 2022. Enrollment in cohort 3 was underway in January 2023 and despite the challenges of enrollment to this type of protocol, we remain optimistic that we will be close to reaching maximum dosage by late 2023 to mid-2024.

*BX3000*

BX3000 is a small molecule that was designed to induce chemical cleaving of BX1000 and BX2000, resulting in the rapid inactivation of those molecules and thus quickly reversing neuromuscular blockade. We are currently engaged with the pre-clinical toxicity studies needed to support an IND filing for BX3000 in the last quarter of 2023. We expect to begin the clinical program for BX3000 in 2023.

***Discovery platform***

In addition to our named product candidates, we are actively engaged in a number of earlier stage discovery programs where we believe our Treg platform may provide therapeutic benefits. These discovery stage initiatives are focused on indications with pathological autoantibodies including myasthenia gravis, membranous nephropathy and neuromyelitis optica. For these and other indications, we plan to use our Treg platform to develop therapeutics that could be used in the treatment of these, and other diseases involving pathological autoantibodies.

***Licenses and Agreements***

*HA FVIII TCR Agreement*

On August 5, 2019, TeraImmune entered into an exclusive worldwide license agreement (the "HA FVIII TCR Agreement") with HJF to utilize the licensed patent rights granted thereunder to research, design, develop, make, use, sell, distribute, exploit, improve and import the licensed products and processes covered thereby. The patent rights covered by the HA FVIII TCR Agreement include certain technologies relating to coagulation factor VIII ("FVIII") specific T cell receptors ("TCRs") or B-cell antigen receptor ("BAR") expressing Tregs, methods of producing and stabilizing FVIII specific TCR or BAR expressing Tregs, and their use in humans. HJF retains the right to grant non-exclusive licenses to the patent rights covered under the HA FVIII TCR Agreement for non-commercial and research purposes. In addition, HJF retains the right to request that TeraImmune relinquish its exclusive rights under the HA FVIII TCR Agreement if it has not obtained FDA or other regulatory approval to a licensed product within ten years of the effective date of the HA FVIII TCR Agreement.

Pursuant to the HA FVIII TCR Agreement, TeraImmune has agreed to pay mid-single digit percent royalties on net sales (as defined therein) in jurisdictions where a valid claim with respect to the patent rights exist, and low-single digit percent royalties on net sales where no valid claim exists or where valid claims have expired. Additionally, TeraImmune agreed to pay a high-teens percentage of its non-royalty sublicense income received prior to regulatory approval of licensed product and a low-teens percentage of its non-royalty sublicense income received after regulatory approval of a licensed product, as well a minimal annual maintenance fee, which shall

be credited against any royalty fees due and payable in for the calendar year relating to such maintenance fee. Further, TeraImmune is obligated to pay an aggregate of $1.3 million in milestone fees in the event such milestones are met. As of March 31, 2023, TeraImmune has paid a license royalty fee and annual royalties of $50,000 to HJF.

The HA FVIII TCR Agreement will remain in effect until the later of (a) the full end of the term or terms of certain patent rights as defined therein on a country-by-country basis or (b) 15 years from the first sale of the licensed product in a given country, whichever is longer, provided, however, that HJF may terminate the HA FVIII TCR Agreement in the event certain milestones are not met within the timeframe required by the HA FVIII TCR Agreement.

*BML Agreement*

On August 26, 2019, TeraImmune entered into the non-exclusive Biological Materials License Agreement (the "BMLA") with the National Cancer Institute ("NCI"), a part of the National Institutes of Health ("NIH"), which is part of the U.S. Government Department of Health and Human Services. Pursuant to the BMLA, TeraImmune was granted a world-wide, non-exclusive license to utilize the licensed patent rights granted thereunder to make, have made, use, sell and import autologous T cell therapy products for the treatment of Hemophilia A utilizing the pMSGV1 vector.

Pursuant to the BMLA, TeraImmune agreed to pay minimal non-refundable license, initial royalty, and annual royalty fees. Further, TeraImmune is required to pay a less than 1.0% royalty on net sales of any licensed products under the BMLA. As of March 31, 2023, TeraImmune has paid a license execution fee and annual royalties of $11,000 to NIH. The BMLA shall terminate in accordance with its terms ten years after the effective date thereof, unless extended by us and NCI.

*HA ODN Agreement*

On June 18, 2020, TeraImmune entered into an exclusive license agreement (the "HA ODN Agreement") with the National Institute of Allergy and Infectious Diseases ("NIAID"), a part of NIH. Pursuant to the HA ODN Agreement, TeraImmune was granted a non-exclusive license to utilize the licensed patent rights granted thereunder to make, have made, use, have used, sell and have sold, offer to sell and import certain autologous T cell therapy products for the treatment of Hemophilia A for patients who have inhibitory anti-FVIII auto-antibodies in the United States.

Pursuant to the HA ODN Agreement, TeraImmune agreed to pay mid-single digit percent royalties on net sales (as defined therein) of any licensed products covered by the HA ODN Agreement. TeraImmune also agreed to a minimal non-refundable license, initial royalty, and annual royalty fees. Additionally, TeraImmune agreed to reimburse NIAID for certain patent expenses on a payment schedule that may amount in total reimbursements of up to $45,000, including expenses incurred in maintaining the patent. As of March 31, 2023, TeraImmune has reimbursed an aggregate expense of $22,000 for patent prosecution fees and paid a license royalty fee and annual royalties of $33,000 to NIAID. The HA ODN Agreement also requires the payment of up to $1.1 million in milestone payments upon the achievement of certain regulatory and commercialization milestones. The HA ODN Agreement will remain in effect until the expiration of the last to expire of certain licensed patent rights or U.S. orphan drug exclusivity, each as defined therein, provided, however, that NIAID may terminate the HA ODN Agreement in the event that certain milestones are not met within the timeframe required by the HA ODN Agreement.

*iTreg Agreement*

On November 11, 2020, TeraImmune entered into an exclusive worldwide license agreement (the "iTreg Agreement") with HJF to utilize the licensed patent rights granted thereunder to practice, research, design, develop, make, use, sell, distribute, exploit, improve and import the licensed products and processes covered thereby. The patents rights covered by the iTreg Agreement include technology related to inducable regulatory T ("iTreg") cells, methods for producing iTreg cells and their use in humans. TeraImmune agreed to take responsibility for the maintenance and prosecution of the Patent Rights in consultation with HJF on all strategic global filing and prosecution decisions. HJF retains the right to grant non-exclusive licenses to the patent rights covered by the iTreg Agreement for non-commercial and research purposes. In addition, HJF retains the right to request that TeraImmune relinquish its exclusive rights under the iTreg Agreement if it has not obtained FDA or other regulatory approval to a licensed product within six years of the effective date of the iTreg Agreement.

Pursuant to the iTreg Agreement, TeraImmune has agreed to pay low-single digit percent royalties to HJF on net sales (as defined therein) of any licensed product covered thereby and a low-teens percentage on its non-royalty sublicense income. TeraImmune paid a non-refundable license fee of $25,000 to HJF in December 2020. The iTreg Agreement will remain in effect until the full end of the term or terms of certain patent rights as defined therein on a country-by-country basis, provided, however, that HJF may terminate the iTreg Agreement in the event that certain milestones are not met within the timeframe required by the iTreg Agreement.

***Intellectual Property***

We license the patents and other intellectual property covering the NMBs and the related reversal agent and related methods of use under a worldwide, exclusive, sublicensable, royalty-bearing license from Cornell University. We exclusively license issued patents in the U.S. and other major foreign markets directed to BX1000 that expire in 2027, subject to any applicable disclaimer or extension, along with a pending PCT application directed to certain methods of using BX1000 that, if issued, would expire in 2041, subject to any applicable disclaimer or extension. We exclusively license issued patents in the U.S. and other major foreign markets directed to BX2000 that expire in 2033, subject to any applicable disclaimer or extension, along with a pending PCT application directed to certain methods of using BX-2000 that, if issued, would expire in 2041, subject to any applicable disclaimer or extension. Under the license agreement, we are obligated to pay Cornell University (i) an annual license maintenance fee payment which ranges from $15,000 to $125,000 until the first commercial sale of a licensed compound; (ii) milestone payments upon the achievement of certain milestones, up to a maximum, for each NMB, of $5 million for U.S. regulatory approval and commercialization milestones and $3 million for European regulatory approval and commercialization milestones; and (iii) royalties on net sales of the NMBs and the related reversal agent at rates ranging from low to mid-single digits, depending on the applicable licensed compound and whether there is a valid patent claim in the applicable country, subject to an annual minimum royalty amount of that increases after the fourth year of sales. In addition, we will reimburse Cornell University for past and ongoing patent costs related to prosecution and maintenance of the patents related to the licensed compounds. The license agreement is terminable by us at any time upon 90 days' written notice and by Cornell University upon our material breach, subject to a cure period, and upon our filing any claim asserting the invalidity of any of Cornell University's licensed patent rights. The royalty term for each licensed compound expires, on a country-by-country basis, on the later of (i) the expiration date of the longest-lived licensed patent, (ii) the expiration of any granted statutory period of marketing exclusivity, or (iii) the first commercial sale of a generic equivalent of the applicable licensed compound. On the last to expire royalty term the license agreement will automatically convert to a royalty-free nonexclusive license.

We have in-licensed a patent family covering methods of producing T cell populations enriched for regulatory T cells and cell culture compositions from U.S. Department of Health and Human Services, as represented by National Institute of Allergy and Infectious Diseases of the NIH under an exclusive, sublicensable royalty-bearing license. We exclusively license 2 issued U.S. patents covering methods of producing a population of cells having stable, regulatory T cells and cell culture compositions containing isolated human regulatory T cells, antibodies and an oligonucleotide that expire in 2033 subject to any applicable disclaimer or extensions. Under the license agreement with the NIH, we are obligated to pay the NIH (i) single-digit royalties on net sales subject a minimum annual royalty, which may be credited against royalties due for sales made in a particular year; and (ii) development milestone payments. Upon expiration of the licensed patent rights, a reduced royalty rate will be applied to net sales for the duration of the U.S. Orphan Drug Exclusivity period. The NIH license agreement is terminable by us at any time upon 60 days written notice and by the NIH if we fail in the performance of any material obligations under the license agreement subject to a cure period.

We have also in-licensed 2 patent families relating to TI-168, nucleic acids constructs encoding T cell receptors, methods of producing TI-168, immunosuppressive induced regulatory T cells and methods of producing these cells from HJF under two worldwide, exclusive, sublicensable royalty-bearing licenses. We exclusively license 2 issued patents in the U.S. and a pending European patent application relating to methods of producing and stabilizing T cell populations enriched for regulatory T cells and cell culture compositions that expire in 2034 subject to any applicable disclaimer or extension. We also exclusively license a family of pending U.S. and foreign patent applications directed to immunosuppressive induced regulatory T cells and methods of producing these cells which if issued would expire in 2041 subject to any applicable disclaimer or extensions. Under the license agreement with HJF, covering the 2 issued U.S. patents and pending European patent application, we are obligated to pay HJF (i) an annual license maintenance fee creditable against royalty payments due in the same

year; (ii) single-digit royalties on net sales until expiration of the licensed patent rights, after which a reduced royalty rate will be applied to net sales for 15 years from the first sale of a licensed product; and (iii) development and funding milestone payments. Under the license agreement with HJF covering the pending U.S. and foreign patent applications directed to immunosuppressive induced regulatory T cells and methods of producing these cells, we are obligated to pay HJF single-digit royalties on net sales until expiration of the patent rights on a country-by-country basis. The HJF license agreements are terminable by us at any time upon 90 days written notice and by HJF if we fail in the performance of any obligations under the license agreement which in some instances are subject to a cure period.

We own patents and patent applications directed to the analgesia indication, formulations and intranasal methods of use of dexmedetomidine in the United States and certain major foreign markets. Several patents have issued outside the United States for transmucosal methods, and the resulting patent protection will last into 2030, subject to any disclaimers or extensions. In addition, patents related to intranasal methods has issued in the United States and certain major foreign markets, and the resulting patent protection will last into 2032, subject to any disclaimers or extensions.

We intend to rely on a combination of patents and trade secrets, as well as confidentiality agreements and license agreements, to protect our product candidates. Our patent strategy is designed to facilitate commercialization of our current product candidates and future product candidates, as well as create barriers to entry for third parties. One focus of our claim strategy is on formulation claims and other related claims.

We are seeking patent protection in the United States and internationally for our product candidates. Our policy is to pursue, maintain and defend patent rights and to protect the technology, inventions and improvements that are commercially important to the development of our business. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents granted to us in the future will be commercially useful in protecting our technology. We also intend to rely on trade secrets to protect our product candidates. Our commercial success also depends in part on our non-infringement of the patents or proprietary rights of third parties.

Our success will depend significantly on our ability to:

- obtain and maintain patent and other proprietary protection for our product candidates;
- defend our patents;
- develop trade secrets as needed and preserve the confidentiality of our trade secrets; and
- operate our business without infringing the patents and proprietary rights of third parties.

We have taken steps to build and will continue to build proprietary positions for our product candidates and related technology in the United States and abroad. We note that the patent laws of foreign countries differ from those in the United States, and the degree of protection afforded by foreign patents may be different from the protection offered by United States patents.

***Government Regulation***

Governmental authorities in the United States at the federal, state and local level, and the equivalent regulatory authorities in other countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, export and import of products such as those we are developing. Our product candidates must be approved by the FDA before they may legally be marketed in the United States. In addition, to the extent we choose to clinically evaluate or market any products in other countries or develop these products for future licensing to third parties, we are subject to a variety of regulatory requirements and to the authority of the competent regulatory authorities of those other countries.

*U.S. Drug Development Process*

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (“FDCA”) and implementing regulations. The process of obtaining regulatory approvals and ensuring compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time

and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process, or after approval, may subject an applicant to administrative enforcement or judicial sanctions. This enforcement could include, without limitation, the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, corrective actions, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies, some of which must be conducted according to good laboratory practices regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to the FDA's good clinical practices ("GCPs") to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of an NDA for a new drug;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities identified in the NDA;
- review and approval of proposed proprietary name; and
- FDA review and approval of the NDA.

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

Once a pharmaceutical product candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, to the FDA as part of the IND. The sponsor must also include a protocol detailing, among other things, the objectives of the initial clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated if the initial clinical trial lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during trials due to safety concerns regarding the product candidate or non-compliance with applicable requirements.

All clinical trials of a product candidate must be conducted under the supervision of one or more qualified investigators, in accordance with GCP regulations. These regulations include the requirement that all research subjects provide informed consent. Further, an IRB must review and approve the plan for any clinical trial before it commences at any institution. The IRB's role is to protect the rights and welfare of human subjects involved in clinical studies by evaluating, among other things, the potential risks and benefits to subjects, processes for obtaining informed consent, monitoring of data to ensure subject safety, and provisions to protect the subjects' privacy. The IRB approves the information regarding the clinical trial and the 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.

Once an IND is in effect, each new clinical protocol, and any amendments to the protocol, must be submitted to the IND for FDA review and to the IRBs for approval. Protocols detail, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase I. The product is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing may be conducted in patients.
- Phase II. Phase II trials involve investigations in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted indications and to determine dosage tolerance and optimal dosage and schedule.
- Phase III. Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for regulatory approval and product labeling.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA, and safety reports must be submitted to the FDA and the investigators for serious and unexpected side effects. Phase I, Phase II and Phase III testing may not be completed successfully within any specified period, if at all. Results from earlier trials are not necessarily predictive of results from later trials. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or 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 has been associated with unexpected serious harm to patients.

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

*U.S. Review and Approval Processes*

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the drug, proposed labeling and other relevant information, are submitted to the FDA as part of an NDA for a new drug, requesting approval to market the product.

The submission of an NDA generally is subject to the payment of a substantial user fee for a human drug application. In addition, under the Pediatric Research Equity Act of 2003, an NDA or supplement to an NDA for a new indication, dosage form, dosing regimen, route of administration, or active ingredient, must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may waive or defer pediatric studies under certain circumstances.

*Section 505(b)(2) New Drug Applications.* As an alternate path to FDA approval, particularly for modifications to drug products previously approved by the FDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA ("Section 505(b)(2) NDA"). Section 505(b)(2) was enacted as part of the Drug Price Competition andPatent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments, and it permits approval of applications other than those for duplicate products and permits reliance for such approvals on literature or on the FDA's findings of safety and effectiveness of an approved drug product. A Section 505(b)(2) NDA is an application where at least some of the information required for approval comes from clinical trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The FDA requires submission of information needed to support any changes relative to a previously approved drug, known as the reference product, such as published data or new studies conducted by the applicant, including bioavailability or bioequivalence studies, or clinical trials demonstrating safety and effectiveness. The FDA may then approve the Section 505(b)(2) NDA for all or some of the labeled indications for which the reference product has been approved, as well as for any new indication sought by the applicant, unless such indications or

uses are protected by patent or exclusivity provisions covering the reference product. To the extent that a Section 505(b)(2) NDA relies on clinical trials conducted for a previously approved drug product or the FDA's prior findings of safety and effectiveness for a previously approved drug product, the Section 505(b)(2) applicant must submit patent certifications in its application with respect to any patents for the reference product that are listed in the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book. Specifically, the applicant must certify for each listed patent that, in relevant part, (1) the required patent information has not been filed; (2) the listed patent has expired; (3) the listed patent has not expired but will expire on a particular date and approval is not sought until after patent expiration; or (4) the listed patent is invalid, unenforceable or will not be infringed by the proposed new product. A certification that the new product will not infringe the previously approved product's listed patent or that such patent is invalid or unenforceable is known as a Paragraph IV certification. If the applicant does not challenge one or more listed patents through a Paragraph IV certification, the FDA will not approve the Section 505(b)(2) NDA until all the listed patents claiming the referenced product have expired.

Further, the FDA will also not approve a Section 505(b)(2) NDA until any non-patent exclusivity, such as, for example, five-year exclusivity for obtaining approval of a new chemical entity, three-year exclusivity for an approval based on new clinical trials, or pediatric exclusivity, listed in the Orange Book for the reference product, has expired.

If the Section 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the owner of the reference product and relevant patent holders within 20 days after the Section 505(b)(2) NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement suit against the Section 505(b)(2) applicant. Under the FDCA, the filing of a patent infringement lawsuit within 45 days of receipt of the notification regarding a Paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA for 30 months, beginning on the date the patent holder receives notice, or until the patent expires or a court deems the patent unenforceable, invalid or not infringed, whichever is earlier. Even if a patent infringement claim is not brought within the 45-day period, a patent infringement claim may be brought under traditional patent law, but it does not invoke the 30-month stay. Moreover, in cases where a Section 505(b)(2) application containing a Paragraph IV certification is submitted after the fourth year of a previously approved drug's five-year exclusivity period, and the patent holder brings suit within 45 days of notice of certification, the 30-month period is automatically extended to prevent approval of the Section 505(b)(2) application until the date that is seven and one-half years after approval of the previously approved reference product. The court also has the ability to shorten or lengthen either the 30-month or the seven and one-half year period if either party is found not to be reasonably cooperating in expediting the litigation. Thus, the Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its product only to be subject to significant delay and patent litigation before its product may be commercialized. Alternatively, if the NDA applicant or relevant patent holder does not file a patent infringement lawsuit within the specified 45-day period, the FDA may approve the Section 505(b)(2) application at any time, assuming the application is otherwise approvable.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years, some pharmaceutical companies and other stakeholders have objected to the FDA's interpretation of Section 505(b)(2). If the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any Section 505(b)(2) NDA that we submit.

*FDA Review of New Drug Applications.* The FDA reviews all NDAs submitted to ensure that they aresufficiently complete for substantive review before it accepts them for filing. If the FDA does not find an NDA to be sufficiently complete for filing, it may request additional information rather than accepting the NDA for filing. In this event, the sponsor must resubmit the NDA with the additional information. The re-submitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether clinical data demonstrates that a product is safe and effective for its intended use and whether its manufacturing process can assure the product's identity, strength, quality and purity. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA

may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. An advisory committee is a panel of independent experts who provide advice and recommendations when requested by the FDA. The FDA is not bound by the recommendation of an advisory committee.

The approval process is lengthy and difficult, and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. The FDA will issue a complete response letter ("CRL") if the agency decides not to approve the NDA in its present form. The CRL usually describes all the specific deficiencies that the FDA identified in the NDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the CRL may include recommended actions that the applicant might take to place the application in a condition for approval. If a CRL is issued, the applicant may either resubmit the NDA, addressing all the deficiencies identified in the letter, withdraw the application or request an opportunity for a hearing.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages, or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling, and the agency also may require a risk evaluation and mitigation strategy ("REMS") if it determines that a REMS is necessary to assure that the benefits of a drug outweigh its risks. In addition, the FDA may require Phase IV testing, which involves clinical trials designed to further assess a drug's safety and effectiveness after NDA approval, and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

*U.S. Biologic nonclinical and clinical development*

Prior to beginning the first clinical trial with a biologic product candidate in the U.S., we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The IND includes the clinical protocols and general development plan, as well as results of animal and in vitro studies assessing the toxicology, pharmacokinetic ("PK"), pharmacology and PD characteristics of the product candidate; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions. In such a case, the IND may be placed on clinical hold until the IND sponsor and the FDA resolve the outstanding concerns or questions. The FDA also may impose clinical holds at any time before or during clinical studies due to safety concerns or non-compliance. If the FDA imposes a clinical hold, studies may not recommence without FDA authorization and then only under terms authorized by the FDA. Submission of an IND therefore does not guarantee that FDA authorization to begin a clinical trial will be granted or that, once begun, issues will not arise that adversely impact, suspend or terminate such studies.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments and additional information such as toxicology or Chemistry, Manufacturing and Controls data in support of the investigational product(s). For new indications, a separate new IND is usually required. Outside of the U.S., clinical trial applications are generally required to conduct clinical studies in each country. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits.

Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely

to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board or independent data monitoring committee, which provides direction for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

Information about most clinical trials must be submitted within specific timeframes for publication on thewww.clinicaltrials.gov website. For purposes of BLA/market authorization application approval, human clinical trials are typically conducted in three sequential phases that may overlap or be combined.

- Phase 1 — The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, tolerability, absorption, metabolism, distribution and elimination of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on pharmacodynamics and effectiveness.
- Phase 2 — The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3 — The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple global clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to support chronic use of a product during marketing.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be made a condition to approval of the BLA or, in certain circumstances, mandated after approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and are commonly intended to generate additional safety data regarding use of the product in a clinical setting or in some cases to support full approval for products that are approved via an accelerated pathway as described below. During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical study investigators. Annual progress reports detailing the results of the clinical studies must be submitted to the FDA, and IND safety reports must be submitted to the FDA, other regulators, and investigators within a regulated timeframe for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or in vitro testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure or adverse events reported by anti-FcRn product candidates developed by others.

Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate and must 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 candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. The FDA may require such testing to occur on a lot-by-lot basis in order to release product for clinical use. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

*BLA Submission, Review and Approval*

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as

positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other information. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. The submission of a BLA requires payment of a substantial application user fee to FDA, unless a waiver or exemption applies. There can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Once a BLA has been submitted, the FDA reviews the BLA within 60 days to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act ("PDUFA"), the FDA's goal is to review standard applications within ten months after it accepts the application for filing, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the FDA does not always meet PDUFA goal dates, and the review process can be significantly extended by FDA requests for additional information or clarification or Company submissions of substantial data during the review. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions with emphasis on risk and benefit of the molecule and proposed indications, and provide a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites, preclinical studies, and/or the sponsor to assure compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the BLA, and where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter prior to inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification, completion of other significant and time-consuming requirements related to clinical trials, and/or conduct of additional preclinical studies or manufacturing activities. Even if such data and information are submitted, the FDA may determine that the BLA does not satisfy the criteria for approval. FDA approval of a BLA must be obtained before a biologic may be marketed in the U.S. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied and may require additional clinical testing or safety information.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed, which could limit the commercial value of the product. For example, the FDA may approve the BLA with a REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product, and could include medication guides, healthcare professional and/or patient communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA will evaluate if any labeling or risk management plans are necessary to ensure safe use of the product in the targeted patient population and indication. Once approved, the FDA has the authority to withdraw the product approval if compliance with pre-and post-marketing requirements is not

maintained or if problems occur after the product reaches the marketplace. The FDA may impose post-marketing requirements and commitments such as additional manufacturing data or testing; additional preclinical data or evaluation; additional clinical data from Phase 3 studies (e.g. long-term extension data); and may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing studies.

*Expedited Development and Review Programs and other Marketing Authorization Procedures*

Any marketing application for a biologic submitted to the FDA for approval may be eligible for FDA programs intended to expedite the FDA review and approval process, such as priority review, fast track designation, breakthrough therapy and accelerated approval.

A product is eligible for priority review if it is intended to treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. Priority review designation means the FDA's goal under PDUFA is to take action on the marketing application within six months of the 60-day filing date (compared with ten months under standard review). To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life threatening disease or condition and demonstrates the potential to address an unmet medical need by providing a therapy where none exists or a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. Fast track designation is intended to facilitate development and expedite review of a product, and also provides opportunities for frequent interactions with the FDA review team. The FDA may also review complete sections of the BLA for a fast track product on a rolling basis before the entire application is submitted, if the sponsor and FDA agree on a schedule for the submission of the application sections, and the sponsor pays any required user fees upon submission of the first section of the BLA. The review clock generally does not begin until the final section of the BLA is submitted.

In addition, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA will take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Additionally, products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical studies establishing that the product has an effect on a validated surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint that can be measured earlier than survival or irreversible morbidity and is reasonably likely to predict an effect on survival, irreversible morbidity or another clinical benefit. As a condition of accelerated approval, the FDA requires the sponsor to perform adequate and well-controlled post-marketing confirmatory clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. Approval may be withdrawn if the confirmatory study does not verify the anticipated clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which the sponsor must plan to provide all commercial materials and seek approval prior to the launch of the product.

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 decide that the time period for FDA review and approval will not be shortened. Furthermore, priority review, fast track designation, breakthrough therapy designation, and accelerated approval do not change the standards for approval and may not ultimately expedite the development or approval process.

*Orphan Drug Designation*

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the U.S., or more than 200,000 individuals in the U.S. for which there is no reasonable expectation that the cost of

developing and making available in the U.S. a drug or biologic for this type of disease or condition will be recovered from sales in the U.S. for that drug or biologic. Orphan designation must be requested before submitting a BLA. After the FDA grants orphan designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or automatically shorten the duration of, the regulatory review or approval process. If a product that has orphan designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity by means of greater effectiveness, greater safety or providing a major contribution to patient care or in instances of drug supply issues. Orphan exclusivity does not prevent FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application fee. A designated orphan product may not receive orphan exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the U.S. may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

*Biosimilars and Reference Product Exclusivity*

The Patient Protection and Affordable Care Act ("Affordable Care Act") signed into law in 2010 includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. To date, a number of biosimilars have been licensed under the BPCIA, but no interchangeable biologic has been approved in the U.S. The FDA has issued several guidance documents outlining its approach to the review and approval of biosimilars. 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 study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic 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 biologic. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products.

*Patent Term Restoration and Marketing Exclusivity*

Depending upon the timing, duration and specific circumstances of FDA marketing 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 restoration term of up to five years for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. Subject to certain limitations, the patent term restoration period is generally equal to one-half of the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. However, each phase of the regulatory review period may be reduced by any time that the FDA finds the applicant did act not act with due diligence. Only one patent applicable to an approved drug is eligible for the extension, it must be the first approval of the active ingredient of the product, and the application for the extension must be submitted prior to the expiration of the patent and

within sixty days of approval of the drug. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restorations of patent term for patents that issue from some of our currently owned or licensed patents or patent applications to add patent life beyond their current expiration dates, depending on the expected length of the clinical trials, the eligibility of the product and other factors involved in the filing of the relevant NDA.

Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to NDAs for products containing chemical entities never previously approved by the FDA alone or in combination. A new chemical entity means a drug that contains no active moiety that has been approved by the FDA in any application submitted under Section 505(b) of the FDCA. An active moiety is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application ("ANDA"), or a Section 505(b) (2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. This exclusivity provision does not prevent the submission or approval of another full Section 505(b)(1) NDA, but such an NDA applicant would be required to conduct its own preclinical and adequate, well-controlled clinical trials to demonstrate safety and effectiveness. The FDCA also provides three years of marketing exclusivity for an NDA, Section 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application. Such clinical trials may, for example, support new indications, dosages, routes of administration or strengths of an existing drug, or for a new use. This exclusivity, which is sometimes referred to as clinical investigation exclusivity, prevents the FDA from approving an application under a Section 505(b)(2) NDA or an ANDA for the same conditions of use associated with the new clinical investigations before the expiration of three years from the date of approval. Such three-year exclusivity, however, would not prevent the approval of another application if the applicant submits a Section 505(b)(1) NDA and has conducted its own adequate, well-controlled clinical trials demonstrating safety and efficacy, nor would it prevent approval of an ANDA or a Section 505(b)(2) NDA product that did not incorporate the exclusivity-protected aspects of the approved drug product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products.

