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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2023

OR

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

Commission File Number 001-33672

PALISADE BIO, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**52-2007292**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
7750 El Camino Real, Suite 2A **Carlsbad, California**	**92009**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (858) 704-4900

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.01 par value	PALI	Nasdaq Capital Market

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the common stock held by non-affiliates of the registrant, based on the closing price of a share of the registrant's common stock on June 30, 2023 as reported by the Nasdaq Capital Market on such date, was approximately $11.6 million. Shares of common stock held by each executive officer and director and by each other person who may be deemed to be an affiliate of the registrant, have been excluded from this computation. The determination of affiliate status for this purpose is not necessarily a conclusive determination for other purposes.

As of March 21, 2024, the registrant had 12,771,015 shares of common stock, $0.01 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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Cautionary Note Regarding Forward-Looking Statements and Risk Factor Summary

This Annual Report on Form 10-K, including "Management's Discussion and Analysis of Financial Condition and Results of Operations," contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements relate to future events or to our future operating or financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Some of these factors are more fully discussed in section 1A of this Annual Report on Form 10-K entitled "Risk Factors" and elsewhere herein.

Forward-looking statements may include, but are not limited to, statements about:

- *estimates about the size and growth potential of the markets for our product candidates, and our ability to serve those markets, including any potential revenue;*
- *future regulatory, judicial, and legislative changes or developments in the United States ("U.S.") and foreign countries and the impact of these changes;*
- *our ability to successfully develop our licensed technologies;*
- *our ability to compete effectively in a competitive industry;*
- *our ability to identify and qualify additional manufacturers to provide active pharmaceutical ingredients ("API") and manufacture drug product;*
- *our ability to enter into commercial supply agreements;*
- *the success of competing technologies that are or may become available;*
- *our ability to attract and retain key scientific or management personnel;*
- *the accuracy of our estimates regarding expenses, capital requirements and needs for additional financing;*
- *our ability to obtain funding for our operations and the development of our product candidates;*
- *our ability to attract collaborators and partners; and*
- *the impact of pandemic, foreign or domestic conflicts, or other global disruptions on our business, our operations, and our supply.*

In some cases, you can identify forward-looking statements by terms such as "may," "will," "intend," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. There can be no assurance that any of the events anticipated by forward-looking statements will occur or, if any of them do occur, what impact they will have on our business, results of operations and financial condition. You should not rely on forward-looking statements as predictions of future events. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties, assumptions, and other factors described in Part I, Item 1A Risk Factors and elsewhere in this Annual Report. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties may emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on any forward-looking statements contained in this Annual Report. These statements reflect our current views with respect to future events and are based on assumptions and are subject to risks and uncertainties. As such, our actual results may differ significantly from those expressed in any forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

Also, these forward-looking statements represent our estimates and assumptions only as of the date of the document containing the applicable statement. Except as required by law, we undertake no obligation to update or revise any

forward-looking statements to reflect new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. You should read this Annual Report on Form 10-K, together with the documents that we have previously filed with the Securities and Exchange Commission ("SEC") completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all the forward-looking statements in the foregoing documents by these cautionary statements.

RISK FACTOR SUMMARY

We face many risks and uncertainties, as more fully described in this Annual Report on Form 10-K under the heading "Risk Factors." The summary below does not contain all the information that may be important to you, and you should read this summary together with the more detailed discussion of these risks and uncertainties contained in "Risk Factors."

Risks Related to Our Development, Commercialization and Regulatory Approval of Our Investigational Therapies

- Our business depends on the successful pre-clinical and clinical development, regulatory approval and commercialization of our recently licensed therapeutic compound, including our lead asset PALI-2108.
- There are substantial risks inherent in drug development, and, as a result, we may not be able to successfully develop PALI-2108.
- We depend on our license agreement with Giiant to permit us to use patents and patent applications relating to PALI-2108. Termination of these rights or the failure to comply with obligations under this agreement could materially harm our business and prevent us from developing or commercializing PALI-2108, our lead product candidate.
- We expect that our operations and development of PALI-2108 will require substantially more capital than we currently have, and we cannot guarantee when or if we will be able to secure such additional funding.
- There can be no assurance that our product candidates will obtain regulatory approval.
- If pre-clinical and clinical studies of PALI-2108 do not yield successful results, then we may not continue to develop PALI-2108.
- Even if our clinical studies are successful and achieve regulatory approval, the approved product label may be more limited than we anticipate, which could limit the commercial prospects of PALI-2108.
- We may in the future conduct clinical trials for PALI-2108 outside the United States ("U.S."), and the U.S. Food and Drug Administration ("FDA") and applicable foreign regulatory authorities may not accept data from such trials.
- We anticipate relying on third-party Contract Research Organizations ("CROs") and other third parties to conduct and oversee our pre-clinical studies and clinical trials. If these third parties do not meet our requirements or otherwise conduct the studies or trials as required, we may not be able to satisfy our contractual obligations or obtain regulatory approval for, or commercialize, our product candidates.
- We have entered into a collaborative research agreement with Giiant related to pre-clinical development, which will require the efforts of Giiant and its personnel, which are out of our control.

Risks Related to Our Business

- We have a limited operating history and have never generated any revenues from product sales.
- Our business model assumes revenue from, among other activities, marketing or out-licensing the products we develop. PALI-2108 is in the early stages of development and because we have a short development history with PALI-2108, there is a limited amount of information about us upon which you can evaluate our business and prospects.

- We have received a delisting notification from the Nasdaq Stock Market based on our Bid Price being under $1.00 for thirty (30) consecutive trading days. If we are not able to regain compliance with the applicable continued listing requirements or standards of The Nasdaq Capital Market, Nasdaq could delist our common stock.
- We have received a notification from the Nasdaq Stock Market that our audit committee does not have three (3) independent members as a result of recent director resignations. If we fail to timely appoint an independent director that meets the Nasdaq Stock Market Requirements for audit committees, Nasdaq could delist our common stock.
- Our success depends on the attracting and retaining of senior management and scientists with relevant expertise.
- We may choose to discontinue developing or commercializing any of our product candidates, or may choose to not commercialize product candidates in approved indications, at any time during development or after approval, which could adversely affect us and our operations.
- Our inability to successfully in-license, acquire, develop and market additional product candidates or approved products could impair our ability to grow our business.

Risks Related to Our Dependence on Third Parties

- We expect to rely on collaborations with third parties for the successful development and commercialization of our product candidates.
- We anticipate relying completely on third-party contractors to supply, manufacture and distribute clinical drug supplies for our product candidates.

Risks Related to Our Financial Operations

- We have expressed substantial doubt about our ability to continue as a going concern.
- We have a history of net losses, and we expect to continue to incur net losses and may never achieve profitability.
- Failure to remediate a material weakness in internal controls over financial reporting could result in material misstatements in our consolidated financial statements.

Risks Related to Our Intellectual Property

- We may not be able to obtain, maintain or enforce global patent rights or other intellectual property rights that cover our product candidates and technologies that are of sufficient breadth to prevent third parties from competing against us.
- If we fail to comply with our obligations under our intellectual property license agreements, we could lose license rights that are important to our business.

Other Risks Related to Our Securities

- We will need to raise additional financing in the future to fund our operations, which may not be available to us on favorable terms or at all.
- Our common stock price may be highly volatile.
- If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.
- Our Board of Directors has broad discretion to issue additional securities, which might dilute the net tangible book value per share of our common stock for existing stockholders.

PART I

As used in this Annual Report on Form 10-K, unless the context indicates or otherwise requires, “Palisade,” “Palisade Bio,” “the Company,” “we,” “us,” and “our” or similar designations in this report refer to Palisade Bio, Inc., a Delaware Corporation, and its subsidiaries. Any reference to “common shares” or “common stock,” refers to our $0.01 par value common stock. Any reference to “Series A Preferred Stock” refers to our Series A 4.5% Convertible Preferred Stock. Any reference to “Leading Biosciences, Inc.” or “LBS” refers to our operations prior to the completion of our merger with Seneca Biopharma, Inc. ("Seneca") on April 27, 2021 (the "Merger"). Any technology that we currently own or may acquire the rights to in the future is referred to by us as either a “product candidate” or "product candidates." Additionally, any reference herein that refers to pre-clinical studies also refers to nonclinical studies.

Item 1. Business.

Overview

On September 1, 2023, we entered into a research collaboration and license agreement for substantially all of Giiant Pharma, Inc.'s (“Giiant”) current and future proposed products (“Giiant License Agreement”). Under the terms of the Giiant License Agreement, we obtained the rights to develop, manufacture, and commercialize all compounds from Giiant, existing now and in the future, and any product containing or delivering any licensed compound, in any formulation or dosage for all human and non-human therapeutic uses for any and all indications worldwide, including those technologies that are the basis of our lead product candidate, PALI-2108 ("Giiant Licensed Assets"). Pursuant to the terms of the Giiant License Agreement, pre-clinical development PALI-2108 will be jointly undertaken by Giiant and us with a portion of development costs being paid by Giiant’s current grants. Upon the first approval of either an investigational new drug application ("IND") or a Canadian Clinical Trial Application ("CTA"), we will assume all development, manufacturing, regulatory and commercialization costs.

On August 9, 2023, we announced topline data from our U.S Phase 2 PROFILE study demonstrating that our previous lead product candidate, LB1148, did not meet its primary endpoint. The randomized patients in the trial also experienced 228 adverse events (“AEs”) reported with 131 reported in patients treated with LB1148 verses 97 treated with placebo. Additionally, there were a total of three serious adverse events (“SAEs”) related to LB1148 versus one related to placebo. Based on the efficacy and safety value results of the U.S. Phase 2 PROFILE study, we terminated the development of LB1148.

Following entering into the Giiant Licensing Agreement, we have significantly reshaped the business into a pre-clinical stage biotechnology company focused on developing and advancing novel therapies for patients living with autoimmune, inflammatory, and fibrotic diseases. We are developing PALI-2108 as a therapeutic for patients living with inflammatory bowel disease ("IBD"), including ulcerative colitis ("UC") and Crohn's disease ("CD").

Strategy

Our objective is to establish ourselves as a leader in the development of differentiated product candidates targeting the autoimmune, inflammatory, and fibrotic disease markets, which we believe will address a large, well-established need among patients living with autoimmune and inflammatory diseases.

We believe the key elements of our strategy include:

- advancing our lead product candidate, PALI-2108 into human clinical trials;
- advancing PALI-1908 in pre-clinical studies;
- leveraging our drug development platform infrastructure to identify product candidates that target autoimmune, inflammatory, and fibrotic diseases;
- pursuing strategic partnerships to further expand our programs and maximize the worldwide potential of our product candidates and platform; and
- pursuing strategy of in-licensing/acquisition or out-licensing/sale of our product candidates.

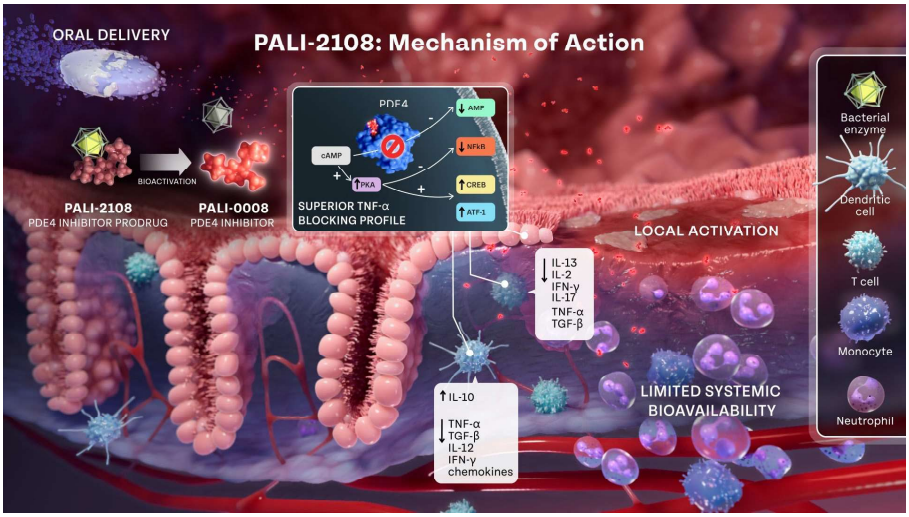
Our Portfolio

We are currently advancing a PALI-2108 for the treatment of IBD, including UC and CD and are researching PALI-1908. The following table summarizes the current stages of our research and pre-clinical programs:

Candidate	Indication	Research and Pre-Clinical	Phase 1	Phase 2	Phase 3
PALI-2108	Inflammatory Bowel Disease, Ulcerative Colitis, and Crohn's Disease	→			
PALI-1908	Fibro Stenotic Crohn's Disease	→			

PALI-2108

PALI-2108, our lead product, is a prodrug PDE4 inhibitor that operates through a sophisticated mechanism within colon tissues, targeting the key enzyme phosphodiesterase-4 (PDE4). This enzyme is pivotal in cAMP hydrolysis, and by inhibiting PDE4, intracellular cAMP levels are elevated. This elevation leads to the downregulation of inflammatory cytokines and a reduction in the expression of cell adhesion molecules. By modulating these processes, PALI-2108 effectively prevents the local infiltration and activation of inflammatory cells in the colon tissues, offering a targeted approach for UC treatment. With a galactose-derived sugar moiety, PALI-2108 remains minimally absorbed until activated by the colonic bacterium enzyme β-glucuronidase. This prodrug exhibits colon preference, as demonstrated in DSS-induced UC mouse models and oxazolone colitis-induced mice, showcasing its localized bioactivation and colon-specific distribution.



Our target engagement study seems to indicate comparable binding to cAMP-specific PDE4, in the colon. PALI-2108's dose-dependent efficacy, lack of systemic toxicity demonstrated in tolerated dose studies, and promising results in preclinical models position it as a novel and targeted therapy for moderate-to-severe UC.