Pediatric exclusivity is another type of exclusivity in the United States. Pediatric exclusivity, if granted, provides an additional six months of exclusivity to any existing exclusivity (*e.g.*, three- or five-year exclusivity) or patent protection for a drug. This six-month exclusivity, which runs from the end of other exclusivity or patent protection, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

*Orange Book Listing*

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product or a method of using the product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an ANDA or an application covered by Section 505(b)(2) of the FDCA. An ANDA provides for marketing of a drug product that has the same active ingredients, generally in the same strengths and dosage form, as the listed drug and has been shown through PK testing to be bioequivalent to the listed drug. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are generally not required to conduct, or submit results of, preclinical studies or clinical tests to prove the safety or effectiveness of their drug product. Section 505(b)(2) applications provide for marketing of a drug product that may have the same active ingredients as the listed drug and contains full safety and effectiveness data as an NDA, but at least

some of this information comes from studies not conducted by or for the applicant. This alternate regulatory pathway enables the applicant to rely, in part, on the FDA's findings of safety and efficacy for an existing product, or published literature, in support of its application. The FDA may then approve the new drug candidate for all or some of the labeled indications for which the referenced product has been approved, as well as for any new indication sought by the 505(b)(2) applicant.

The ANDA or Section 505(b)(2) applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA or Section 505(b)(2) applicant may also elect to submit a statement certifying that its proposed ANDA label does not contain, or carves out, any language regarding a patented method of use rather than certify to such listed method of use patent. If the applicant does not challenge the listed patents by filing a certification that the listed patent is invalid or will not be infringed by the new product, the ANDA or Section 505(b)(2) application will not be approved until all the listed patents claiming the referenced product have expired.

A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA or Section 505(b)(2) applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA or Section 505(b)(2) application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or Section 505(b)(2) application until the earliest of 30 months, expiration of the patent, settlement of the lawsuit, and a decision in the infringement case that is favorable to the ANDA or Section 505(b)(2) applicant. This prohibition is generally referred to as the 30-month stay. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation.

The ANDA or Section 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired.

*Post-Approval Requirements*

Any drugs for which we receive FDA approval will be subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements.

The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other government agencies enforce the laws and regulations prohibiting the false or misleading promotion of drugs. The FDA also limits the promotion of product candidates prior to their approval. With limited exceptions, pre-approval promotion is prohibited under the FDA's regulations.

Further, manufacturers of drugs must continue to comply with cGMP requirements, which are extensive and require considerable time, resources and ongoing investment to ensure compliance. In addition, changes to the manufacturing process may require prior FDA approval before being implemented, and other types of changes to the approved product, such as adding new indications and additional labeling claims, are subject to further FDA review and approval. Drug manufacturers and other entities involved in the manufacturing and distribution of approved drugs, and those supplying products, ingredients, and components of them, are required to list their products and to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, applicable product tracking and tracing requirements, and other laws. The cGMP requirements apply to all stages of the manufacturing process, including the production, processing, sterilization, packaging, labeling, storage and shipment of the drug. Manufacturers must establish validated systems to ensure that products meet specifications and regulatory standards and test each product batch or lot prior to its release. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our product candidates. FDA and

state inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution or may require substantial resources to correct.

The FDA may withdraw a product approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Further, the failure to maintain compliance with regulatory requirements may result in administrative or judicial actions, such as fines, untitled and warning letters, holds on clinical trials, product recalls or seizures, product detention or refusal to permit the import or export of products, refusal to approve pending applications or supplements, restrictions on marketing or manufacturing, consent decrees, injunctions or the imposition of civil or criminal penalties.

From time to time, legislation is drafted, introduced and passed in the U.S. Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition to new legislation, the FDA regulations and policies are often revised or reinterpreted by the agency in ways that may significantly affect our business and our product candidates. It is impossible to predict whether further legislative or FDA regulation or policy changes will be enacted or implemented and what the impact of such changes, if any, may be.

*Foreign Regulation*

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials of our product candidates and commercial sales and distribution of any product for which we obtain regulatory approval outside of the United States. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. As in the United States, post-approval regulatory requirements, such as those regarding product manufacture, marketing or distribution, would apply to any product that is approved outside the United States.

For example, in the European Union, we may submit applications for marketing authorizations either under a centralized, decentralized, or mutual recognition marketing authorization procedure. The centralized procedure provides for the grant of a single marketing authorization for a medicinal product by the European Commission on the basis of a positive opinion by the European Medicines Agency. A centralized marketing authorization is valid for all European Union member states and three of the four European Free Trade Association States (Iceland, Liechtenstein and Norway). The decentralized procedure and the mutual recognition procedure apply between European Union member states. The decentralized marketing authorization procedure involves the submission of an application for marketing authorization to the competent authority of all European Union member states in which the product is to be marketed. One national competent authority, selected by the applicant, assesses the application for marketing authorization. The competent authorities of the other European Union member states are subsequently required to grant marketing authorization for their territory on the basis of this assessment, except where grounds of potential serious risk to public health require this authorization to be refused. The mutual recognition procedure provides for mutual recognition of marketing authorizations delivered by the national competent authorities of European Union member states by the competent authorities of other European Union member states. The holder of a national marketing authorization may submit an application to the competent authority of a European Union member state requesting that this authority recognize the marketing authorization delivered by the competent authority of another European Union member state for the same medicinal product.

We are also subject to the U.K. Bribery Act, and other third country anti-corruption laws and regulations pertaining to our financial relationships with foreign government officials. The U.K. Bribery Act, which applies to any company incorporated or doing business in the UK, prohibits giving, offering, or promising bribes in the public and private sectors, bribing a foreign public official or private person, and failing to have adequate procedures to prevent bribery amongst employees and other agents. Penalties under the Bribery Act include potentially unlimited fines for companies and criminal sanctions for corporate officers under certain circumstances. Liability in relation to breaches of the U.K. Bribery Act is strict. This means that it is not necessary to demonstrate elements of a corrupt state of mind. However, a defense of having in place adequate procedures designed to prevent bribery is available.

*Formulary Approvals and Third-Party Payer Coverage and Reimbursement*

In both the United States and foreign markets, our ability to successfully commercialize our product candidates for which we receive regulatory approval, and to attract commercialization partners for our product candidates, depends in significant part on the availability of institutional formulary approvals and on adequate financial coverage and reimbursement from third-party payers, including, in the United States. These payers include the Centers for Medicare & Medicaid Services ("CMS"), the federal program that runs the Medicare program, and monitors the Medicaid programs offered by each state, as well as national and regional commercial plans. Medicare is a federally funded program managed by CMS through local Medicare Administrative Contractors that administer coverage and reimbursement for certain healthcare items and services furnished to the elderly, disabled and other individuals with certain conditions. Medicaid is an insurance program for certain categories of patients whose income and assets fall below state defined levels that is both federally and state funded and managed by each state. The federal government sets general guidelines for Medicaid and each state creates specific regulations that govern its individual program. Each government or commercial plan has its own process and standards for determining whether it will cover and reimburse a procedure or particular product and how much it will pay for that procedure or product. Commercial plans often rely on the lead of the governmental payers in rendering coverage and reimbursement determinations. Therefore, achieving favorable Medicare coverage and reimbursement is usually an essential component of successfully launching a new product. The competitive position of some of our products will depend, in part, upon the extent of coverage and adequate reimbursement for such products and for the procedures in which such products are used. Reimbursement can be subject to challenge, reduction or denial by government and other commercial plans.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government healthcare programs and other third-party payers are increasingly challenging the prices charged for medical products and services and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy, and have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payers are challenging the prices charged for medical products and requiring that drug companies provide them with predetermined discounts from list prices.

The Inflation Reduction Act of 2022 (the "IRA") contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services that would require manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and requires manufacturers to provide discounts on Part D drugs. Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the IRA. The IRA could have the effect of reducing the prices we can charge and reimbursement we receive for our products, if approved, thereby reducing our profitability, and could have a material adverse effect on our financial condition, results of operations, and growth prospects. The effects of the IRA on our business and the pharmaceutical industry in general is not yet known.

Payers also are increasingly changing the metrics for reimbursement rates, such as basing payment on average sales price, average manufacturer price, and wholesale acquisition cost. The existing data for reimbursement based on these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates. CMS surveys and publishes retail community pharmacy acquisition cost information in the form of National Average Drug Acquisition Cost files to provide state Medicaid agencies with a basis of comparison for their own reimbursement and pricing methodologies and rates. It may be difficult to project the impact of these evolving reimbursement mechanics on the willingness of payers to cover any products.

If we successfully commercialize any of our products, we may participate in the Medicaid Drug Rebate Program. Participation is required for federal funds to be available for our products under Medicaid and Medicare Part B. Under the Medicaid Drug Rebate Program, we would be required to pay a quarterly rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Part B of the Medicare program.

Federal law requires that any company that participates in the Medicaid Drug Rebate Program also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B drug pricing program requires participating

manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients.

Additionally, in order to be eligible to have its products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, a manufacturer also must participate in the Department of Veterans Affairs, Federal Supply Schedule ("FSS"), pricing program, established by Section 603 of the Veterans Health Care Act of 1992 ("VHCA"). Under this program, the manufacturer is obligated to make its innovator and single source products available for procurement on an FSS contract and charge a price to four federal agencies, Department of Veterans Affairs, Department of Defense ("DoD"), Public Health Service, and Coast Guard, that is no higher than the statutory Federal Ceiling Price. Moreover, pursuant to regulations issued by the DoD's TRICARE Management Activity, now the Defense Health Agency, to implement Section 703 of the National Defense Authorization Act for Fiscal Year 2008, manufacturers are required to provide rebates on utilization of their innovator and single source products that are dispensed to TRICARE beneficiaries by TRICARE network retail pharmacies. The formula for determining the rebate is established in the regulations and is based on the difference between the annual non-federal average manufacturer price and the Federal Ceiling Price (these price points are required to be calculated by us under the VHCA). The requirements under the 340B, FSS, and TRICARE programs could reduce the revenue we may generate from any products that are commercialized in the future.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers costs, including research, development, manufacturing, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover costs and may only be temporary. Reimbursement rates vary according to the use of the drug and the clinical setting in which it is used. Product reimbursement may also be incorporated into existing bundled payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or commercial payers and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Limited coverage may impact the demand for, or the price of, any product candidate for which marketing approval is obtained. Third-party payers also may seek additional clinical evidence, including expensive pharmacoeconomic studies, beyond the data required to obtain marketing approval, demonstrating clinical benefits and value in specific patient populations, before covering our products for those patients. If reimbursement is available only for limited indications, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and commercial payers for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

*United States Healthcare Reform*

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system, including implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs.

In the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the "Affordable Care Act"), was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry, and impose additional health policy reforms.

Among the provisions of the Affordable Care Act that have been implemented since enactment and are of importance to the commercialization of our product and product candidates, if approved, are the following:

- an annual, nondeductible fee on any entity that manufactures, or imports specified branded prescription drugs or biologic agents;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the U.S. civil False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- requirements to report certain financial arrangements with physicians and teaching hospitals;
- a requirement to annually report certain information regarding drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

There have been significant ongoing judicial, administrative, executive and legislative efforts to modify or eliminate the Affordable Care Act. For example, the Tax Act enacted on December 22, 2017, repealed the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code, commonly referred to as the individual mandate. Other legislative changes have been proposed and adopted since passage of the Affordable Care Act. The Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve its targeted deficit reduction of an amount greater than $1.2 trillion for the fiscal years 2012 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions included aggregate reductions to Medicare payments to healthcare providers of up to 2.0% per fiscal year, which went into effect in April 2013. Subsequent litigation extended the 2% reduction, on average, to 2030 unless additional Congressional action is taken. The Coronavirus Aid, Relief and Economic Security Act, which was designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 to March 31, 2022. From April through June 2022, a 1% reduction was in effect. As of July 2, 2022, the 2% cut resumed. The sequester will remain in place through 2030. On January 2, 2013, the American Taxpayer Relief Act was signed into law, which, among other things, 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.

The Affordable Care Act has also been subject to challenges in the courts. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional and remanded the case to the Texas District Court to reconsider its earlier invalidation of the entire Affordable Care Act. An appeal was taken to the U.S. Supreme Court. On June 17, 2021, the Supreme Court ruled that the plaintiffs lacked standing to challenge the law as they had not alleged personal injury traceable to the allegedly unlawful conduct. As a result, the Supreme Court did not rule on the constitutionality of the Affordable Care Act or any of its provisions.

Further changes to and under the Affordable Care Act remain possible but it is unknown what form any such changes or any law proposed to replace or revise the Affordable Care Act would take, and how or whether it

may affect our business in the future. We expect that changes to the Affordable Care Act, the Medicare and Medicaid programs, changes allowing the federal government to directly negotiate drug prices and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry. We also expect that the Affordable Care Act, as well as other healthcare reform measures that have 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 our product and product candidates, if approved. Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payers.

*Other Healthcare Laws and Compliance Requirements*

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our activities will be subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil False Claims Act, and laws and regulations pertaining to limitations on and reporting of healthcare provider payments (physician sunshine laws). These laws and regulations are interpreted and enforced by various federal, state and local authorities including CMS, the Office of Inspector General for the U.S. Department of Health and Human Services, the U.S. Department of Justice, individual U.S. Attorney offices within the Department of Justice, and state and local governments. These laws 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, 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 arranging for or recommending the purchase, lease or order of, any good or service, for which payment may be made, in whole or in part, under federal 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. civil False Claims Act (which can be enforced through "qui tam," or whistleblower actions, by private citizens on behalf of the federal government), prohibits any person from, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment of government funds or knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the U.S. federal government;
- U.S. federal Health Insurance Portability and Accountability Act of 1996, which imposes criminal liability and amends provisions on the reporting, investigating, enforcement, and penalizing of 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 by a healthcare benefit program, which includes both government and privately funded benefits programs; 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;
- state laws and regulations, including state anti-kickback and false claims laws, that 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 payer, 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; and 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; and
- the Physician Payments Sunshine Act, implemented as the Open Payments program, and its implementing regulations, 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 CMS information related to certain payments made in the preceding calendar year

and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; beginning in 2022, applicable manufacturers were required to report such information regarding payments and transfers of value provided, as well as ownership and investment interests held, during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives.

Violations of any of these laws or any other governmental regulations that may apply to us, may subject us to significant civil, criminal and administrative sanctions including penalties, damages, fines, imprisonment, and exclusion from government funded healthcare programs, such as Medicare and Medicaid, and/or adverse publicity.

Moreover, government entities and private litigants have asserted claims under state consumer protection statutes against pharmaceutical and medical device companies for alleged false or misleading statements in connection with the marketing, promotion and/or sale of pharmaceutical and medical device products, including state investigations and litigation by certain government entities regarding the marketing of opioid products.

*Foreign Corrupt Practices Act*

The Foreign Corrupt Practices Act ("FCPA") generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our industry is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently, the SEC and Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies. Violations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business.

***Corporate Information***

We were incorporated in Pennsylvania in 2019 and our office headquarters is located at 490 Lapp Road, Malvern, Pennsylvania 19355.

## BAUDAX MANAGEMENT FOLLOWING THE ACQUISITION

*Board of Directors*

The following table provides information about those persons who serve as directors of the Company following completion of the Acquisition.

| Name | Age | | Committees[1] | | | Class – Election Year |
|---|---|---|---|---|---|---|
| | | | Audit | Comp | N&CG | |
| Andrew Drechsler | 51 | Director | **C** | X | | Class I – 2026 |
| Gerri Henwood | 70 | Director | | | | Class I – 2026 |
| William L. Ashton | 72 | Director | X | **C** | | Class II – 2024 |
| Wayne B. Weisman | 67 | Chair of the Board | X | X | X | Class II – 2024 |
| Yong Chan Kim, Ph.D. | 49 | Director | | | | Class II – 2024 |
| Arnold Baskies, M.D. | 74 | Director | | | X | Class III – 2025 |
| Winston J. Churchill | 82 | Director | X | X | **C** | Class III – 2025 |

(1) "C" indicates Chair of the applicable committee.

*Andrew Drechsler* has served as director since August 2020. Mr. Drechsler has also served as a Senior Finance Executive at BioDrex since April 2017. From September 2017 to December 2021, Mr. Drechsler served as Chief Financial Officer of Provention Bio, a publicly-traded biopharmaceutical company dedicated to intercepting and preventing immune-mediated diseases. From 2012 to March 2017, Mr. Drechsler was the Chief Financial Officerat Insmed Incorporated, a publicly-traded biopharmaceutical company dedicated to improving the lives of patients with orphan pulmonary diseases. Prior to that, Mr. Drechsler was Chief Financial Officer at VaxInnate, aprivately held biotechnology company, and Chief Financial Officer for Valera Pharmaceuticals, Inc. Mr. Drechsler received a B.S. in Accountancy from Villanova University, graduating Magna Cum Laude. He obtained his Certified Public Accountant license in the State of New Jersey and actively raises funds for and awareness of type one diabetes via the Juvenile Diabetes Research Foundation.

***Skills & Qualifications:*** Mr. Drechsler's financial, accounting management and audit expertise, as well as his extensive executive leadership experience provide him with the qualifications and skills to serve on our Board.

*Gerri Henwood* has served as our President and Chief Executive Officer and a director of the Company since2019. Ms. Henwood previously served as the President and Chief Executive Officer of Societal CDMO, Inc. ("Societal CDMO") (f/k/a Recro Pharma, Inc.), which she founded in 2008, until 2020. From 2006 to 2013, Ms. Henwood served as the President of Malvern Consulting Group, Inc., a pharmaceutical incubator and consulting firm. From 1999 to 2006, Ms. Henwood was the President and Chief Executive Officer of Auxilium Pharmaceuticals, Inc., a biopharmaceutical company she founded in late 1999. From 1985 to 1999, Ms. Henwood was the founder and Chief Executive Officer of IBAH, Inc., a contract research organization. Ms. Henwood began her career with Smith Kline & French, now part of GlaxoSmithKline plc. She rose through the ranks to be a brand manager, then the head of Regulatory and Medical Affairs for the U.S. business and then to the position of Group Director—Marketing in the International Pharmaceutical Division. Ms. Henwood previously served on the board of directors of Societal CDMO from 2008 until January 2022, and Tetraphase Pharmaceuticals, Inc., a position she held from May 2015 until the first half of 2020. Ms. Henwood also served on the compensation committee of Tetraphase Pharmaceuticals, Inc. She served on the board of directors of Alkermes, Inc. and its successor company, Alkermes, plc, a global biopharmaceutical company, from 2003 until March 2015, and on the board of directors of MAP Pharmaceuticals, Inc., a biopharmaceutical company, from 2004 until its acquisition by Allergan, Inc. in March 2013. Ms. Henwood holds a B.S. in Biology from Neumann University.

***Skills & Qualifications:*** Ms. Henwood's expertise in developing, financing and providing strong executive leadership to numerous biopharmaceutical companies, her strong background in pharmaceutical marketing and commercialization, clinical and product development and substantial knowledge of the pharmaceutical industry,her corporate governance experience as a board member of multiple publicly traded and privately held companies, as well as her extensive knowledge of our business, contributed to our Board's conclusion that she should serve as a director of our Company.

*William L. Ashton* has served as a director since 2019. Since the beginning of 2013, Mr. Ashton has been a principal at Harrison Consulting Group, Inc., a privately-held biopharmaceutical consulting firm. From

August 2009 to June 2013, Mr. Ashton was the senior vice president of external affairs reporting to the president and an assistant professor at the University of the Sciences in Philadelphia, Pennsylvania. From August 2005 to August 2009, Mr. Ashton was the founding Dean of the Mayes College of Healthcare Business and Policy. Mr. Ashton has 29 years' experience in the biopharmaceutical industry. From 1989 to 2005, Mr. Ashton held a number of positions at Amgen Inc., a biotechnology company, including vice president of U.S. sales and vice president of commercial and government affairs. Mr. Ashton currently serves on the boards of directors of Societal CDMO and Spectrum Pharmaceuticals, Inc. and has served on the boards of Galena Biopharma, Inc. and Sucampo Pharmaceuticals, Inc. He is also a member of the board of directors of the National Osteoporosis Foundation and Friends of the National Library of Medicine at the National Institutes of Health. Mr. Ashton holds a B.S., Education, from the California University of Pennsylvania and an M.A., Education, from the University of Pittsburgh.

***Skills & Qualifications:*** Mr. Ashton's extensive experience with pharmaceutical and biological product commercialization, including developing and leading a commercial sales force, as well as his governance experience as a board member of public and privately-held companies, member of the National Association of Corporate Directors and his reimbursement expertise contributed to our Board's conclusion that he should serve as a director of our Company.

*Wayne B. Weisman* has been a director of the Company since 2019. Since 2007, Mr. Weisman has been a director of the corporate general partner of the common general partner of SCP Vitalife. He has also served as a managing member of SCP Vitalife Management Company, LLC, which by contract provides certain management services to the common general partner of SCP Vitalife. He has also led the activities of SCP Private Equity Partners II, L.P., a venture capital fund of which he and Mr. Churchill are principals, in the life sciences area; these activities include investments in the United States and Israel. He has also led several other technology investments for SCP Private Equity Partners II, L.P. He has been a member of the investment committee of the Vitalife Life Sciences funds since their inception in 2002 and has worked closely with these funds since then. From 1992 to 1994, Mr. Weisman was executive vice president and member of the board of directors of a public drug delivery technology company. In addition, he also operated a management and financial advisory firm focusing on the reorganization and turnaround of troubled companies and began his career practicing reorganization law at a large Philadelphia law firm. Mr. Weisman possesses extensive experience in venture capital investing, particularly in the life sciences area. Mr. Weisman serves on the board of Societal CDMO, ReWalk Robotics Ltd. and on a number of private company boards. He is the vice chairman of the board of trustees of Young Scholars Charter School, where he served as chairman from 2010 to 2017. He is also an advisory board member of Mid-Atlantic Diamond Ventures, the venture forum of Temple University. Mr. Weisman holds a B.A. from the University of Pennsylvania and a J.D. from the University of Michigan Law School.

***Skills & Qualifications:*** Mr. Weisman's leadership as a director of various pharmaceutical and healthcare companies, experience serving on the board of directors of life sciences companies, insight into the legal issues facing our business, as well as his in-depth knowledge of our business and history, contributed to our Board's conclusion that he should serve as a director of our Company.

*Yong Chan Kim, Ph.D.* has been a director of the Company since 2023. Dr. Kim has served as the CEO and Director of TeraImmune, Inc. since April 2019. Dr. Kim served as Vice President of Research of TeraImmune, LLC from April 2017 until March 2019. He also previously served as a Research Assistant Professor at the Uniformed Services University of the Health Sciences from May 2015 until March 2018. Dr. Kim received his Ph.D. in Biochemistry from Chungnam National University and completed his post-doctoral fellowship at the Uniformed Services University of the Health Sciences.

***Skills & Qualifications:*** Dr. Kim's experience in the biotechnology industry and experience with drug development contributed to our Board's conclusion that he should serve as a director of our Company.

*Dr. Arnold Baskies* has served as director since August 2020. From 2007 to 2010, Dr. Baskies served as the Chief Medical Officer for the American Cancer Society of New York and New Jersey and was elected as President of the American Cancer Society for New York and New Jersey in September 2010. In 2016, he served as Science Officer to the ACS National Board, and in 2017, he served as Chairman of the National Board of Directors of ACS. He currently serves on the Executive Committee of the Commission on Cancer and the Global Breast Cancer Initiative of the World Health Organization (WHO). Dr. Baskies is the recipient of major awards

in cancer research from the Society of Surgical Oncology, the American Radium Society, the Society of Head and Neck Surgeons and the American Cancer Society. In addition, he is a recipient of the St. George Medal from ACS, the recipient of the EPIC Award from the NJ Institute of Nursing and awarded the Silver Chalice Award from the American Cancer Society, for his role in providing leadership in cancer prevention and treatment for the citizens of New Jersey. Dr. Baskies has maintained a medical practice in southern New Jersey for 44 years and is a Clinical Professor of Surgery at Rowan School of Medicine and Jefferson School of Nursing. He holds major state and national leadership roles in cancer prevention and treatment. He has personally treated over 5,000 patients with various types of cancer and performed over 10,000 surgical procedures. Dr. Baskies received his Bachelor of Arts degree summa cum laude, Phi Beta Kappa, at Boston University. He graduated from the Boston University School of Medicine and completed his surgical residency at Boston Medical Center and his fellowship in surgical oncology at the National Cancer Institute.

***Skills & Qualifications:*** Dr. Baskies' expertise in the life sciences industry and extensive medical experience provide him with the qualifications and skills to serve on our Board.

*Winston J. Churchill* has been a member of our Board since November 2019. Since 2007, Mr. Churchill has beena director of the corporate general partner of the common general partner of SCP Vitalife. He has also served as a managing member of SCP Vitalife Management Company, LLC, which by contract provides certain management services to the common general partner of SCP Vitalife. Since 1993, Mr. Churchill has served as the President of CIP Capital Management, Inc., the general partner of CIP Capital, L.P., an SBA-licensed private equity fund. Prior to that, Mr. Churchill was a managing partner of Bradford Associates, which managed private equity funds on behalf of Bessemer Securities Corporation and Bessemer Trust Company. From 1967 to 1983, Mr. Churchill practiced law at the Philadelphia firm of Saul Ewing, LLP, where he served as Chairman of the Banking and Financial Institutions Department, Chairman of the Finance Committee and was a member of the Executive Committee. Mr. Churchill is a director of Societal CDMO, Innovative Solutions and Support, Inc., Amkor Technology, Inc. and various SCP Vitalife portfolio companies. He also previously served as a director of Griffin Industrial Realty from April 1997 until May 2016. In addition, he serves as a director on the boards of several charities and as a trustee of educational institutions including the Gesu School and Young Scholars Charter School, Inc., as a Trustee Fellow of Fordham University, and Trustee Emeritus of Georgetown University. From 1989 to 1993, Mr. Churchill served as Chairman of the Finance Committee of the Pennsylvania Public School Employees' Retirement System. He was awarded a B.S. in Physics, summa cum laude, from Fordham University followed by an M.A. in Economics from Oxford University, where he studied as a Rhodes Scholar, and a J.D. from Yale Law School.

***Skills & Qualifications:*** Mr. Churchill's insight into financial and investment matters from his experience in private equity investing in life sciences companies, his financial and corporate governance experience fromserving on numerous public and private boards of directors, as well as his extensive knowledge of our business and history, contributed to our Board's conclusion that he should serve as a director of our Company.

*Board of Directors following Approval of Conversion Proposal*

Under the terms of the Merger Agreement, in connection with the closing of the Acquisition, Dr. Kim was appointed to the Company's Board of Directors. In addition, under the terms of the Merger Agreement, if shareholder approval of the Conversion Proposal is obtained, the Company is required to use reasonable best efforts and take all necessary action so that immediately after the date on which shareholder approval of the Conversion Proposal is obtained, three individuals nominated by unanimous agreement of Ms. Henwood, the Company's President and Chief Executive Officer, and certain stockholders of TeraImmune immediately prior to the closing of the Acquisition and approved by the Nominating and Corporate Governance Committee of the Company's Board of Directors shall be appointed to the Company's Board of Directors (provided that a sufficient number of such additional board designees shall qualify as "independent directors" to the extent necessary to ensure that the composition of the Company's Board of Directors complies with applicable SEC and Nasdaq rules).

*Executive Management*

The following table provides information about those persons who serve as executive officers of the Company following completion of the Acquisition.

| Name | Age | Position(s) Held in Company Following the Acquisition |
|---|---|---|
| Gerri Henwood | 70 | President, Chief Executive Officer |
| Jillian Dilmore | 37 | Corporate Controller |

* Ms. Henwood is a member of our Board of Directors. *See* "Baudax Management Following the Acquisition — *Board of Directors*" above for more information about Ms. Henwood.

*Jillian Dilmore* has served as our Corporate Controller since January 2021 and previously served as Director of Accounting from November 2019 to January 2021. Prior to joining us, Ms. Dilmore was Director of Accounting from January 2019 to December 2020, and Senior Manager of Financial Reporting from September 2017 to January 2019 with Societal CDMO. Ms. Dilmore was previously Assistant Controller at DSM, a division ofRoyal DSM (listed on Euronext Amsterdam), a global science-based company active in health, nutrition, and materials. Ms. Dilmore was also Senior Accountant at the Kensey Nash Corporation, a medical device company, and a Senior Auditor at Deloitte & Touche. Ms. Dilmore received a B.A. in both Accounting and Business Finance from Muhlenberg College. She maintains her Certified Public Accountant license in Pennsylvania and is also a Chartered Global Management Accountant.

## PROPOSALS

## PROPOSAL NO. 1:
## APPROVAL OF CONVERSION PROPOSAL

***Overview***

As described above, the Company issued 27,089.719 shares of Series X Preferred Stock in the Acquisition. The Series X Preferred Stock is intended to have rights that are generally equivalent to our common stock, provided that the Series X Preferred Stock does not have the right to vote on most matters (including the election of directors). Upon conversion of the above-described Series X Preferred Stock, 27,089,719 shares of common stock are issuable, assuming approval of this Proposal No. 1 and subject to certain beneficial ownership limitations.

Subject to shareholder approval, each share of Series X Preferred Stock is convertible into 1,000 shares of common stock. This Proposal No. 1 would provide the necessary approval to permit such conversion automatically upon receipt of such approval. In the event that shareholders do not elect to permit conversion of the Series X Preferred Stock, then the holders of the Series X Preferred Stock may, commencing on December 29, 2023, elect to have such shares redeemed by the Company at the then-current as-converted fair value (as such term is defined in the Series X Certificate of Designation) of the Series X Preferred Stock. *See* "Risk Factors — *Risks Relating to Ownership of Our Common Stock*." Pursuant to the terms of the Merger Agreement, we are required to use reasonable best efforts to recommend that our shareholders approve the conversion of all outstanding shares of our Series X Preferred Stock into shares of our common stock. We cannot guarantee that our shareholders will approve this matter, and if they fail to do so, we may be required to settle their shares of Series X Preferred Stock for cash at a price per share equal to the as-converted fair value of such shares of Series X Preferred Stock and our operations may be materially harmed.

***Shares Issuable Upon Conversion***

As described above, the Company issued 27,089.719 shares of Series X Preferred Stock in the Acquisition. There are 27,089,719 shares of common stock that are potentially issuable upon conversion of the Series X Preferred Stock. The sale into the public market of the underlying common stock could materially and adversely affect the market price of our common stock. *See* "Risk Factors — Risks Relating to Ownership of Our Common Stock."

Immediately following the closing of the Acquisition, on an as-converted, fully-diluted basis and excluding certain out-of-the-money warrants held by equityholders of the Company as of immediately prior to the Mergers, (i) the former stockholders of TeraImmune as of immediately prior to the Mergers owned approximately 82% of the Company's outstanding common stock and (ii) equityholders of the Company as of immediately prior to the Mergers owned approximately 18% of the Company's outstanding common stock. Assuming the approval of this Proposal No. 1, the total number of shares of common stock issued and outstanding or reserved for issuance (determined on an as-converted basis) will be approximately .

***Description of Series X Preferred Stock***

***Conversion***. Subject to shareholder approval of this Proposal No. 1, the Series X Preferred Stock is convertible into common stock at a rate of 1,000 shares of common stock for every one share of Series X Preferred Stock that is converted. Following shareholder approval of the Conversion Proposal, each share of Series X Preferred Stock then outstanding shall automatically convert into 1,000 of shares of common stock (subject to adjustments set forth in the Series X Certificate of Designation), subject to certain limitations, including that the Company shall not effect any conversion of shares of Series X Preferred Stock into shares of Common Stock if: (i) as a result of such conversion, such holder, together with its affiliates, would beneficially own more 19.99% of the total number of shares of Common Stock issued and outstanding immediately after giving effect to such conversion or (ii) the number of shares of Common Stock into which such shares of Series X Preferred Stock can then be converted exceeds the maximum number of unissued and otherwise unreserved shares of Common Stock which the Company may issue under its articles of incorporation at any given time.

***Voting Rights***. Except as otherwise required by law, the Series X Preferred Stock does not have voting rights. However, as long as any shares of Series X Preferred Stock are outstanding, the Company will not, without the affirmative vote of the holders of a majority of the then-outstanding shares of the Series X Preferred Stock,

(a) alter or change adversely the powers, preferences or rights given to the Series X Preferred Stock, (b) alter or amend the Series X Certificate of Designation, (c) amend its articles of incorporation or other charter documents in any manner that adversely affects any rights of the holders of Series X Preferred Stock, (d) issue further shares of Series X Preferred Stock or increase the number of authorized shares of Series X Preferred Stock, (e) prior to the shareholder approval of this Conversion Proposal or at any time while at least 30% of the originally issued Series X Preferred Stock remains issued and outstanding, consummate a Fundamental Transaction (as defined in the Series X Certificate of Designation) or any merger or consolidation of the Company with or into another entity or any stock sale to, or other business combination in which the shareholders of the Company immediately before such transaction do not hold at least a majority of the capital stock of the Company immediately after such transaction, or (f) enter into any agreement with respect to any of the foregoing. The Series X Preferred Stock shall rank on parity with the common stock as to distributions of assets upon liquidation, dissolution or winding up of the Company, whether voluntarily or involuntarily.

***Dividends***. Holders of Series X Preferred Stock are entitled to receive dividends on shares of Series X Preferred Stock equal, on an as-if-converted-to-Common-Stock basis, and in the same form as dividends actually paid on shares of the common stock.

***Liquidation and Dissolution***. The Series X Preferred Stock ranks on parity with our common stock upon any liquidation, dissolution or winding up of the Company.

***Reasons for Shareholder Approval***

The Company's common stock is listed on the Nasdaq Capital Market and, as such, the Company is subject to the applicable Nasdaq rules, including Nasdaq Listing Rule 5635(a), which requires shareholder approval in connection with the acquisition of another company if the Nasdaq-listed company will issue more than 20% of its common stock in connection with such acquisition. While shareholder approval of the Acquisition was not required under Nasdaq rules, in order to permit the issuance of common stock upon conversion of the Series X Preferred Stock, the Company must first obtain shareholder approval of this issuance.

***Beneficial Ownership Limitations***

Assuming that Proposal No. 1 is approved, the Series X Preferred Stock will continue to have a beneficial ownership conversion limit that would prevent a shareholder from converting their shares if, as a result of such conversion, they would beneficially own a number of shares above their applicable conversion blocker (which cannot exceed 19.9% of the outstanding common stock).

***Vote Required; Recommendation of Board of Directors***

The affirmative vote of the holders of shares of common stock representing a majority of the votes present or represented and voting on the matter is required for the approval of this Proposal No. 1 (subject to the separate tabulation of votes described in "*How many votes can be cast by all shareholders?*" set forth above). Broker non-votes (if any) and abstentions will not be counted as votes cast on the matter and will have no effect on the outcome of this proposal.

**THE BOARD RECOMMENDS THAT BAUDAX'S SHAREHOLDERS VOTE FOR THIS PROPOSAL NO. 1: THE APPROVAL OF, UNDER APPLICABLE NASDAQ LISTING RULES, THE ISSUANCE OF SHARES OF COMMON STOCK UPON CONVERSION OF THE SERIES X PREFERRED STOCK.** ✔

## PROPOSAL NO. 2
## APPROVAL OF THE AMENDMENT TO THE AMENDED AND RESTATED ARTICLES OF INCORPORATION TO EFFECT THE REVERSE STOCK SPLIT

***Overview***

Our Board has deemed it advisable, has approved and is hereby soliciting shareholder approval of, an amendment to our Amended and Restated Articles of Incorporation to effect a reverse stock split (the "Reverse Stock Split") at a ratio between one-for- (1: ) and one-for- (1: ) (the "Split Ratio Range"), in the form set forth in Annex A to this proxy statement. The Reverse Stock Split Proposal, if approved by shareholders, would not immediately cause a reverse stock split, but rather would grant authorization to our Board to effect a reverse stock split (without reducing the number of authorized shares of our common stock), if, and when determined by our Board.

If we receive the required shareholder approval, our Board would have the sole authority to elect, at any time within one year of the date of the Special Meeting, whether or not to effect a reverse stock split. Even with shareholder approval of the Reverse Stock Split Proposal, our Board will not be obligated to pursue the Reverse Stock Split. Rather, our Board will have the flexibility to decide whether or not a reverse stock split (and at what ratio within the Split Ratio Range) is in the best interests of the Company.

If approved by our shareholders and, following such approval, our Board determines that effecting a reverse stock split is in the best interests of the Company and our shareholders, the Reverse Stock Split would become effective upon filing an amendment to our Amended and Restated Articles of Incorporation with the Secretary of the Commonwealth of Pennsylvania. As filed, the amendment would state the number of outstanding shares to be combined into one share of our common stock, at the ratio approved by our Board within the Split Ratio Range. The amendment would not change the par value of our common stock and would not impact the total number of authorized shares of our common stock. Therefore, upon effectiveness of a reverse stock split, the number of shares of our common stock that are authorized and unissued will increase relative to the number of issued and outstanding shares of our common stock.

We reserve the right to abandon the Reverse Stock Split without further action by our shareholders at any time before the effectiveness of the filing with the Secretary of the Commonwealth of Pennsylvania of the Articles of Amendment to the Articles, even if the authority to effect the Reverse Stock Split has been approved by our shareholders at the Special Meeting. By voting in favor of the Reverse Stock Split, you are expressly also authorizing the Board to delay, not to proceed with, and abandon, the Reverse Stock Split if it should so decide, in its sole discretion, that such action is in the best interests of the Company.

***Purpose of the Reverse Stock Split***

Our primary objective in effectuating the Reverse Stock Split would be to attempt to raise the per-share trading price of our common stock to meet Nasdaq's initial listing requirements, which requires, among other things, that our common stock have a per share bid price that is greater than or equal to $4.00 per share. On , 2023, the closing bid price for our common stock on the Nasdaq Capital Market was $ per share. The Board of Directors also believes that a higher stock price may help generate investor interest in the Company and help the Company attract and retain employees.

If the Reverse Stock Split successfully increases the per share price of our common stock, the Board of Directors also believes this increase may increase trading volume in our common stock and facilitate future financings by the Company.

*Nasdaq Listing Requirements*

On November 18, 2022, the Nasdaq Listing Qualifications Department ("Staff") informed us that we did not comply with Nasdaq Listing Rule 5550(b)(1). The Staff granted our request for an extension until May 15, 2023, to comply with Nasdaq Listing Rule 5550(b). On May 17, 2023, we received a delist determination letter from the Staff advising us that the Staff had determined that we did not meet the terms of such extension. We requested an appeal of the Staff's determination and submitted a hearing request to the Nasdaq Hearings Panel ("Panel"), which request stayed any delisting action by the Staff at least until the hearing process concludes and any extension granted by the Panel expires.

On June 9, 2023, we received a deficiency letter from the Staff notifying us that we are not in compliance with Nasdaq Listing Rule 5550(a)(2) and because we effected two reverse stock splits over the previous two-year period with a cumulative ratio of 250 shares or more to one, we are not eligible for any compliance period specified in Nasdaq Listing Rule 5810(c)(3)(A). Our noncompliance with Nasdaq Listing Rule 5550(a)(2) serves as an additional basis for delisting of our securities from the Nasdaq and the Panel will consider this matter in rendering a determination regarding the our continued listing on the Nasdaq. On June 29, 2023, our hearing with the Panel was held and we submitted our plan for compliance to the Panel. On July 24, 2023, we received a letter from the Staff ("Hearing Decision") notifying us of its decision to grant our request to continue our listing on Nasdaq on a conditional basis, subject to, among other things, our ability to demonstrate compliance with the Nasdaq initial listing requirements by or before November 13, 2023. There can be no assurance that we will meet the conditions set forth by the Staff in the Hearing Decision, or that we will be able to regain compliance with such applicable Nasdaq listing requirements.

Furthermore, we believe that our acquisition of TeraImmune will, upon shareholder approval of Proposal No. 1, be considered a "change of control" transaction under Nasdaq rules. As such, the Company must meet Nasdaq's initial listing requirements. Accordingly, the Company must meet all the requirements set forth in Nasdaq Listing Rule 5505(a) and at least one of the standards set forth in Nasdaq Listing Rule 5505(b).

The listing standards of Nasdaq Listing Rule 5505(a) require the Company to have, among other things:

- a minimum bid price that is greater than or equal to $4.00 per share;
- at least 1,000,000 unrestricted publicly held shares;
- at least 300 round-lot holders, and at least 50% of such round lot holders must each hold unrestricted securities with a market value of at least $2,500;
- at least three registered and active market makers; and
- a minimum average daily trading volume of 2,000 shares over the 30 trading day period prior to listing, with trading occurring on more than half of those 30 days, unless such security is listed on Nasdaq in connection with a firm commitment underwritten public offering of at least $4 million.

The Company must also satisfy at least one of the following Nasdaq Listing Rule 5505(b) requirements:

- shareholders' equity of at least $5 million, a market value of unrestricted publicly held shares of at least $15 million, and two years of operating history;
- a market value of listed securities of at least $50 million, shareholders' equity of at least $4 million, and a market value of unrestricted publicly held shares of at least $15 million; or
- net income from continuing operations of $750,000 in the most recently completed fiscal year or in two of the three most recently completed fiscal years, shareholders' equity of at least $4 million, and a market value of unrestricted publicly held shares of at least $5 million.

Failure to approve the Reverse Stock Split may have serious, adverse effects on the Company and its shareholders. Our common stock could be delisted from Nasdaq because shares of our common stock may continue to trade below the requisite $4.00 per share price needed to comply with the initial listing requirements of Nasdaq or maintain our listing. Our shares may then be quoted on the OTC Bulletin Board or other small trading markets, which are generally considered to have less volume and be less efficient markets. We believe an investor likely would find it less convenient to sell, or to obtain accurate quotations in seeking to buy, our common stock on an over-the-counter market. Many investors likely would not buy or sell our common stock due to difficulty in accessing over-the-counter markets, policies preventing them from trading in securities not listed on a national exchange, or other reasons. In that event, the common stock could trade thinly as a microcap or penny stock, adversely decrease to nominal levels of trading and may be avoided by retail and institutional investors, resulting in the impaired liquidity of our common stock.

As of the record date, our common stock closed at $ per share on Nasdaq. The Reverse Stock Split, if effected, should have the immediate effect of increasing the price of our common stock as reported on Nasdaq, therefore reducing the risk that our common stock could be delisted from Nasdaq.

Our Board strongly believes that the Reverse Stock Split is necessary to maintain our listing on Nasdaq. Accordingly, the Board recommended that our shareholders approve the Reverse Stock Split Proposal to effect the Reverse Stock Split and directed that this proposal be submitted to our shareholders for approval at the Special Meeting.

*Appeal to a Broader Range of Investors to Generate Greater Investor Interest in the Company*

An increase in our stock price may make our common stock more attractive to investors. Brokerage firms may be reluctant to recommend lower-priced securities to their clients lower-priced securities. Many institutional investors have policies prohibiting them from holding lower-priced stocks in their portfolios, which reduces the number of potential purchasers of our common stock. Investment funds may also be reluctant to invest in lower-priced stocks. Investors may also be dissuaded from purchasing lower-priced stocks because the brokerage commissions, as a percentage of the total transaction, tend to be higher for such stocks. Moreover, the analysts at many brokerage firms do not monitor the trading activity or otherwise provide coverage of lower-priced stocks. Giving the Board the ability to effect the Reverse Stock Split, and thereby increase the price of our common stock, would give the Board the ability to address these issues if it is deemed necessary.

*Improve the Perception of Our Common Stock as an Investment Security*

The Board believes that effecting the Reverse Stock Split is one potential means of increasing the share price of our common stock to improve the perception of our common stock as a viable investment security. Lower-priced stocks have a perception in the investment community as being risky and speculative, which may negatively impact not only the price of our common stock, but also our market liquidity.

*Risks Associated with the Reverse Stock Split*

There are risks associated with the Reverse Stock Split, including that the Reverse Stock Split may not result in an increase in the per share price of our common stock.

The Company cannot predict whether the Reverse Stock Split will increase the market price for our common stock. The history of similar stock split combinations for companies in like circumstances is varied. There is no assurance that:

- the market price per share will achieve the $4.00 minimum bid price requirement for a sufficient period for our common stock to be approved for listing by Nasdaq;
- we would otherwise meet the initial listing requirements that would allow continued listing of our common stock on Nasdaq;
- the market price per share of our common stock after the Reverse Stock Split will rise in proportion to the reduction in the number of shares of our common stock outstanding before the Reverse Stock Split Effective Time;
- the Reverse Stock Split will result in a per share price that will attract brokers and investors who do not trade in lower-priced stocks;
- the Reverse Stock Split will result in a per share price that will increase the ability of the Company to attract and retain employees;
- the Reverse Stock Split would promote greater liquidity for our shareholders with respect to their shares.

Further, there is uncertainty as to whether Pennsylvania courts would find the use of our Series C Preferred Stock to approve the Reverse Stock Split Proposal to be sufficient under Pennsylvania Law. The use of super-voting preferred stock, such as the Series C Preferred Stock, to approve an amendment to a company's articles of incorporation has not been validated by a Delaware court to date and has been neither specifically prohibited by, nor provided for, in applicable statutes. There can be no assurance that a Pennsylvania court would not find that the use of our Series C Preferred Stock to approve the Reverse Stock Split Proposal does not alter or change the powers, preferences, or special rights of our common stock, or is not otherwise determined to be an insufficient method for approving the Reverse Stock Split Proposal.

In addition, the Reverse Stock Split would reduce the number of outstanding shares of our common stock without reducing the number of shares of available but unissued common stock, increasing the number of

authorized but unissued shares of common stock. Therefore, the number of shares of our common stock that are authorized and unissued will increase relative to the number of issued and outstanding shares of our common stock following the Reverse Stock Split. The Board may authorize the issuance of the remaining authorized and unissued shares without further shareholder action for a variety of purposes, except as such shareholder approval may be required in particular cases by our Amended and Restated Articles of Incorporation, applicable law, or the rules of any stock exchange on which our securities may then be listed. The issuance of additional shares would be dilutive to our existing shareholders and may cause a decline in the trading price of our common stock.

The market price of our common stock will also be based on the performance of the Company and other factors, some of which are unrelated to the number of shares outstanding. If the Reverse Stock Split is effected and the market price of our common stock declines, the percentage decline as an absolute number and as a percentage of the overall market capitalization of the Company may be greater than would occur in the absence of the Reverse Stock Split.

***Effects of the Reverse Stock Split***

If our shareholders approve the proposed Reverse Stock Split and the Board elects to effect the Reverse Stock Split, our issued and outstanding shares of common stock, for example, would decrease at a rate of approximately one (1) share of common stock for every ten (10) shares of common stock currently outstanding in a one-for-ten split. The Reverse Stock Split would be effected simultaneously for all of our common stock, and the exchange ratio would be the same for all shares of common stock. The Reverse Stock Split would affect all of our shareholders uniformly and would not affect any shareholders' percentage ownership interests in the Company, except to the extent that it results in a shareholder receiving cash in lieu of fractional shares. The Reverse Stock Split would not affect the relative voting or other rights that accompany the shares of our common stock, except to the extent that it results in a shareholder receiving cash in lieu of fractional shares. Common stock issued pursuant to the Reverse Stock Split would remain fully paid and non-assessable. The Reverse Stock Split would not affect our securities law reporting and disclosure obligations, and we would continue to be subject to the periodic reporting requirements of the Securities Exchange Act of 1934, as amended. We have no current plans to take the Company private. Accordingly, the Reverse Stock Split is not related to a strategy to do so.

In addition to the change in the number of shares of common stock outstanding, the Reverse Stock Split would have the following effects:

*Increase the Per Share Price of our Common Stock*

By effectively condensing a number of pre-split shares into one share of common stock, the per share price of a post-split share is generally greater than the per share price of a pre-split share. The amount of the initial increase in per share price and the duration of such increase, however, is uncertain. The Board may utilize the Reverse Stock Split as part of its plan to maintain the required minimum per share price of the common stock under the Nasdaq listing standards.

*Increase in the Number of Shares of Common Stock Available for Future Issuance*

By reducing the number of shares outstanding without reducing the number of shares of available but unissued common stock, the Reverse Stock Split will increase the number of authorized but unissued shares. The Board believes the increase is appropriate for use to fund the future operations of the Company.

The following table contains approximate information relating to our common stock, based on share information as of June 30, 2023:

| | Current | After the Reverse Split if the Minimum 1: Ratio is Selected | After the Reverse Stock Split if the Maximum 1: Ratio is Selected |
|---|---|---|---|
| **Authorized common stock** | 190,000,000 | 190,000,000 | 190,000,000 |
| **Common stock issued and outstanding (including common stock issuable upon conversion of the Preferred Stock)** | | | |
| **Warrants to purchase common stock outstanding** | | | |
| **Common stock issuable upon exercise of outstanding stock options, and settlement of restricted stock units** | | | |
| **Common stock reserved for issuance for future grants under 2019 Equity Incentive Plan** | | | |
| **Common stock authorized but unissued and unreserved/unallocated** | | | |
| **Authorized Preferred Stock** | 10,000,000 | 10,000,000 | 10,000,000 |

Although the Reverse Stock Split would not have any dilutive effect on our shareholders, the Reverse Stock Split without a reduction in the number of shares authorized for issuance would reduce the proportion of shares owned by our shareholders relative to the number of shares authorized for issuance, giving the Board an effective increase in the authorized shares available for issuance, in its discretion. The Board from time to time may deem it to be in the best interests of the Company to enter into transactions and other ventures that may include the issuance of shares of our common stock. If the Board authorizes the issuance of additional shares subsequent to the Reverse Stock Split, the dilution to the ownership interest of our existing shareholders may be greater than would occur had the Reverse Stock Split not been effected.

*Require Adjustment to Currently Outstanding Securities Exercisable or Convertible into Shares of our Common Stock*

The Reverse Stock Split would effect a reduction in the number of shares of common stock issuable upon the exercise or conversion of our outstanding stock options, settlement of restricted stock units and exercise of our outstanding warrants in proportion to the reverse stock split ratio. The exercise price of outstanding options and warrants would increase, likewise in proportion to the reverse stock split ratio.

*Require Adjustment to the Number of Shares of Common Stock Available for Future Issuance Under our 2019 Equity Incentive Plan*

In connection with any reverse stock split, the Board would also make a corresponding reduction in the number of shares available for future issuance under the foregoing plan so as to avoid the effect of increasing the number of authorized but unissued shares available for future issuance under such plans.

***Procedure for Effecting Reverse Stock Split***

If the Reverse Stock Split is approved by our shareholders, the Board, in its sole discretion, would determine whether to implement the Reverse Stock Split, taking into consideration the factors discussed above, and, if implemented, determine the ratio of the Reverse Stock Split. We would then file Articles of Amendment amending the Articles with the Secretary of the Commonwealth of Pennsylvania. The form of the Articles of Amendment is attached to this Proxy Statement as Annex A and is considered a part of this Proxy Statement. Upon the filing of the Articles of Amendment, without any further action on our part or our shareholders, the issued shares of common stock held by shareholders of record as of the effective date of the Reverse Stock Split would be converted into a lesser number of shares of common stock calculated in accordance with the Reverse Stock Split ratio of any whole number between 1-for- and 1-for- .

***Effect on Beneficial Holders (i.e., Shareholders Who Hold in "Street Name")***

If the proposed Reverse Stock Split is approved and effected, we intend to treat common stock held by shareholders in "street name," through a bank, broker or other nominee, in the same manner as shareholders whose shares are registered in their own names. Banks, brokers or other nominees will be instructed to effect the Reverse Stock Split for their customers holding common stock in "street name." However, these banks, brokers or other nominees may have different procedures than registered shareholders for processing the Reverse Stock Split. If you hold shares of common stock with a bank, broker or other nominee and have any questions in this regard, you are encouraged to contact your bank, broker or other nominee.

***Effect on Registered "Book-Entry" Holders (i.e., Shareholders That are Registered on the Transfer Agent's Books and Records but do not Hold Certificates)***

All of our registered holders of common stock hold their shares electronically in book-entry form with our transfer agent, Broadridge Corporate Issuer Solutions, Inc. These shareholders do not have stock certificates evidencing their ownership of common stock. They are, however, provided with a statement reflecting the number of shares registered in their accounts. If a shareholder holds registered shares in book-entry form with our transfer agent, no action needs to be taken to receive post-reverse stock split shares or fractional shares, if applicable. If a shareholder is entitled to post-reverse stock split shares, a transaction statement will automatically be sent to the shareholder's address of record indicating the number of shares (including fractional shares) of common stock held following the Reverse Stock Split.

***Fractional Shares***

No fractional shares will be issued in connection with the Reverse Stock Split. Shareholders of record who otherwise would be entitled to receive fractional shares will be entitled to an amount in cash (without interest or deduction) equal to the fraction of one share to which such shareholder would otherwise be entitled multiplied by the product of: (i) the average of the closing prices of our common stock on the Nasdaq Capital Market for the five consecutive trading days immediately preceding the effective date of the Reverse Stock Split and (ii) the reverse stock split factor chosen by the Board. Except for the right to receive the cash payment in lieu of fractional shares, shareholders will not have any voting, dividend or other rights with respect to the fractional shares they would otherwise be entitled to receive.

Shareholders should be aware that, under the escheat laws of the various jurisdictions where shareholders may reside, where we are domiciled, and where the funds will be deposited, sums due for fractional interests that are not timely claimed after the effective date of the Reverse Stock Split may be required to be paid to the designated agent for each such jurisdiction, unless correspondence has been received by us or the exchange agent concerning ownership of such funds within the time permitted in such jurisdiction. Thereafter, shareholders otherwise entitled to receive such funds will have to seek to obtain them directly from the state to which they were paid.

***No Going Private Transaction***

Notwithstanding the decrease in the number of outstanding shares following the Reverse Stock Split, our Board of Directors does not intend for this transaction to be the first step in a "going private transaction" within the meaning of Rule 13e-3 of the Securities Exchange Act of 1934, as amended.

***Accounting Matters***

The par value of our common stock would remain unchanged at $0.01 per share, if the Reverse Stock Split is effected.

The Company's shareholders' equity in its consolidated balance sheet would not change in total. However, the Company's stated capital (i.e., $0.01 par value times the number of shares issued and outstanding), would be proportionately reduced based on the reduction in shares of common stock outstanding. Additional paid in capital would be increased by an equal amount, which would result in no overall change to the balance of shareholders' equity.

Additionally, net income or loss per share for all periods would increase proportionately as a result of the Reverse Stock Split since there would be a lower number of shares outstanding. We do not anticipate that any other material accounting consequences would arise as a result of the Reverse Stock Split.

***Potential Anti-Takeover Effect***

Even though the proposed Reverse Stock Split would result in an increased proportion of unissued authorized shares to issued shares, which could, under certain circumstances, have an anti-takeover effect (for example, by permitting issuances that would dilute the stock ownership of a person seeking to effect a change in the composition of the Board or contemplating a tender offer or other transaction for the combination of us with another company), the Reverse Stock Split is not being proposed in response to any effort of which we are aware to accumulate shares of our common stock or obtain control of us, nor is it part of a plan by management to recommend a series of similar amendments to the Board and our shareholders.

***No Appraisal Rights***

Our shareholders are not entitled to appraisal rights with respect to the Reverse Stock Split, and we will not independently provide shareholders with any such right.

***Federal Income Tax Consequences of a Reverse Stock Split***

The following discussion is a summary of certain U.S. federal income tax consequences of the reverse stock split to the Company and to shareholders that hold shares of common stock as capital assets for U.S. federal income tax purposes. This discussion is based upon provisions of the U.S. Internal Revenue Code of 1986, as amended (the "Code"), the Treasury regulations promulgated under the Code, and U.S. administrative rulings and court decisions, all as in effect on the date hereof and all of which are subject to change, possibly with retroactive effect, and differing interpretations. Changes in these authorities may cause the U.S. federal income tax consequences of the reverse stock split to vary substantially from the consequences summarized below.

This summary does not address all aspects of U.S. federal income taxation that may be relevant to shareholders in light of their particular circumstances or to shareholders who may be subject to special tax treatment under the Code, including, without limitation, dealers in securities, commodities or foreign currency, persons who are treated as non-U.S. persons for U.S. federal income tax purposes, certain former citizens or long-term residents of the United States, insurance companies, tax-exempt organizations, banks, financial institutions, small business investment companies, regulated investment companies, real estate investment trusts, retirement plans, persons that are partnerships or other pass-through entities for U.S. federal income tax purposes, persons whose functional currency is not the U.S. dollar, traders that mark-to-market their securities, persons subject to the alternative minimum tax, persons who hold their shares of common stock as part of a hedge, straddle, conversion or other risk reduction transaction, or who acquired their shares of common stock pursuant to the exercise of compensatory stock options, the vesting of previously restricted shares of stock or otherwise as compensation. If a partnership or other entity classified as a partnership for U.S. federal income tax purposes holds shares of common stock, the tax treatment of a partner thereof will generally depend upon the status of the partner and upon the activities of the partnership. If you are a partner in a partnership holding shares of the Company's common stock, you should consult your tax advisor regarding the tax consequences of the Reverse Stock Split.

The Company has not sought and will not seek an opinion of counsel or a ruling from the Internal Revenue Service, regarding the federal income tax consequences of the Reverse Stock Split. The state and local tax consequences of the Reverse Stock Split may vary as to each shareholder, depending on the jurisdiction in which

such shareholder resides. This discussion should not be considered as tax or investment advice, and the tax consequences of the reverse stock split may not be the same for all shareholders. Shareholders should consult their own tax advisors to know their individual federal, state, local and foreign tax consequences.

*Tax Consequences to the Company*

We believe that the Reverse Stock Split will constitute a reorganization under Section 368(a)(1)(E) of the Code. Accordingly, we should not recognize taxable income, gain or loss in connection with the Reverse Stock Split. In addition, we do not expect the Reverse Stock Split to affect our ability to utilize our net operating loss carryforwards.

*Tax Consequences to Shareholders*

Shareholders should not recognize any gain or loss for U.S. federal income tax purposes as a result of the Reverse Stock Split, except to the extent of any cash received in lieu of a fractional share of common stock (which fractional share will be treated as received and then exchanged for cash). Each shareholder's aggregate tax basis in the common stock received in the Reverse Stock Split, including any fractional share treated as received and then exchanged for cash, should equal the shareholder's aggregate tax basis in the common stock exchanged in the Reverse Stock Split. In addition, each shareholder's holding period for the common stock it receives in the Reverse Stock Split should include the shareholder's holding period for the common stock exchanged in the Reverse Stock Split.