We have produced investigational drug batches of PALI-2108 that are compliant with Good Manufacturing Practice ("GMP"). We have completed rodent and initiated non-rodent non-pivotal IND/CTA-enabling pre-clinical studies of PALI-2108 and are currently initiating pivotal IND/CTA-enabling pre-clinical studies, which we expect to be completed by the end of the third quarter of 2024. We plan to submit an IND/CTA in the third quarter of 2024 and initiate clinical trials of PALI-2108 in the fourth quarter of 2024. By the end of 2024, we plan to submit an IND/CTA and initiate a Phase 1a single ascending dose ("SAD") and multiple ascending dose ("MAD") clinical study including food effects in normal healthy volunteers evaluating the safety, tolerability, and pharmacokinetics as well as evaluate a MAD cohort of UC patients with elevated PDE4-associated biomarkers for pharmacodynamic effects. Topline data from the Phase 1a SAD/MAD trial is expected late in the first half of 2025. Following the completion of the Phase 1a SAD/MAD trial, we plan to initiate a Phase 1b/2 POC trial in UC patients in the second half of 2025.

PALI-1908

PALI-1908 is an oral, selective PDE4 inhibitor prodrug that is locally bioactivated in the terminal ileum of CD patients and has been designed to have high selectivity for PDE4. PALI-1908 is currently in the research stage and we have undertaken silico bioinformatics programs to demonstrate the potential benefits of PALI-1908, which is pleiotropic-acting (anti-inflammatory and anti-fibrotic) in IBD. We plan to initiate pre-clinical development of PALI-1908 in the first half of 2025. In addition, we are currently working on silico bioinformatics programs to demonstrate the potential benefits of PALI-1908, which is pleiotropic-acting (anti-inflammatory and anti-fibrotic) in IBD.

Pre-clinical Developments and Assessments of PALI-2108

Our current pre-clinical assessments as described below seem to demonstrate that PALI-2108 has a dose dependent clinical efficacy in established mice models for UC. We believe that PALI-2108 is a promising therapeutic due to the local, gut restricted delivery of a potent PDE4 inhibitor, which is key in a well characterized inflammatory pathway.

Pre-clinical assessment of test compounds in a model of DSS-induced acute colitis

The goal of our assessment was to test the efficacy of PDE4 inhibitors in a mouse model of DSS-induced colitis. The study showed the expected colitis-induced body weight loss and clinical score (DAI) increased beginning at day 4 until sacrifice at day 7. Treatment with PALI-2108 at 21, 4 and 0.75 mg/kg BID and 1.5 mg/kg daily significantly decreased the mean DAI score (all days considered) compared to DSS control group (Fig 1). Body weight loss was also significantly slowed in 21 and 4 mg/kg BID treatment groups (Fig 2). Based on the findings of this assessment, we believe PAL2108 has a dose dependent decrease in the burdens associated with colitis and warrants further investigation.

Figure 1

PALI-2108 reduced the mean DAI score over time (reported as AUC over 7 days) compared to the DSS untreated group at doses of 21, 4, 0.75 mg/kg BID, and 1.5 mg/kg daily.

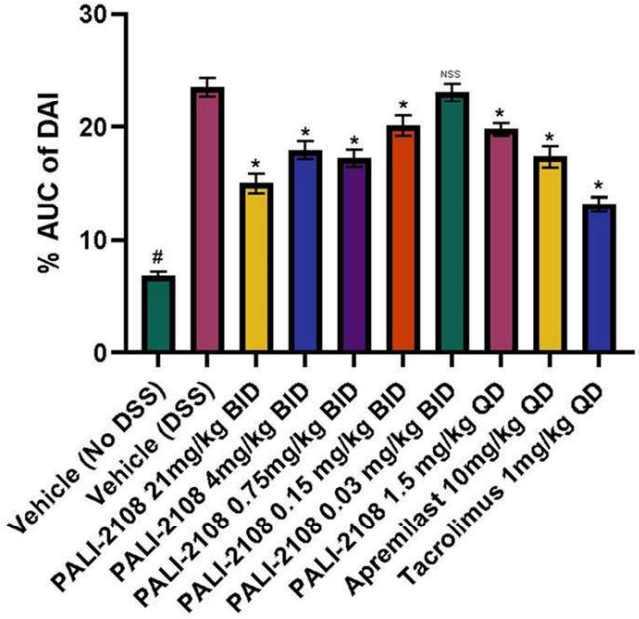
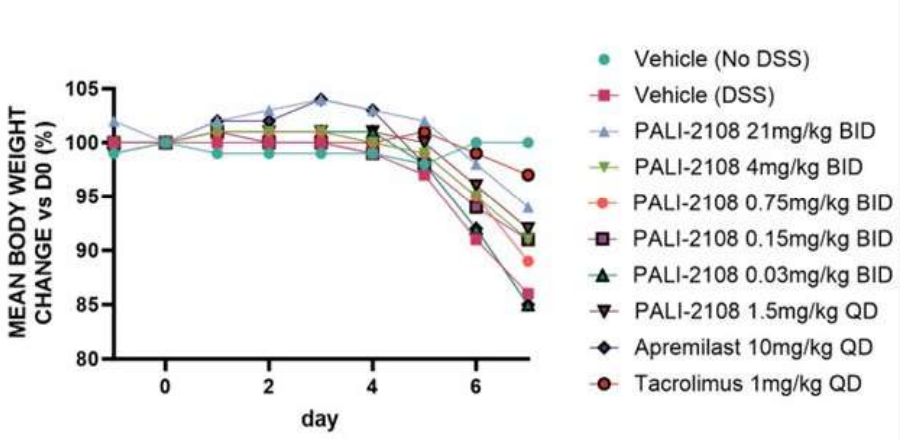


Figure 2

Body Weight over time in DSS mouse model.



Assessment of PALI-2108 distribution in the gut versus plasma.

In this assessment, we dosed mice with 3% oxazolone (another acute colitis mouse model) to induce colitis. Following dosing, we treated the mice with PALI-2108 at BID 4.2mg/kg for three days and then compared the distribution of PALI-2108, PALI-0708 (inactive intermediate) and PALI-0008 (active drug product from prodrug PALI-2108). The study demonstrated preferential bioactivation of PALI-2108 as compared to PALI-0008 in the colon tissue, while plasma levels remained virtually undetectable for all forms. Based on the assessment in diseased animals, we believe that PALI-2108 is primarily activated in the colin while maintaining acceptable systemic levels.

Target engagement of PDE4 in mouse colon homogenates

We developed a classic cellular thermal shift assay (CETSA) to assess on-target PDE4 binding within colon tissue homogenates dosed with apremilast, PALI-2108, or vehicle and detected changes in thermal stability. This target engagement study indicated comparable binding of apremilast and PALI-2108 to PDE4 in colon homogenates. Furthermore, target engagement was then validated in tissue from animals that were in vivo dosed with apremilast, PALI-2108, or vehicle controls. For both studies, a thermal stabilization effect on PDE4 was observed confirming target engagement of PALI-2108 to PDE4.

In sum, PALI-2108's dose-dependent efficacy, lack of systemic toxicity demonstrated in tolerated dose studies, and promising results in pre-clinical models position it as a novel and targeted therapy for moderate-to-severe UC.

Market for IBD

IBD is a chronic condition characterized by inflammation within the gastrointestinal tract. It encompasses two main disorders: UC and CD. UC primarily affects the colon and the rectum. Inflammation occurs in the innermost lining of the colon leading to ulcers. Symptoms include bloody diarrhea, abdominal pain, bowel urgency, and frequent bowel movements. CD can affect any part of the gastrointestinal tract, from the mouth to the anus. It is characterized by inflammation that extends through multiple layers of the bowel wall. Symptoms include abdominal pain, diarrhea, weight loss, fatigue, and complications such as strictures or fistulas. Both conditions can significantly impact patients' quality of life in terms of physical health, emotional well-being, and the unpredictability of symptom onset.

IBD affects millions of individuals worldwide, with increasing prevalence and incidence in both developed and developing countries. In the United States, it is estimated that approximately 2.4 million individuals currently have IBD, with approximately 70,000 patients newly diagnosed every year. The prevalence of UC in the United States is approximately 900,000 individuals, and the prevalence of CD in the United States is approximately 800,000 individuals. Based on research from the Crohn's and Colitis Foundation of America, the market for IBD therapeutics is expected to experience steady growth, driven by rising disease prevalence, increasing diagnosis rates, and evolving treatment paradigms.

A range of pharmaceutical options exists, including anti-inflammatory drugs, immunosuppressants, and biologics. Treatment plans are often tailored to the individual patient's disease severity, location, and response to therapy. In some cases, surgical interventions such as bowel resection or ostomy formation may be necessary to manage complications or improve quality of life.

Unmet Needs in IBD

Despite the availability of various treatments, there are significant unmet needs in managing IBD. These challenges impact patient outcomes and overall disease management. We believe improvements to key existing therapies in IBD are necessary.

- Inadequate Primary Response to Medical Treatment - *Many patients experience low rates of clinical response to initial medical treatments.*
- Secondary Loss of Clinical Response or Drug Intolerance – *A portion of patients initially respond well to treatment but later experience a loss of clinical response or develop intolerance to currently available drugs.*
- Patient Selection - *Identifying patients likely to respond to specific drugs is critical.*
- Safety Concerns and Long-Term Medication Use - *Existing drugs may have side effects and safety concerns, including black box warnings, associated with prolonged use.*

- Limited Options for Refractory or Severe Disease – *A portion of patients face refractory or severe disease that does not respond adequately to available treatments.*
- Enhancing Treatment Adherence **--***Frequent or inconvenient dosing regimens, including infusions and injections, can hinder patient adherence.*

Based on our pre-clinical research and development, we believe that PALI-2108 has the potential to address many of the areas of needed improvement.

Our Precision Medicine Approach

We are developing a biomarker-based patient selection approach which, if developed, will aid clinicians in identifying patients who may respond to therapy with a locally acting PDE4 inhibitor such as PALI-2108. We are working with our team of precision medicine focused bioinformatics developers to identify biomarkers and develop optimal algorithms to aid in patient selection which we believe may enrich the responder population and improve the rate of clinical response previously demonstrated with PDE4 inhibitors. This involves the use of clinical and multiomics data from a large patient population which will be used to identify PDE4-related biomarkers which are associated with disease, correlate with severity, correlate with clinical biomarkers, and are modified with local PDE4 inhibitor therapy in the colon. Further, we have curated clinical study data, including longitudinal biomarker and clinical outcome data, to develop a deep understanding of the potential for patient response to PDE4 therapy. Finally, we are in discussions with potential partners to access additional large scale IBD databanks with clinical, patient-reported, and molecular data that will be used to support and further validate the approach. Additionally, we have initiated the development of corresponding biomarker assays for these PDE4-related biomarkers that will be used in clinical studies with the aim to develop FDA-approved tests for selecting potential responders to PALI-2108.

Strategic Agreement and Collaborations

Giiant License Agreement

On September 1, 2023, we entered into the Giiant License Agreement. Under the terms of the Giiant License Agreement, we obtained the rights to develop, manufacture, and commercialize all compounds from Giiant, existing now and in the future, and any product containing or delivering any licensed compound, in any formulation or dosage for all human and non-human therapeutic uses for any and all indications worldwide, including those technologies that are the basis of PALI-2108. Pursuant to the terms of the Giiant License Agreement, pre-clinical development PALI-2108 will be jointly undertaken by us and representatives of Giiant and we will pay or reimburse a portion of the joint development expenses. Upon the first approval of either an IND or CTA, we will assume all development, manufacturing, regulatory and commercialization costs. Additionally, per the terms of the Giiant License Agreement, we will pay (i) certain milestone payments (in cash or stock at our election) and (ii) royalty payments.

Co-Development and Distribution Agreement with Newsoara

LBS entered into a co-development and distribution agreement with Newsoara, a joint venture established with Biolead Medical Technology Limited, as amended, (the "Newsoara Co-Development Agreement"). Pursuant to the Newsoara Co-Development Agreement (and subsequent assignment agreement), LBS granted or licensed Newsoara an exclusive right under certain patents to develop, use, sell, offer to sell, import, and otherwise commercialize licensed products (the "Newsoara Licensed Products") for any and all indications in the People's Republic of China, including the regions of Hong Kong and Macao, but excluding Taiwan (the "Territory"). The Newsoara Licensed Products only include the drug asset referred to as LB1148. The right includes the right to grant sublicenses to third parties, subject to LBS' written consent, provided that both parties agreed that Newsoara would be permitted to use a certain partner for development purposes. The Newsoara Co-Development Agreement obligates Newsoara to initially use LBS as the exclusive supplier for all of Newsoara's requirements for Newsoara Licensed Products in the Territory. During the term of the Newsoara Co-Development Agreement, Newsoara may request to manufacture the Newsoara Licensed Products in the Territory, subject to satisfying certain conditions to LBS' reasonable satisfaction. LBS is obligated to approve Newsoara manufacturing rights without undue refusal or delay. Where we perform any research and development or manufacturing activities under the Newsoara Co-Development Agreement, we record the expense reimbursement from Newsoara as a reduction to research and development expense.

In consideration of the rights granted to Newsoara under the Newsoara Co-Development Agreement, Newsoara paid LBS a one-time upfront fee of $1.0 million. In addition, Newsoara is obligated to make (i) payments of up to $6.75 million in the aggregate upon achievement of certain regulatory and commercial milestones, (ii) payments in the low six-digit range per licensed product upon achievement of a regulatory milestone, and (iii) tiered royalty payments ranging from the mid-single-digit to low-double-digit percentage range on annual net sales of Licensed Products, subject to adjustment to the royalty percentage in certain events, including a change of control, the expiration of certain patents rights, and royalties paid by Newsoara third parties. To date, Newsoara has met all of its payment obligations under the Newsoara Co-Development Agreement.

The Newsoara Co-Development Agreement will expire upon the later of the expiration date of the last valid claim of any licensed patent covering the Newsoara Licensed Products in the Territory. In addition, the Newsoara Co-Development Agreement can be terminated (i) by either party for the other party's material breach that remains uncured for a specified time period after written notice or for events related to the other party's insolvency, (ii) by LBS if Newsoara challenges or attempts to interfere with any licensed patent rights and, (iii) by Newsoara for any reason upon specified prior written notice.

License Agreements with the Regents of the University of California

We entered into three license agreements, as amended, with the Regents of the University of California ("Regents") for exclusive commercial rights to certain patents, technology and know-how. Concurrent with our decision to terminate the development of LB1148, on October 20, 2023 we terminated two of our license agreements with Regents. As of December 31, 2023, the only license agreement remaining with Regents is that entered into with LBS in August 2015, as amended in December 2019 and September 2022 (the "2015 UC License"). The 2015 UC License was retained for the sole purpose of maintaining the Newsoara Co-Development Agreement under which we may receive future milestone or royalty payments through the term of the license. Accordingly, pursuant to the 2015 UC License, we are obligated to pay a percentage of non-royalty licensing revenue we receive from Newsoara under the Newsoara Co-Development Agreement to Regents ranging from 30 percent to 35 percent of one-third of the upfront payment and milestone payments received from Newsoara.