In general, a shareholder who receives cash in lieu of a fractional share of common stock pursuant to the Reverse Stock Split should be treated for U.S. federal income tax purposes as having received a fractional share pursuant to the Reverse Stock Split and then as having received cash in exchange for the fractional share and should generally recognize capital gain or loss equal to the difference between the amount of cash received and the shareholder's tax basis allocable to the fractional share. Any capital gain or loss will generally be long term capital gain or loss if the shareholder's holding period in the fractional share is greater than one year as of the effective date of the Reverse Stock Split. Special rules may apply to cause all or a portion of the cash received in lieu of a fractional share to be treated as dividend income with respect to certain shareholders who own more than a minimal amount of common stock (generally more than 1%) or who exercise some control over the affairs of the Company. Shareholders should consult their own tax advisors regarding the tax effects to them of receiving cash in lieu of fractional shares based on their particular circumstances.

***Interests of Directors and Executive Officers***

Our directors and executive officers have no substantial interests, directly or indirectly, in the matters set forth herein regarding the proposed Reverse Stock Split except to the extent of their ownership of shares of our common stock.

***Reservation of Right to Abandon Reverse Stock Split***

We reserve the right to abandon the Reverse Stock Split without further action by our shareholders at any time before the effectiveness of the filing with the Secretary of the Commonwealth of Pennsylvania of the Articles of Amendment to the Charter, even if the authority to effect the Reverse Stock Split has been approved by our shareholders at the Special Meeting. By voting in favor of the Reverse Stock Split, you are expressly also authorizing the Board to delay, not to proceed with, and abandon, the Reverse Stock Split if it should so decide, in its sole discretion, that such action is in the best interests of the Company.

***Vote Required; Recommendation of Board of Directors***

The affirmative vote of the holders of shares of common stock and Series C Preferred Stock representing a majority of the voting power of our capital stock issued and outstanding as of the record date (and not redeemed prior to the opening of the polls at the Special Meeting) is required to approve the Reverse Stock Split Proposal. The holders of common stock have the right to cast one vote per share of common stock on this proposal. The holders of Series C Preferred Stock have the right to cast 1,000,000 votes per share of Series C Preferred Stock, or an aggregate of votes, on this proposal, provided, that such votes must be counted by the Company in the same proportion as the aggregate shares of common stock that are voted on this proposal, without regard to abstentions by holders of common stock or broker non-votes. As an example, if 60% of the votes cast by holders

of common stock present, by virtual participation or proxy, and entitled to vote are voted at the Special Meeting in favor of this proposal, the Company can count 60% of the votes cast by the holders of the Series C Preferred Stock as votes in favor of this Proposal No. 2. Because the voting standard for this Proposal No. 2 is a majority of the voting power represented by the outstanding shares of common stock and Series C Preferred Stock entitled to vote on the proposal, voting together and counted as a single class, abstentions and broker non-votes will have the effect of a vote "AGAINST" the proposal.

Shares of Series C Preferred Stock that are automatically redeemed in the Initial Redemption will not be counted as part of the issued and outstanding shares of capital stock of the Company entitled to vote at the Company's Special Meeting for purposes of determining the presence of a quorum or approval of the Reverse Stock Split Proposal. For illustrative purposes only, if the Company had 1,000,000 shares of common stock outstanding as of the Special Meeting record date, each with one vote per share, and 1,000 shares of Series C Preferred Stock, each with 1,000,000 votes per share, the total number of votes attributable to the Company's capital stock would be 1,001,000,000. In this scenario, 500,500,001 votes would be required to approve the Reverse Stock Split Proposal. Further, if 500 shares of Series A Preferred Stock are redeemed in the Initial Redemption, the total number of votes attributable to the Company's capital stock for purposes of the Special Meeting would be 501,000,000. In such scenario, 250,500,001 votes would be required to approve the Reverse Stock Split Proposal.

There were shares of common stock and shares of Series C Preferred Stock outstanding on the Record Date. If no shares of Series C Preferred Stock are redeemed in the Initial Redemption, the Reverse Stock Split Proposal shall require the affirmative vote of at least total votes. The threshold required to approve the Reverse Stock Split Proposal at this Special Meeting shall be reduced proportionally as a result of any shares of Series C Preferred Stock redeemed in the Initial Redemption.

If the proposal is approved, it will become effective upon the filing of the Certificate of Amendment with the Secretary of the Commonwealth of Pennsylvania, which will occur at the sole discretion of the Board of Director's within one year of such approval.

**THE BOARD RECOMMENDS THAT BAUDAX'S SHAREHOLDERS VOTE FOR THIS PROPOSAL NO. 2: TO APPROVE THE AMENDMENT TO THE AMENDED AND RESTATED ARTICLES OF INCORPORATION TO EFFECT THE REVERSE STOCK SPLIT.**

## PROPOSAL NO. 3:
## RATIFICATION OF APPOINTMENT OF EISNERAMPER AS OUR INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM FOR 2023

The Audit Committee of the Board has appointed and engaged EisnerAmper LLP ("EisnerAmper") to serve as our independent registered public accounting firm to audit the consolidated financial statements of the Company and its subsidiaries for the 2023 fiscal year, and to perform audit-related services. EisnerAmper has served as our independent registered public accounting firm since 2022.

Shareholders are hereby asked to ratify the Audit Committee's appointment of EisnerAmper as our independent registered public accounting firm for the 2023 fiscal year.

The Audit Committee is solely responsible for selecting our independent auditors. Although shareholder ratification of the appointment of EisnerAmper to serve as our independent registered public accounting firm is not required by law or our organizational documents, the Board has determined that it is desirable to seek shareholders ratification as a matter of good corporate governance in view of the critical role played by independent registered public accounting firms in maintaining the integrity of financial controls and reporting. If the shareholders do not ratify the appointment of EisnerAmper, the Audit Committee will reconsider its selection and whether to engage an alternative independent registered public accounting firm.

Representatives of EisnerAmper are expected to virtually attend the Special Meeting where they will be available to respond to appropriate questions and, if they desire, to make a statement.

**THE BOARD RECOMMENDS THAT BAUDAX'S SHAREHOLDERS VOTE FOR THIS PROPOSAL NO. 3: TO RATIFY THE APPOINTMENT OF EISNERAMPER.** ✔

## PROPOSAL NO. 4:
## APPROVAL OF ADJOURNMENT OF THE SPECIAL MEETING

***General***

If the Company fails to receive a sufficient number of votes to approve Proposal Nos. 1, 2, and/or 3, the Company may propose to adjourn or postpone the Special Meeting. The Company currently does not intend to propose adjournment or postponement at the Special Meeting if there are sufficient votes to approve Proposal Nos. 1, 2, and/or 3.

***Vote Required; Recommendation of Board of Directors***

The affirmative vote of the holders of shares of common stock representing a majority of the votes present or represented and voting on the matter is required for approval of this Proposal No. 4 (for the purpose of soliciting additional proxies to approve Proposal Nos. 1, 2, and/or 3), if a quorum is present at the Special Meeting. If a quorum is not present at the Special Meeting, the affirmative vote of the shareholders holding a majority of the voting power present in person or by proxy at the Special Meeting is required for approval of this Proposal No. 4. The holders of common stock have the right to cast one vote per share of common stock on this Proposal No. 4. Broker non-votes (if any) and abstentions will not be counted as votes cast on the matter and will have no effect on the outcome of this proposal.

**THE BOARD RECOMMENDS THAT BAUDAX'S SHAREHOLDERS VOTE FOR THIS PROPOSAL NO. 4: TO ADJOURN THE SPECIAL MEETING, IF NECESSARY, TO SOLICIT ADDITIONAL PROXIES.** ✔

## OTHER INFORMATION

## DESCRIPTION OF COMMON STOCK

The following description sets forth certain material terms and provisions of the Company's securities that are registered under Section 12 of the Securities Exchange Act of 1934, as amended.

The following description is a summary and does not purport to be complete. It is subject to, and qualified in its entirety by reference to, the Company's Amended and Restated Articles of Incorporation and our Second Amended and Restated Bylaws. The terms of these securities also may be affected by the Delaware General Corporate Law.

### *Authorized Capital Stock*

We are authorized to issue a total of 200,000,000 shares of capital stock consisting of 190,000,000 shares of common stock, par value $0.01 per share, and 10,000,000 shares of preferred stock, par value $0.01. Our common stock is listed on the Nasdaq Capital Market under the trading symbol "BXRX."

As of the date of this proxy statement, shares of common stock are issued and outstanding and shares of common stock were reserved for the issuance upon the exercise of outstanding warrants and options to purchase common stock (including options issued as a result of the conversion of outstanding TeraImmune options pursuant to the Merger Agreement), outstanding restricted stock units, the conversion of the Series C Preferred Stock and the Series X Preferred Stock and shares available for grant under our 2019 Equity Incentive Plan.

### *Common Stock*

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of shareholders, including the election of directors, and do not have cumulative voting rights. Directors are elected by a plurality of the votes cast.

Subject to preferences that may be applicable to any then-outstanding shares of preferred stock, holders of our common stock are entitled to receive ratably dividends when, as, and if declared by our board of directors out of funds legally available therefor, subject to any preferential dividend rights of outstanding preferred stock. In the event of our liquidation, dissolution, or winding up, holders of our common stock will be entitled to ratably receive the net assets of our company available after the payments of all debts and other liabilities and subject to the prior rights of the holders of any then-outstanding shares of preferred stock.

Holders of our common stock have no preemptive, subscription, redemption or conversion rights. The rights and privileges of the holders of the common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

### *Description of Preferred Stock and Preferred Stock Convertible Into Common Stock*

We are authorized to issue 10,000,000 shares of preferred stock, of which shares have been designated Series C Preferred Stock and 27,089.719 shares have been designated as Series X Preferred Stock.

The holders of Series C Preferred Stock have 1,000,000 votes per whole share of Series C Preferred Stock (i.e., 1,000 votes per one one-thousandth of a share of Series C Preferred Stock) and are entitled to vote with the common stock, together as a single class, on the Reverse Stock Split Proposal and Adjournment Proposal, but are not otherwise entitled to vote on the other proposals to be presented at the Special Meeting. All shares of Series C Preferred Stock that are not present in person or by proxy at the Special Meeting as of immediately prior to the opening of the polls at the Special Meeting will be automatically redeemed. Any outstanding shares of Series C Preferred Stock that have not been redeemed pursuant to the Initial Redemption will be redeemed in whole, but not in part, (i) if and when ordered by our Board or (ii) automatically upon the approval by the Company's shareholders of the Reverse Stock Split at any meeting of the shareholders held for the purpose of voting on such proposal.

As of the date of this proxy statement, there were shares of Series C Preferred Stock outstanding and 27,089.719 shares of Series X Preferred Stock outstanding. No other shares of preferred stock were outstanding.

### *Certain Anti-Takeover Provisions of Our Amended and Restated Articles of Incorporation and Bylaws*

Provisions of our Amended and Restated Articles of Incorporation and Bylaws may delay or discourage transactions involving an actual or potential change of control or change in our management, including

transactions in which shareholders might otherwise receive a premium for their shares, or transactions that our shareholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our Amended and Restated Articles of Incorporation and Bylaws:

- divide our Board of Directors into three classes with staggered three-year terms;
- provide that a special meeting of shareholders may be called only by a majority of our Board of Directors, the chairman of our Board of Directors, the chief executive officer or the president;
- establish advance notice procedures with respect to shareholder proposals to be brought before a shareholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the Board of Directors or a committee of Board of Directors;
- provide that shareholders may only act at a duly organized meeting; and
- provide that members of our Board of Directors may be removed from office by our shareholders only for cause by the affirmative vote of 75% of the total voting power of all shares entitled to vote generally in the election of directors.

***Anti-Takeover Provisions under Pennsylvania Law***

Provisions of the PBCL applicable to us provide, among other things, that:

- we may not engage in a business combination with an "interested shareholder," generally defined as a holder of 20% of a corporation's voting stock, during the five-year period after the interested shareholder became such except under certain specified circumstances;
- holders of our common stock may object to a "control transaction" involving us (a control transaction is defined as the acquisition by a person or group of persons acting in concert of at least 20% of the outstanding voting stock of a corporation), and demand that they be paid a cash payment for the "fair value" of their shares from the "controlling person or group";
- holders of "control shares" will not be entitled to voting rights with respect to any shares in excess of specified thresholds, including 20% voting control, until the voting rights associated with such shares are restored by the affirmative vote of a majority of disinterested shares and the outstanding voting shares of the Company; and
- any "profit," as defined, realized by any person or group who is or was a "controlling person or group" with respect to us from the disposition of any equity securities of within 18 months after the person or group became a "controlling person or group" shall belong to and be recoverable by us.

*No Shareholder Action by Written Consent; Special Meeting of Shareholders*

Our Amended and Restated Articles of Incorporation and our Bylaws do not provide for action by written consent in lieu of a meeting by shareholders, which may require our shareholders to wait for a regularly scheduled annual meeting to change the composition of our Board of Directors. Our Amended and Restated Articles of Incorporation and our Bylaws also provide that special meetings of our shareholders may be called only by the Board of Directors, the Chairman of the Board of Directors or by our chief executive officer or president. In no event may our shareholders call a Special Meeting of shareholders. Our Amended and Restated Articles of Incorporation require the affirmative vote of the holders of at least 66 2/3% of the shares of our capital stock issued and outstanding and entitled to vote to amend or repeal these provisions.

*Advance Notification of Shareholder Nominations and Proposals*

Our Bylaws establish an advance notice procedure for shareholder proposals to be brought before any meeting of shareholders, including proposed nominations of persons for election to our Board of Directors.

***Listing***

Our common stock is listed on The Nasdaq Capital Market under the symbol "BXRX."

***Transfer Agent and Registrar***

The transfer agent and registrar for our common stock is Broadridge Corporate Issuer Solutions, Inc. The transfer agent and registrar's address is 2 Gateway Center, 283-299 Market Street, 15th Floor Newark, NJ 07102.

## PRINCIPAL SHAREHOLDERS

The following table sets forth information, to the extent known by us or ascertainable from public filings, with respect to the beneficial ownership of our common stock as of , 2023 by:

- each of our directors;
- each of our executive officers;
- all of our directors and executive officers as a group; and
- each person, or group of affiliated persons, who is known by us to beneficially own greater than 5.0% of our common stock.

The column titled "Shares Beneficially Owned" is based on a total of shares of our common stock outstanding as of , 2023.

We have determined beneficial ownership in accordance with the rules of the SEC, and the information in the table below is not necessarily indicative of beneficial ownership for any other purpose. The SEC has defined "beneficial" ownership of a security to mean the possession, directly or indirectly, of voting power and/or investment power. In computing the percentage ownership of each person, shares of common stock subject to options, warrants, or rights held by that person that are currently exercisable, or exercisable within 60 days of , 2023, are deemed to be outstanding and beneficially owned by that person. These shares, however, are not deemed outstanding for the purpose of computing the percentage ownership of any other person.

To our knowledge and except as indicated in the notes to this table and pursuant to applicable community property laws, each shareholder named in the table has sole voting and investment power with respect to the shares set forth opposite such shareholder's name. All fractional common share amounts have been rounded to the nearest whole number. To our knowledge, except as noted below, no person or entity is the beneficial owner of more than 5% of the voting power of the Company's stock.

| | SHARES BENEFICIALLY OWNED | | | |
|---|---|---|---|---|
| NAME OF BENEFICIAL OWNER | NUMBER OF SHARES OF COMMON STOCK | NUMBER OF SHARES OF SERIES C PREFERRED STOCK | PERCENTAGE OF COMMON STOCK | PERCENTAGE OF SERIES C PREFERRED STOCK |
| **5% or Greater Shareholders** | | | | |
| Entities affiliated with Black Horse Capital LP | (1) | | | |
| **Named Executive Officers and Directors** | | | | |
| Gerri Henwood | (2) | | % | % |
| Richard S. Casten | (3) | | % | % |
| Jillian Dilmore | (4) | | % | % |
| William L. Ashton | (5) | | % | % |
| Arnold Baskies, M.D. | (6) | | % | % |
| Winston J. Churchill | (7)(8) | | % | % |
| Andrew Drechsler | (9) | | % | % |
| Wayne Weisman | (8)(10) | | % | % |
| Yong Chan Kim, Ph.D. | (11) | | % | % |
| All current directors and executive officers as a group (9 individuals) | (12) | | % | % |

* Denotes less than 1% beneficial owner.

(1) According to a Schedule 13G, filed with the SEC on July 10, 2023, reporting beneficial ownership by the Black Horse Entities (as defined below), the number of shares beneficially owned represents (i) 40,000 shares held by Black Horse Capital LP ("BHC"), (ii) 125,000 shares held by Black Horse Capital Master Fund Ltd. ("BHCMF") and (iii) 335,000 shares held by Cheval Holdings, Ltd. ("Cheval" and collectively with BHCMF and BHC, the "Black Horse Entities"). The business address of each of BHC and BHCMF is c/o Opus Equum, Inc. P.O. Box 788, Dolores, Colorado 81323. The business address of Cheval is P.O Box 309G, Ugland House, Georgetown, Grand Cayman, Cayman Islands KY1-1104.

(2) Ms. Henwood holds (i) shares of our common stock, which includes shares of our common stock held by Ms. Henwood's husband, Thomas Henwood, and (ii) stock options to purchase shares of our common stock that may be exercised within 60 days of , 2023. As spouses, Mr. and Ms. Henwood may be deemed to beneficially own the shares of our common stock that are held by the other spouse. Mr. and Ms. Henwood disclaim beneficial ownership of the shares of our common stock that are held by the other spouse.

(3) Based on the latest available information, Mr. Casten holds shares of our common stock.

(4) Ms. Dilmore holds shares of our common stock and shares of our common stock that may be exercised within 60 days of , 2023.

(5) Mr. Ashton holds shares of our common stock and stock options to purchase shares of our common stock that may be exercised within 60 days of , 2023.

(6) Dr. Baskies holds shares of our common stock and stock options to purchase shares of our common stock that may be exercised within 60 days of , 2023.

(7) Mr. Churchill holds shares of our common stock and stock options to purchase shares of our common stock that may be exercised within 60 days of , 2023.

(8) SCP Vitalife Partners II, L.P., or SCP Vitalife Partners, SCP Vitalife Partners (Israel) II, L.P., or SCP Vitalife Israel, SCP Vitalife II Associates, L.P., or SCP Vitalife Associates, SCP Vitalife II GP, LTD (SCP Vitalife GP), Winston J. Churchill, Jeffrey Dykan, and Wayne B. Weisman. SCP Vitalife Partners beneficially owns shares of common stock and SCP Vitalife Israel beneficially owns shares of common stock. As the general partner of SCP Vitalife Partners and SCP Vitalife Israel, SCP Vitalife Associates may be deemed to beneficially own shares of common stock. As the general partner of SCP Vitalife Associates, SCP Vitalife GP may be deemed to beneficially own shares of common stock. As directors of SCP Vitalife GP, Messrs. Churchill, Dykan and Weisman may be deemed to beneficially own shares of common stock. SCP Vitalife Partners shares dispositive and voting power with respect to the shares of common stock owned. SCP Vitalife Israel shares dispositive and voting power with respect to the shares of common stock owned. SCP Vitalife Associates, SCP Vitalife GP, Messrs. Churchill, Dykan and Weisman have shared dispositive and voting power with respect to the aggregate shares of common stock owned by SCP Vitalife Partners and SCP Vitalife Israel.

(9) Mr. Drechsler holds shares of our common stock and stock options to purchase shares of our common stock that may be exercised within 60 days of , 2023.

(10) Mr. Weisman holds shares of our common stock and stock options to purchase shares of our common stock that may be exercised within 60 days of , 2023.

(11) Dr. Kim holds shares of our common stock and shares of our Series X Preferred Stock.

(12) Includes stock options to purchase shares of our common stock that may be exercised within 60 days of , 2023.

## CHANGE IN INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

On June 21, 2022, we dismissed KPMG LLP ("KPMG") as our independent registered public accounting firm. The dismissal of KPMG was recommended by the Audit Committee and approved by the Board. On June 24, 2022, in connection with the dismissal of KPMG, the Board approved the engagement of EisnerAmper as our new independent registered public accounting firm to audit our financial statements for the year ending December 31, 2022. The decision to retain EisnerAmper was recommended by the Audit Committee, and approved by the Board, after taking into account the results of a competitive review process and other business factors.

During the years ended December 31, 2021 and 2020 and through June 21, 2022, there were no disagreements or reportable events between KPMG and us on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreements if not resolved to the satisfaction of KPMG, would have caused KPMG to make reference in connection with their opinion to the subject matter of the disagreements or reportable events. The reports of KPMG on the financial statements for the years ended December 31, 2021 and 2020 did not contain any adverse opinion or a disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope or accounting principles, except as follows:

- KPMG's report on our consolidated financial statements as of and for the years ended December 31, 2021 and 2020 contained a separate paragraph stating that "As discussed in Note 2 to the consolidated financial statements, we have incurred recurring losses and negative cash flows from operations and has an accumulated deficit of $132.1 million as of December 31, 2021 that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty."
- KPMG's report on our consolidated and combined financial statements as of and for the years ended December 31, 2020 and 2019, contained a separate paragraph stating that "As discussed in Note 2 to the consolidated and combined financial statements, we have incurred recurring losses and negative cash flows from operations and has an accumulated deficit of $112.3 million as of December 31, 2020 that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated and combined financial statements do not include any adjustments that might result from the outcome of this uncertainty."

During the years ended December 31, 2021 and 2020 and the subsequent interim period through June 24, 2022, neither we nor anyone on our behalf consulted with EisnerAmper regarding (i) the application of accounting principles to a specific transaction, either completed or proposed, (ii) the type of audit opinion that might be rendered on our financial statements and neither a written report nor oral advice was provided to us that EisnerAmper concluded was an important factor considered by us in reaching a decision as to accounting, auditing or financial reporting issues, (iii) any matter that was the subject of a disagreement (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions), or (iv) any reportable event (as described in Item 304(a)(1)(v) of Regulation S-K).

## INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM FEES

The Audit Committee works with our management to negotiate appropriate fees with our independent registered public accounting firm and is ultimately responsible for approving those fees. The following is a summary of (i) audit fees paid or payable to KPMG for each of our years ended December 31, 2021, and the fees billed by KPMG for other services in 2021, and (ii) audit fees paid or payable to EisnerAmper for the year ended December 31, 2022 and the fees billed by EisnerAmper for other services in 2022:

**KPMG**

| SERVICE | 2021 |
|---|---|
| Audit Fees | $466,712 |
| Audit-Related Fees | — |
| Tax Fees | $ 15,418 |
| All Other Fees | — |
| **Total** | $482,130 |

| | EISNERAMPER |
|---|---|
| **SERVICE** | **2022** |
| Audit Fees | $435,750 |
| Audit-Related Fees | — |
| Tax Fees | — |
| All Other Fees | — |
| **Total** | $435,750 |

"**Audit fees**" represented the aggregate fees for professional services rendered for the audit of our consolidated and combined financial statements and the review of our quarterly financial statements on Form 10-K and Form 10-Q, respectively, that are customary under the standards of the Public Company Accounting Oversight Board (United States), and in connection with regulatory requirements. The amount also includes other services that are normally provided by KPMG and EisnerAmper in connection with statutory and regulatory filings or engagements.

"**Tax fees**" consisted of fees related to tax compliance, tax planning and tax advice.

## WHERE YOU CAN FIND ADDITIONAL INFORMATION

We file annual and quarterly reports and other reports and information with the SEC. The SEC maintains an Internet web site that contains reports, proxy and information statements, and other information regarding issuers, including us, that file electronically with the SEC. The public can obtain any documents that we file electronically with the SEC at http://www.sec.gov. We will provide without charge to you, upon written or oral request, a copy of the reports and other information filed with the SEC.

Any requests for copies of information, reports or other filings with the SEC should be directed to Baudax Bio, Inc., 409 Lapp Road, Malvern, Pennsylvania 19355, Attention: Corporate Secretary.

In order to receive timely delivery of the documents in advance of the Special Meeting, you must make your request for information no later than , 2023.

## HOUSEHOLDING

Some banks, brokers and other nominee record holders may be participating in the practice of "householding" proxy statements and annual reports. This means that only one copy of our documents, including the annual report to shareholders and proxy statement, may have been sent to multiple shareholders in your household. We will promptly deliver a separate copy of either document to you upon written or oral request to Baudax Bio, Inc., 490 Lapp Road, Malvern, PA 19355, Attention: Corporate Secretary, telephone: (484) 395-2440. If you want to receive separate copies of the proxy statement or annual report to shareholders in the future, or if you are receiving multiple copies and would like to receive only one copy per household, you should contact your bank, broker or other nominee record holder, or you may contact us at the above address and phone number.

## OTHER MATTERS

Our Board of Directors does not know of any other matters to be brought before the Special Meeting. If any other matters not mentioned in this proxy statement are properly brought before the Special Meeting, the individuals named in the enclosed proxy intend to use their discretionary voting authority under the proxy to vote the proxy in accordance with their best judgment on those matters.

**ANNEX A**

**PROPOSED AMENDMENT TO AMENDED AND RESTATED ARTICLES OF INCORPORATION**

Articles of Amendment of Baudax Bio, Inc.

In compliance with the requirements of the applicable provisions (relating to articles of amendment) of the Pennsylvania Business Corporation Law of 1988, as amended, the undersigned, desiring to amend its Amended and Restated Articles of Incorporation, hereby states that:

1. The name of the Corporation is Baudax Bio, Inc. (the "Corporation").
2. The address of the Corporation's registered office in the Commonwealth of Pennsylvania is 490 Lapp Road, Malvern, Pennsylvania 19355, Chester County.
3. The Corporation was incorporated under the Pennsylvania Business Corporation Law of 1988.
4. The date of the Corporation's incorporation was July 6, 2015.
5. The amendment shall be effective upon filing these Articles of Amendment in the Pennsylvania Department of State.
6. The amendment was adopted by the Corporation by the Board of Directors and shareholders of the Corporation under 15 Pa.C.S. §§ 1912(a) and 1914(a).
7. The amendment adopted by the Corporation is:

RESOLVED, that the Amended and Restated Articles of Incorporation of the Corporation is hereby amended by amending and restating the first paragraph of Article IV in its entirety as follows:

"The total number of shares of capital stock which the Corporation shall have authority to issue is 200,000,000, which (i) 190,000,000 shall be designated as common stock, par value $0.01 per share (the "**Common Stock**"), and (ii) 10,000,000 shares shall be a class designated as undesignated preferred stock, par value $0.01 per share (the "**Undesignated Preferred Stock**")." As of the effective date of the filing of the Articles of Amendment containing this Amendment with the Pennsylvania Department of State (the "**Effective Date**"), every [__][1] (the "**Reverse Split Factor**") outstanding shares of Common Stock shall without further action by this Corporation or the holder thereof be combined into and automatically become one share of Common Stock (the "**Reverse Stock Split**"). No fractional shares will be issued in connection with the Reverse Stock Split. A shareholder of record who otherwise would be entitled to receive fractional shares will be entitled to receive cash (without interest and subject to applicable withholding taxes) in lieu of such fractional shares in an amount equal to the product obtained by multiplying such fractional share of Common Stock by the Reverse Split Factor times the average closing price per share of Common Stock on the securities trading market on which the shares were traded for the five trading days immediately preceding the effective date of this amendment to the Amended and Restated Articles of Incorporation."

Except as set forth in these Articles of Amendment, the Amended and Restated Articles of Incorporation remain in full force and effect.

[1] The Board of Directors will have the discretion to effect the Reverse Stock Split at a ratio of any whole number between 1-for- and 1-for- .

**ANNEX B**

**AUDITED FINANCIAL STATEMENTS AND ACCOMPANYING NOTES OF TERAIMMUNE, INC.**
**(December 31, 2022 and December 31, 2021)**

**Index to Consolidated Financial Statements**

**TeraImmune, Inc.**

**Contents**

HORNE

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of TeraImmune, Inc.

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of TeraImmune, Inc. and its subsidiary (the "Company") as of December 31, 2022 and 2021, the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for the years then ended, and the related notes to the consolidated financial statements (collectively, 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, 2022 and 2021, 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.

**Going Concern Uncertainty**

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and its total liabilities exceed its total assets. This raises substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters also are described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**Basis for Opinion**

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

We conducted our audits 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 on the effectiveness of the Company's internal control over financial reporting as of December 31, 2022 or 2021.

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.

**Critical Audit Matters**

Critical audit matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. We determined that there are no critical audit matters.

We have served as the Company's auditor since 2023.

/s/ HORNE LLP

Ridgeland, Mississippi
June 26, 2023

**TeraImmune, Inc.**
**Consolidated Balance Sheets**
**(in thousands, except share data)**

| | December 31, 2022 | December 31, 2021 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 917 | $ 2,235 |
| Prepaid expenses and other current assets | 473 | 107 |
| Total current assets | 1,390 | 2,342 |
| Property and equipment, net | 4,041 | 1,556 |
| Operating lease right-of-use assets | 1,730 | 52 |
| Other assets | 2 | 33 |
| Total assets | $ 7,163 | $ 3,983 |
| **Liabilities and stockholders' equity (deficit)** | | |
| Current liabilities: | | |
| Accounts payable | $ 418 | $ 557 |
| Convertible bonds payable, current portion | 1,000 | — |
| Operating lease liabilities, current portion | 241 | 60 |
| Accrued expenses | 588 | 44 |
| Total current liabilities | 2,247 | 661 |
| Non-current liabilities: | | |
| Operating lease liabilities, net of current portion | 2,888 | — |
| Convertible bonds payable, net of current portion | 3,543 | — |
| Other liabilities | 35 | — |
| Total liabilities | 8,713 | 661 |
| Commitments and contingencies | | |
| Stockholders' equity (deficit): | | |
| Common stock, $0.0001 par value: 10,000,000 shares authorized at December 31, 2022 and 2021; 2,939,575 shares issued and outstanding at December 31, 2022 and 2021 | 1 | 1 |
| Additional paid-in capital | 11,192 | 10,616 |
| Accumulated deficit | (12,743) | (7,295) |
| Total stockholders' equity (deficit) | (1,550) | 3,322 |
| Total liabilities and stockholders' equity (deficit) | $ 7,163 | $ 3,983 |

See accompanying notes.

**TeraImmune, Inc.**
**Consolidated Statements of Operations**
**(in thousands, except share and per share data)**

| | Years Ended December 31, | |
|---|---|---|
| | **2022** | **2021** |
| Operating expenses: | | |
| Research and development | $ 2,295 | $ 3,113 |
| General and administrative | 2,589 | 1,982 |
| Total operating expenses | 4,884 | 5,095 |
| | | |
| Loss from operations | (4,884) | (5,095) |
| | | |
| Other income (expense): | | |
| Interest expense | (415) | 1 |
| Foreign exchange loss | (157) | (4) |
| Other income (expense), net | 8 | 52 |
| Net loss | $ (5,448) | $ (5,046) |
| Basic and diluted net loss per common share | $ (1.85) | $ (1.72) |
| Weighted average common shares outstanding used to calculate basic and diluted net loss per common share | 2,939,575 | 2,939,575 |

See accompanying notes.

**TeraImmune, Inc.**
**Consolidated Statements of Stockholders' Equity (Deficit)**
**(in thousands, except share data)**

| | Common Stock | | Additional Paid-In Capital | Accumulated Deficit | Total Stockholders' Equity (Deficit) |
|---|---|---|---|---|---|
| | Shares | Amount | | | |
| Balances at January 1, 2021 | 2,939,575 | $ 1 | $10,165 | $ (2,249) | $ 7,917 |
| Stock-based compensation expense | — | — | 451 | — | 451 |
| Net loss | — | — | — | (5,046) | (5,046) |
| Balances at December 31, 2021 | 2,939,575 | 1 | 10,616 | (7,295) | 3,322 |
| Stock-based compensation expense | — | — | 576 | — | 576 |
| Net loss | — | — | — | (5,448) | (5,448) |
| Balances at December 31, 2022 | 2,939,575 | $ 1 | $11,192 | $(12,743) | $(1,550) |

See accompanying notes.

**TeraImmune, Inc.**
**Consolidated Statements of Cash Flows**
**(in thousands)**

| | Years Ended December 31, | |
|---|---|---|
| | **2022** | **2021** |
| **Operating activities:** | | |
| Net loss | $(5,448) | $(5,046) |
| | | |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 244 | 137 |
| Noncash operating lease expense | 287 | 105 |
| Stock-based compensation expense | 576 | 451 |
| Gain on forgiveness of debt | — | (51) |
| Loss on disposal of property and equipment | 1 | — |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other assets | (335) | (95) |
| Accounts payable | (139) | 554 |
| Lease liabilities | 3,069 | (113) |
| Accrued expenses | 544 | (30) |
| Other liabilities | 35 | — |
| Net cash used in operating activities | (1,166) | (4,088) |
| | | |
| **Investing activities:** | | |
| Purchases of property and equipment | (2,738) | (1,186) |
| Proceeds from sales of property and equipment | 5 | — |
| Net cash used in investing activities | (2,733) | (1,186) |
| | | |
| **Financing activities:** | | |
| Proceeds from issuance of convertible bonds | 2,590 | — |
| Deferred financing costs | (9) | — |
| Net cash provided by (used in) financing activities | 2,581 | — |
| | | |
| Net decrease in cash and cash equivalents | (1,318) | (5,274) |
| Cash and cash equivalents at beginning of period | 2,235 | 7,509 |
| Cash and cash equivalents at end of period | $ 917 | $ 2,235 |
| | | |
| **Supplemental disclosure of non-cash investing and financing activities:** | | |
| Right-of-use assets from new operating lease agreements | $ 1,834 | $ — |
| Convertible bond payable | $ 1,962 | $ — |
| **Supplemental disclosure of cash investing and financing activities:** | | |
| Cash paid for interest | $ 1 | $ — |

See accompanying notes.

**TERAIMMUNE, INC.**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**
**DECEMBER 31, 2022 AND 2021**
**(in thousands, unless otherwise indicated, except share and per share data)**

## 1. Organization and Description of Business

***Description of the Business***

TeraImmune, Inc. ("TeraImmune") is a C-corporation incorporated under the laws of the State of Delaware in 2019 with its principal place of business and registered office at 20400 Century Boulevard, Suite 125, Germantown, Maryland 20874. On August 24, 2022, TeraImmune Therapeutics, Co., Ltd. ("TIT" or the "Subsidiary"), a wholly-owned subsidiary of the Company was established under the laws of South Korea for the purpose of shareholder relations and to seek grant and funding opportunities in South Korea. Hereinafter, TeraImmune and TIT are collectively defined as the "Company".

The Company is a pre-clinical stage biotech company developing immune cell therapies using human regulatory T cells ("Treg"). The Company's proprietary and patented technology platforms are a method for expansion of the Treg without losing its function and stability (TREGable™ and TREGing™) and the target specific receptors including T cell receptor ("TCR"), Chimeric Antigen Receptor ("CAR") and B cell Antibody Receptor ("BAR"). TeraImmune has developed manufacturing procedures in accordance with the regulatory guidance from the US Food and Drug Administration (the "FDA"). In June 2022, the Company's Investigational New Drug ("IND") application to apply the Factor VIII ("FVIII") TCR-Treg for the refractory Hemophilia A patients was cleared by the FDA to begin clinical trials.

The Company believes that its FVIII TCR-Treg will offer advantages, such as eradication of anti-FVIII antibodies and induction of immune tolerance to anti-FVIII antibodies. The Company plans to initiate its Phase 1/2a clinical trial of FVIII TCR-Treg in 2024.

***Liquidity and Going Concern***

The Consolidated Financial Statements for the years ended December 31, 2022 and 2021 were prepared on the basis of a going concern, which contemplates that the Company will be able to realize assets and discharge liabilities in the normal course of business. However, the Company has incurred net losses since its inception, and has negative operating cash flows and its total liabilities exceed total assets. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

As of December 31, 2022, the Company had cash and cash equivalents of $0.9 million. As of December 31, 2022, the Company had defaulted on its 5% Convertible Term Loan (see Note 3), as it had failed to repay these loans on the stated maturity date of November 30, 2022. The total amount due on the 5% Convertible Term Loan at December 31, 2022 was $1.2 million, including accrued interest and default interest penalty. The Company seeks to cure this default by converting the 5% Convertible Term Loan into shares of the Company's common stock or by providing the noteholders with a repayment plan. Considering the Company's current cash resources and its current and expected levels of operating expenses for the next twelve months, the Company requires additional capital to fund its planned operations.

The Company intends to seek to lower its operating expenses by subleasing its office/laboratory space. The Company also may seek to raise such additional capital through private equity offerings, or convertible and other debt financing. If the Company raises additional funds through collaborations, strategic alliances, or licensing arrangements with third parties, the Company may have to relinquish rights to its technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to the Company.

The Company has executed a non-binding letter of intent and is engaged in exclusive negotiations relating to a proposed business combination with a publicly held biopharmaceutical company, which contemplates a tax-free stock-for-stock merger. The Company is seeking external financing in connection with the potential business combination. There can be no assurance that the potential business combination or financing will be consummated on favorable terms or at all.

While management believes its plans to raise additional funds will alleviate the conditions that raise substantial doubt about the Company's ability to continue as a going concern, these plans are not entirely within the Company's control and cannot be assessed as being probable of occurring.

**TERAIMMUNE, INC.**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**
**DECEMBER 31, 2022 AND 2021**
**(in thousands, unless otherwise indicated, except share and per share data)**

**2. Summary of Significant Accounting Policies**

***Basis of Presentation and Use of Estimates***

The accompanying Consolidated Financial Statements have been prepared in accordance with US generally accepted accounting principles ("US GAAP") and include all adjustments necessary for the presentation of the Company's consolidated financial position, results of operations and cash flows for the periods presented. The Consolidated Financial Statements include the accounts of the Company and its wholly-owned subsidiary These Consolidated Financial Statements have been prepared on a basis that assumes that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business.

The preparation of financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the amounts and disclosures reported in the Consolidated Financial Statements and accompanying notes. Actual results could differ materially from those estimates. The Company believes judgment is involved in accounting for the determination of the fair value-based measurement of stock-based compensation and accruals. The Company evaluates its estimates and assumptions as facts and circumstances dictate. As future events and their effects cannot be determined with precision, actual results could differ from these estimates and assumptions, and those differences could be material to the Consolidated Financial Statements.

***Principles of Consolidation***

The Consolidated Financial Statements include the accounts of the Company and its wholly-owned subsidiary, TIT. All significant intercompany transactions and balances have been eliminated in consolidation.

***Foreign Currency Translation***

The financial statements of the Company's subsidiary, TIT, are measured using the local currency as the functional currency. Assets and liabilities are translated at the rates of exchange at the balance sheet date. Income and expense items are translated at average annual rates of exchange. Management determined translation adjustments for 2022 are immaterial to the consolidated financial statements and have not presented translations adjustments separately in the statements of stockholders' equity. Gains and losses from foreign currency transactions are included in foreign exchange loss in the accompanying consolidated statements of operations.

***Cash and Cash Equivalents***

The Company considers all highly liquid instruments with a maturity of three months or less at the time of purchase to be cash equivalents. Cash and cash equivalents primarily consist of deposits with commercial banks in checking, interest-bearing and demand money market accounts.

***Concentrations of Credit Risk***

The Company's financial instruments that are exposed to concentrations of credit risk consist primarily of cash and cash equivalents. Although the Company maintains cash deposits and cash equivalent balances with multiple financial institutions, the deposits, at times, may exceed federally insured limits. Cash and cash equivalents may be withdrawn or redeemed on demand. The Company believes that the financial institutions that hold its cash and cash equivalents are financially sound and, accordingly, minimal credit risk exists with respect to these balances.

***Research and Development Expenses***

Development costs incurred in the research and development of new product candidates are expensed as incurred, including expenses that may or may not be reimbursed under research and development collaboration arrangements. Research and development costs include, but are not limited to, salaries, benefits, stock-based compensation, laboratory supplies, allocated overhead, fees for professional service providers and costs associated

with product development efforts, including the cost of consultants and contract manufacturing organizations ("CMOs") that manufacture drug products for use in our preclinical studies and clinical trials as well as all other expenses associated with preclinical studies and clinical trials.

The Company records upfront and milestone payments made to third parties under licensing arrangements as an expense. Upfront payments are recorded when incurred and milestone payments are recorded when the specific milestone has been achieved.

***Property and Equipment***

Property and equipment are stated at cost, less accumulated depreciation. Major renewals and betterments are charged to property accounts while replacements, maintenance and repairs, which do not improve or extend the lives of the respective assets, are expensed as incurred. The cost of assets sold or otherwise disposed of and the accumulated depreciation thereon are eliminated from the accounts and the resulting gain or loss is reflected in income. Depreciation expense is calculated using the straight-line method over the useful lives of the various classes of property as follows:

| | |
|---|---|
| Furniture and fixtures | 7 years |
| Computer and software | 3 years |
| Office equipment and R&D equipment | 3-7 years |
| Leasehold improvements | Lesser of economic life or term of lease |

***Impairment of Long-Lived Assets***

Long-lived assets held and used by the Company are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. In the event that facts and circumstances indicate that the cost of any long-lived assets may be impaired, an evaluation of recoverability would be performed. As of December 31, 2022 and 2021, no long-lived assets have been impaired.

***Stock-Based Compensation Expense***

The Company measures stock-based compensation expense for stock awards at the grant date, based on the fair value-based measurement of the award, and the expense is recorded over the related service period, generally the vesting period, net of estimated forfeitures. The Company calculates the fair value-based measurement of stock options using the Black-Scholes valuation model and the simplified method and recognizes expense using the straight-line attribution approach.

Estimating the fair value of share-based awards requires the input of subjective assumptions, including the estimated fair value of the Company's common stock, the expected life of the options and stock price volatility. The fair value of the Company's common stock is determined by the Board reasonably and in good faith with an independent valuation review, which requires judgmental inputs and assumptions such as cash flow projections, peer company comparisons, market data, growth rates and discount rate.

The expected term of the stock options is estimated using the "simplified method" as the Company has no historical information from which to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for its stock option grants. The simplified method is the midpoint between the vesting period and the contractual term of the option. For stock price volatility, the Company uses comparable public companies as a basis for its expected volatility to calculate the fair value of option grants. The risk-free rate is based on the US Treasury yield curve commensurate with the expected term of the option. The expected dividend yield is 0% because the Company has not historically paid, and does not expect, for the foreseeable future, to pay a dividend on its common stock.

***Income Tax***

The Company accounts for income taxes under an asset-and-liability approach. Deferred income taxes reflect the impact of temporary differences between assets and liabilities recognized for tax and financial reporting purposes measured by applying enacted tax rates and laws that will be in effect when the differences are expected to

(in thousands, unless otherwise indicated, except share and per share data)

reverse, net operating loss carryforwards and tax credits. Valuation allowances are provided when necessary to reduce net deferred tax assets to an amount that is more likely than not to be realized. The Company's policy is to include interest and penalties related to unrecognized tax benefits within the Company's provision for income taxes.

***Net Loss Per Common Share***

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and potentially dilutive securities outstanding for the period determined using the treasury-stock and if-converted methods. For purposes of the diluted net loss per share calculation, stock options and convertible debt are considered to be potentially dilutive securities but are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive. Therefore, basic and diluted net loss per share were the same for all periods presented.

The following shares subject to outstanding potentially dilutive securities have been excluded from the computations of diluted net loss per common share as the effect of including such securities would be antidilutive:

| | 2022 | 2021 |
|---|---|---|
| Options to purchase common stock | 185,341 | 205,000 |
| Convertible debt | 625,905 | — |
| | 811,246 | 205,000 |

***Leases***

The Company accounts for leases in accordance with Accounting Standards Update ("ASU") 2016-02, Leases (Topic 842). The Company determines if an arrangement is a lease at inception. The Company has elected to not recognize a lease liability or right-of-use ("ROU") asset for short-term leases (leases with a term of twelve months or less that do not include an option to purchase the underlying asset). Operating lease ROU assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. The interest rate the Company uses to determine the present value of future payments is its incremental borrowing rate because the rate implicit in its leases is not readily determinable. The Company's incremental borrowing rate is a hypothetical rate for collateralized borrowings in economic environments where the leased asset is located based on credit rating factors. Operating lease assets also include adjustments for prepaid lease payments and lease incentives.

Lease expense for operating leases is recognized on a straight-line basis over the lease term. Right-of-use assets represent the Company's right to use the office/laboratory space for the lease term and the lease liability represents the Company's obligation to make lease payments arising from the lease. Right-of-use assets and lease liabilities are recognized at the lease commencement date based on the estimated present value of lease payments over the lease term.

Certain lease contracts include obligations to pay for other services, such as operations and maintenance. The Company elected the practical expedient whereby it records all lease components and the related minimum non-lease components as a single lease component. Cash payments made for variable lease costs are not included in the measurement of the Company's operating lease assets and liabilities. The Company's lease terms may include one or more options to renew. The Company does not assume renewals in its determination of the lease term unless it is reasonably certain that it will exercise that option. Lease costs for minimum lease payments for operating leases are recognized on a straight-line basis over the lease term. The Company's lease agreements do not contain any residual value guarantees.

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***Adoption of New Accounting Standards***

***ASU 2020-06***

The Company has elected to early adopt ASU 2020-06 "Accounting for Convertible Instruments and Contracts in an Entity's Own Equity" ("ASU 2020-06"), effective for its fiscal year beginning January 1, 2021. The new guidance simplifies an issuer's accounting for convertible instruments by eliminating two of the three models in Financial Accounting and Standards Board ("FASB") Accounting Standards Codification ("ASC") Subtopic 470-20 "Debt—Debt with Conversion and Other Options" ("ASC 470-20") that require separate accounting for embedded conversion features (cash conversion features and beneficial conversion features).

**3. Debt**

The following table summarizes components of the Company's debt as of December 31, 2022 and 2021:

| | As of December 31, | |
|---|---|---|
| | **2022** | **2021** |
| 5% Convertible Term Loan, due November 30, 2022 | $ 1,000 | $— |
| 7% Convertible Term Loan, due October 21, 2025[1] | 1,590 | — |
| 10% Unsecured Convertible Promissory Note, due November 24, 2024 | 1,962 | — |
| Total principal amount of debt | 4,552 | — |
| Bond issuance expense | (9) | — |
| Less: current portion | (1,000) | — |
| Total long-term debt | $ 3,543 | $— |

(1) The 7% Convertible Term Loan is denominated in a foreign currency so the balance of this debt may fluctuate based on changes in foreign currency exchange rates.

The following is a summary of principal maturities on the Convertible Term Loans for each of the next five years:

| | |
|---|---|
| Due in 2023 | $1,000 |
| 2024 | 1,962 |
| 2025 | 1,590 |
| Total | $4,552 |

***5% Convertible Term Loan***

On March 22, 2022, the Company entered into a bond agreement pursuant to which it borrowed an aggregate of $1.0 million (the "5% Notes"). The 5% Notes accrued interest at a rate of 5% per annum during the period from April 8, 2022 to the maturity date of November 30, 2022, at which date the principal and accrued interest was to be paid in a lump sum. The Company failed to repay the loan on the maturity date and, as a result, the 5% Notes became subject to a default interest penalty of 20% on the defaulted balance as of November 30, 2022. The proceeds for the loans were used for working capital.

Interest expense recorded during the year ended December 31, 2022 related to the 5% Notes was approximately $0.2 million, including the default interest penalty.

***7% Convertible Term Loan***

On October 21, 2022, TIT issued a convertible bond (the "7% Note") to a third party (the "Bondholder") pursuant to which TIT borrowed an aggregate principal amount of 2 billion KRW or the equivalent of $1.4 million USD as of the date of issuance and $1.6 million USD as of December 31, 2022. The 7% Note has a

maturity date of October 21, 2025, at which time the principal and unpaid accrued interest of 7% per annum is due and payable, unless the 7% Note has been previously repaid or converted. The Bondholder may request early repayment before maturity for all or part of the amount equal to the principal of the 7% Note and unpaid accrued interest of 7% per annum starting on the date of 2 years and 6 months from the issuance date and every 3 months thereafter. The proceeds of the loan were used for working capital.

The 7% Note specifies certain events of default upon which repayment of the principal and interest shall be the sum of the larger amount between the principal of the 7% Note outstanding at the time of default and (1) the amount based on the guaranteed interest rate of 7% from the payment date to the Maturity Date and (2) the amount based on an interest rate of 12% per annum.

The Bondholder has the right to convert the 7% Note into common stock of the Subsidiary at any time from the date six months past the issuance date to the day before the maturity date. The number of shares to be issued is based on a conversion value and conversion rate that is subject to a set of adjustments under seven scenarios, including if by certain specified dates the Subsidiary sold its equity in an Initial Public Offering on a Korean or other public exchange, or if the Subsidiary or the Company becomes listed on a public exchange through a merger or stock exchange with a company listed on a public stock exchange.

The Bondholder has the right to exchange all or part of the common shares issued by the Subsidiary acquired following the conversion of the 7% Note for common shares of TeraImmune on a one-for-one ratio, subject to adjustments due to a stock split or merger. The Bondholder must exercise the exchange right within two months from the date of request for Conversion of the 7% Note, and if not exercised within that period, the right to exchange shall expire.

In event the Subsidiary issues equity securities for capital-raising purposes, the Bondholder is entitled to convertible bonds comparable to the total number of shares with voting rights of the Subsidiary calculated as of the day before the date of the resolution on issuance of the relevant equity securities.

If TeraImmune plans to dispose of all or part of their shares of the Company, the Bondholder has the preemption right to purchase such shares under the same terms and conditions. Further, the Bondholder has the right to sell shares under the same terms and conditions as TeraImmune.

The Company evaluated whether the 7% Note involved a substantial premium or discount and concluded that based on a number of factors, such as the market versus stated interest rate and the probability of certain of the triggering events occurring within the specified dates, the terms of the 7% Note did not include features whose estimated fair values as of the issuance date or as of December 31, 2022 met the significance criteria. Therefore, the Company did not record an adjustment to the carrying value of the 7% Note.

Interest expense recorded during the year ended December 31, 2022 related to the 7% Note was approximately $22 thousand.

***10% Convertible Term Loan***

The Company engaged a contractor to perform certain services for the Company pursuant to a services agreement dated December 3, 2021, under which the Company incurred debt to the contractor equal to a total amount of $2.0 million for services. On December 8, 2022, the Company issued an unsecured convertible promissory note (the “10% Note”) to the contractor (the “Noteholder”) for the services performed. The 10% Note is due on November 30, 2024, at which time the principal of $2.0 million and accrued unpaid interest (collectively, the "Loan Balance") is due, unless the maturity date is extended for up to one year at the option of the Noteholder.

The 10% Note specifies certain events of default upon which the entire unpaid principal amount of the 10% Note, together with accrued and unpaid interest thereon, shall become immediately due and payable. Interest after default shall be increased to 15% per annum.

The 10% Note shall automatically convert (“Automatic Conversion”), upon the closing of the Company’s next issuance of preferred equity securities for capital-raising purposes resulting in net proceeds (individually or in the

aggregate) to the Company of at least $5.0 million (excluding any amounts received in connection with the conversion of the 10% Note) (a ”Qualifying Financing”), into that whole number of preferred equity securities issued in the Qualifying Financing equal to the number obtained by dividing the then-outstanding Loan Balance by 90% of the price per preferred equity security paid by investors in the Qualifying Financing.

If on or prior to the Maturity Date no (i) Qualifying Financing, (ii) Change in Control or (iii) repayment in full has occurred, then the Noteholder shall have the option at the maturity date to: (a) demand immediate repayment of an amount equal to the then-outstanding Loan Balance, or (b) convert the then-outstanding Loan Balance into the common equity securities (or equivalent thereto) of the Company, in an amount equal to the ratio of (x) the then-outstanding Loan Balance over (y) the ratio of $150.0 million divided by the fully-diluted capitalization of the Company immediately prior to conversion.

At the Noteholder’s option, the Noteholder shall have a right to participate in the Company's financing rounds that may occur after a Qualifying Financing which would have triggered Automatic Conversion (each a “Future Round,” and collectively “Future Rounds”) for a share equal to the Noteholder’s fully diluted percentage equity ownership in the Company (assuming and after giving effect to Automatic Conversion discussed above). If the Noteholder fails to exercise its right to purchase its full pro rata shares in a Future Round, then the Noteholder’s pro rata rights shall terminate for all subsequent Future Rounds.

Upon the occurrence of a Change in Control (as defined in the loan agreement and other than in connection with or resulting from a Qualifying Financing), the Noteholder shall have the option to either (i) convert the Loan Balance of the 10% Note into common securities of the Company in an amount equal to the ratio of (x) the then-outstanding Loan Balance over (y) the ratio of $150.0 million divided by the fully-diluted capitalization of the Company immediately prior to the Change in Control, or (ii) demand immediate repayment of an amount equal to the sum of (A) the outstanding principal amount together with any accrued unpaid interest due under the 10% Note, plus (B) an additional amount equal to 20% of the original principal amount.

The Company evaluated whether the 10% Note involved a substantial premium or discount and concluded that based on a number of factors, such as the market versus stated interest rate and the probability of certain of the triggering events occurring within the specified dates, the terms of the note did not include features whose estimated fair values as of the issuance date or as of December 31, 2022 met the significance criteria. Therefore, the Company did not record an adjustment to the carrying value of the 10% Note.

Interest expense recorded during the year ended December 31, 2022 related to the 10% Notes was approximately $13 thousand.

***Debt covenant compliance***

The debt agreements discussed above contain customary representations and warranties, affirmative and negative covenants.

As of December 31, 2022, the Company had defaulted on its 5% Convertible Term Loan as it had failed to repay these loans on the stated maturity date of November 30, 2022. The Company seeks to cure this default by converting the 5% Convertible Term Loans into shares of the Company’s common stock or by providing the noteholders with a repayment plan.

***Line of Credit***

On September 21, 2022, the Company entered into a Business Loan Agreement with Fulton Bank (the “Fulton Agreement”). The Fulton agreement provides for a $0.1 million revolving credit facility. The interest rate is US Prime plus 3%. The interest rate was 10.5% at December 31, 2022. All inventory, equipment, accounts receivable, letter-of-credit rights, and deposit accounts collateralize borrowings on the line of credit. As of December 31, 2022, the Company had not made any borrowings under the revolving credit facility. The Fulton Agreement may be terminated by mutual agreement of the Company and Fulton Bank.

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***Paycheck Protection Program***

In May 2020, the Company received loan proceeds in the amount of $50 thousand under the Paycheck Protection Program ("PPP"). Established as part of the Coronavirus Aid, Relief and Economic Security Act ("CARES ACT"), the PPP provides for loans to qualifying businesses in amounts up to 2.5 times the business's average monthly payroll expenses. PPP loans and accrued interest are forgivable after a "covered period" (eight or twenty-four weeks) as long as the borrower maintains its payroll levels and uses the loan proceeds for eligible purposes, including payroll, employee benefits, rent, and utilities. The forgiveness amount would be reduced if the borrower terminates employees or reduces salaries during the covered period. Any unforgiven portion of a PPP loan was payable over two or five years at an interest rate of 1%, with a deferral of payments for 10 months after the end of the covered period.

The loan proceeds were spent on payroll costs and other eligible expenses as required and the Company has been released from the loan obligation for the loan amount and interest accrued of $51 thousand on June 28, 2021. Accordingly, the forgiven loan and interest were reclassified to other income on the accompanying 2021 Consolidated Financial Statements.

***Employee Promissory Notes***

In October 2022, the Company entered into promissory note agreements for accrued salaries with its employees (the "Employee Promissory notes"). The Employee Promissory notes deferred the payment of salaries of all Company employees and management by between 20-50% until such time as the Company completes a $5.0 million fundraising. The Employee Promissory notes provide that if the Company is unable to repay these notes by December 31, 2022, 5% simple interest would be paid along with the accrued amounts of deferred compensation. As of December 31, 2022, the Employee Promissory notes totaled $0.3 million.

**4. Property and Equipment, Net**

Property and equipment, net consisted of the following:

| | As of December 31, | |
|---|---|---|
| | **2022** | **2021** |
| Furniture and fixtures | $ 45 | $ 45 |
| Computers and software | 58 | 74 |
| Equipment | 887 | 890 |
| Leasehold improvements | 3,488 | 754 |
| Total | 4,478 | 1,763 |
| Accumulated depreciation and amortization | (437) | (207) |
| Property and equipment, net | $4,041 | $1,556 |

Depreciation and amortization expense for the years ended December 31, 2022, and 2021 was $0.2 million and $0.1 million, respectively.

**5. Leases**

***Operating Leases***

On December 19, 2019, the Company entered into a sixty-three month lease for a laboratory and office in Gaithersburg, Maryland (the "Gaithersburg lease"). The initial monthly rent was $10 thousand, with annual increases of 3% commencing January 3, 2020. The Company made a security deposit of $32 thousand in the form of an unconditional and irrevocable letter of credit upon execution of the lease agreement. In June 2022, the Company's headquarters moved to the new location in Germantown, Maryland and the Gaithersburg lease was terminated. There were no termination penalties due to the early termination. The ROU asset was amortized until the termination of the lease and there was no recognition of gain or loss.

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On May 24, 2021, the Company signed an operating lease agreement with ARE-Maryland No. 52, LLC (the "Landlord") for approximately 10,309 square feet of space located in Germantown, Maryland (the "Germantown lease"). The Germantown lease commenced on March 1, 2022 with an initial monthly rent amount of $32 thousand and annual increases of 3% for a period of 117 months. The Company has incurred costs of leasehold improvements associated with the Germantown lease in the amount of $3.5 million through December 31, 2022, which are recorded as property and equipment on the Consolidated Balance Sheets. The Landlord agreed to provide tenant improvement allowances in the maximum amount of $1.3 million which is included in the base rent. The Company provided a security deposit of $95 thousand in the form of an unconditional and irrevocable letter of credit upon execution of the lease agreement. The Germantown lease provides for an optional five-year extension; however, the optional period is not included in the lease term used to determine the ROU asset or lease liability associated with this lease as the Company did not consider it reasonably certain it would exercise the option.

This lease is classified as an operating lease at the rent commencement date. The Company uses a 5% incremental borrowing rate to calculate the present value of lease payments. On the lease commencement date, the Company recognized an operating lease right-of-use asset in the amount of $1.8 million.