The 2015 UC License will expire upon the expiration date of the longest-lived patent right licensed under the 2015 UC License. The Regents may terminate the 2015 UC License if: (i) a material breach by us is not cured within 60 days, (ii) we file a claim asserting the Regents licensed patent rights are invalid or unenforceable, or (iii) we file for bankruptcy. We also have the right to terminate the 2015 UC License at any time upon at least 90 days' written notice.

Commercial

Should any of our product candidates be approved for commercialization, we intend to develop a plan to commercialize them in the United States and other key markets, through internal infrastructure and/or external partnerships in a manner that will enable us to realize the full commercial value of our programs. Given our stage of development, we have not yet established a commercial organization or distribution capabilities.

Manufacturing and Supply

We do not currently own or operate facilities for product manufacturing, testing, storage, and distribution. We rely on third parties for both our pre-clinical and clinical supply of our active pharmaceutical ingredient ("API") used in PALI-2108 and to supply the Newsoara Licensed Products to Newsoara.

As we progress through the development of our lead product candidates, our strategy for manufacturing and supply chain management is designed to ensure the highest quality, compliance, and efficiency in producing our product candidates.

To support the pre-clinical and clinical manufacture of the product candidates we are developing we engage a network of third-party Contract Development and Manufacturing Organizations ("CDMOs") and Contract Manufacturing Organizations ("CMOs"). These partnerships are strategically chosen based on a rigorous review of criteria including technological capabilities, regulatory compliance, quality assurance systems, and production capacity.

Our selection process for CDMOs and CMOs involves an in-depth evaluation of potential partners to ensure alignment with our quality standards, production needs, and timeline requirements. These organizations are responsible for various stages of drug development and manufacturing, including but not limited to:

- *API Production:* High-quality synthesis of active ingredients under stringent regulatory standards.

- *Formulation Development:* Design and development of stable and effective drug formulations suitable for clinical trials.
- *Clinical Trial Material Manufacturing:* Production of investigational medicinal products in compliance with GMP for use in clinical trials.
- *Packaging and Labeling:* Secure and compliant packaging and labeling solutions for clinical trial materials, ensuring patient safety and regulatory adherence.
- *Quality Control and Assurance:* Comprehensive testing and validation processes to ensure the safety, efficacy, and quality of the clinical supplies.

PALI-2108

We currently have agreements in place with third parties to provide pre-clinical and clinical supply of our API. These agreements are generally non-specific master services agreements that allow an entity to begin the process of future manufacturing or toxicology services, respectively. As clinical development activities are commenced by us, we anticipate these agreements will be revised to provide for the specific deliverables and associated costs that are needed under our development plan.

LB1148

Pursuant to our Newsoara Co-Development Agreement, we are Newsoara's exclusive supplier of the Newsoara Licensed Products. We currently have an agreement with ThermoFisher Scientific ("Thermo") to supply us with the Newsoara Licensed Product as required under the Newsoara Co-Development Agreement. The agreement with Thermo is a non-specific master services agreement that allows us to alter the scope of services as needed.

Competition

As a pre-clinical biotechnology company, we face competition from a wide array of companies in the pharmaceutical and biotechnology industries. This competition includes both small companies and large companies with greater financial and technical resources and longer operating histories than our own. We also compete with the intellectual property, technology, and product development efforts of academic, governmental, and private research institutions.

Our competitors may have significantly greater financial resources; a more established presence in the market; greater expertise in research and development, manufacturing, pre-clinical and clinical testing; more experience in obtaining regulatory approvals and reimbursement; and greater expertise in marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific, sales, marketing and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly if they establish collaborative arrangements with large companies.

We operate in a competitive landscape within the biopharmaceutical industry. Our focus on PDE4 inhibitor prodrugs that are locally acting and the use of precision medicine for IBD presents both opportunities and challenges.

While PDE4 inhibitors that are systemically available have been demonstrated to have significant efficacy, there was dose limiting toxicity. As well, precision medicine has been successfully applied in oncology and its adoption in IBD remains an unmet need. Our competitors include established biopharmaceutical companies, emerging biotechnology companies, and generic manufacturers.

Large pharmaceutical companies with extensive resources and established pipelines compete in the IBD space. Their existing products and research efforts pose a significant challenge to our ability to compete. These competitors have a track record of developing and commercializing therapies for IBD, which may impact on our market share.

Emerging public and private biotech companies are also working to develop novel therapeutics for the treatment of IBD. However, Palisade is not aware of other PDE4 inhibitors in development for ulcerative colitis (UC) or fibro stenotic Crohn's disease. Emerging biotech companies have similar agility and focus to Palisade Bio allowing them to explore novel approaches. Palisade Bio competes with these emerging players for funding, talent, and market attention.

Generic and biosimilar manufacturers are developing generic versions of existing IBD drugs and biosimilars are a threat to the market. As patents expire, competition intensifies. Palisade Bio must differentiate its PDE4 inhibitor with

precision medicine approach to stand out from generic alternatives. However, we are not aware of PDE4 inhibitors approved for IBD that will become generic.

The key competitive factors affecting the success of any products that we develop, if approved, are likely to be their efficacy, safety, convenience, price, and the availability of reimbursement from government and other third-party payors. Our commercial opportunity for any of our product candidates could be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, and may commercialize products more quickly than we do.

If approved for the treatment of patients with moderate-to-severe IBD, our portfolio of products would compete with TNF antibodies including Humira (AbbVie), Remicade (Johnson & Johnson), and Simponi (Johnson & Johnson); IL-12/23 and IL-23 antibodies including Stelara (Johnson & Johnson) and Skyrizi (AbbVie); α4ß7 antibody Entyvio (Takeda); JAK inhibitors including Xeljanz (Pfizer), Rinvoq (AbbVie); and S1P1 receptor modulating therapies including Zeposia (Bristol Myers Squibb).

We are aware of several companies with product candidates in development for the treatment of patients with IBD, including Merck's MK-7240, Roivant's RVT-3101, and Teva's TEV-48574 TL1A antibodies and Spyre's SPY002; additional IL-23s including Tremfya (Johnson & Johnson) and mirikizumab (Lilly) and Spyre's SPY003; additional S1P1 modulator etrasimod (Pfizer); and oral anti-integrin agents including Morphic Therapeutic's MORF-057, Gilead's GS-1427, Ventyx's VTX002, Spyre's SPY001 and a discovery program at Dice Therapeutics (Lilly).

These technologies, along with other modalities, such as small molecules and biologics, may be used to develop therapeutic candidates that would compete against our current, and potentially future, product candidates. In addition, we expect any oxygen-evolving compounds we develop to compete with established therapeutic treatments, if any, in their target indication.

Intellectual Property

Patents

We have exclusively licensed a worldwide patent portfolio from Giiant consisting of pending patent applications related to the assets licensed, including PALI-2108. In the United States, we have exclusive rights to one pending patent application (Application no. 17927827). Internationally, we have seven patent applications pending (Application Nos. (i) 2021280418, (ii) 3174137, (iii) 20218005868815, (iv) 21813913, (v) 2022-573665, (vi) 1020227045933, and (vii) MX/a/2022/014416).

The pending patents all relate to (i) the methods of making pharmaceutical composition, (ii) the pharmaceutical compositions, and (iii) the methods of using the pharmaceutical composition of PALI-2108 and the other assets licensed from Giiant.

Our success will depend in part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our technology, including PALI-2108 and the other assets licensed from Giiant. We also rely in part on trade secret, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. We seek to protect our proprietary position by filing and prosecuting patent applications in the United States and abroad related to our technology and product candidates.

In addition to our pending patents related to PALI-2108, we also maintain the patent family related to LB1148. The remaining patent family is directed to compositions comprising four components of LB1148 and their therapeutic use in treating shock and other indications. This patent family includes a patent in Europe, three granted patents in the United States, two granted patents in Taiwan, granted patents in Australia, India, Japan, Mexico, Korea (KR 2397379) and Canada (CA 2942358), and a pending application in the U.S., all of which we solely own. In addition, this family includes a granted patent in China that we previously assigned to Newsoara to support our co-development agreement, which is described above. The expected expiration date of the issued patents (or any patents that may issue from pending applications) is 2035, excluding any adjustments or extensions of patent term that may be available.

The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance,

scope, validity, enforceability and commercial value of our licensed patents and any patents we own are highly uncertain. The steps we and our licensor have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside of the United States.

Further, the examination process may require us to narrow the claims for our licensed pending patent applications, which may limit the scope of patent protection that may be obtained if these applications are issued. Our pending licensed and future patent applications may not result in patents being issued that protect our product candidates, in whole or in part, or which prevent others from commercializing competitive product candidates. The scope of a patent may also be reinterpreted after issuance. The rights that may be granted under the patents we have applied for may not provide us with the proprietary protection or competitive advantages we are seeking. Even if patent applications are issued as patents, they may not issue be issued in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. If we are unable to obtain and maintain patent protection for our technology or for PALI-2108 or our other product candidates, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize products similar or superior to ours in a non-infringing manner, and our ability to successfully commercialize PALI-2108 or our other product candidates and future technologies may be adversely affected. It is also possible that we will fail to identify patentable aspects of inventions made in the course of our development and commercialization activities before it is too late to obtain patent protection on them.

In addition, the patent prosecution process is expensive, time consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. It is also possible that we will fail to identify patentable aspects of our research and development efforts in time to obtain patent protection.

Our licensed pending applications cannot be enforced against third parties practicing the inventions claimed in such applications unless and until a patent is issued from such applications with a claim that covers infringing third-party activity. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we license from third parties or own in the future may be challenged in the courts or patent offices in the United States and abroad, including through opposition proceedings, derivation proceedings, post-grant review, inter partes review, interference proceedings or litigation. Such proceedings may result in the loss of patent protection, the narrowing of claims in such patents or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical products or limit the duration of the patent protection for our technology. Protecting against the unauthorized use of our patented inventions, trademarks and other intellectual property rights is expensive, time consuming, difficult and in some cases may not be possible. In some cases, it may be difficult or impossible to detect third-party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult. If we are unable to obtain, maintain, and protect our intellectual property our competitive advantage could be harmed, and it could result in a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

Trade Secrets and Confidentiality

We rely, in some circumstances, on trade secrets and other confidential information to protect our unpatented technology. However, trade secrets can be difficult to protect. We seek to protect our trade secrets and proprietary technology and processes, in part, by entering into non-disclosure and confidentiality agreements with our employees, consultants, collaborators, scientific advisors, suppliers, contractors and other third parties. In addition, we enter into employment agreements that require employees to assign to us any inventions, trade secrets or know-how that they develop while employed by us.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and our trade secrets and other proprietary information may be disclosed. We may not have adequate remedies for any breach and could lose our trade secrets and other proprietary information through such a breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants,

contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting trade secrets, know-how and inventions.

Government Regulation and Product Approval

In the United States, the FDA regulates pharmaceutical products under the Federal Food, Drug, and Cosmetic Act ("FDCA"), the Provincial Health Services Authority ("PHSA"), and regulations and guidance documents implementing these laws. The FDCA, PHSA and their corresponding regulations govern, among other things, the testing, manufacturing, safety, purity, potency, labeling, packaging, storage, record keeping, distribution, reporting, advertising and other promotional practices involving pharmaceutical products. Consent from the FDA is required before conducting human clinical testing of drug products. FDA approval of a new drug application ("NDA") also must be obtained before marketing a new drug product. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the continued expenditure of substantial time and financial resources.

U.S. Small Molecule New Drug Product Development Process

Any new drug product must be approved by the FDA before it may be legally marketed in the United States. FDA approval is also required before marketing an approved drug product for a new indication or condition of use. The process required by the FDA before a new drug product candidate may be marketed in the United States generally involves the following:

- Completion of pre-clinical laboratory tests and in vivo studies in accordance with the FDA's Good Laboratory Practice ("GLP") regulations and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- Submission to the FDA of an IND application, which allows human clinical trials to begin unless FDA objects (issues a "clinical hold") within 30 calendar days;
- Approval by an independent institutional review board ("IRB"), reviewing each proposed clinical trial and clinical site before each clinical trial may be initiated;
- Performance of adequate and well-controlled human clinical trials in accordance with the protocol contained in the approved IND and in accordance with the FDA's Good Clinical Practice ("GCP") regulations, and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed product candidate for its intended use;
- Preparation and submission to the FDA of a NDA for marketing approval that includes substantial evidence of safety and efficacy from results of nonclinical testing and clinical trials;
- Review of the product by an FDA advisory committee, if applicable;
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the product candidate is produced to assess compliance with current Good Manufacturing Practice ("cGMP") requirements and to assure that the facilities, methods and controls are adequate to preserve the product candidate's identity, safety, strength, quality, potency and purity;
- Potential FDA audit of the nonclinical and clinical trial sites that generated the data in support of the NDA; and
- Payment of user fees and FDA review and approval of the NDA.

The testing and approval process of product candidates requires substantial time, effort, and financial resources. Satisfaction of the FDA's pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease. Before testing any product candidate in humans, the product candidate must undergo pre-clinical testing. Pre-clinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as in vivo animal studies to assess the potential safety and activity of the product candidate and to establish a rationale for therapeutic use. The conduct of the pre-clinical tests must comply with federal regulations and requirements including GLPs.

Concurrent with clinical trials, companies usually must complete some long-term pre-clinical testing, such as animal tests of reproductive adverse events and carcinogenicity and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the drug 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, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug 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.

A clinical trial sponsor must submit the results of the pre-clinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some pre-clinical testing may continue even after the IND is submitted. The IND automatically becomes active 30 calendar days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to a proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks, and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA also may impose partial or full clinical holds on a product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not begin, or recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, that issues arise that partially or fully suspend or terminate such studies.

Human Clinical Trials Under an IND

Clinical trials involve the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, which are generally physicians not employed by, or under, the control of the trial sponsor. Clinical trials must be conducted under written study protocols detailing, among other things, the objectives of the trial, subject selection and exclusion, the trial procedures, the parameters to be used in monitoring safety, the criteria to be evaluated, and a statistical analysis plan. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND.

Further, clinical trials must be conducted in accordance with federal regulations and GCP requirements, which include the requirements that all research subjects provide their informed consent in writing for their participation in any clinical trial, as well as review and approval by an IRB at each study site participating in the clinical trial or a central IRB. An IRB is charged with protecting the welfare and rights of trial participants and considers items such as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject, or their legal representative, reviews and approves the study protocol, and must monitor the clinical trial until completed.

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

- Phase 1. The product candidate initially is introduced into a small number of healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early understanding of its value in treating patients. In the case of some product candidates for severe or life-threatening diseases, especially when the product candidate may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- Phase 2. The product candidate is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product candidate for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- Phase 3. Phase 3 clinical trials are commonly referred to as “pivotal” or “registrational” studies, which typically denotes a study that presents data the FDA or other relevant regulatory agency will use to determine whether to approve a product. In Phase 3 studies, the product candidate is administered to an expanded patient population, generally at multiple geographically dispersed clinical trial sites in adequate and well-controlled clinical trials to generate sufficient data to statistically demonstrate the efficacy and safety of the product for approval. These clinical trials are intended to establish the overall risk/benefit ratio of the product candidate and provide an adequate basis for product labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be required by FDA, or may be voluntarily conducted after initial approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA.

Written IND safety reports must be promptly submitted to the FDA and the investigators for: serious and unexpected adverse events; any findings from other studies, in vivo laboratory tests 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. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Relevant additional information obtained by the sponsor that pertains to a previously submitted IND safety report must be submitted as a follow-up IND safety report. Such report should be submitted within 15 calendar days after the sponsor receives the information.

Information about certain clinical trials, including a description of the study and, in some cases, study results, must be submitted within specific timeframes to the National Institutes of Health, for public dissemination on their clinicaltrials.gov website. Manufacturers or distributors of investigational products for the diagnosis, monitoring, or treatment of one or more serious or life-threatening diseases or conditions where no other comparable or satisfactory therapeutic options exist must also have a publicly available policy on evaluating and responding to requests for expanded access, sometimes called "compassionate use" requests.

Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor that regularly reviews accumulated data and advises the study sponsor regarding the continuing safety of the trial. This group, known as a Data and Safety Monitoring Board or Data and Safety Monitoring Committee, may also review interim data to assess the continuing validity and scientific merit of the clinical trial. This group receives special access to unblinded data during the clinical trial and may advise the sponsor to halt the clinical trial if it determines there is an unacceptable safety risk for subjects or on other grounds, such as no demonstration of efficacy.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements or if the trial poses an unexpected serious harm to subjects. The FDA or an IRB may also impose conditions on the conduct of a clinical trial. Clinical trial sponsors may also choose to discontinue clinical trials as a result of risks to subjects, a lack of favorable results, or changing business priorities.

Compliance with cGMP Requirements

Manufacturers of pharmaceutical products must comply with applicable cGMP regulations, including quality control and quality assurance and maintenance of records and documentation. Manufacturers and others involved in the manufacture and distribution of such products also must register their establishments with the FDA and certain state agencies. Both domestic and foreign manufacturing establishments must register and provide additional information to the FDA upon their initial participation in the manufacturing process. Establishments may be subject to periodic, unannounced inspections by government authorities to ensure compliance with cGMP requirements and other laws. Discovery of problems may result in a government entity placing restrictions on a product, manufacturer or holder of an approved NDA, and may extend to requiring withdrawal of the product from the market. The FDA will not approve an NDA 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 specification.

Concurrent with clinical trials, companies usually complete additional pre-clinical studies and must also develop additional information about the physical characteristics of the product candidate as well as finalize a process for manufacturing the product candidate in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents or of causing other adverse events with the use of small molecule products, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other requirements, the sponsor must develop methods for testing the identity, strength, quality,

potency and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted, to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

In relation to the clinical trials that may be conducted in other countries with a view to obtaining a marketing authorization, there are comparable cGMP requirements and other regulatory rules that are implemented nationally.

U.S. FDA Review and Approval Process

Assuming successful completion of the required clinical and pre-clinical testing, the results of the pre-clinical tests and clinical trials together with detailed information relating to the product's CMC, including negative or ambiguous results as well as positive findings, and proposed labeling, among other things, are submitted to the FDA for NDA approval to market the product for one or more indications.

Under the Prescription Drug User Fee Act ("PDUFA"), as amended, each NDA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. The PDUFA also imposes an annual program fee for approved therapeutic products. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs for product candidates designated as orphan drugs, unless the product candidate also includes a non-orphan indication.

In addition, under the Pediatric Research Equity Act ("PREA"), an NDA for a new active ingredient, indication, dosage form, dosage regimen, or route of administration, must contain data that are adequate to assess the safety and potential of the product 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. Also, applications for product candidates intended for the treatment of adult cancer directed at molecular targets that the FDA determines to be substantially relevant to the growth or progression of pediatric cancer, in place of the PREA investigations, sponsors must submit, with the application, reports from molecularly targeted pediatric cancer investigations designed to yield clinically meaningful pediatric study data, using appropriate formulations, to inform potential pediatric labeling. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Orphan products are also exempt from the PREA requirements.

The FDA reviews an NDA within 60 days of submission to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any NDA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In that event, the NDA must be resubmitted with the additional information. The resubmitted 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 of the NDA.

The FDA reviews the NDA to determine, among other things, whether the proposed product candidate is safe and effective for its intended use, has an acceptable purity profile and whether the product candidate is being manufactured in accordance with cGMP to assure and preserve the product candidate's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel therapeutic products or therapeutic products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the product approval process, the FDA also will determine whether a risk evaluation and mitigation strategy, ("REMS") is necessary to assure the safe use of the product candidate. REMS use risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events, and whether the product is a new molecular entity. A REMS could include medication guides, physician communication plans and elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without a REMS, if required.

Before approving an NDA, the FDA will inspect the facilities at which the product candidate is manufactured. The FDA will not approve the product candidate if it determines that the manufacturing processes and facilities are not in compliance with cGMP requirements or otherwise are not adequate to assure consistent production of the product

candidate within required specifications. Additionally, before approving an NDA, the FDA typically will inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements.

On the basis of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities, 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 generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter.

If a product candidate receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing or dispensing in the form of a REMS, or otherwise limit the scope of any approval. The FDA may also require post-marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a product's safety, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Every five years, the FDA agrees to specified performance goals in the review of NDAs under the PDUFA. One such current goal is to review standard NDAs in ten months after the FDA accepts the NDA for filing, and priority NDAs in six months, whereupon a review decision is to be made. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs and its review goals are subject to change from time to time. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

Expedited Development and Review Programs

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drugs and biologics that meet certain criteria. Specifically, new drugs and biologics are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and pre-clinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to both the product and the specific indication for which it is being studied. The sponsor can request the FDA to designate the product for Fast Track status any time before receiving NDA approval, but ideally no later than the pre-NDA meeting.

Any product submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product may be eligible for priority review if it is intended to treat a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies.

A Fast Track product may also be eligible for rolling review, where the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

A product may also be eligible for accelerated approval if it is intended to treat a serious or life-threatening condition and generally provide a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality ("IMM"), which is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. If the FDA concludes that a drug shown to be effective can be safely used only if distribution or use is restricted, it may require such post-marketing restrictions as it deems necessary to assure safe use of the product.

Additionally, a drug may be eligible for designation as a Breakthrough Therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. The benefits of Breakthrough Therapy designation include the same benefits as Fast Track designation, plus intensive guidance from the FDA to ensure an efficient drug

development program. Fast Track designation, priority review, accelerated approval and Breakthrough Therapy designation do not change the standards for approval but may expedite the development or approval process.

Post-Approval Requirements

After approval, there also are continuing annual program user fee requirements for approved products, excluding, under certain circumstances, orphan products.

Rigorous and extensive FDA regulation of pharmaceutical products continues after approval, particularly with respect to cGMP requirements. Manufacturers are required to comply with applicable requirements in the cGMP regulations, including quality control and quality assurance and maintenance of records and documentation. To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the United States and between states.

Other post-approval requirements applicable to pharmaceutical products include reporting of cGMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information, and complying with electronic record and signature requirements. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, and potency of pharmacological products.

In addition, manufacturers and other entities involved in the manufacture and distribution of approved pharmaceuticals are required to register their establishments with the FDA and certain state agencies, list their products, and are subject to periodic announced and unannounced inspections by the FDA and these state agencies for compliance with current cGMP and other requirements, which impose certain procedural and documentation requirements upon us and third-party manufacturers. Manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with current cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered. In addition, changes to the manufacturing process or facility generally require prior FDA approval or notification before being implemented, and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Moreover, the Drug Quality and Security Act imposes obligations on manufacturers of pharmaceutical products related to product tracking and tracing.

Adverse event reporting and submission of periodic reports, including annual reports and deviation reports, are required following FDA approval of an NDA. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in significant regulatory actions. Such actions may include refusal to approve pending applications, license suspension or revocation, imposition of a partial or full clinical hold or termination of clinical trials, warning letters, untitled letters, modification of promotional materials or labeling, provision of corrective information, imposition of post-market requirements including the need for additional testing, imposition of distribution or other restrictions under a REMS, product recalls, product seizures or detentions, refusal to allow imports or exports, total or partial suspension of production or distribution, FDA debarment, injunctions, fines, consent decrees, corporate integrity agreements, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from participation in federal and state healthcare programs, restitution, disgorgement, or civil or criminal penalties, including fines and imprisonment, and result in adverse publicity, among other adverse consequences.

A sponsor also must comply with the FDA's advertising and promotion requirements, such as the prohibition on promoting products for uses or in patient populations that are inconsistent with the product's approved labeling (known as "off-label use"). The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Violations relating to the promotion of off-label uses may lead to investigations alleging violations of federal and state healthcare fraud and abuse and other laws, as well as state consumer protection laws. Companies, however, may generally share truthful and non-misleading information that is otherwise consistent with a product's FDA approved labeling. Discovery of previously unknown problems or the failure to comply with the applicable regulatory

requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions.

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 or manufacturer to administrative or judicial civil or criminal actions and adverse publicity. These actions could include refusal to approve pending applications or supplemental applications, withdrawal of an approval, clinical hold, suspension or termination of a clinical trial by an IRB, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines or other monetary penalties, refusals of government contracts, mandated corrective advertising or communications with healthcare providers, debarment, restitution, disgorgement of profits or other civil or criminal penalties.

Broadly equivalent requirements and controls typically apply in other countries to the submission of marketing authorization applications and, post-approval, to the holding of such marketing authorizations.

The Hatch-Waxman Amendments and Generic Competition

Orange Book Listing

Once a drug product is approved under an NDA, the product is listed in the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the Orange Book. An NDA-approved drug product will be designated in the Orange Book as a Reference Listed Drug ("RLD"). Sponsors of approved NDAs are required to list with the FDA patents whose claims cover the product's active ingredient, formulation, or an approved method of using the drug.

Patent Term Extensions

Depending upon the timing, duration and specifics of FDA approval of the use of our therapeutic candidates, some of our United States patents may be eligible for limited patent term extension under the Hatch-Waxman Amendments to the FDCA ("Hatch-Waxman"). Hatch-Waxman permits a patent restoration term of up to five years as compensation for patent term lost during drug 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 or therapeutic candidate's approval date. The patent term restoration period is generally 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, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved product or therapeutic candidate is eligible for the extension and the application for extension must be made prior to expiration of the patent. The USPTO, 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 some of our currently owned or licensed patents to add patent life beyond their current expiration date, depending on the expected length of clinical trials and other factors involved in the submission of the relevant NDA(s).

ANDA Approval Process for Generic Drugs

Hatch-Waxman also established an abbreviated FDA approval process for generic drugs that are shown to be pharmaceutically equivalent and bioequivalent to drugs previously approved by the FDA through the NDA process. Approval to market and distribute these drugs is obtained by filing an abbreviated new drug application("ANDA"), with the FDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown to be bioequivalent to the listed drug. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. ANDAs are termed abbreviated because they generally do not include pre-clinical and clinical data to demonstrate safety and effectiveness. Instead, a generic applicant must demonstrate that its product is bioequivalent to the innovator drug. In some cases involving drugs with no or limited systemic absorption, an ANDA must include clinical endpoint (efficacy) studies in order to demonstrate bioequivalence. 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.

Section 505(b)(2) NDA Approval Process

As an alternative path to FDA approval for modifications to formulations or uses of products previously approved by the FDA under a "full" NDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Hatch-Waxman Amendments and enables the applicant to rely, in part, on the FDA's previous approval of a similar product, and/or published literature, in support of the safety and/or efficacy of its drug product. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. If the Section 505(b)(2) applicant can establish that reliance on FDA's previous findings of safety and effectiveness is scientifically appropriate, it may eliminate the need to conduct certain pre-clinical studies or clinical trials of the new product. The FDA may also require companies to perform additional studies or measurements, including clinical trials, to support the change from the approved reference drug. The FDA may then approve the new product candidate for all, or some, of the label indications for which the reference drug has been approved or for any new indication sought by the Section 505(b)(2) applicant.

ANDA and 505(b)(2) products may be significantly less costly to bring to market than the reference listed drug, and companies that produce generic products are generally able to offer them at lower prices. Moreover, generic versions of RLDs are often automatically substituted for the RLD by pharmacies when dispensing a prescription written for the RLD. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference listed drug is typically lost to the generic product.

ANDA and 505(b)(2) NDA Patent Certification Requirements

Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a Section 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA, as applicable, that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is, in the applicant's opinion, invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a paragraph IV certification. If an ANDA or 505(b)(2) NDA is submitted to FDA with a Paragraph IV Certification, the applicant must also provide a "Paragraph IV Notification" to the holder of the NDA for the RLD and to the owner of the listed patent(s) being challenged by the applicant, providing a detailed written statement of the bases for the applicant's position that the relevant patent(s) is invalid or would not be infringed. If the patent owner brings a patent infringement lawsuit against the applicant within 45 days of the Paragraph IV Notification, FDA approval of the ANDA or 505(b)(2) NDA will be automatically stayed for 30 months, or until 7 ½ years after the RLD's NDA approval date if the ANDA or 505(b)(2) NDA was filed between 4 years and 5 years after the NDA approval. Any such stay will be terminated earlier if the court rules that the patent is invalid or would not be infringed. The applicant may, in certain circumstances, elect to submit a "section viii" statement with respect to a listed method of use patent, certifying that the proposed ANDA or 505(b)(2) product's labeling does not contain (or carves out) any language that would infringe a method of use patented listed in the Orange Book for the RLD.