Maturities of lease liabilities as of December 31, 2022, are as follows:

| | |
|---|---|
| 2023 | $ 390 |
| 2024 | 400 |
| 2025 | 412 |
| 2026 | 424 |
| 2027 | 437 |
| Thereafter | 1,843 |
| Total undiscounted lease payments | 3,906 |
| Less: | |
| Imputed interest | (777) |
| Net lease liabilities | $3,129 |

Lease expense for the operating and short-term leases for the years ended December 31, 2022 and 2021 was as follows:

| | Year Ended December 31 | |
|---|---|---|
| | 2022 | 2021 |
| Operating lease expense | $287 | $105 |
| Short-term lease expense | 27 | 22 |
| Variable lease expense | 167 | 56 |
| Total lease expense | $481 | $183 |

On December 9, 2020, the Company entered into an 11-month lease for a small office in South Korea which expired in November 2021. Then, the Company extended the lease for 10-month lease at the same location until August 31, 2022.

In September 2022, TIT entered into a new month-to-month lease for a shared office in South Korea for $1,123 per month.

**6. Stockholders' Equity**

***2019 Equity Plan***

On April 5, 2019, the Company adopted the 2019 Stock Option and Restricted Stock Plan (the "2019 Equity Plan"). The 2019 Equity Plan provides for the granting of incentive stock options, non-statutory stock options

and restricted stock awards. The Company's employees, officers, independent directors, and other persons are eligible to receive awards under the 2019 Equity Plan. As of December 31, 2022, there were 580,000 shares of the Company's common stock authorized to be issued, of which 358,201 shares were available for future issuance.

The amount, terms of grants, and exercisability provisions are determined and set by the Company's Board of Directors. The Company measures employee stock-based awards at grant-date fair value and records compensation expense on a straight-line basis over the vesting period of the award. Options generally vest and become exercisable over two years and expire seven years from the date of grant.

***Stock Option Activity***

The following table summarizes stock option activity for the years ended December 31, 2022 and 2021:

| | Number of Shares | Weighted Average Exercise Price (per share) | Weighted Average Remaining Contractual Term (in years) | Aggregate Intrinsic Value ($000's)(1) |
|---|---|---|---|---|
| Outstanding at January 1, 2021 | 106,000 | $11.81 | | |
| Granted | 138,000 | 13.00 | | |
| Exercised | — | | | |
| Cancelled (forfeited) | (39,000) | 11.62 | | |
| Cancelled (expired) | — | | | |
| Outstanding at December 31, 2021 | 205,000 | $12.65 | | |
| Granted | 106,341 | 13.07 | | |
| Exercised | — | | | |
| Cancelled (forfeited) | (126,000) | 12.86 | | |
| Cancelled (expired) | — | | | |
| Outstanding at December 31, 2022 | 185,341 | $12.75 | 6.13 | $— |
| Options vested and expected to vest | 185,341 | $11.65 | 6.13 | $— |
| Exercisable | 40,000 | $11.65 | 4.36 | $— |

(1) The aggregate intrinsic value is calculated as the difference between the exercise price of the option and the fair value of the Company's common stock for in-the-money options at December 31, 2022.

The stock options outstanding and exercisable by exercise price at December 31, 2022 are as follows:

| | Stock Options Outstanding | | | Stock Options Exercisable | |
|---|---|---|---|---|---|
| Range of Exercise Prices | Number of Shares | Weighted Average Remaining Contractual Life in years | Weighted-Average Exercise Price Per Share | Number of Shares | Weighted-Average Exercise Price Per Share |
| $11.2 - $13.08 | 185,341 | 6.13 | $12.75 | 40,000 | $11.65 |
| | 185,341 | 6.13 | $12.75 | 40,000 | $11.65 |

***Stock-Based Compensation***

The Company's stock-based compensation expense for stock options is estimated at the grant date based on the award's fair value as calculated by the Black-Scholes option pricing model and is recognized as expense over the requisite service period. The Black-Scholes option pricing model requires various highly judgmental assumptions

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including expected volatility and expected term. The expected volatility is based on the combined historical stock volatilities of the publicly listed peers over a period equal to the expected terms of the options as the Company does not have any trading history to rely solely on the volatility of its own common stock. To estimate the expected term, the Company has opted to use the simplified method, which is the use of the midpoint of the vesting term and the contractual term. If any of the assumptions used in the Black-Scholes option pricing model changes significantly, stock-based compensation expense may differ materially in the future from that recorded in the current period.

The weighted-average fair value-based measurement of stock options granted under the Company's stock plans in the years ended December 31, 2022 and 2021 was $13.08 and $13.00 per share, respectively. The fair value-based measurement of stock options granted under the Company's stock plans was estimated at the date of grant using the Black-Scholes model with the following assumptions:

| | Year Ended December 31, | |
|---|---|---|
| | 2022 | 2021 |
| Expected term | 4 - 5 years | 4 - 6 years |
| Expected volatility | 104.91% - 116.02% | 113.91% - 122.37% |
| Risk-free interest rate | 1.39% - 4.01% | 0.27% - 1.25% |
| Expected dividend yield | 0% | 0% |

Total expense for stock option grants recognized was as follows:

| | Year Ended December 31, | |
|---|---|---|
| | 2022 | 2021 |
| General and administrative | $196 | $185 |
| Research and development | 380 | 266 |
| Total stock-based compensation | $576 | $451 |

At December 31, 2022, the Company had $0.6 million of total unrecognized compensation expense related to outstanding stock options that will be recognized over a weighted-average period of 6.13 years.

**7. Income Taxes**

No provision for federal income taxes has been recorded for the years ended December 31, 2022 and 2021 due to net losses and the valuation allowance established.

The actual expenses for the years ended December 31, 2022 and 2021 differ from the "expected" tax expenses (computed by applying the U.S. federal corporate income tax rate of 21% to earnings before income taxes) primarily due to the following:

| | As of December 31, | |
|---|---|---|
| | 2022 | 2021 |
| Computed "expected" tax benefit | $(1,144) | $(1,060) |
| Increase (reduction) in income taxes from: | | |
| Permanent differences | 148 | 125 |
| Tax credits | (224) | (224) |
| Change in valuation allowance | 1,220 | 1,477 |
| Prior year adjustment and others | — | (318) |
| | $ — | $ — |

(in thousands, unless otherwise indicated, except share and per share data)

The tax effect of temporary differences that give rise to the deferred tax assets and deferred tax liabilities at December 31, 2022 and 2021 is presented below:

| | As of December 31, | |
|---|---|---|
| | 2022 | 2021 |
| Deferred tax assets (liabilities): | | |
| Leases under ASC 842 | $ 283 | $ 2 |
| Depreciation and amortization | (123) | (181) |
| R&D expense capitalization | 402 | — |
| Net operating loss carry forward | 2,402 | 1,763 |
| Foreign tax credits | 172 | — |
| R&D tax credits | 426 | 320 |
| Total gross deferred tax assets | 3,562 | 1,904 |
| Less: valuation allowance | (3,562) | (1,904) |
| Net deferred tax assets | $ — | $ — |

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that all or some portion of the deferred tax assets will be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. Based on the level of the historical taxable income and projection for future taxable income over the periods in which the deferred tax assets are deductible, management believes it is not more likely than not that the Company will realize the benefits of these deductible differences and valuation allowance against deferred tax assets was provided as of December 31, 2022 and 2021.

At December 31, 2022 and 2021, the Company has net operating loss carryforwards for federal income tax purpose of approximately $8.8 million and $6.4 million, respectively, with an indefinite carryforward period.

The Company had no unrecognized tax benefits and consequently had not accrued interest and penalties related thereto at the beginning or end of 2022 and 2021. The Company does not expect its unrecognized tax benefit balance to change significantly in the next 12 months as of December 31, 2022. The Company's tax returns for 2019, 2020, and 2021 remain open to examination by the federal and state taxing jurisdictions.

**8. Employee Benefit Plan**

The Company has established a 401(k) tax-deferred savings plan (the "401(k) Plan"), which permits participants to make contributions by salary deduction pursuant to Section 401(k) of the Internal Revenue Code of 1986, as amended. The Company is responsible for administrative costs of the 401(k) Plan. The Company matches 100% of the first 3% of the participants' deferral contributions to the 401(k) Plan. The Company contributed $16 and $17 thousand in matching contributions to the 401(k) Plan for the years ended December 31, 2022 and 2021, respectively.

**9. License and Collaboration Agreements**

***HA FVIII TCR Agreement***

On August 5, 2019, the Company entered into an exclusive worldwide license agreement (the "HA FVIII TCR Agreement") with the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. ("HJF") for certain technologies used to create Factor VIII (FVIII) specific T cell Receptor ("TCR") or B cell targeting Antibody Receptor ("BAR") expressing regulatory T cells ("Tregs") for human uses.

Pursuant to the FVIII TCR Agreement, the Company has paid a license royalty fee and annual royalties of $58 thousand to HJF since September 2019.

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***BML Agreement***

On August 26, 2019, the Company entered into the non-exclusive Biological Materials License Agreement ("BML Agreement") with the National Cancer Institute ("NCI"), a part of National Institute for Health ("NIH"), which is part of the US Government Department of Health and Human Services. This agreement allows the Company to use the pMSGV1 vector for the production of T cell products transduced with the retroviral vectors.

Pursuant to the BMLA Agreement, the Company has paid a license execution fee and annual royalties of $11 thousand to NIH since August 2019.

***NIAID CRADA***

On September 23, 2019, the Company entered into a three-year Cooperative Research and Development Agreement ("NIAID CRADA") with the National Institute of Allergy and Infectious Diseases ("NIAID"), a part of NIH. This agreement aims to develop personalized clinical-grade FVIII TCR Tregs using a viral gene transfer system and FVIII-specific TCR transgene for a proof-of-concept clinical trial in Hemophilia A patients who develop FVIII inhibitor antibody under current standards of treatment. This collaboration will develop GMP ancillary materials and related cGMP-compliant ex vivo manufacturing protocols for clinic-grade FVIII TCR-Tregs by combining oligonucleotide phosphorothioate (ODNps25) treatment Treg stabilization technology.

Pursuant to NIAID CRADA, the Company performed all physical and experimental activities at its own expense. In turn, a principal investor of the NIAID provided scientific advice on the experiments for cGMP-grade Treg manufacturing and developing pre-/early clinical stage protocols for the Company. The NIAID CRADA was extended in October 2022 for an additional two years.

***HJF CRADA***

On May 19, 2020, the Company entered into a two-year Cooperative Research and Development Agreement ("HJF CRADA") with the Uniformed Services University of the Health Sciences ("USU"), an institution within the US Government Department of Defense. HJF is a tax-exempt cooperation organization that acts as patent management for USU to support the development and commercialization of scientific and medical technologies on behalf of USU. This collaborative agreement aims to further the licensed intellectual property rights developing the CMC (chemistry, manufacturing, and control) setting and collect the pre-clinical data of autologous FVIII-specific TCR Treg product ("FVIII TCR-Tregs") for the IND clearance and Phase I clinical study. HJF CRADA has been extended until May 2025.

Pursuant to the CRADA, the Company paid $0.1 million to HJF in July2020.

***HA ODN Agreement***

On June 18, 2020, the Company entered into an exclusive license agreement (the "HA ODN Agreement") with the NIAID, a part of NIH. This license agreement allows the Company to use the rights of patent for producing T cell populations enriched for stable regulatory T cells (Tregs) aimed at developing Treg cell therapy for patients with Hemophilia A who have inhibitory anti-FVIII auto-antibodies.

Pursuant to the HA ODN Agreement, the Company has paid a license royalty fee and annual royalties of $55 thousand to NIAID since August 2020. The HA ODN Agreement also requires the payment of milestones and royalties upon the achievement of certain regulatory and commercialization milestones.

***iTreg Agreement***

On November 11, 2020, the Company entered into an exclusive worldwide license agreement (the "iTreg Agreement") with HJF for technology used for producing methods of induced regulatory T ("iTreg") cells and human uses. The license was pending the status of provisional filing on the signing date, and the Company agreed to take responsibility for the maintenance and prosecution of the Patent Rights in consultation with HJF on all strategic global filing and prosecution decisions.

Under the iTreg Agreement, the Company paid a license fee of $25 thousand to HJF in December 2020.

***IGU MOU***

On January 1, 2021, the Company entered into a two-year Memorandum of Understanding (the "IGU MOU") with the IGlobal University ("IGU"), which is now Washington University of Science and Technology ("WUST"), for a joint educational and cultural collaboration. The IGU MOU promotes individual scientists to develop their carrier experience in the biotech industry. IGU provides the scientists an affiliation and the Company provides wages to them. The IGU MOU was terminated on December 31, 2022.

Pursuant to the terms of the IGU MOU, the Company paid $0.2 million since 2021.

***SNU Collaboration***

On March 1, 2021, the Company entered into a one-year Research Collaborative Agreement ("SNU Collaboration") with the Seoul National University (SNU) Industry-University Cooperation Foundation for genomic pattern analysis of regulatory T cells, which was expanded by the Company's proprietary technology. Under the SNU Collaboration, the Company agreed to fund $0.2 million in the research area of a high-throughput chromogenic Single Cell Multiome Sequencing. As a result of the SNU Collaboration, the Company will gain access to data and authorship on the publications, and if research produces intellectual property, the Company will have a co-ownership.

***MS TCR Agreement***

On July 15, 2021, the Company entered into an exclusive worldwide license agreement (the "MS TCR Agreement") with HJF for certain technologies used to create a specific TCR expressing Tregs for use in Multiple Sclerosis patients. The license covers various patent applications and know-how developed by the CEO of the Company under the supervision of HJF.

Pursuant to the MS TCR Agreement, the Company has paid a license royalty fee and annual royalties of $8 thousand to HJF since July 2021. The FVIII TCR Agreement also requires the payment of milestones and royalties upon the achievement of certain regulatory and commercialization milestones.

***NINDS Agreement***

On July 19, 2021, the Company entered into a three-year collaboration agreement for the transfer of human materials (the "NINDS Agreement") with the National Institute of Neurological Disorders and Stroke ("NINDS"), a part of NIH. The scope of NINDS Agreement is 'Phenotypic and functional investigation of the expanded T regulatory cells obtained from healthy donors and patients with Multiple Sclerosis.'

***CNU Agreement***

On September 16, 2022, TIT entered into a technology transfer agreement to acquire the patent rights from Chungnam National University ("CNU") in South Korea. The patent claims the use of proteasome inhibitor to prevent or treat Atopic Dermatitis. TIT made one-time payment of $12 thousand to acquire the patent.

***UFRF Agreement***

On September 22, 2021, the Company entered into an exclusive US/worldwide license agreement (the "UFRF Agreement") with the University of Florida Research Foundation, Incorporated ("UFRF") for FVIII Chimeric Antigenic receptor Tregs for tolerance induction in Hemophilia A ("FVIII CAR Tregs"). The license covers a patent application and know-how developed by UFRF. The licensed technology has the potential to broaden the Company's position in the prevention of FVIII inhibitor formation aimed at treating Hemophilia A patients with FVIII CAR Tregs.

Pursuant to the UFRF agreement, the Company paid a license fee of $17 thousand since 2021.

**TERAIMMUNE, INC.**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**
**DECEMBER 31, 2022 AND 2021**
**(in thousands, unless otherwise indicated, except share and per share data)**

**10. Subsequent Events**

The Company has evaluated subsequent events from the balance sheet date through June 26, 2023, the date at which the financial statements were issued and has determined that there are no such events to report outside of the below:

On April 17, 2023, the Company entered into an exclusive license agreement for the use of Oligodeoxynucleotide in manufacturing Treg products for patients with Multiple Sclerosis (the "MS ODN Agreement"). Pursuant to the agreement, the Company shall pay $3 thousand and $3 thousand as a license issue royalty and minimum annual royalty within 90 days after the execution, respectively. Then, another $20 thousand and $27 thousand shall be paid for additional license issue royalties within 150 days and 180 days, respectively. The agreement also requires the payment of milestones and royalties upon the achievement of certain regulatory and commercialization milestones.

On June 20, 2023, the Company executed a non-binding letter of intent and is currently engaged in exclusive negotiations relating to a proposed business combination with a publicly held biopharmaceutical company, which contemplates a tax-free stock-for-stock merger. The Company is seeking external financing in connection with the potential business combination. There can be no assurance that the potential business combination or financing will be consummated on favorable terms or at all.

**ANNEX C**

**UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
AND ACCOMPANYING NOTES OF TERAIMMUNE, INC.
(Three Months Ended March 31, 2023 and 2022)**

**TeraImmune, Inc.**

**Unaudited Condensed Consolidated Financial Statements**
**Three Months Ending March 31, 2023 and 2022**

**TeraImmune, Inc.**

**Index**

**TeraImmune, Inc.**
**Unaudited Condensed Consolidated Balance Sheets**
**(in thousands, except share data)**

| | March 31, 2023 | December 31, 2022 |
|---|---|---|
| | | (audited) |
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 718 | $ 917 |
| Prepaid expenses and other current assets | 117 | 473 |
| Total current assets | 835 | 1,390 |
| Property and equipment, net | 3,911 | 4,041 |
| Operating lease right-of-use assets, net | 1,779 | 1,730 |
| Other assets | 2 | 2 |
| Total assets | $ 6,527 | $ 7,163 |
| | | |
| **Liabilities and stockholders' equity (deficit)** | | |
| Current liabilities: | | |
| Accounts payable | $ 393 | $ 418 |
| Convertible bonds payable, current portion | 1,000 | 1,000 |
| Operating lease liabilities, current portion | 301 | 241 |
| Accrued expenses | 665 | 588 |
| Total current liabilities | 2,359 | 2,247 |
| | | |
| Non-current liabilities: | | |
| Operating lease liabilities, net of current portion | 2,861 | 2,888 |
| Convertible bonds payable, net of current portion | 3,493 | 3,543 |
| Other liabilities | 110 | 35 |
| Total liabilities | 8,823 | 8,713 |
| | | |
| Commitments and contingencies | | |
| | | |
| Stockholders' equity (deficit): | | |
| Common stock, $0.0001 par value: 10,000,000 shares authorized; 2,939,575 shares issued and outstanding as of March 31, 2023 and December 31, 2022 | 1 | 1 |
| Additional paid-in capital | 11,266 | 11,192 |
| Accumulated deficit | (13,563) | (12,743) |
| Total stockholders' deficit | (2,296) | (1,550) |
| Total liabilities and stockholders' equity (deficit) | $ 6,527 | $ 7,163 |

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

**TeraImmune, Inc.**
**Unaudited Condensed Consolidated Statements of Operations**
**(in thousands, except share and per share data)**

| | Three Months Ended March 31, | |
|---|---|---|
| | **2023** | **2022** |
| Operating expenses: | | |
| Research and development | $ 224 | $ 764 |
| General and administrative | 573 | 653 |
| Total operating expenses | 797 | 1,417 |
| | | |
| Loss from operations | (797) | (1,417) |
| | | |
| Other income (expense): | | |
| Interest expense | (79) | — |
| Foreign exchange gain | 40 | — |
| Other income | 16 | 1 |
| Net loss | $ (820) | $ (1,416) |
| Basic and diluted net loss per common share | $ (0.28) | $ (0.48) |
| Weighted average common shares outstanding used to calculate basic and diluted net loss per common share | 2,939,575 | 2,939,575 |

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

**TeraImmune, Inc.**
**Unaudited Condensed Consolidated Statements of Stockholders' Equity (Deficit)**
**(in thousands, except share data)**

| | Common Stock | | Additional Paid-In Capital | Accumulated Deficit | Total Stockholders' Equity (Deficit) |
|---|---|---|---|---|---|
| | Shares | Amount | | | |
| **Balances at December 31, 2021 (audited)** | 2,939,575 | $ 1 | $10,616 | $(7,295) | $ 3,322 |
| Stock-based compensation expense | — | — | 191 | — | 191 |
| Net loss | — | — | — | (1,416) | (1,416) |
| Balances at March 31, 2022 | 2,939,575 | $ 1 | $10,807 | $(8,711) | $ 2,097 |

| | Common Stock | | Additional Paid-In Capital | Accumulated Deficit | Total Stockholders' Equity (Deficit) |
|---|---|---|---|---|---|
| | Shares | Amount | | | |
| **Balances at December 31, 2022 (audited)** | 2,939,575 | $ 1 | $11,192 | $(12,743) | $ (1,550) |
| Stock-based compensation expense | — | — | 74 | — | 74 |
| Net loss | — | — | — | (820) | (820) |
| Balances at March 31, 2023 | 2,939,575 | $ 1 | $11,266 | $(13,563) | $(2,296) |

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

**TeraImmune, Inc.**
**Unaudited Condensed Consolidated Statements of Cash Flows**
**(in thousands)**

| | Three Months Ended March 31, | |
|---|---|---|
| | **2023** | **2022** |
| **Operating activities:** | | |
| Net loss | $(820) | $ (1,416) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 130 | 40 |
| Noncash operating lease expense | 113 | 50 |
| Stock-based compensation expense | 74 | 191 |
| Gain on foreign currency translation | (50) | — |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other assets | 356 | (36) |
| Accounts payable | (25) | 194 |
| Lease liabilities | (129) | (31) |
| Accrued expenses | 77 | 113 |
| Other liabilities | 75 | — |
| Net cash used in operating activities | (199) | (895) |
| | | |
| **Investing activities:** | | |
| Purchases of property and equipment | — | (783) |
| Net cash used in investing activities | — | (783) |
| | | |
| Net decrease in cash and cash equivalents | (199) | (1,678) |
| Cash and cash equivalents at beginning of period | 917 | 2,235 |
| Cash and cash equivalents at end of period | $ 718 | $ 557 |
| | | |
| **Supplemental disclosure of non-cash investing and financing activities:** | | |
| Right-of-use assets and lease liabilities from operating lease agreements | 88 | 1,834 |
| Accounts payable for purchases of property and equipment | — | 635 |

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

**TeraImmune, Inc.**
**Notes to the Unaudited Condensed Consolidated Financial Statements**
**(in thousands, unless otherwise indicated, except share and per share data)**

## 1. Organization and Description of Business

***Description of the Business***

TeraImmune, Inc. ("TeraImmune") is a C-corporation incorporated under the laws of the State of Delaware in 2019 with its principal place of business and registered office at 20400 Century Boulevard, Suite 125, Germantown, Maryland 20874. On August 24, 2022, TeraImmune Therapeutics, Co., Ltd. ("TIT" or the "Subsidiary"), a wholly-owned subsidiary of the Company was established under the laws of South Korea for the purpose of shareholder relations and to seek grant and funding opportunities in South Korea. Hereinafter, TeraImmune and TIT are collectively defined as the "Company".

The Company is a pre-clinical stage biotech company developing immune cell therapies using human regulatory T cells ("Treg"). The Company's proprietary and patented technology platforms are a method for expansion of the Treg without losing its function and stability (TREGableTM and TREGingTM) and the target specific receptors including T cell receptor ("TCR"), Chimeric Antigen Receptor ("CAR") and B cell Antibody Receptor ("BAR"). TeraImmune has developed manufacturing procedures in accordance with the regulatory guidance from the US Food and Drug Administration (the "FDA"). In June 2022, the Company's Investigational New Drug ("IND") application to apply the Factor VIII ("FVIII") TCR-Treg for the refractory Hemophilia A patients was cleared by the FDA to begin clinical trials.

The Company believes that its FVIII TCR-Treg will offer advantages, such as eradication of anti-FVIII antibodies and induction of immune tolerance to anti-FVIII antibodies. The Company plans to initiate its Phase 1/2a clinical trial of FVIII TCR-Treg in 2024.

On June 29, 2023, the Company completed a merger with Baudax Bio, Inc. ("Baudax Bio"), a publicly held biopharmaceutical company (see Note 7).

***Liquidity and Going Concern***

The unaudited condensed consolidated financial statements as of March 31, 2023 and the three months ended March 31, 2023 and 2022, and as of December 31, 2022 were prepared on the basis of a going concern, which contemplates that the Company will be able to realize assets and discharge liabilities in the normal course of business. The Company has incurred net losses since its inception and has negative operating cash flows and its total liabilities exceed total assets. The Company has no products approved for commercial sale, has not generated any revenue from product sales, and cannot guarantee when or if it will generate any revenues from product sales associated with its development programs. Substantially all of the Company's operating losses result from expenses incurred in connection with its research and development activities and from general and administrative costs associates with its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

The Company had defaulted on its 5% Convertible Term Loan (see Note 3), as it had failed to repay these loans on the stated maturity date of November 30, 2022. The total amount due on the 5% Convertible Term Loan at March 31, 2023 was $1.2 million, including accrued interest and default interest penalty. The Company seeks to cure this default by converting the 5% Convertible Term Loan into shares of the Company's common stock or by providing the noteholders with a repayment plan. Considering the Company's current cash resources and its current and expected levels of operating expenses for the next twelve months, the Company requires additional capital to fund its planned operations.

The Company may seek to raise such additional capital through private equity offerings, or convertible and other debt financing with Baudax Bio. If the Company raises additional funds through collaborations, strategic alliances, or licensing arrangements with third parties, the Company may have to relinquish rights to its technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to the Company.

While management believes its plans to raise additional funds will alleviate the conditions that raise substantial doubt about the Company's ability to continue as a going concern, these plans are not entirely within the Company's control and cannot be assessed as being probable of occurring.

**TeraImmune, Inc.**
**Notes to the Unaudited Condensed Consolidated Financial Statements**
**(in thousands, unless otherwise indicated, except share and per share data)**

**2. Summary of Significant Accounting Policies**

During the three months ended March 31, 2023, there have been no significant changes to the Company's summary of significant accounting policies contained in the Company's annual audited consolidated financial statements for the year ended December 31, 2022. A condensed summary of significant accounting policies follow:

***Basis of Presentation and Use of Estimates***

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with US generally accepted accounting principles ("US GAAP") and include all adjustments necessary for the presentation of the Company's consolidated financial position, results of operations and cash flows for the periods presented. The unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. These unaudited condensed consolidated financial statements have been prepared on a basis that assumes that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business.

The preparation of unaudited condensed consolidated financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the amounts and disclosures reported in the unaudited condensed consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates. The Company believes judgment is involved in accounting for the determination of the fair value-based measurement of stock-based compensation and accruals. The Company evaluates its estimates and assumptions as facts and circumstances dictate. As future events and their effects cannot be determined with precision, actual results could differ from these estimates and assumptions, and those differences could be material to the unaudited condensed consolidated financial statements. The December 31, 2022 Condensed Consolidated Balance Sheet was derived from the audited financial statements, but does not include all disclosures required by US GAAP. These interim financial results are not necessarily indicative of the results to be expected for the year ending December 31, 2023, or for any other future annual or interim period.

***Principles of Consolidation***

The unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, TIT. All significant intercompany transactions and balances have been eliminated in consolidation.

***Foreign Currency Translation***

The financial statements of the Company's subsidiary, TIT, are measured using Korean won ("KRW") as its functional currency. For consolidation purposes, TIT assets and liabilities are translated into United States dollars (US$) at the rates of exchange prevailing at the balance sheet date. Income and expense items are translated at average rates of exchange for the period. Management determined translation adjustments for the March 31, 2023 and December 31, 2022 periods were immaterial to the unaudited condensed consolidated financial statements and have presented translation adjustments in foreign exchange gain in the accompanying condensed consolidated statements of operations.

Gains and losses foreign currency transactions into are included in foreign exchange gain in the accompanying condensed consolidated statements of operations.

***Cash and Cash Equivalents***

The Company considers all highly liquid instruments with a maturity of three months or less at the time of purchase to be cash equivalents. Cash and cash equivalents primarily consist of deposits with commercial banks in checking, interest-bearing and demand money market accounts.

***Concentrations of Credit Risk***

The Company's financial instruments that are exposed to concentrations of credit risk consist primarily of cash and cash equivalents. Although the Company maintains cash deposits and cash equivalent balances with multiple

financial institutions, the deposits, at times, may exceed federally insured limits. Cash and cash equivalents may be withdrawn or redeemed on demand. The Company believes that the financial institutions that hold its cash and cash equivalents are financially sound and, accordingly, minimal credit risk exists with respect to these balances.

***Research and Development Expenses***

Development costs incurred in the research and development of new product candidates are expensed as incurred, including expenses that may or may not be reimbursed under research and development collaboration arrangements. Research and development costs include, but are not limited to, salaries, benefits, stock-based compensation, laboratory supplies, allocated overhead, fees for professional service providers and costs associated with product development efforts, including the cost of consultants and contract manufacturing organizations ("CMOs") that manufacture drug products for use in our preclinical studies and clinical trials as well as all other expenses associated with preclinical studies and clinical trials.

The Company records upfront and milestone payments made to third parties under licensing arrangements as an expense. Upfront payments are recorded when incurred and milestone payments are recorded when the specific milestone has been achieved.