The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the reference drug has expired as described in further detail below.

Regulatory Exclusivities

New Chemical Entity Exclusivity

The Hatch-Waxman Amendments provide a period of five years of non-patent marketing exclusivity for the first approved drug containing a new chemical entity ("NCE") as an active ingredient. An NCE is an active moiety that has not been approved by the FDA in any other NDA. A fixed combination drug product may receive NCE exclusivity if one of its active ingredients is an NCE, but not if all of its active ingredients have previously been approved. An "active moiety" is defined as the molecule or ion responsible for the drug substance's physiological or pharmacologic action. During the five-year exclusivity period, the FDA cannot accept for filing any ANDA or 505(b)(2) NDA seeking approval of a product that contains the same active moiety, except that the FDA may accept such an application for filing after four years if the application includes a paragraph IV certification to a listed patent. In the case of such applications accepted for filing between four and five years after approval of the reference drug, the 30-Month Stay of approval triggered by a timely patent infringement lawsuit is extended by the amount of time necessary to extend the stay until 7 ½ years after the approval of the reference drug NDA.

New Clinical Trial (3-Year) Exclusivity

A drug, including one approved under Section 505(b)(2), may obtain a three-year period of exclusivity for a particular indication or condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical trials (other than bioavailability studies) was essential to the approval of the application or supplemental application and was conducted/sponsored by the applicant. Should this occur, the FDA would be precluded from approving any ANDA or Section 505(b)(2) application for the protected modification until after that three-year exclusivity period has run. However, unlike NCE exclusivity, the FDA can accept an application and begin the review process during the three-year exclusivity period.

Orphan Drug Designation and Orphan Exclusivity Under the Orphan Drug Act

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

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

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety, or providing a major contribution to patient care or in instances of drug supply issues. However, competitors may receive approval of either a different product for the same indication or the same product for a different indication but that could be used off-label in the orphan indication. Orphan drug exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval before we do for the same product, as defined by the FDA, for the same indication we are seeking approval, or if a product candidate is determined to be contained within the scope of the competitor's product for the same indication or disease. If one of our products is designated as an orphan drug and receives marketing approval for an indication broader than that for which it is designated, it may not be entitled to orphan drug exclusivity. Orphan drug status in the European Union has similar, but not identical, requirements and benefits.

Pediatric Exclusivity

Pediatric exclusivity is another type of non-patent marketing exclusivity available in the United States and, if granted, it provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity or listed patents. Under the Best Pharmaceuticals for Children Act certain therapeutic candidates may obtain an additional six months of exclusivity if the sponsor conducts pediatric research and submits new clinical information requested in writing by the FDA, referred to as a Written Request, relating to the use of the active moiety of the product or therapeutic candidate in children. The data do not need to support a label change for pediatric use; rather, the additional protection is granted if the pediatric clinical trial is deemed to have fairly responded to the FDA's Written Request. Although the FDA may issue a Written Request for studies on either approved or unapproved indications, it may only do so where it determines that information relating to that use of a product or therapeutic candidate in a pediatric population, or part of the pediatric population, may produce health benefits in that population. The issuance of a Written Request does not require the sponsor to undertake the described trials. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

Other Healthcare Laws and Regulations

Our business activities, including but not limited to, research, sales, promotion, distribution, medical education, and other activities following product approval will be subject to regulation by numerous federal and state regulatory and law enforcement authorities in the United States in addition to the FDA, including potentially the Department of Justice, the Department of Health and Human Services ("HHS") and its various divisions, including the Office of Inspector General, the Centers for Medicare & Medicaid Services ("CMS") and the Health Resources and Services Administration, the Department of Veterans Affairs, the Department of Defense, and state and local governments.

Healthcare providers and third-party payors play a primary role in the recommendation and use of pharmaceutical products that are granted marketing approval. Arrangements with third-party payors, existing or potential customers and referral sources, including healthcare providers, are subject to broadly applicable fraud and abuse laws and regulations, and these laws and regulations may constrain the business or financial arrangements and relationships through which manufacturers conduct clinical research, market, sell and distribute the products for which they obtain marketing approval. Such restrictions under applicable federal and state healthcare laws and regulations include the following:

- The federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or kind, in exchange for, or to induce, either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers, formulary managers and other individuals and entities on the other. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, "the ACA") amended the intent requirement of the federal Anti-Kickback Statute such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to commit a violation;
- The federal civil and criminal false claims, including the civil FCA, and Civil Monetary Penalties Laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent, or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government. Certain marketing practices, including off-label promotion, also may implicate the FCA. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA;
- The federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, therapeutic products and medical supplies for which payment is available under Medicare, Medicaid, or the Children’s Health Insurance Program, with specific exceptions, to report annually to the CMS, information related to payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members;
- Health Insurance Portability and Accountability Act of 1996 ("HIPAA") prohibits knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, a healthcare benefit program, regardless of whether the payor is public or private, in connection with the delivery or payment for health care benefits, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items, or services relating to healthcare matters. Additionally, the ACA amended the intent requirement of certain of these criminal statutes under HIPAA so that a person or entity no longer needs to have actual knowledge of the statute, or the specific intent to violate it, to have committed a violation; and
- State and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial 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 federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers and drug pricing and/or marketing expenditures; and state and local laws requiring the registration of pharmaceutical sales representatives and state laws governing the privacy and security of health information in certain circumstances, many of

which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Further, we may be subject to data privacy and security regulation by both the federal government and the states and foreign jurisdictions in which we conduct our business. HIPAA, as amended by the Health Information Technology for Clinical Health Act of 2009 ("HITECH"), and its respective implementing regulations imposes certain requirements, including mandatory contractual terms, on covered entities, business associates and their covered subcontractors relating to the privacy, security, and transmission of certain individually identifiable health information known as protected health information. Among other things, HITECH, through its implementing regulations, makes HIPAA's security standards and certain privacy standards directly applicable to business associates, defined as a person or organization, other than a member of a covered entity's workforce, that creates, receives, maintains, or transmits protected health information on behalf of a covered entity for a function or activity regulated by HIPAA. HITECH also strengthened the civil and criminal penalties that may be imposed against covered entities, business associates, subcontractors, and individuals, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, other federal and state laws may govern the privacy and security of health and other information in certain circumstances, many of which differ from each other in significant ways and may not be pre-empted by HIPAA, thus complicating compliance efforts.

To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

In the EU, the data privacy laws are generally perceived to be stricter than those that apply in the United States and include specific requirements for the transfer of personal data outside the EU to the United States to ensure that EU standards of data privacy will be applied to such data.

Violation of the laws described above or any other governmental laws and regulations may result in significant penalties, including administrative, civil and criminal penalties, damages, fines, the curtailment or restructuring of operations, the exclusion from participation in federal and state healthcare programs, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, imprisonment, and additional reporting requirements and oversight if a person becomes subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws. Furthermore, efforts to ensure that business activities and business arrangements comply with applicable healthcare laws and regulations can be costly for manufacturers of branded prescription products.

Health Reform

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by federal and state legislative initiatives, including those designed to limit the pricing, coverage, and reimbursement of pharmaceutical products, especially under government-funded health care programs, and increased governmental control of drug pricing.

By way of example, in March 2010, the ACA was signed into law, 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 taxes and fees on the healthcare industry and impose additional health policy reforms. Among the provisions of the ACA of importance to our business are:

- An annual, non-deductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;

- An increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- A 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;
- Extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- Expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- A Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- Expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; and
- A Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical research, along with funding for such research.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, on June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, re-examining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. In addition, in August 2022, President Biden signed the Inflation Reduction Act of 2022 (the "IRA") into law, which among other things, extends enhanced subsidies for individuals purchasing coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program.

Other legislative changes have been proposed and adopted in the United States since the ACA. For example, through the process created by the Budget Control Act of 2011, there are automatic reductions of Medicare payments to providers up to 2% per fiscal year that went into effect in April 2013 and, following passage of the Bipartisan Budget Act of 2015 and the Infrastructure Investment and Jobs Act, will remain in effect until 2031 unless additional Congressional action is taken. However, COVID-19 relief support legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2022. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester.

The heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics, also has resulted in executive orders, congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, President Trump used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders, and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. The FDA concurrently released a final rule and guidance in September 2020 implementing a portion of the importation executive order providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers,

unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. The implementation of the rule has been delayed until 2032. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA directs the Secretary of HHS to establish a Drug Price Negotiation Program (the Program) to lower prices for certain single-source prescription drugs and biologics covered under Medicare Parts B and D, based on criteria established under the IRA. Under the Program, the Secretary of HHS will publish a list of "selected drugs," and will then negotiate maximum fair prices with their manufacturers. Beginning in 2026, the first year of the Program, the number will be limited to 10 Part D drugs and biologics. By 2029, and in subsequent years thereafter, the number will increase to 20 drugs and biologics covered under Part D and Part B. Agreements between HHS and manufacturers will remain in place until a drug or biologic is no longer considered a "selected drug" for negotiation purposes. Manufacturers who do not comply with the negotiated prices set under the Program will be subject to an excise tax based on a percentage of total sales of a "selected drug" up to 95% and the potential of civil monetary penalties. Further, the IRA imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. In addition, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report within ninety (90) days on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries.

At the state level, individual states in the United States have increasingly passed legislation and implemented regulations designed to control pharmaceutical and therapeutic product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some third-party payors also require pre-approval of coverage for new or innovative devices or therapies before they will reimburse healthcare providers that use such therapies.

We expect that these initiatives, as well as other healthcare reform measures that may be adopted in the future, as well as the trend toward managed healthcare and increasing influence of managed care organizations, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. It is also possible that additional governmental action is taken in response to the COVID-19 pandemic. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of current and future cost containment measures or other healthcare reforms may adversely affect our operations and prevent us from being able to generate revenue, attain profitability or commercialize our product candidates.

Data Privacy and Security

In the ordinary course of our business, we collect, process and store confidential and sensitive information, including personal information, intellectual property, trade secrets, and proprietary information owned or controlled by ourselves or other third parties. We, and third parties upon whom we rely, use sophisticated information technology, software and services to process, store, use, generate, transfer and disclose information, as well as other sensitive information controlled by ourselves or other third parties.

We may also be subject to federal, state, and foreign data privacy and security laws and regulations. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations (e.g., Section 5 of the FTC Act), govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners, vendors, or other third parties on whom we rely. The legislative and regulatory framework related to the collection, use, retention, safeguarding, disclosure, sharing, transfer, security and other processing of personal data worldwide is rapidly evolving. The number and scope of data protection laws and regulations is changing, subject to differing applications and interpretations, and may be inconsistent among jurisdictions, or in conflict with other rules, laws or other data processing obligations. Efforts to ensure that our current and future business arrangements, including our relationship with our CROs or other vendors

who process data on our behalf, comply with applicable data privacy and data security laws and regulations will involve substantial costs.

For example, HIPAA, as amended by HITECH, and its implementing regulations, impose requirements relating to the privacy, security and transmission of individually identifiable health information on certain health care providers, health plans and health care clearinghouses, known as covered entities, as well as their business associates and covered subcontractors that perform certain services that involve creating, receiving, maintaining or transmitting individually identifiable health information for or on behalf of such covered entities. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Further, entities that knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA may be subject to civil and criminal penalties. Even when HIPAA does not apply, according to the FTC, violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5 of the FTC Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

Likewise, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the EU and other jurisdictions, such as the California Consumer Privacy Act of 2018 ("CCPA"), which has been characterized as the first "GDPR-like" privacy statute to be enacted in the United States. Although the CCPA exempts certain data processed in the context of clinical trials, the CCPA, to the extent applicable to our business and operations, may increase our compliance costs and potential liability with respect to the personal information we maintain about California residents. The CCPA among other effects, creates individual privacy rights for California consumers (as defined in the law), places increased privacy and security obligations on entities handling certain personal data of consumers or households, requires covered companies to provide disclosures to consumers regarding data collection, use and sharing practices, requires covered companies to allow users to opt-out of certain sales or transfers of personal information, and provides consumers with a private right of action for certain data breaches. The CCPA became effective on January 1, 2020, and the California Attorney General's authority to begin bringing enforcement actions began July 1, 2020. As currently written, the CCPA may impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information. Further, the California Privacy Rights Act ("CPRA") was recently voted into law by California residents. The CPRA significantly amends the CCPA and imposes additional data protection obligations on covered companies doing business in California, including additional consumer rights processes and opt outs for certain uses of sensitive data. It also creates a new California data protection agency specifically tasked to enforce the law, which would likely result in increased regulatory scrutiny of California businesses in the areas of data protection and security. The substantive requirements for businesses subject to the CPRA went into effect on January 1, 2023, and become enforceable on July 1, 2023. A similar law, the Consumer Data Protection Act was recently passed in Virginia and went into effect on January 1, 2023.

We also are or will become subject to privacy laws in the jurisdictions in which we are established or in which we sell or market our products or run clinical trials. For example, in the EU, we are subject to Regulation (EU) 2016/679, the GDPR, in relation to our collection, control, processing, and other use of personal data (i.e. data relating to an identified or identifiable living individual). We process personal data in relation to participants in our clinical trials in the European Economic Area ("EEA"), including the health and medical information of these participants. The GDPR is directly applicable in each EU and EEA Member State, however, it provides that EU and EEA Member States may introduce further conditions, including limitations that could limit our ability to collect, use and share personal data (including health and medical information), or could cause our compliance costs to increase, ultimately having an adverse impact on our business. As noted above, the GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and implement policies as part of its mandated privacy governance framework. It also requires data controllers to be transparent and disclose to data subjects (in a concise, intelligible and easily accessible form) how their personal information is to be used, imposes limitations on retention of personal data; defines for the first time pseudonymized (i.e., key-coded) data; introduces mandatory data breach notification requirements; and sets higher standards for data controllers to demonstrate that they have obtained

valid consent for certain data processing activities. We are also subject to EEA rules with respect to cross-border transfers of personal data outside of the EEA. As noted above, recent legal developments in the EU have created complexity and uncertainty regarding transfers of personal data from the EEA to the United States, e.g. on July 16, 2020, the Court of Justice of the European Union ("CJEU"), invalidated the EU-U.S. Privacy Shield Framework, or the Privacy Shield, under which personal data could be transferred from the EEA to U.S. entities who had self-certified under the Privacy Shield scheme. While the CJEU upheld the adequacy of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of the standard contractual clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place, however, the nature of these additional measures is currently uncertain. On June 4, 2021, the European Commission adopted new standard contractual clauses under the GDPR for data transfers from entities that are subject to the GDPR to transfer personal data outside of the EEA. The new standard contractual clauses impose additional obligations, including the obligation to conduct a transfer impact assessment and, depending on a party's role in the transfer, to implement additional security measures and to update internal privacy practices. If we elect to rely on the standard contractual clauses for data transfers, we may be required to incur significant time and resources to update our contractual arrangements and to comply with new obligations. Additionally, on September 8, 2020, the Swiss Data Protection Authority (the Federal Data Protection and Information Commissioner) concluded that the Swiss-U.S. Privacy Shield does not provide an adequate level of protection for personal data transfer from Switzerland to the U.S. pursuant to the Swiss Federal Act on Data Protection. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the standard contractual clauses cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

We are subject to the supervision of local data protection authorities in those EU jurisdictions where we are established or otherwise subject to the GDPR. Fines for certain breaches of the GDPR are significant: up to the greater of €20.0 million or 4% of total global annual turnover. Further, following the withdrawal of the United Kingdom from the EU on January 31, 2020, pursuant to the transitional arrangements agreed between the United Kingdom and the EU, we will have to comply with the GDPR and separately the GDPR as implemented in the United Kingdom, each regime having the ability to fine up to the greater of €20 million / £17 million or 4% of global turnover. Following December 31, 2020, and the expiry of the post-Brexit transitional arrangements between the United Kingdom and EU, although it is likely that the data protection obligations of the GDPR will continue to apply to UK-related processing of personal data in substantially unvaried form and fashion, for at least the short term thereafter, the relationship between the United Kingdom and the EU in relation to certain aspects of data protection law remains unclear. For example, it is not yet clear whether the United Kingdom will be the subject of a so-called adequacy decision of the European Commission, and it is therefore unclear how data transfers between EU/EEA Member States and the United Kingdom will be treated. Any changes relating to the UK and EU position regarding aspects of data protection law may lead to additional compliance costs and could increase our overall risk. In addition to the foregoing, a breach of the GDPR or other applicable privacy and data protection laws and regulations could result in regulatory investigations, reputational damage, orders to cease/change our use of data, enforcement notices, an inability to process personal data or to operate in certain jurisdictions, or potential civil claims including class action type litigation.

Moreover, we use third-party service providers and sub-processors to help us operate our business and engage in processing on our behalf. If we, our service providers, partners, or other relevant third-parties have experienced, or in the future experience, any security incident(s) that result in any data loss, deletion or destruction, unauthorized access to, loss of, unauthorized acquisition or disclosure of, or inadvertent exposure or disclosure of sensitive information, or compromise related to the security, confidentiality, integrity of our (or their) information technology, software, services, communications or data, it may result in a material adverse impact, including without limitation, regulatory investigations or enforcement actions, litigation, or an inability to process data in some jurisdictions. Furthermore, applicable data protection laws, privacy policies and data protection obligations may require us to notify relevant stakeholders of security breaches, including affected individuals, customers, and regulators. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could result in a material adverse impact, including without limitation, regulatory investigations or enforcement actions.

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservation and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern the use, handling and disposal of various biologic, chemical and radioactive substances used in, and wastes generated by, operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. Equivalent laws have been adopted in other countries that impose similar obligations.

U.S. Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act ("FCPA") prohibits U.S. corporations and individuals from engaging in certain activities to obtain or retain business abroad or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value, directly or indirectly, to any foreign government official, government staff member, official or employee of a public international organization, or a political party or political candidate for the purpose of influencing any act or decision of the foreign entity in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. The scope of the FCPA includes interactions with healthcare professionals of foreign state-owned or affiliated hospitals, universities, or research institutions. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Activities that violate the FCPA, even if they occur wholly outside the United States, can result in criminal and civil fines, imprisonment, disgorgement, oversight, and suspension and debarment from government contracts, and refusal of orders under existing government contracts. Equivalent laws have been adopted in other foreign countries that impose similar or arguably broader obligations.

Subsidiaries

We two wholly owned subsidiaries, Suzhou Neuralstem Biopharmaceutical Co., Ltd. ("Suzhou"), organized under the laws of the People's Republic of China, and LBS. Suzhou was established by Seneca to sponsor the non-GDP Phase 2 clinical trial of NSI-566 that was conducted between 2013 and 2016 in Beijing, China. As of December 31, 2023, Suzhou has limited operations and exists for the sole purpose of continuing to observe a small group of patients that participated in the clinical trial of NSI-566, and administering the wind down of the NSI-566 asset, which it does through the engagement of a consultant. Suzhou has no employees or other operations. We are currently in the process of winding down the Suzhou subsidiary. Our other subsidiary is Leading Biosciences, Inc., which is our operating entity.

Contingent Value Right

Immediately prior to the closing of the Merger, Seneca issued each share of its common stock held by Seneca stockholders of record, one contingent value right ("CVR"). The CVR entitled the holder (the "CVR Holder") to receive, pro rata with the other CVR Holders, 80% of the net proceeds, if any and subject to certain minimum distribution limitations ("CVR Payment Amount"), received from the sale or licensing of the intellectual property owned, licensed or controlled by Seneca immediately prior to the closing of the Merger (the "Legacy Technology"); provided however that the CVR Holders are only entitled to receive such CVR Payment Amount if the sale or licensing of such Legacy Technology occurred on or before October 27, 2022 ("Legacy Monetization"). Pursuant to the terms of the CVR agreement ("CVR Agreement"), CVR Holders are only entitled to receive CVR Payment Amounts received within 48-months following the closing of the Merger. The CVR Agreement also provides that no distributions will be made to the CVR Holders in the event such distribution is less than $0.3 million.

As discussed below, with respect to the Legacy Technology, during the CVR Legacy Monetization period we entered into: (i) an asset transfer agreement ("ATA") related to NSI-189, and (ii) a license related to NSI-532.IGF-1.

NSI-189 – Exclusive License and Subsequent Exercise of Purchase Option

Prior to the Merger, Seneca exclusively licensed certain patents and technologies, including a sublicense covering a synthetic intermediate, of our NSI-189 assets ("189 License"), along with a purchase option through December 16, 2023 ("Purchase Option"). On October 22, 2021, Alto Neuroscience ("Alto") agreed to terms of an early exercise of the Purchase Option under the 189 License and entered into an asset transfer agreement ("ATA"). Alto is a U.S.-based

public, clinical-stage biopharmaceutical company with a mission to redefine psychiatry by leveraging neurobiology to develop personalized and highly effective treatment options.

Pursuant to the terms of the CVR Agreement, no distribution was required to be made to the CVR Holders because the CVR Payment Amount after deducting costs and expenses required to maintain the 189 License was less than $0.3 million. In accordance with the terms of the CVR Agreement, the net proceeds from the sale of the NSI-189 assets, less any applicable transaction costs and expenses, were deposited into the CVR escrow to be used to pay costs and expenses associated with the monetization of our other Legacy Technologies.

In addition, Alto will be required to pay us up to an aggregate of $4.5 million upon the achievement of certain development and regulatory approval milestones for NSI-189 (or a product containing or otherwise derived from NSI-189), which is now known as ALTO-100. If Alto sells or grants to a third party a license to the patents and other rights specific to ALTO-100 prior to the achievement of a specified clinical development milestone, Alto will be required to pay us a low-double digit percentage of any consideration received by Alto from such license or sale, provided that the maximum aggregate consideration Alto will be required to pay to us under the ATA, including the upfront payment and all potential milestones and transaction-related payments, will not exceed $5.0 million.

Alto has successfully completed a Phase 2a clinical trial of ALTO-100 and is currently enrolling a Phase 2b clinical trial from which topline data is expected in the second half of 2024. Upon the enrollment of a patient in a Phase 3 clinical trial of ALTO-100, a milestone payment of $1.5 million will be due from Alto under the ATA. If this occurs within 48-months of the closing of the Merger, the CVR Holders will be entitled to a CVR Payment Amount, with the remaining 20% of the net proceeds deposited into the CVR escrow. If the milestone is met after 48-months of the closing of the Merger, all the net proceeds will be paid to us. There can be no assurance that CVR holders will receive CVR Payment Amounts from the sale of the NSI-189 assets.

NSI-532.IGF-1

On October 27, 2022, we entered an agreement to license NSI-532.IGF-1 to the Regents of the University of Michigan ("University of Michigan") for maintaining NSI-532.IGF-1 cell lines, continued development, maintaining patent protection, and seeking licensees. We received no upfront fees for the license. NSI-532.IGF-1 is a pre-clinical cell therapy being investigated as a potential therapy for prevention and treatment of Alzheimer’s disease. The University of Michigan shall bear 100% of the costs for patent filing, prosecution, maintenance, and enforcement of the patent rights. We will receive 50% of net revenues received by the University of Michigan from the licensing of patent rights through the last-to-expire patent in patent rights, unless otherwise earlier terminated, less all reasonable and actual out-of-pocket costs incurred in the litigation of patent rights. There can be no assurance that NSI-532.IGF-1 will ever be successfully monetized or that CVR holders will receive CVR Payment Amounts from the sale of the NSI-532.IGF-1 assets.

Human Capital Resources

Overview

As of December 31, 2023, we had nine full-time employees and no part-time employees. Of these full-time employees, four employees are engaged in primarily research and development activities and five employees are primarily engaged in finance, corporate strategy and business development, and other general administrative functions. We engage a number of temporary employees and consultants to assist with finance, operations, human resources, legal, investor relations and information technology functions, as well as, to the extent needed, our pre-clinical and clinical operations. We have no collective bargaining agreements with our employees, and we have not experienced any work stoppages. We had a reduction-in-workforce on October 27, 2023, which consisted primarily of a reduction of approximately 25% in workforce to better align our resources with our proposed business plan.

We consider our relations with our employees to be good.

Compensation, Benefits, and Professional Development

Our compensation programs, including our equity incentive programs, are designed to align our employees' interests with the drivers of growth and stockholder returns by supporting achievement of our primary business goals. Our goal is to attract and retain employees whose talents, expertise, leadership, and contributions are expected to support and facilitate growth and drive long-term stockholder value. Consequently, we provide employee wages that we believe are competitive within our industry, and we regularly evaluate the effectiveness of our compensation and benefit

programs against industry benchmarks. We seek to align our employees' interests with those of stockholders by linking annual changes in compensation to overall company performance, as well as each individual's contribution to the results achieved. The emphasis on overall company performance is intended to align the employee's financial interests with the interests of shareholders. We are also committed to providing comprehensive benefit options and it is our intention to offer benefits that will allow our employees and their families to live healthier and more secure lives. All employees are eligible for medical, dental, and vision insurance, paid and unpaid leaves, group life and personal accident insurance coverage as well as the option to participate in our 401(k) plan and supplemental group life and short-term disability coverage.

Corporate Information

The registrant was originally incorporated in 2001 in the State of Delaware under the name Neuralstem, Inc. In October of 2019, Neuralstem, Inc. changed its name to Seneca Biopharma, Inc. In April of 2021, we effected the Merger, whereby LBS became a wholly owned subsidiary of Seneca. In April of 2021, we changed our name from Seneca Biopharma, Inc. to Palisade Bio, Inc. Our principal executive offices are located at 7750 El Camino Real, Suite 2A, Carlsbad, California 92009, our telephone number is (858) 704-4900 and our website address is www.palisadebio.com.

The information on our website is not incorporated by reference in this annual report on Form 10-K or in any other filings we make with the Securities and Exchange Commission ("SEC"). We make available on or through our website certain reports and amendments to those reports that we file with or furnish to the SEC in accordance with the Securities Exchange Act of 1934, as amended. These include our annual reports on Form 10-K, our quarterly reports on Form 10-Q, and our current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act. We make this information available on or through our website free of charge as soon as reasonably practicable after we electronically file the information with, or furnish it to, the SEC.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. We have described below a number of uncertainties and risks that, in addition to uncertainties and risks presented elsewhere in this Annual Report, may adversely affect our business, operating results and financial condition. The uncertainties and risks enumerated below as well as those presented elsewhere in this Annual Report should be considered carefully when evaluating us, our business and the value of our securities. On September 1, 2023, we announced that we had entered into the Giiant License Agreement with Giiant for the exclusive worldwide license to Giiant's assets. As a result, we changed our strategic focus.

Risks Related to our Development, Commercialization and Regulatory Approval of our Investigational Therapies

Our business depends on the successful pre-clinical and clinical development, regulatory approval, and commercialization of our recently licensed therapeutic compound, including our lead asset PALI-2108.

On September 1, 2023, we announced that we had entered into the Giiant License Agreement, pursuant to which we licensed all of Giiant's current and future technologies, including PALI-2108. PALI-2108 is a pre-clinical asset and is our only asset being actively developed. Our success depends on the development of PALI-2108, which is subject to a number of risks, including:

- the continued enforceability of our research collaboration and license agreement with Giiant;
- the successful completion of our IND or CTA enabling studies and research;
- the submission and approval of an IND or CTA;
- our ability to develop and implement clinical trial designs and protocols;
- the successful initiation and completion of our planned pre-clinical studies and clinical trials;
- the approval by the FDA or other regulatory authority to commence the marketing of our product candidates;
- the ability for us and third-parties, if applicable, to achieve and maintain compliance with our contractual obligations and applicable regulatory requirements;

- the ability of our contract manufacturers to manufacture sufficient supply of our product candidates to meet the required pre-clinical studies and clinical trial supplies;
- the ability of our contract manufacturers to remain in good standing with regulatory agencies and to develop, validate and maintain commercially viable manufacturing facilities and processes that are compliant with cGMP;
- our ability to obtain favorable labeling for our product candidates through regulators that allows for successful commercialization;
- acceptance by physicians, insurers, payors, and patients of the beneficial quality, safety and efficacy of our product candidates, if approved, including relative to alternative and competing treatments;
- our ability to price our product candidates to recover our development costs and applicable milestone or royalty payments, and generate a satisfactory profit margin; and
- our ability and our applicable collaboration and licensing partners' ability to establish and enforce intellectual property rights related to our product candidates and technologies.