***Property and Equipment***

Property and equipment are stated at cost, less accumulated depreciation. Major renewals and betterments are charged to property accounts while replacements, maintenance and repairs, which do not improve or extend the lives of the respective assets, are expensed as incurred. The cost of assets sold or otherwise disposed of and the accumulated depreciation thereon are eliminated from the accounts and the resulting gain or loss is reflected in income. Depreciation expense is calculated using the straight-line method over the useful lives of the various classes of property as follows:

| | |
|---|---|
| Furniture and fixtures | 7 years |
| Computer and software | 3 years |
| Office equipment and R&D equipment | 3-7 years |
| Leasehold improvements | Lesser of economic life or term of lease |

***Stock-Based Compensation Expense***

The Company measures stock-based compensation expense for stock awards at the grant date, based on the fair value-based measurement of the award, and the expense is recorded over the related service period, generally the vesting period, net of estimated forfeitures. The Company calculates the fair value-based measurement of stock options using the Black-Scholes valuation model and the simplified method and recognizes expense using the straight-line attribution approach.

Estimating the fair value of share-based awards requires the input of subjective assumptions, including the estimated fair value of the Company's common stock, the expected life of the options and stock price volatility. The fair value of the Company's common stock is determined by the Board reasonably and in good faith with an independent valuation review, which requires judgmental inputs and assumptions such as cash flow projections, peer company comparisons, market data, growth rates and discount rate.

The expected term of the stock options is estimated using the "simplified method" as the Company has no historical information from which to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for its stock option grants. The simplified method is the midpoint between the vesting period and the contractual term of the option. For stock price volatility, the Company uses comparable public companies as a basis for its expected volatility to calculate the fair value of option grants. The risk-free rate is based on the US Treasury yield curve commensurate with the expected term of the option. The expected dividend yield is 0% because the Company has not historically paid, and does not expect, for the foreseeable future, to pay a dividend on its common stock.

**TeraImmune, Inc.**
**Notes to the Unaudited Condensed Consolidated Financial Statements**
**(in thousands, unless otherwise indicated, except share and per share data)**

***Net Loss Per Common Share***

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and potentially dilutive securities outstanding for the period determined using the treasury-stock and if-converted methods. For purposes of the diluted net loss per share calculation, stock options and convertible debt are considered to be potentially dilutive securities but are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive.

The following shares subject to outstanding potentially dilutive securities have been excluded from the computations of diluted net loss per common share as the effect of including such securities would be antidilutive:

| | As of March 31, | |
|---|---|---|
| | 2023 | 2022 |
| Options to purchase common stock | 200,341 | 215,000 |
| Convertible debt | 635,794 | — |
| | 836,135 | 215,000 |

***Leases***

The Company accounts for leases in accordance with Accounting Standards Update ("ASU") 2016-02, Leases (Topic 842). The Company determines if an arrangement is a lease at inception. The Company does not recognize a lease liability or right-of-use ("ROU") asset for short-term leases (leases with a term of twelve months or less that do not include an option to purchase the underlying asset). Operating lease ROU assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. The interest rate the Company uses to determine the present value of future payments is its incremental borrowing rate because the rate implicit in its leases is not readily determinable. The Company's incremental borrowing rate is a hypothetical rate for collateralized borrowings in economic environments where the leased asset is located based on credit rating factors. Operating lease assets also include adjustments for prepaid lease payments and lease incentives.

Lease expense for operating leases is recognized on a straight-line basis over the lease term. Right-of-use assets represent the Company's right to use the office/laboratory space for the lease term and the lease liability represents the Company's obligation to make lease payments arising from the lease. Right-of-use assets and lease liabilities are recognized at the lease commencement date based on the estimated present value of lease payments over the lease term.

Certain lease contracts include obligations to pay for other services, such as operations and maintenance. The Company elected the practical expedient whereby it records all lease components and the related minimum non-lease components as a single lease component. Cash payments made for variable lease costs are not included in the measurement of the Company's operating lease assets and liabilities. The Company's lease terms may include one or more options to renew. The Company does not assume renewals in its determination of the lease term unless it is reasonably certain that it will exercise that option. Lease costs for minimum lease payments for operating leases are recognized on a straight-line basis over the lease term. The Company's lease agreements do not contain any residual value guarantees.

***New Accounting Pronouncements***

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") that the Company has or will adopt as of a specified date. Unless otherwise noted, the Company does not believe that any other recently issued accounting pronouncements issued by the FASB had, or is expected to have, a material impact on the Company's present or future financial statements.

**TeraImmune, Inc.**
**Notes to the Unaudited Condensed Consolidated Financial Statements**
**(in thousands, unless otherwise indicated, except share and per share data)**

**3. Debt**

The following table summarizes components of the Company's debt as of March 31, 2023 and December 31, 2022:

| | March 31, 2023 | December 31, 2022 |
|---|---|---|
| 5% Convertible Term Loan, due November 30, 2022 | $ 1,000 | $ 1,000 |
| 7% Convertible Term Loan, due October 21, 2025[1] | 1,540 | 1,590 |
| 10% Unsecured Convertible Promissory Note, due November 24, 2024 | 1,962 | 1,962 |
| Total principal amount of debt | 4,502 | 4,552 |
| Bond issuance cost | (9) | (9) |
| Less: current portion | (1,000) | (1,000) |
| Total long-term debt | $ 3,493 | $ 3,543 |

(1) The 7% Convertible Term Loan is denominated in a foreign currency so the balance of this debt may fluctuate based on changes in foreign currency exchange rates.

The following is a summary of principal maturities on the Convertible Term Loans for each of the next five years:

| | |
|---|---|
| Due in 2023 | $1,000 |
| 2024 | 1,962 |
| 2025 | 1,540 |
| Total | $4,502 |

***5% Convertible Term Loan***

On March 22, 2022, the Company entered into a bond agreement pursuant to which it borrowed an aggregate of $1.0 million (the "5% Notes"). The 5% Notes accrued interest at a rate of 5% per annum during the period from April 8, 2022 to the maturity date of November 30, 2022, at which date the principal and accrued interest was to be paid in a lump sum. The proceeds for the loans were used for working capital.

The Company defaulted on its 5% Convertible Term Loan as it had failed to repay these loans on the stated maturity date of November 30, 2022. The Company seeks to cure this default by converting the 5% Convertible Term Loans into shares of the Company's common stock or by providing the noteholders with a repayment plan.

***7% Convertible Term Loan***

On October 21, 2022, TIT issued a convertible bond (the "7% Note") to a third party (the "Bondholder") pursuant to which TIT borrowed an aggregate principal amount of KRW 2 billion or the equivalent of $1.4 million as of the date of issuance, and $1.5 million and $1.6 million as of March 31, 2023 and December 31, 2022, respectively. The 7% Note has a maturity date of October 21, 2025, at which time the principal and unpaid accrued interest of 7% per annum is due and payable, unless the 7% Note has been previously repaid or converted. The Bondholder may request early repayment before maturity for all or part of the amount equal to the principal of the 7% Note and unpaid accrued interest of 7% per annum starting on the date of 2 years and 6 months from the issuance date and every 3 months thereafter. The proceeds of the loan were used for working capital.

The 7% Note specifies certain events of default upon which repayment of the principal and interest shall be the sum of the larger amount between the principal of the 7% Note outstanding at the time of default and (1) the amount based on the guaranteed interest rate of 7% from the payment date to the maturity date and (2) the amount based on an interest rate of 12% per annum.

**TeraImmune, Inc.**
**Notes to the Unaudited Condensed Consolidated Financial Statements**
**(in thousands, unless otherwise indicated, except share and per share data)**

The Bondholder has the right to convert the 7% Note into common stock of the Subsidiary at any time from the date six months past the issuance date to the day before the maturity date. The number of shares to be issued is based on a conversion value and conversion rate that is subject to a set of adjustments under seven scenarios, including if by certain specified dates the Subsidiary sold its equity in an Initial Public Offering on a Korean or other public exchange, or if the Subsidiary or the Company becomes listed on a public exchange through a merger or stock exchange with a company listed on a public stock exchange.

The Bondholder has the right to exchange all or part of the common shares issued by the Subsidiary acquired following the conversion of the 7% Note for common shares of TeraImmune on a one-for-one ratio, subject to adjustments due to a stock split or merger. The Bondholder must exercise the exchange right within two months from the date of request for Conversion of the 7% Note, and if not exercised within that period, the right to exchange shall expire.

In event the Subsidiary issues equity securities for capital-raising purposes, the Bondholder is entitled to convertible bonds comparable to the total number of shares with voting rights of the Subsidiary calculated as of the day before the date of the resolution on issuance of the relevant equity securities.

If TeraImmune plans to dispose of all or part of their shares of the Company, the Bondholder has the preemption right to purchase such shares under the same terms and conditions. Further, the Bondholder has the right to sell shares under the same terms and conditions as TeraImmune.

The Company evaluated whether the 7% Note involved a substantial premium or discount and concluded that based on a number of factors, such as the market versus stated interest rate and the probability of certain of the triggering events occurring within the specified dates, the terms of the 7% Note did not include features whose estimated fair values as of the issuance date or as of March 31, 2023 met the significance criteria. Therefore, the Company did not record an adjustment to the carrying value of the 7% Note.

Interest expense recorded for three months ended March 31, 2023 related to the 7% Note was approximately $28 thousand.

***10% Convertible Term Loan***

The Company engaged a contractor to perform certain services for the Company pursuant to a services agreement dated December 3, 2021, under which the Company incurred debt to the contractor equal to a total amount of $2.0 million for services. On December 8, 2022, the Company issued an unsecured convertible promissory note (the "10% Note") to the contractor (the "Noteholder") for the services performed. The 10% Note is due on November 30, 2024, at which time the principal of $2.0 million and accrued unpaid interest (collectively, the "Loan Balance") is due, unless the maturity date is extended for up to one year at the option of the Noteholder.

The 10% Note specifies certain events of default upon which the entire unpaid principal amount of the 10% Note, together with accrued and unpaid interest thereon, shall become immediately due and payable. Interest after default shall be increased to 15% per annum.

The 10% Note shall automatically convert ("Automatic Conversion"), upon the closing of the Company's next issuance of preferred equity securities for capital-raising purposes resulting in net proceeds (individually or in the aggregate) to the Company of at least $5.0 million (excluding any amounts received in connection with the conversion of the 10% Note) (a "Qualifying Financing"), into that whole number of preferred equity securities issued in the Qualifying Financing equal to the number obtained by dividing the then-outstanding Loan Balance by 90% of the price per preferred equity security paid by investors in the Qualifying Financing.

If on or prior to the Maturity Date no (i) Qualifying Financing, (ii) Change in Control or (iii) repayment in full has occurred, then the Noteholder shall have the option at the maturity date to: (a) demand immediate repayment of an amount equal to the then-outstanding Loan Balance, or (b) convert the then-outstanding Loan Balance into the common equity securities (or equivalent thereto) of the Company, in an amount equal to the ratio of (x) the then-outstanding Loan Balance over (y) the ratio of $150.0 million divided by the fully-diluted capitalization of the Company immediately prior to conversion.

**TeraImmune, Inc.**
**Notes to the Unaudited Condensed Consolidated Financial Statements**
**(in thousands, unless otherwise indicated, except share and per share data)**

At the Noteholder's option, the Noteholder shall have a right to participate in the Company's financing rounds that may occur after a Qualifying Financing which would have triggered Automatic Conversion (each a "Future Round," and collectively "Future Rounds") for a share equal to the Noteholder's fully diluted percentage equity ownership in the Company (assuming and after giving effect to Automatic Conversion discussed above). If the Noteholder fails to exercise its right to purchase its full pro rata shares in a Future Round, then the Noteholder's pro rata rights shall terminate for all subsequent Future Rounds.

Upon the occurrence of a Change in Control (as defined in the loan agreement and other than in connection with or resulting from a Qualifying Financing), the Noteholder shall have the option to either (i) convert the Loan Balance of the 10% Note into common securities of the Company in an amount equal to the ratio of (x) the then-outstanding Loan Balance over (y) the ratio of $150.0 million divided by the fully-diluted capitalization of the Company immediately prior to the Change in Control, or (ii) demand immediate repayment of an amount equal to the sum of (A) the outstanding principal amount together with any accrued unpaid interest due under the 10% Note, plus (B) an additional amount equal to 20% of the original principal amount.

The Company evaluated whether the 10% Note involved a substantial premium or discount and concluded that based on a number of factors, such as the market versus stated interest rate and the probability of certain of the triggering events occurring within the specified dates, the terms of the note did not include features whose estimated fair values as of the issuance date or as of March 31, 2023 met the significance criteria. Therefore, the Company did not record an adjustment to the carrying value of the 10% Note.

Interest expense recorded for the three months ended March 31, 2023 related to the 10% Notes was approximately $48 thousand.

***Debt covenant compliance***

The debt agreements discussed above contain customary representations and warranties, affirmative and negative covenants.

***Line of Credit***

On September 21, 2022, the Company entered into a Business Loan Agreement with Fulton Bank (the "Fulton Agreement"). The Fulton agreement provides for a $0.1 million revolving credit facility. The interest rate is US Prime plus 3%. As at March 31, 2023, the interest rate was 11.0%. All inventory, equipment, accounts receivable, letter-of-credit rights, and deposit accounts collateralize borrowings on the line of credit. As of March 31, 2023, the Company had not made any borrowings under the revolving credit facility. The Fulton Agreement may be terminated by mutual agreement of the Company and Fulton Bank.

***Employee Promissory Notes***

In October 2022, the Company entered into promissory note agreements for accrued salaries with its employees (the "Employee Promissory notes"). The Employee Promissory notes deferred the payment of salaries of all Company employees and management by between 20-50% until such time as the Company completes a $5.0 million fundraising. The Employee Promissory notes provide that a 5% simple interest would be paid along with the accrued amounts of deferred compensation if the Company is unable to repay these notes by December 31, 2022. As of March 31, 2023, the Employee Promissory notes totaled $0.3 million.

Interest expense recorded for the three months ended March 31, 2023 related to the Employee Promissory Notes was approximately $2 thousand.

**TeraImmune, Inc.**
**Notes to the Unaudited Condensed Consolidated Financial Statements**
**(in thousands, unless otherwise indicated, except share and per share data)**

**4. Property and Equipment, Net**

Property and equipment, net consisted of the following:

| | March 31, 2023 | December 31, 2022 |
|---|---|---|
| Furniture and fixtures | $ 45 | $ 45 |
| Computers and software | 56 | 58 |
| Equipment | 888 | 887 |
| Leasehold improvements | 3,488 | 3,488 |
| Total | 4,477 | 4,478 |
| Accumulated depreciation and amortization | (566) | (437) |
| Property and equipment, net | $3,911 | $4,041 |

Depreciation and amortization expense for the three months ended March 31, 2023 and 2022 was $0.1 million and $0.04 million, respectively.

**5. Leases**

***Operating Leases***

On May 24, 2021, the Company signed an operating lease agreement with ARE-Maryland No. 52, LLC (the "Landlord") for approximately 10,309 square feet of space located in Germantown, Maryland (the "Germantown lease"). The Germantown lease commenced on March 1, 2022 with an initial monthly rent amount of $32 thousand and annual increases of 3% for a period of 117 months. The Company has incurred costs of leasehold improvements associated with the Germantown lease in the amount of $3.5 million through March 31, 2023, which are recorded as property and equipment on the unaudited condensed consolidated balance sheets. The Landlord agreed to provide tenant improvement allowances in the maximum amount of $1.3 million which is included in the base rent. The Company provided a security deposit of $95 thousand in the form of an unconditional and irrevocable letter of credit upon execution of the lease agreement. The Germantown lease provides for an optional five-year extension; however, the optional period is not included in the lease term used to determine the ROU asset or lease liability associated with this lease as the Company did not consider it reasonably certain it would exercise the option.

This lease is classified as an operating lease at the rent commencement date. The Company uses a 5% incremental borrowing rate to calculate the present value of lease payments. On the lease commencement date, the Company recognized an operating lease right-of-use asset in the amount of $1.8 million.

Maturities of lease liabilities as of March 31, 2023, are as follows:

| | |
|---|---|
| 2023 | $ 301 |
| 2024 | 412 |
| 2025 | 424 |
| 2026 | 437 |
| 2027 | 450 |
| Thereafter | 1,897 |
| Total undiscounted lease payments | 3,921 |
| Less: | |
| Imputed interest | (759) |
| Net lease liabilities | $3,162 |

**TeraImmune, Inc.**
**Notes to the Unaudited Condensed Consolidated Financial Statements**
**(in thousands, unless otherwise indicated, except share and per share data)**

Lease expense for the operating and short-term leases for the three months ended March 31, 2023 and 2022 was as follows:

| | Three Months Ended March 31, | |
|---|---|---|
| | 2023 | 2022 |
| Operating lease expense | $113 | $50 |
| Short-term lease expense | — | 12 |
| Variable lease expense | 32 | 26 |
| Total lease expense | $145 | $88 |

**6. Stock-Based Compensation**

***2019 Equity Plan***

As of March 31, 2023, there were 580,000 shares of the Company's common stock authorized to be issued, of which 343,201 shares were available for future issuance.

***Stock Option Activity***

During the three months ended March 31, 2023, the Company granted 20,000 stock options under the Company's 2019 Stock Option and Restricted Stock Plan (the "2019 Equity Plan"). The amount, terms of grants, and exercisability provisions are determined and set by the Company's Board of Directors. The stock options generally vest and become exercisable over two years and expire seven years from the date of grant.

The following table summarizes stock option activity for the three months ended March 31, 2023:

| | Number of Shares | Weighted Average Exercise Price (per share) | Weighted Average Remaining Contractual Term (in years) | Aggregate Intrinsic Value ($000's)(1) |
|---|---|---|---|---|
| Outstanding at December 31, 2022 (audited) | 185,341 | $ 12.75 | 6.13 | |
| Granted | — | — | | |
| Exercised | — | — | | |
| Cancelled (forfeited) | (5,000) | 13.00 | | |
| Cancelled (expired) | — | — | | |
| Outstanding at March 31, 2023 | 180,341 | $ 12.74 | 5.86 | $— |
| Options vested and expected to vest | 180,341 | $ 12.74 | 5.86 | $— |
| Exercisable | 55,000 | | 5.70 | $— |

(1) The fair value-based measurement of stock options granted under the Company's stock plans was estimated at the date of grant using the Black-Scholes model with the following assumptions:

| | March 31, 2023 | March 31, 2022 |
|---|---|---|
| Expected term | 1 year | 4 years |
| Expected volatility | 110.18% | 104.91% |
| Risk-free interest rate | 4.01% | 1.39% |
| Expected dividend yield | 0% | 0% |

**TeraImmune, Inc.**
**Notes to the Unaudited Condensed Consolidated Financial Statements**
**(in thousands, unless otherwise indicated, except share and per share data)**

For the three months ended March 31, 2023 and 2022, the Company recognized stock option grants expenses was as follows:

| | Three Months Ended March 31, | |
|---|---|---|
| | 2023 | 2022 |
| General and administrative | $15 | $ 68 |
| Research and development | 59 | 123 |
| Total stock-based compensation | $74 | $191 |

At March 31, 2023, the Company had $0.6 million of total unrecognized compensation expense related to outstanding stock options that will be recognized over a weighted-average period of 5.86 years.

***Restricted Stock Unit Awards***

During the three months ended March 31, 2023, the Company issued restricted stock ("RSU") to an employee which will be vested upon a certain milestone. The fair value of an RSU is equal to the fair market value price of the Company's common stock on the date of grant.

The following table summarizes RSUs activity during the three months ended March 31, 2023:

| | Number of Shares | Weighted Average Grant Date Fair Value (per share) |
|---|---|---|
| Outstanding at December 31, 2022 (audited) | — | $ — |
| Granted | 20,000 | 1.81 |
| Exercised | — | — |
| Cancelled (forfeited) | — | — |
| Cancelled (expired) | — | — |
| Outstanding at March 31, 2023 | 20,000 | $1.81 |

**7. Subsequent Events**

The Company has evaluated subsequent events from the balance sheet date through July 28, 2023, the date at which the unaudited condensed consolidated financial statements were available to be issued and has determined that there are no such events to report outside of the below:

On April 17, 2023, the Company entered into an exclusive license agreement for the use of Oligodeoxynucleotide in manufacturing Treg products for patients with Multiple Sclerosis (the "MS ODN Agreement"). Pursuant to the agreement, the Company shall pay $3 thousand and $3 thousand as a license issue royalty and minimum annual royalty within 90 days after the execution, respectively. Then, another $20 thousand and $27 thousand shall be paid for additional license issue royalties within 150 days and 180 days, respectively. The agreement also requires the payment of milestones and royalties upon the achievement of certain regulatory and commercialization milestones.

On June 29, 2023 (the "Effective Date"), the Company executed an Agreement and Plan of Merger (the "Merger Agreement") with Baudax Bio, pursuant to which, upon the terms and subject to the satisfaction of the conditions described within the Merger Agreement, the Company shall merge and become a wholly-owned subsidiary of Baudax Bio (the "Merger"). The Merger is intended to qualify as a tax-free reorganization for U.S. Federal income tax purposes. The Company is seeking external financing in connection with the business combination.

**ANNEX D**

## UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL STATEMENTS

The following unaudited pro forma condensed combined financial information has been prepared in accordance with Article 11 of Regulation S-X under the Securities Act of 1933, as amended (the "Securities Act") and presents the combined historical consolidated financial position and consolidated results of operations of Baudax Bio, Inc ("Baudax" or the "Company") and the historical combined financial position and results of operations of TerraImmune, Inc ("TeraImmune"), adjusted to give effect to (i) the June 29, 2023 ("Closing Date") acquisition of TeraImmune as further described in Note 1 — *Description of the Transaction* (the "Transaction") and (ii) the pro forma effects of certain assumptions and adjustments described in "Notes to the Unaudited Pro Forma Condensed Combined Financial Information" below.

The following unaudited pro forma combined financial information is presented to illustrate the estimated effects of the Transaction, the mandatory conversion of outstanding Series X Non-Voting Convertible Preferred Stock ("Series X Preferred Stock") into common stock and related stock options for Series X Preferred Stock into options for common stock, based on the historical financial statements and accounting records of Baudax and TeraImmune after giving effect to these transactions and the related pro forma adjustments as described in the notes included below.

The unaudited pro forma combined statement of operations for the three months ended March 31, 2023 and for the year ended December 31, 2022, combine the historical statements of operations of Baudax and TeraImmune, giving effect to the Transaction as if it had occurred on January 1, 2022.

The historical financial statements of Baudax and TeraImmune have been adjusted to give pro forma effect to events that are (1) directly attributable to the Transaction, (2) factually supportable, and (3) with respect to the unaudited pro forma combined statements of operations, expected to have a continuing impact on the combined results of operations of the combined company. The unaudited pro forma combined financial statements should be read in conjunction with the accompanying notes to the unaudited pro forma combined financial statements.

The following unaudited pro forma condensed combined financial information and related notes are based on and should be read in conjunction with:

(i) the historical unaudited consolidated financial statements of Baudax and the related notes included in Baudax's Quarterly Report on Form 10-Q as of and for the three months ended March 31, 2023;

(ii) the historical audited consolidated financial statements of Baudax and the related notes included in Baudax's Annual Report on Form 10-K as of and for the year ended December 31, 2022;

(iii) the historical unaudited condensed consolidated financial statements of TeraImmune and the related notes as of and the three months ended March 31, 2023; and

(iv) the historical audited consolidated financial statements of TeraImmune and the related notes as of and for the year ended December 31, 2022.

With respect to the Transaction, the unaudited pro forma combined financial information has been prepared by Baudax using the acquisition method of accounting in accordance with U.S. generally accepted accounting principles. Baudax has been treated as the acquirer in the Transaction for accounting purposes as TeraImmune is deemed to be a variable interest entity to which Baudax is the primary beneficiary. The assets acquired and liabilities assumed by Baudax in the Transaction have been preliminarily measured at their respective estimated fair values as of June 29, 2023. Differences between these preliminary estimates of fair value and the final acquisition accounting will occur, and those differences could have a material impact on the accompanying unaudited pro forma combined financial statements and the combined company's future results of operations and financial position. Baudax will finalize the acquisition accounting (including the necessary valuation and other studies) as soon as practicable within the required measurement period, but in no event later than one year following completion of the Transaction.

The pro forma adjustments are preliminary and have been made solely for the purpose of providing unaudited pro forma combined financial information prepared in accordance with the rules and regulations of the Securities and Exchange Commission (the "SEC").

The unaudited pro forma combined financial information has been presented for informational purposes only. The unaudited pro forma combined financial information does not purport to represent the actual results of operations that Baudax and TeraImmune would have achieved had the companies been combined during the periods presented in the unaudited pro forma combined financial statements and is not intended to project the future results of operations that the combined company may achieve after the Transaction. The unaudited pro forma combined financial information does not reflect any potential cost savings that may be realized as a result of the Transaction and also does not reflect any restructuring or integration-related costs to achieve those potential cost savings.

**Unaudited Pro Forma Condensed Combined Balance Sheet**
**As of March 31, 2023**
**(in thousands)**

| | Baudax Bio, Inc. (Historical) | TeraImmune, Inc. (Historical) | Transaction Adjustments | Notes | Pro Forma Combined |
|---|---|---|---|---|---|
| **ASSETS** | | | | | |
| Current assets: | | | | | |
| Cash and cash equivalents | $ 3,803 | $ 718 | $ (1,293) | A | $ 3,228 |
| Prepaid expenses and other current assets | 305 | 117 | — | | 422 |
| Total current assets | **4,108** | **835** | **(1,293)** | | **3,650** |
| Property and equipment, net | 1 | 3,911 | — | | 3,912 |
| Intangible assets -- In process R&D assets | — | — | 3,500 | B | 3,500 |
| Goodwill | 2,127 | — | 6,868 | C | 8,995 |
| Operating lease right of use assets, net | — | 1,779 | — | | 1,779 |
| Other assets | 829 | 2 | — | | 831 |
| Total assets | **$ 7,065** | **$ 6,527** | **$ 9,075** | | **$ 22,667** |
| **LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)** | | | | | |
| Current liabilities: | | | | | |
| Accounts payable | $ 3,837 | $ 393 | $ — | | $ 4,230 |
| Accrued expenses and other current liabilities | 2,534 | 665 | (239) | D | 2,960 |
| Current portion of long-term debt, net | 6,000 | — | — | | 6,000 |
| Current portion of convertible bonds | — | 1,000 | (1,000) | D | — |
| Operating lease liabilities | — | 301 | — | | 301 |
| Total current liabilities | **12,371** | **2,359** | **(1,239)** | | **13,491** |
| Long-term debt | 1,433 | — | — | | 1,433 |
| Convertible bonds, net of current portion | — | 3,493 | (3,493) | D | — |
| Operating lease liabilities, net of current portion | — | 2,861 | — | | 2,861 |
| Other liabilities | 574 | 110 | (110) | | 574 |
| Total liabilities | **14,378** | **8,823** | **(4,842)** | | **18,359** |
| Stockholders' equity (deficit): | | | | | |
| Common stock | 26 | 1 | 282 | E | 309 |
| Additional paid-in capital | 172,161 | 11,266 | 1,365 | E | 184,792 |
| Accumulated deficit | (179,500) | (13,563) | 12,270 | E | (180,793) |
| Total stockholders' equity (deficit) | (7,313) | (2,296) | 13,917 | | 4,308 |
| Total stockholders' equity (deficit) | **(7,313)** | **(2,296)** | **13,917** | | **4,308** |
| Total liabilities and stockholders' equity (deficit) | **$ 7,065** | **$ 6,527** | **$ 9,075** | | **$ 22,667** |

See accompanying notes to the unaudited pro forma condensed combined financial statements.

**Unaudited Pro Forma Condensed Combined Statements of Operations**
**For the Three Months Ended March 31, 2023**
**(in thousands, except share and per share amounts)**

| | Baudax Bio, Inc. (Historical) | TeraImmune, Inc. (Historical) | Transaction Adjustments | Notes | Pro Forma Combined |
|---|---|---|---|---|---|
| Operating expenses: | | | | | |
| Research and development | $ 2,917 | $ 224 | $ — | | $ 3,141 |
| Selling, general and administrative | 1,771 | 573 | — | | 2,344 |
| Total operating expenses | 4,688 | 797 | — | | 5,485 |
| Loss from operations | (4,688) | (797) | — | | (5,485) |
| Non-operating income (expense): | | | | | |
| Interest expense | — | (79) | 79 | F | — |
| Foreign exchange gain | — | 40 | — | | 40 |
| Other inccome (expense), net | (2,698) | 16 | — | | (2,682) |
| Net loss from continuing operations | (7,386) | (820) | 79 | | (8,127) |
| Income from discontinued operations | 18,790 | — | — | | 18,790 |
| Net income (loss) | $ 11,404 | $ (820) | $ 79 | | $ 10,663 |
| | | | | | |
| Per share information: | | | | | |
| Net loss per share from continuing operations, basic and diluted | $ (3.19) | $ (0.28) | NA | | $ (0.27) |
| Net income from share from discontinued operations, basis and diluted | $ 8.10 | $ — | NA | | $ 0.61 |
| Net income (loss) per share - basic and diluted | $ 4.92 | $ (0.28) | NA | | $ 0.35 |
| Weighted average common shares outstanding, basic and diluted | 2,318,539 | 2,939,575 | 25,362,346 | G | 30,620,460 |

See accompanying notes to the unaudited pro forma condensed combined financial statements.