If we do not achieve one or more of these factors, many of which are beyond our control, in a timely manner or at all, we could experience significant delays or an inability to obtain regulatory approvals or commercialize our proposed product candidate. Such delays may result in increased costs and the failure to complete any required regulatory activity. Even if regulatory approvals are obtained, we may never be able to successfully commercialize our product candidates. Accordingly, we cannot make assurances that we will ever be able to generate sufficient revenue through the sale of any product candidates, if approved, to internally fund our business.

There are substantial risks inherent in drug development, and, as a result, we may not be able to successfully develop PALI-2108.

Our research and development efforts are focused on a therapeutic based on PDE4 inhibitors. Our development of PALI-2108 is in the early stages. However, such technology's commercial feasibility and acceptance in our target indication of inflammatory bowel disease are unknown. Scientific research and development requires significant amounts of capital and takes a long time to reach commercial viability, if it can be achieved at all. During the research and development process, we may experience technological barriers that we may be unable to overcome. Further, certain underlying premises in our development programs have not been proven. Because of these and similar uncertainties, it is possible that our product candidates will not reach commercialization. If we are unable to successfully develop and commercialize our product candidates, we will be unable to generate revenue or build a sustainable or profitable business.

We depend on our license agreement with Giiant to permit us to use patents and patent applications relating to PALI-2108. Termination of these rights or the failure to comply with obligations under this agreement could materially harm our business and prevent us from developing or commercializing PALI-2108, our lead product candidate.

We are a party to a license agreement with Giiant under which we have been granted rights to patents and patent applications that are important to our business. We rely on this license agreement to be able to use various proprietary technologies that are material to our business, including certain trade secrets and patent applications that cover PALI-2108. Our rights to use this intellectual property and employ the inventions claimed in these patent applications and contained in the trade secrets are subject to the continuation of and our compliance with the terms of our license agreement. If we fail to comply with any of our obligations under the license agreement with Giiant, Giiant may have the right to terminate the license agreement, in which event we would not be able to continue the development of PALI-2108. Additionally, disputes may arise under the license agreement regarding the intellectual property that is subject to such license agreement. If disputes over intellectual property that we have licensed, or in the future may license, prevent or impair our ability to maintain any of our license agreements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates and technologies.

Pre-clinical and clinical drug development is very expensive, time-consuming and uncertain.

The pre-clinical and clinical development of product candidates is very expensive, time-consuming, difficult to design and implement, and the outcomes are inherently uncertain. Most product candidates that commence clinical trials are never approved by regulatory authorities for commercialization and of those that are approved, many do not cover

their costs of development. In addition, we, any partner with which we may in the future collaborate, the FDA, or other regulatory authorities, including state and local agencies and counterpart agencies in foreign countries, or institutional review boards ("IRB") at our trial sites, may suspend, delay, require modifications to or terminate our clinical trials, once begun, at any time.

We expect that our operations and development of PALI-2108 will require substantially more capital than we currently have, and we cannot guarantee when or if we will be able to secure such additional funding.

We have historically funded our operations and prior development efforts through the sale of our securities. Based on our existing cash resources and our current or future plan of operations, we do not have adequate capital to fund our anticipated operations through the completion of the development of PALI-2108. As a result, we may need to secure additional funding. If we are not able to obtain financing in the future or on acceptable terms, we may have to curtail our research and development efforts as well as our operations.

There can be no assurance that our product candidates will obtain regulatory approval.

The sale of human therapeutic products in the U.S. and foreign jurisdictions is subject to extensive and time-consuming regulatory approval, which requires, among other things:

- pre-clinical data required for the submission of an IND or CTA;
- controlled research and human clinical testing;
- establishment of the safety and efficacy of the proposed product candidate;
- government review and approval of a submission containing manufacturing, pre-clinical and clinical data; and
- adherence to cGMP regulations during production and storage.

The proposed product candidate we currently have under development, PALI-2108, will require significant development, pre-clinical and clinical testing and the investment of significant funds to gain regulatory approval before it can be commercialized. The results of our research and human clinical testing of PALI-2108 may not meet regulatory requirements. If approved, PALI-2108 may also require the completion of post-market studies. There can be no assurance that PALI-2108 will be successfully developed and approved. The process of completing pre-clinical and clinical testing and obtaining the required approvals is expected to take a number of years and require the use of substantial resources. Further, there can be no assurance that PALI-2108 will be shown to be safe and effective in clinical trials or receive applicable regulatory approvals. If we fail to obtain regulatory approvals, it will not be able to market PALI-2108 and our operations may be adversely affected.

If pre-clinical and clinical studies of PALI-2108 do not yield successful results, then we may not continue to develop PALI-2108.

We must demonstrate that PALI-2108 is safe and efficacious in humans through extensive pre-clinical and clinical testing. Our research and development programs are at an early stage of development. We may experience numerous unforeseen events during, or as a result of, the testing process that could delay or prevent commercialization of any products, including the following:

- the results of pre-clinical studies may be inconclusive, or they may not be indicative of results that will be obtained in human clinical trials;
- safety and efficacy results attained in early human clinical trials, if approved, may not be indicative of results that are obtained in later clinical trials;
- after reviewing test results, we may abandon projects that it previously believed to be promising;
- we or our regulators may suspend or terminate our clinical trials because the participating subjects or patients are being exposed to unacceptable health risks; and
- PALI-2108 may not have the desired effects or may include undesirable side effects or other characteristics that preclude regulatory approval or limit their commercial use if approved.

It may take us longer than we estimate to complete pre-clinical studies and clinical trials, and we may not be able to complete them at all.

Although for planning purposes we project the commencement, continuation and completion of our pre-clinical studies and clinical trials; a number of factors, including scheduling conflicts with participating researchers and/or clinicians and research or clinical institutions, and difficulties in identifying or enrolling patients who meet trial eligibility criteria, may cause significant delays. We may not commence or complete pre-clinical studies or clinical trials involving PALI-2108 as currently contemplated or may not be able to conduct them successfully.

Even if our clinical studies are successful and achieve regulatory approval, the approved product label may be more limited than we anticipate, which could limit the commercial prospects of PALI-2108.

At the time therapeutic drugs are approved for marketing, they are given a "product label" from the FDA or other regulatory body. In most countries this label sets forth the approved indication for marketing, and identifies potential safety concerns for prescribing physicians and patients. While we intend to seek as broad a product label as possible for PALI-2108, we may receive a narrower label than is expected by either us or third parties, such as stockholders and securities analysts. For example, any approved products may only be indicated to treat refractory patients (i.e., those who have failed some other first-line therapy). Similarly, it is possible that only a specific sub-set of patients safely responds to PALI-2108. As a result, even if successful in clinical trials, PALI-2108 could be approved only for a subset of patients. Additionally, safety considerations may result in contraindications that could further limit the scope of an approved product label. Any of these or other safety and efficacy considerations could limit the commercial prospects of PALI-2108.

Even if PALI-2108 is approved for commercialization, future regulatory reviews or inspections may result in its suspension or withdrawal, closure of a facility or substantial fines.

If regulatory approval to sell PALI-2108 is received, regulatory agencies will subject PALI-2108, as well as the manufacturing facilities, to continual review and periodic inspection. If previously unknown problems with a product or manufacturing and laboratory facility are discovered, or we fail to comply with applicable regulatory approval requirements, a regulatory agency may impose restrictions on PALI-2108 or us. The agency may require the withdrawal of PALI-2108 from the market, closure of the facility or substantial fines.

We may in the future conduct clinical trials for PALI-2108 outside the United States, and the FDA or applicable foreign regulatory authorities may not accept data from such trials.

We may in the future choose to conduct clinical trials outside of the U.S. Although the FDA or applicable foreign regulatory authority may accept data from clinical trials conducted outside the U.S. or the applicable jurisdiction, acceptance of such study data by the FDA or applicable foreign regulatory authority may be subject to certain conditions or exclusion. Where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless such data are applicable to the U.S. population and U.S. medical practice; the studies were performed by clinical investigators of recognized competence; and the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Many foreign regulatory bodies have similar requirements. In addition, such foreign studies would be subject to the applicable local laws of the foreign jurisdictions where the studies are conducted. There can be no assurance the FDA or applicable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable home country. If the FDA or applicable foreign regulatory authority does not accept such data, it would likely result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan.

We anticipate relying on third-party CROs and other third parties to conduct and oversee our pre-clinical studies and clinical trials. If these third parties do not meet our requirements or otherwise conduct the studies or trials as required, we may not be able to satisfy our contractual obligations or obtain regulatory approval for, or commercialize, our product candidates.

We may rely on third-party CROs to conduct and oversee our anticipated pre-clinical studies and clinical trials and other aspects of product development. We also expect to rely on various medical institutions, clinical investigators and contract laboratories to conduct our trials in accordance with our clinical protocols and all applicable regulatory requirements, including the FDA's regulations and good clinical practice ("GCP") requirements, which are an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors,

administrators and monitors, and state regulations governing the handling, storage, security and recordkeeping for drug and biologic products. These CROs and other third parties are expected to play a significant role in the conduct of these trials and the subsequent collection and analysis of data from the clinical trials. We expect to rely heavily on these parties for the execution of our clinical trials and pre-clinical studies and will control only certain aspects of their activities. We and our CROs and other third-party contractors will be required to comply with GCP and good laboratory practice ("GLP") requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities. Regulatory authorities enforce these GCP and GLP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP and GLP requirements, or reveal noncompliance from an audit or inspection, any clinical data generated in our clinical trials may be deemed unreliable and the FDA or other regulatory authorities may require us to perform additional clinical trials before approving our or our partners' marketing applications. We cannot assure that upon inspection by a given regulatory authority, such regulatory authority will determine whether or not any of our clinical or pre-clinical trials comply with applicable GCP and GLP requirements. In addition, our clinical trials generally must be conducted with compounds produced under cGMP regulations. Our failure to comply with these regulations and policies may require it to repeat clinical trials, which would be costly and delay the regulatory approval process. If any of our CROs were to terminate their involvement with us, there is no assurance that we would be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms.

The successful commercialization of PALI-2108, if approved, will depend in part on the extent to which government authorities and health insurers establish adequate reimbursement levels and pricing policies.

Sales of any approved drug candidate will depend in part on the availability of coverage and reimbursement from third-party payers such as government insurance programs, including Medicare and Medicaid, private health insurers, health maintenance organizations and other health care related organizations, who are increasingly challenging the price of medical products and services. Accordingly, coverage and reimbursement may be uncertain. Adoption of any drug by the medical community may be limited if third-party payers will not offer coverage. Additionally, significant uncertainty exists as to the reimbursement status of newly approved drugs. Cost control initiatives may decrease coverage and payment levels for any drug and, in turn, the price that we will be able to charge and/or the volume of our sales. We are unable to predict all changes to the coverage or reimbursement methodologies that will be applied by private or government payers. Any denial of private or government payer coverage or inadequate reimbursement could harm our business or future revenues, if any. If we partner with third parties with respect to any of our product candidates, we may be reliant on that partner to obtain reimbursement from government and private payors for the drug, if approved, and any failure of that partner to establish adequate reimbursement could have a negative impact on our revenues and profitability.

In addition, both the federal and state governments in the United States and foreign governments continue to propose and pass new legislation, regulations, and policies affecting coverage and reimbursement rates, which are designed to contain or reduce the cost of health care. Further federal and state proposals and healthcare reforms are likely, which could limit the prices that can be charged for the product candidates that we develop and may further limit our commercial opportunity. There may be future changes that result in reductions in potential coverage and reimbursement levels for our product candidates, if approved and commercialized, and we cannot predict the scope of any future changes or the impact that those changes would have on our operations.

If future reimbursement for PALI-2108, subject to approval, are substantially less than projected, or rebate obligations associated with them are substantially greater than expected, our future net revenue and profitability, if any, could be materially diminished.

We face potential product liability exposure, and if successful claims are brought against us, it may incur substantial liability for a product candidate and may have to limit our commercialization.

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by clinical trial participants, consumers, health-care providers, pharmaceutical companies, or others selling our products. If we cannot successfully defend ourselves against these claims, it may incur substantial liabilities. Regardless of merit or eventual outcomes of such claims, product liability claims may result in:

- decreased demand for our product candidates;
- impairment of our business reputation;

- withdrawal of clinical trial participants;
- costs of litigation;
- substantial monetary awards to patients or other claimants; and
- loss of revenues.

Our insurance coverage may not be sufficient to reimburse it for all expenses or losses it may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect it against losses.

Even if a product candidate obtains regulatory approval, it may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success.

The commercial success of our product candidates, if approved, will depend significantly on attaining broad adoption and use of the drug by physicians and patients. The degree and rate of physician and patient adoption of a product, if approved, will depend on a number of factors, including but not limited to:

- patient demand for approved products that treat the indication for which they are approved;
- the effectiveness of a product compared to other available therapies or treatment regimens;
- the availability of coverage and adequate reimbursement from managed care plans and other healthcare payors;
- the cost of treatment in relation to alternative treatments and willingness to pay on the part of patients;
- insurers' willingness to see the applicable indication as a disease worth treating;
- proper administration by physicians or patients;
- patient satisfaction with the results, administration and overall treatment experience;
- limitations or contraindications, warnings, precautions or approved indications for use different than those sought by us that are contained in the final FDA-approved labeling, or other authoritative regulatory body approved labeling, for the applicable product;
- any FDA requirement, or other authoritative regulatory body requirement, to undertake a risk evaluation and mitigation strategy;
- the effectiveness of our sales, marketing, pricing, reimbursement and access, government affairs, and distribution efforts;
- adverse publicity about a product or favorable publicity about competitive products;
- new government regulations and programs, including price controls and/or limits or prohibitions on ways to commercialize drugs, such as increased scrutiny on direct-to-consumer advertising of pharmaceuticals; and
- potential product liability claims or other product-related litigation.

If any of our product candidates are approved for use but fail to achieve the broad degree of physician and patient adoption necessary for commercial success, our operating results and financial condition will be adversely affected, which may delay, prevent or limit our ability to generate revenue and continue our business.

We have entered into a collaborative research agreement with Giiant related to pre-clinical development, which will require the efforts of Giiant and its personnel, which are out of our control.