**Unaudited Pro Forma Condensed Combined Statements of Operations**
**For the Year Ended December 31, 2022**
**(in thousands, except share and per share amounts)**

| | Baudax Bio, Inc. (Historical) | TeraImmune, Inc. (Historical) | Transaction Adjustments | Notes | Pro Forma Combined |
|---|---|---|---|---|---|
| Operating expenses: | | | | | |
| Research and development | $ 3,200 | $ 2,295 | $ — | | $ 5,495 |
| Selling, general and administrative | 14,713 | 2,589 | — | | 17,302 |
| Change in warrant valuation | (7) | — | — | | (7) |
| Total operating expenses | 17,906 | 4,884 | — | | 22,790 |
| Loss from operations | (17,906) | (4,884) | — | | (22,790) |
| Non-operating income (expense): | | | | | |
| Interest expense | — | (415) | 415 | F | — |
| Other expense, net | (2,298) | (149) | — | | (2,447) |
| Net loss from continuing operations | (20,204) | (5,448) | 415 | | (25,237) |
| Net loss on discontinued operations | (38,591) | — | — | | (38,591) |
| Net loss | $ (58,795) | $ (5,448) | | | $ (63,828) |
| | | | | | |
| Per share information: | | | | | |
| Net loss per share from continuing operations - basic and diluted | $ (60.93) | $ (1.85) | | | $ (0.88) |
| Net loss per share from discountineud operations, basic and diluted | $ (116.37) | — | | | (1.35) |
| Net loss per share, basic and diluted | $ (177.30) | (1.85) | | | (2.23) |
| Weighted average common shares outstanding, basic and diluted | 331,615 | 2,939,575 | 25,362,346 | G | 28,633,536 |

See accompanying notes to the unaudited pro forma condensed combined financial statements.

## NOTES TO UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

### 1. Description of Transactions and Basis of Presentation

***Description of the Transaction***

On June 29, 2023 (the "Effective Date"), Baudax acquired TeraImmune in accordance with the terms of the Agreement and Plan of Merger, dated as of the Effective Date (the "Merger Agreement") by and among Baudax, Bounce Merger Sub I, Inc., a Delaware corporation and a wholly-owned subsidiary of Baudax Bio ("First Merger Sub"), Bounce Merger Sub II, LLC, a Delaware limited liability company and a wholly-owned subsidiary of Baudax Bio ("Second Merger Sub"), and TeraImmune. Pursuant to the Merger Agreement, First Merger Sub merged with and into TeraImmune, pursuant to which TeraImmune was the surviving corporation and became a wholly-owned subsidiary of Baudax (the "First Merger"). Immediately following the First Merger, TeraImmune merged with and into Second Merger Sub, pursuant to which Second Merger Sub was the surviving entity (together with the First Merger, the "Merger") which name will subsequently change to TeraImmune, LLC.

Under the terms of the Merger Agreement, at the closing of the Merger (the "Closing"), Baudax will issue to the existing common stockholders of TeraImmune (the "Target Stockholders") an aggregate of 1,212,185 shares of the common stock of Baudax Bio, par value $0.01 per share ("Common Stock") and 27,089.719 shares of Series X Non-Voting Convertible Preferred Stock, par value $0.01 per share (the "Series X Preferred Stock"), each share of which is convertible into 1,000 shares of Common Stock (subject to certain conditions as described below). As at Closing, a total of 1,212,185 shares of Common Stock and 27,090 shares of Series X Preferred Stock of Baudax were issued of which 314,282 shares of Common Stock and 7,023.51 shares of Series X Preferred Stock were escrow shares. Under the terms of the Merger Agreement, all options to purchase or acquire shares of TeraImmune held by Continuing Employees (as defined in the Merger Agreement) were assumed by Baudax and converted into options to purchase shares of Common Stock and Series X Preferred Stock of Bio on the same terms and conditions as applied to such options and restricted stock awards immediately prior to the Merger (but with such changes as Baudax in good faith determined were necessary to reflect such assumption and conversion). Following the closing of the Merger, Baudax had 7,276,149 shares of Common Stock issued and outstanding.

Pursuant to the Merger Agreement, Baudax has agreed to hold a shareholders' meeting (the "Special Meeting") to submit the approval of the conversion of the Series X Preferred Stock into shares of Common Stock in accordance with Nasdaq Listing Rule 5635(a), among other matters, to its shareholders for their consideration (the "Merger Agreement Meeting Proposals"). In connection with these matters, Baudax intends to file with the Securities and Exchange Commission (the "SEC") a proxy statement and other relevant materials.

The foregoing summary of the transactions contemplated by the Merger Agreement is subject to, and qualified in its entirety by, the full text of the Merger Agreement, a copy of which was attached as Exhibit 2.1 to the Current Report on Form 8-K filed by Baudax with the SEC on July 5, 2023.

***Basis of Presentation***

The unaudited pro forma combined financial information was prepared using the acquisition method of accounting and is based on the historical financial statements of Baudax and TeraImmune. The acquisition method of accounting is based on Accounting Standards Codification ("ASC") 805, Business Combinations, with the Company as the accounting acquirer, and uses the fair value concepts defined in ASC 820, Fair Value Measurement.

ASC 805 requires, among other things, that most assets acquired and liabilities assumed be recognized at their fair values as of the acquisition date. In addition, ASC 805 requires that the consideration transferred be measured at the date the acquisition is completed at the then-current market price.

ASC 820 defines the term "fair value," sets forth the valuation requirements for any asset or liability measured at fair value, expands related disclosure requirements and specifies a hierarchy of valuation techniques based on the nature of the inputs used to develop the fair value measures. Fair value is defined in ASC 820 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." This is an exit price concept for the valuation of the asset or liability. In addition, market participants are assumed to be buyers and sellers in the principal (or the most advantageous)

market for the asset or liability. Fair value measurements for an asset assume the highest and best use by these market participants. As a result of these standards, Baudax may be required to record the fair value of assets which are not intended to be used or sold and/or to value assets at fair value measures that do not reflect Baudax's intended use of those assets. Many of these fair value measurements can be highly subjective, and it is possible that other professionals, applying reasonable judgment to the same facts and circumstances, could develop and support a range of alternative estimated amounts.

Under the acquisition method of accounting, the assets acquired and liabilities assumed are recorded, as of the completion of the acquisition, primarily at their respective fair values, with the excess of the purchase consideration over the fair value of TeraImmune's net assets, allocated to goodwill, if any, and added to those of Baudax. Financial statements and reported results of operations of Baudax issued after completion of the acquisition will reflect these values but will not be retroactively restated to reflect the historical financial position or results of operations of TeraImmune. The pro forma allocation of the purchase price reflected in the unaudited pro forma condensed combined financial information is preliminary and thus subject to adjustment and may vary materially from the final purchase price allocation that will be completed within the measurement period, but in no event later than one year following the Closing Date since, among other reasons, prior to the closing of the Transaction, both companies were limited in their ability to share information.

Under ASC 805, acquisition-related transaction costs (e.g., advisory, legal and other professional fees) are not included as a component of consideration transferred but are accounted for as expenses in the periods in which such costs are incurred. Total acquisition-related transaction costs expected to be incurred by Baudax and TeraImmune are estimated to be $1.3 million and incurred after March 31, 2023. These acquisition related transaction costs are not reflected as a pro forma adjustment to the unaudited pro forma combined statements of operations because those costs are not expected to have a continuing impact on the combined company's results.

The unaudited pro forma combined financial statements do not include any adjustments to the realization of any costs (or cost savings) from operating efficiencies, synergies, or other restructuring activities that might result from the Transaction. Further, there may be additional charges (or costs savings) related to restructuring or other integration activities resulting from the Transaction, the timing, nature, and amount of which the Company's management cannot currently identify, and thus, such charges (or cost savings) are not reflected in the unaudited pro forma condensed combined financial statements. The restructuring and integration-related costs will be expensed in the appropriate accounting periods after completion of the acquisition as incurred. The pro forma adjustments represent management's best estimates and are based upon currently available information and certain assumptions that the Company believes are reasonable under the circumstances.

The unaudited pro forma combined financial information is presented for informational purposes only and does not necessarily indicate the financial results of the combined company had the companies been combined at the beginning of the period presented, nor does it necessarily indicate the results of operations in future periods or the future financial position of the combined company.

**2. Accounting Policies**

As part of preparing the pro forma condensed combined financial information, the Company conducted a preliminary review of the accounting policies of TeraImmune in order to determine if any differences require adjustment or reclassification of TeraImmune's financial position and results of operations to conform to Baudax's accounting policies and classifications. See Note 5 for additional information.

**3. Consideration Transferred**

The preliminary fair value of the consideration totaled approximately $12.9 million, summarized as follows:

| (in thousands) | Amount |
|---|---|
| Common stock of Baudax issued to TeraImmune stockholders | $ 642 |
| Series X Convertible Preferred Stock of Baudax issued to TeraImmune Stockholders | 12,204 |
| TeraImmune stock options and restricted stock allocated to total consideration paid | 68 |
| Total Consideration Transferred | $12,914 |

**4. Preliminary Estimates of Assets Acquired and Liabilities Assumed**

The Company recorded the assets acquired and liabilities assumed as of the date of the acquisition based on the information available at that date. The following table presents the preliminary allocation of the total consideration paid to the estimated fair values of the assets acquired and liabilities assumed as of the acquisition date, and includes a reconciliation to the total consideration transferred:

| (in thousands) | Amounts |
|---|---|
| **Asset acquired** | |
| Cash and cash equivalents | $ 718 |
| Prepaid expenses and other current assets | 117 |
| Property and equipment | 3,911 |
| Goodwill | 6,868 |
| In process research and development assets | 3,500 |
| Operating lease right-of-use assets | 1,779 |
| Other assets | 2 |
| Total assets acquired | 16,895 |
| **Liabilities assumed** | |
| Accounts payable | 393 |
| Accrued expenses | 426 |
| Operating lease liabilities | 3,162 |
| Total liabilities assumed | 3,981 |
| **Net assets acquired** | **$ 12,914** |

The above allocation of the purchase price is based upon certain preliminary valuations and other analyses that have not been completed as of the date of this filing. Any changes in the estimated fair values of the net assets recorded for this business combination upon the finalization of more detailed analyses of the facts and circumstances that existed at the date of the Transaction will change the allocation of the purchase price. As such, the purchase price allocations for the acquisition are preliminary estimates, which are subject to change within the measurement period.

As of the completion of the acquisition, identifiable intangible assets are required to be measured at fair value, and these acquired assets could include assets that are not intended to be used or sold or that are intended to be used in a manner other than their highest and best use. For purposes of these unaudited pro forma combined financial statements and consistent with the ASC 820 requirements for fair value measurements, it is assumed that all acquired assets will be used, and that all acquired assets will be used in a manner that represents the highest and best use of those acquired assets.

The goodwill recorded related to the acquisition is the excess of the fair value of the consideration transferred by the acquirer over the fair value of the net identifiable assets acquired and liabilities assumed at the date of acquisition. The goodwill recorded is not deductible for tax purposes.

**5. Pro Forma Adjustments**

The unaudited pro forma combined financial information includes pro forma adjustments that are (1) directly attributable to the Transaction (2) factually supportable, and (3) with respect to the unaudited pro forma combined statements of operations, expected to have a continuing impact on the results of operations of the combined company.

The pro forma adjustments reflecting the completion of the transaction are based upon the accounting analysis conclusion that the Transaction should be accounted for under the acquisition method of accounting and upon the assumptions set forth below.

The pro forma adjustments, based on preliminary estimates that may change significantly as additional information is obtained, are as follows:

A. Reflects the payment of Baudax and TeraImmune transaction costs of $1.1 million and $0.2 million, respectively, upon consummation of the Merger.

B. Reflects the fair value of the intangible assets acquired representing In Process Research and Development Assets ("IPR&D Assets").

C. Reflects the excess consideration paid to acquire TeraImmune over the net assets acquired of TeraImmune.

D. Reflects the elimination of the TeraImmune convertible bonds upon consummation of the Merger in exchange for common stock.

E. To record the (i) consideration paid to TeraImmune selling shareholders, and (ii) the elimination of TeraImmune's historical equity carrying value:

| (Dollar amounts in thousands) | Common Stock Shares | Common Stock Amount | Additional Paid In Capital | Accumulated Deficit | Total |
|---|---|---|---|---|---|
| Issuance of common stock and stock options | 28,301,921 | $283 | $ 12,631 | $ (1,293) | $11,621 |
| Elimination of TeraImmune's historical carrying values | — | (1) | (11,266) | 13,563 | 2,296 |
| | 28,301,921 | $282 | $ 1,365 | $12,270 | $13,917 |

F. Elimination of TeraImmune interest expense and amortization of debt premium/discount associated with convertible bonds that were converted immediately prior to the acquisition.

G. The pro forma combined basic and diluted loss per share have been adjusted to reflect the pro forma net loss for the three months ended March 31, 2023 and for the year ended December 31, 2022. In addition, the number of shares used in calculating the pro forma combined basic and diluted loss per share has been adjusted to reflect the estimated total number of shares of common stock of the combined company that would be outstanding as of the closing of the Merger including the estimated total number of shares of Series X Preferred Stock on an as-converted to common stock basis. The following table sets forth the calculation of the pro forma weighted-average number of common shares outstanding—basic and diluted.

| | Three Months Ended March 31, 2023 | Year Ended December 31, 2022 |
|---|---|---|
| Elimination of historical TeraImmune weighted average shares | (2,939,575) | (2,939,575) |
| Issuance of shares of common stock of the continuing company to TeraImmune shareholders | 28,301,921 | 28,301,921 |
| | 25,362,346 | 25,362,346 |

**ANNEX E**

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

### Overview

On June 29, 2023 (the "Effective Date"), Baudax Bio, Inc. (the "Company") completed its acquisition of TeraImmune, Inc. pursuant to the Agreement and Plan of Merger (the "Acquisition"). Prior to the Acquisition, TeraImmune, Inc., together with its wholly-owned subsidiary, TeraImmune Therapeutics, Co., Ltd. ("TeraImmune Therapeutics") (collectively, "TeraImmune"), was a privately held pre-clinical stage biotechnology company focused on developing immune cell therapies using human regulatory T cells ("Treg").

TeraImmune's proprietary and patented technology platforms are a method for expansion of the Treg without losing its function and stability (TREGable™ and TREGing™) and the target specific receptors including T cell receptor ("TCR"), Chimeric Antigen Receptor ("CAR") and B cell Antibody Receptor ("BAR"). TeraImmune has developed manufacturing procedures in accordance with the regulatory guidance from the U.S. Food and Drug Administration (the "FDA"). In June 2022, its Investigational New Drug ("IND") application to apply the Factor VIII ("FVIII") TCR-Treg for the refractory Hemophilia A patients was cleared by the FDA to begin clinical trials. TeraImmune believes that its FVIII TCR-Treg may provide a therapeutic option in controlling anti-FVIII antibody formation in refractory Hemophilia A patients, and have the potential to perform better than CAR Treg therapies. TeraImmune Therapeutics plans to initiate its Phase 1/2a clinical trial of FVIII TCR-Treg in 2024.

The acquisition of TeraImmune adds TeraImmune's TI-168 asset to the Company's portfolio, a promising next-generation, autologous FVIII TCR-Treg cell therapy candidate to eliminate clotting factor VIII (FVIII) inhibitors in Hemophilia A patients. Hemophilia A is a rare genetic bleeding disorder that is caused by a lack of FVIII, with an IND application already FDA-cleared.

TeraImmune was incorporated as a C-corporation in Delaware in 2019. TeraImmune Therapeutics was incorporated under the laws of South Korea in 2022 for the purpose of shareholder relations and to seek grant and funding opportunities in South Korea.

TeraImmune has incurred net losses since its inception, has negative operating cash flows and its total liabilities exceed total assets for the years ended December 31, 2022 and 2021 and the three months ended March 31, 2023 and 2022. TeraImmune has no products approved for commercial sale, has not generated any revenue from product sales, and cannot guarantee when or if it will general any revenues from product sales associated with its development programs. Substantially all of TeraImmune's operating losses result from expenses incurred in connection with its research and development activities and from general and administrative costs associated with its operations. TeraImmune expects to continue to incur significant expenses and losses for the foreseeable future.

TeraImmune defaulted on its Convertible Bond Agreement, dated March 22, 2022, with EoFlow Co., Ltd. ("Convertible Bond Agreement") as it had failed to repay these loans on the stated maturity date of November 30, 2022. The total amount due on the Convertible Bond Agreement at March 31, 2023 was $1.2 million, including accrued interest, at 5% per annum, and default interest penalty. TeraImmune seeks to cure this default by converting the Convertible Bond Agreement into shares of TeraImmune's common stock or by providing the noteholders with a repayment plan. Considering TeraImmune's current cash resources and its current and expected levels of operating expenses for the next twelve months, TeraImmune requires additional capital to fund its future business operations.

Prior to the Acquisition, TeraImmune had no sources of product revenue and its ability to continue as a going concern was dependent on its ability to raise capital to fund its future business plans and activities.

**Comparison of Results of Operations for the Years Ended December 31, 2022 and 2021**

| (in thousands) | Year Ended December 31, 2022 | Year Ended December 31, 2021 | Variance $ | Variance % |
|---|---|---|---|---|
| Operating Expenses | | | | |
| Research and development | $ 2,295 | $ 3,113 | (818) | -26% |
| General and administrative | 2,589 | 1,982 | 607 | 31% |
| Total Operating Expenses | 4,884 | 5,095 | (211) | -4% |
| Loss from Operations | (4,884) | (5,095) | (211) | -4% |
| Other Income (Expense) | | | | |
| Interest income (expense), net | (415) | 1 | (416) | -41600% |
| Foreign exchange loss | (157) | (4) | 153 | 3825% |
| Other income | 8 | 52 | (44) | -85% |
| Net loss | $(5,448) | $(5,046) | 402 | 8% |

***Research and Development Expenses***

Research and development costs decreased by $0.8 million from $3.1 million for the year ended December 31, 2021 to $2.3 million for the year ended December 31, 2022. The decrease is primarily attributable to the completion of certain preclinical development activities for TI-168 (FVIII TRC-Treg) in order to complete an IND application, which was approved in October 2022.

***General and Administrative Expenses***

General and administrative expenses increased by $0.6 million from $2.0 million for the year ended December 31, 2021 to $2.6 million for the year ended December 31, 2022. The increase was primarily attributable to increases in professional fees of $0.2 million, lease related expenses of $0.2 million, amortization and depreciation of $0.1 million, and taxes of $0.1 million.

***Other Non-Operating Expenses, Net***

Other non-operating expense, net was $0.6 million for the year ended December 31, 2022 and primarily attributable to the interest expense associated with TeraImmune's convertible notes issued during fiscal year 2022 and the fluctuations in foreign currencies that TeraImmune transacted in for its research and development activities during the year ended December 31, 2022. Other non-operating income, net was immaterial during the year ended December 31, 2021.

**Comparison of Results of Operations for the Three Months Ended March 31, 2023 and 2022**

| (in thousands) | Three Months Ended March 31, 2023 | Three Months Ended March 31, 2022 | Variance $ | Variance % |
|---|---|---|---|---|
| Operating Expenses | | | | |
| Research and development | $ 224 | $ 764 | (540) | -71% |
| General and administrative | 573 | 653 | (80) | -12% |
| Total Operating Expenses | 797 | 1,417 | (620) | -44% |
| Loss from Operations | (797) | (1,417) | (620) | -44% |
| Other Income (Expense) | | | | |
| Interest expense | (79) | — | (79) | 100% |
| Foreign exchange gain | 40 | — | 40 | 100% |
| Other income | 16 | 1 | 15 | 1500% |
| Net loss | $(820) | $(1,416) | (596) | -42% |

***Research and Development Expenses***

Research and development costs decreased by $0.6 million, from $0.8 million for the three months ended March 31, 2022 to $0.2 million for the three months ended March 31, 2023. The decrease was primarily

attributable to TeraImmune's preparation and completion of its preclinical development activities for TI-168 (FVIII TRC-Treg) in fiscal year 2022 to which TeraImmune focused on obtaining the necessary financing and preparation efforts for a Phase 1/2a clinical trial of FVIII TRC-Treg.

***General and Administrative Expenses***

General and administrative expenses decreased by $0.1 million, from $0.7 million for the three months ended March 31, 2022 to $0.6 million for the three months ended March 31, 2023. The decrease was primarily attributable to a decrease in personnel-related costs and professional services.

***Other Non-Operating Income (Expense), Net***

Other non-operating expense, net was $0.02 million for the three months ended March 31, 2023 and primarily attributable to the interest expense associated with TeraImmune's convertible notes that was offset by the fluctuation in foreign currencies that TeraImmune transacted in for its research and development activities. Other non-operating income, net was immaterial for the three months ended March 31, 2022.

***Liquidity and Capital Resources***

*Management's Plans*

Similar to other development stage biotechnology companies, TeraImmune's product candidates have not yet generated any revenue to achieve profitability. As a result, TeraImmune had historically suffered recurring losses and required significant cash resources to execute its business plans. These losses are expected to continue for the foreseeable future.

To date, TeraImmune's operations have been financed primarily by its convertible term loans. As of March 31, 2023, TeraImmune had cash of $0.7 million. While TeraImmune's management believes its cash is not subject to excessive risk, TeraImmune maintains a significant amount of cash at one or more financial institutions that are in excess of federally insured limits.

In addition, in the course of normal business operations, TeraImmune has agreements with contract service providers to assist in the performance of its research and development and manufacturing activities. TeraImmune can elect to discontinue the work under these agreements, subject to a cancelation charge in certain instances. TeraImmune could also enter into additional collaborative research, contract research, manufacturing and supplier agreements in the future, which may require upfront payments and even long-term commitments of cash.

Prior to the Acquisition, TeraImmune recognized that it would need to raise additional capital in order to continue to execute its business plan in the future. Following the Acquisition, there can be no assurance that additional financings will be available when needed or that the Company will be able to obtain financing on terms acceptable to it, or at all, or whether the Company will become profitable and generate positive operating cash flow. If the Company is unable to raise sufficient additional funds, it will have to further scale back its operations. The Company believes it has sufficient capital to fund its obligations, as they become due, in the ordinary course of business into the third quarter of 2023.

**Comparison of Cash Flow Statements for the Years Ended December 31, 2022 and 2021 and the Three Months Ended March 31, 2023 and 2022**

| (in thousands) | Year Ended December 31, 2022 | Year Ended December 31, 2021 | Variance $ | Variance % |
|---|---|---|---|---|
| Net cash used in operating activities | $(1,166) | $(4,088) | $(2,922) | -71% |
| Net cash used in investing activities | (2,733) | (1,186) | 1,547 | 130% |
| Net cash provided by financing activities | 2,581 | — | 2,581 | 100% |
| Net decrease in cash and cash equivalents for the period | $(1,318) | $(5,274) | (3,956) | -75% |

*Operating Activities.*

Net cash used in operating activities of $1.2 million for the year ended December 31, 2022 was primarily attributable to TeraImmune's net loss of $5.4 million, partially offset by $1.1 million of non-cash expenses consisting of stock-based compensation, depreciation and amortization expenses and noncash operating lease expenses and $3.2 million due to a net increase in operating assets and liabilities.

Net cash used in operating activities of $4.1 million for the year ended December 31, 2021 was primarily attributable to TeraImmune's net loss of $5.0 million, partially offset by $0.6 million of non-cash expenses consisting of stock-based compensation, depreciation and amortization expenses and noncash operating lease expenses and $0.3 million due to a net increase in operating assets and liabilities.

*Investing activities.*

Net cash used by investing activities was $2.7 million and $1.2 million for the years ended December 31, 2022 and 2021, respectively, and attributable to the purchase of property and equipment.

*Financing Activities.*

Net cash provided by financing activities of $2.6 million for the year ended December 31, 2022 was primarily attributable to the proceeds from TeraImmune's convertible bonds. There were no cash flows from financing activities during the year ended December 31, 2021.

| (in thousands) | Three Months Ended March 31, 2023 | Three Months Ended March 31, 2022 | Variance $ | Variance % |
|---|---|---|---|---|
| Net cash used in operating activities | $(199) | $ (895) | $ (696) | -78% |
| Net cash used in investing activities | — | (783) | (783) | -100% |
| Net decrease in cash and cash equivalents for the period | $(199) | $(1,678) | $(1,479) | -88% |

*Operating Activities.*

Net cash used in operating activities was $0.2 million for the three months ended March 31, 2023 and primarily attributable to TeraImmune's net loss of $0.8 million, partially offset by $0.2 million for non-cash expenses consisting of stock-based compensation, depreciation and amortization expenses, gain on foreign currency debt translation and noncash operating lease expenses and $0.4 million to a net increase in operating assets and liabilities.

Net cash used in operating activities was $0.9 million for the three months ended March 31, 2022 and primarily attributable to TeraImmune's net loss of $1.4 million, partially offset by $0.3 million for non-cash expenses consisting of stock-based compensation, depreciation and amortization expenses and noncash operating lease expenses and $0.2 million net increase in our operating assets and liabilities.

*Investing activities.*

There were no cash flows for investing activities for the three months ended March 31, 2023. Net cash used by investing activities of $0.8 million for the three months ended March 31, 2022 was primarily attributable to the purchase of property and equipment.

*Financing Activities.*

There were no cash flows for financing activities during the three months ended March 31, 2023 and 2022.

*BAUDAX BIO, INC.*
*C/O BROADRIDGE CORPORATE ISSUER SOLUTIONS, INC.*
*P.O. BOX 1342*
*BRENTWOOD, NY 11717*


**VOTE BY INTERNET**
*Before The Meeting* - Go to **www.proxyvote.com or scan the QR Barcode above**

Use the Internet to transmit your voting instructions and for electronic delivery of information. Vote by 11:59 p.m. Eastern Time on [TBD], 2023. Have your proxy card in hand when you access the web site and follow the instructions to obtain your records and to create an electronic voting instruction form.

*During The Meeting* - Go to **www.virtualshareholdermeeting.com/[TBD]**

You may attend the meeting via the Internet and vote during the meeting. Have the information that is printed in the box marked by the arrow available and follow the instructions.

**VOTE BY PHONE - 1-800-690-6903**
Use any touch-tone telephone to transmit your voting instructions. Vote by 11:59 p.m. Eastern Time on [TBD], 2023. Have your proxy card in hand when you call and then follow the instructions.

**VOTE BY MAIL**
Mark, sign and date your proxy card and return it in the postage-paid envelope we have provided or return it to Vote Processing, c/o Broadridge, 51 Mercedes Way, Edgewood, NY 11717.

TO VOTE, MARK BLOCKS BELOW IN BLUE OR BLACK INK AS FOLLOWS:

V21541-S72084

KEEP THIS PORTION FOR YOUR RECORDS
DETACH AND RETURN THIS PORTION ONLY

**THIS PROXY CARD IS VALID ONLY WHEN SIGNED AND DATED.**

**BAUDAX BIO, INC.**

| **The Board of Directors recommends you vote FOR the following proposals:** | **For** | **Against** | **Abstain** |
|---|---|---|---|
| 1. Proposal to approve the issuance of shares of the Company's common stock upon conversion of the Company's Series X Non-Voting Convertible Preferred Stock issued on June 29, 2023. | ☐ | ☐ | ☐ |
| 2. Proposal to approve an amendment to the Amended and Restated Articles of Incorporation to effect a reverse stock split of the common stock at a ratio to be determined by the Company's Board of Directors within a range of one-for- [TBD] (1:[TBD]) and one-for- [TBD] (1:[TBD]) (or any number in between), to be effected in the sole discretion of the Board of Directors at any time within one year of the date of the Special Meeting without further approval or authorization from the Company's shareholders. | ☐ | ☐ | ☐ |
| 3. Proposal to ratify the selection of EisnerAmper LLP as the Company's independent registered public accounting firm for the 2023 fiscal year. | ☐ | ☐ | ☐ |
| 4. Proposal to approve the adjournment or postponement of the Special Meeting, if necessary, to continue to solicit votes for Proposal Nos. 1, 2, and/or 3. | ☐ | ☐ | ☐ |

Please sign exactly as your name(s) appear(s) hereon. When signing as attorney, executor, administrator, or other fiduciary, please give full title as such. Joint owners should each sign personally. All holders must sign. If a corporation or partnership, please sign in full corporate or partnership name by authorized officer.

| | | | |
|---|---|---|---|
| | | | |
| Signature [PLEASE SIGN WITHIN BOX] | Date | Signature (Joint Owners) | Date |

**Important Notice Regarding the Availability of Proxy Materials for the Special Meeting:**

The Proxy Statement and Shareholder Letter are available at www.proxyvote.com.

V21542-S72084

**BAUDAX BIO, INC.**
**Special Meeting of Shareholders**
**[TBD] - [TBD] AM EDT**
**This proxy is solicited by the Board of Directors**

The undersigned hereby appoints Gerri Henwood and Jillian Dilmore, or either of them, as proxies, each with the power to appoint their substitute, and hereby authorizes them to represent and to vote, as designated on the reverse side of this ballot, all of the shares of Common Stock of BAUDAX BIO, INC. that the undersigned is entitled to vote at the Special Meeting of Shareholders to be held virtually at [TBD] AM, EDT, on [TBD], 2023 via www.virtualshareholdermeeting.com/[TBD], and any adjournment or postponement thereof.

**This proxy, when properly executed, will be voted in the manner directed herein. If no such direction is made, this proxy will be voted in accordance with the Board of Directors' recommendations.**

**Continued and to be signed on reverse side**