The license agreement with Giiant provides for certain joint research and development of PALI-2108 related to pre-clinical studies and development. Our business strategy relies on such collaboration to shorten the time required to file and IND and accelerate the knowledge transfer of trade secrets and other know-how associated with the licensed technologies. Overall, the success of the development PALI-2108 will depend on our ability to manage such relationship, and to a certain extent, to the efforts of Giiant, which are beyond our control.

Risks Related to our Business

We have a limited operating history and have never generated any revenues from product sales.

We are a biopharmaceutical company with a limited operating history that may make it difficult to evaluate the success of our business to date and to assess our future viability. We were initially formed in 2001 and our operations, to date, have been limited to business planning, raising capital and other research and development activities related to our product candidates. We have not yet demonstrated an ability to successfully complete any clinical trials and has never completed the development of any product candidate, nor has it ever generated any revenue from product sales or otherwise. Consequently, we have no meaningful operations upon which to evaluate our business, and predictions about our future success or viability may not be as accurate as they could be if it had a longer operating history or a history of successfully developing and commercializing biopharmaceutical products.

Our business model assumes revenue from, among other activities, marketing or out-licensing the products we develop. PALI-2108 is in the early stages of development and because we have a short development history with PALI-2108, there is a limited amount of information about us upon which you can evaluate our business and prospects.

We have no approved drugs and thus have not begun to market or generate revenues from the commercialization of any products. We recently in-licensed PALI-2108 and accordingly, we only have a limited history upon which we can evaluate our ability to develop PALI-2108 as it is still at an early stage of development. Thus, we have limited experience and have not yet demonstrated our ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area.

For example, to execute our business plan, we will need to:

- Execute product development activities using unproven technologies;
- Build, maintain, and protect a strong intellectual property portfolio;
- Demonstrate safety and efficacy of our drug candidates in multiple human clinical studies;
- Receive FDA approval and approval from similar foreign regulatory bodies;
- Gain market acceptance for the development and commercialization of any drugs we develop;
- Ensure our products are reimbursed by commercial and/or government payors at a rate that permits commercial viability;
- Develop and maintain successful strategic relationships with suppliers, distributors, and commercial licensing partners;
- Manage our spending and cash requirements as our expenses will increase in the near term if we add programs and additional pre-clinical and clinical trials; and
- Effectively market any products for which we obtain marketing approval.

If we are unsuccessful in accomplishing these objectives, we may not be able to develop our proposed products, raise capital, expand our business or continue our operations.

We have received a delisting notification from the Nasdaq Stock Market based on our Bid Price being under $1.00 for thirty (30) consecutive trading days. If we are not able to regain compliance with the applicable continued listing requirements or standards of The Nasdaq Capital Market, Nasdaq could delist our common stock.

Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if we are delisted from the Nasdaq Capital Market or if we are unable to transfer our listing to another stock market. In order to maintain this listing, we must satisfy minimum financial and other continued listing requirements and standards, including a requirement to maintain a minimum bid price of our common stock of $1.00 per share ("Minimum Bid Price Requirement"). On October 19, 2023, we received notice (the "Notice") from the Nasdaq Stock Market LLC ("Nasdaq") advising us that for 30 consecutive trading days preceding the date of the Notice, the bid price of our common stock had closed below the $1.00 per share minimum required for continued listing on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2). Under Nasdaq Listing Rule 5810(c)(3)(A), we have until April 16, 2024 to regain compliance with the Minimum Bid Price Requirement. If at any time during this period the

closing bid price of our common stock is at least $1.00 for a minimum of 10 consecutive business days, we will regain compliance with the Minimum Bid Price Requirement and our common stock will continue to be eligible for listing on The Nasdaq Capital Market absent noncompliance with any other requirement for continued listing. In the event that we do not regain compliance by April 16, 2024, we may be eligible for an additional 180 calendar day grace period if we meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market with the exception of bid price, and we provide written notice to Nasdaq of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary.

If we do not regain compliance within the allotted compliance period, including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that our common stock will be subject to delisting. We will then be entitled to appeal the determination to a Nasdaq Listing Qualifications Panel and request a hearing. We cannot be sure that our share price will comply with the requirements for continued listing of our shares on the Nasdaq Capital Market in the future or that it will comply with the other continued listing requirements.

Notwithstanding, we cannot assure you that, in the future, our securities will meet the continued listing requirements to be listed on Nasdaq. If our common stock is delisted by Nasdaq, it could lead to a number of negative implications, including an adverse effect on the price of our common stock, increased volatility in our common stock, reduced liquidity in our common stock, a limited availability of market quotations for our common stock, the loss of federal preemption of state securities laws and greater difficulty in obtaining financing. In addition, delisting of our common stock could deter broker-dealers from making a market in or otherwise seeking or generating interest in our common stock, could result in a loss of current or future coverage by certain sell-side analysts and might deter certain institutions and persons from investing in our securities at all. Delisting could also cause a loss of confidence from our collaborators, vendors, suppliers and employees, which could harm our business and future prospects.

If our common stock is delisted by Nasdaq, our common stock may be eligible to trade on the OTC Bulletin Board, OTCQB or another over-the-counter market. Any such alternative would likely result in it being more difficult for us to raise additional capital through the public or private sale of equity securities and for investors to dispose of, or obtain accurate quotations as to the market value of, our common stock. In addition, there can be no assurance that our common stock would be eligible for trading on any such alternative exchange or markets. Moreover, if our common stock is delisted, it may come within the definition of "penny stock" under the Exchange Act, which imposes additional sales practice requirements on broker-dealers who sell securities to persons other than established customers and accredited investors. For example, we and/or broker-dealers are required to make a special suitability determination for purchases of such securities and must receive a purchaser's written consent to the transaction prior to any purchase. Additionally, unless exempt, prior to a transaction involving a penny stock, the penny stock rules require the delivery of a disclosure schedule prescribed by the SEC relating to the penny stock market. The broker-dealer must also disclose the commissions payable to the broker-dealer, current quotations for the securities and, if the broker-dealer is the sole market-maker for the security, the fact that they are the sole market-maker and their presumed control over the market. Finally, monthly statements disclosing recent price information on the limited market in penny stocks must be sent to holders of such penny stocks. These requirements may reduce trading activity in the secondary market for our common stock and may impact the ability or willingness of broker-dealers to sell our securities, which could limit the ability of stockholders to sell their securities in the public market.

We have received a notification from the Nasdaq Stock Market that our audit committee does not have three (3) independent members as a result of recent director resignations. If we fail to timely appoint an independent director that meets the Nasdaq Stock Market Requirements for audit committees, Nasdaq could delist our common stock.

Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if we are delisted from the Nasdaq Capital Market or if we are unable to transfer our listing to another stock market. In order to maintain this listing, we must satisfy certain continued listing standards, including but not limited to the composition of our Audit Committee. On March 22, 2024, we received a notice from Nasdaq stating that pursuant to the recent resignation of certain members of the Board of Directors ("Board"), we became noncompliant with the requirements set forth in Nasdaq Listing Rule 5605(c)(2)(A), which requires us to have an audit committee of at least three (3) independent directors. We currently only have two (2) independent directors serving on the Audit Committee.

The Notice states that, consistent with Nasdaq Listing Rule 5605(c)(4), Nasdaq will provide us with a cure period in order to regain compliance (i) until the earlier of the Company's next annual shareholders' meeting or March 4, 2025,

or (ii) if the next annual shareholders' meeting is held before September 3, 2024, then we must evidence compliance no later than September 3, 2024.

If we do not regain compliance within the allotted compliance period, including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that our common stock will be subject to delisting. We will then be entitled to appeal the determination to a Nasdaq Listing Qualifications Panel and request a hearing. We cannot be sure that we will be able to appoint a new director, with suitable experience and expertise to serve on our Audit Committee to comply with the requirements for continued listing of our shares on the Nasdaq Capital Market in the future or that we will be able to comply with the other continued listing requirements.

Our success depends on attracting and retaining senior management and scientists with relevant expertise.

Our future success depends to a significant extent on the continued services of our key employees, including our senior scientific, technical and managerial personnel. We do not maintain key person life insurance for any of our executives and we do not maintain employment agreements with many senior employees. Competition for qualified employees in the pharmaceutical industry is high, and our ability to execute our strategy will depend in part on our ability to continue to attract and retain qualified scientists and management. If we are unable to find, hire and retain qualified individuals, it will have difficulty implementing our business plan in a timely manner, or at all.

We may choose to discontinue developing or commercializing any of our product candidates, or may choose to not commercialize product candidates in approved indications, at any time during development or after approval, which could adversely affect us and our operations.

At any time, we may decide to discontinue the development of, or temporarily pause the development of, any of our product candidates then in existence, for a variety of reasons, including the appearance of new technologies that make our product candidates obsolete, competition from a competing product or changes in or failure to comply with applicable regulatory requirements. If we temporarily pause or terminate a program in which we have invested significant resources, we will not receive any return on our investment and we will have missed the opportunity to have allocated those resources to potentially more productive uses, which could have an adverse effect on us and our business.

Our inability to successfully in-license, acquire, develop and market additional product candidates or approved products could impair our ability to grow our business.

PALI-2108 is currently our only product candidate being actively developed. We may in-license, acquire, develop and market additional products and product candidates. Since our internal research and development capabilities are limited, it may be dependent on pharmaceutical companies, academic or government scientists and other researchers to sell or license products or technology to it. The success of this strategy depends partly on our ability to identify and select promising pharmaceutical product candidates and products, negotiate licensing or acquisition agreements with their current owners, and finance these arrangements.

The process of identifying, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing, sales and other resources, may compete with us for the license or acquisition of product candidates and approved products. Moreover, we may devote resources to potential acquisitions or licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that it finds acceptable or at all.

Further, any product candidate that we acquire or licenses may require additional development efforts prior to commercial sale, including pre-clinical or clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any approved products that it acquires will be manufactured or sold profitably or achieve market acceptance.

We may seek to avail ourselves of mechanisms to expedite the development or approval for product candidates it may pursue in the future, such as Fast Track or breakthrough designation, but such mechanisms may not actually lead to a faster development or regulatory review or approval process.

We may seek to avail ourselves of Fast Track designation, breakthrough designation, or priority review for product candidates it may pursue in the future. For example, if a drug is intended for the treatment of a serious or

life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA Fast Track designation. However, the FDA has broad discretion with regard to these mechanisms, and even if we believe a particular product candidate is eligible for any such mechanism, it cannot guarantee that the FDA would decide to grant it. Even if we believe a product candidate meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. Even if it does obtain Fast Track or priority review designation or pursue an accelerated approval pathway, we may not experience a faster development process, review, or approval compared to conventional FDA procedures. The FDA may withdraw a particular designation if it believes that the designation is no longer supported by data from our clinical development program.

Risks Related to our Dependence on Third Parties

We expect to rely on collaborations with third parties for the successful development and commercialization of our product candidates.

We expect to rely upon the efforts of third parties for the successful development and commercialization of our product candidates. The clinical and commercial success of our product candidates may depend upon maintaining successful relationships with third-party partners, which are subject to a number of significant risks, including the following:

- our partners' ability to execute their responsibilities in a timely, cost-efficient and compliant manner;
- reduced control over delivery and manufacturing schedules;
- price increases;
- manufacturing deviations from internal or regulatory specifications;
- quality incidents;
- the failure of partners to perform their obligations for technical, market or other reasons;
- misappropriation of our product candidates; and
- other risks in potentially meeting our product commercialization schedule or satisfying the requirements of our end-users.

We cannot provide any assurance that we will be able to establish or maintain third-party relationships in order to successfully develop and commercialize our product candidates.

We anticipate relying completely on third-party contractors to supply, manufacture and distribute clinical drug supplies for our product candidates.

We do not currently have, nor do we plan to acquire, the infrastructure or capability to supply, store, manufacture or distribute pre-clinical, clinical or commercial quantities of drug substances or products. Additionally, we have not entered into a long-term commercial supply agreement to provide us with such drug substances or products. As a result, our ability to develop and commercialize, if approved, our product candidates is dependent on our ability to obtain the APIs and other substances and materials used in our product candidates successfully from third parties and to have finished products manufactured by third parties in accordance with regulatory requirements and in sufficient quantities for pre-clinical and clinical testing and commercialization. If we fail to develop and maintain supply and other technical relationships with these third parties, we may be unable to continue to develop or commercialize our products and product candidates, which could adversely affect us and our business.

We are dependent on our contract suppliers and manufacturers for day-to-day compliance with applicable laws and cGMP for production of our proposed products and API. If the safety or quality of any product or product candidate or component is compromised due to a failure to adhere to applicable laws or for other reasons, we may not be able to commercialize or obtain regulatory approval for the affected product or product candidates successfully, and we may be held liable for injuries sustained as a result.

We expect to continue to depend on third-party contract suppliers and manufacturers. Our supply and manufacturing agreements do not guarantee that a contract supplier or manufacturer will provide services adequate for our needs. Additionally, any damage to or destruction of our third-party manufacturers' or suppliers' facilities or equipment, even by force majeure, may significantly impair our ability to have our products and product candidates manufactured on a timely basis. Our reliance on contract manufacturers and suppliers further exposes us to the possibility that they,

or third parties with access to their facilities, may misappropriate our trade secrets or other proprietary information. In addition, the manufacturing facilities of certain of our suppliers may be located outside of the United States. This may give rise to difficulties in importing our products or product candidates or their components into the United States or other countries.

Risks Related to Our Financial Operations

We have expressed substantial doubt about our ability to continue as a going concern.

Management has determined that there is substantial doubt about our ability to continue as a going concern for a period of one year following the issuance of this report. This determination was based on conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the financial statements are issued, including: (i) the probability that significant changes to our anticipated level of operations, due to factors that are within or outside of our control, would cause our available cash as of the date of this filing to not be sufficient to fund our anticipated level of operations for the next 12 months; and (ii) the uncertainties of the cost and timing of our efforts to in-license or acquire a new product candidate. Our future consolidated financial statements may include a similar qualification about our ability to continue as a going concern. Our year-end and interim consolidated financial statements were prepared assuming that it will continue as a going concern and do not include any adjustments that may result from the outcome of this uncertainty.

If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all.

We have a history of net losses, and we expect to continue to incur net losses and may never achieve profitability.

We have incurred net losses since our inception, including net losses of $12.3 million and $14.3 million for the years ended December 31, 2023 and December 31, 2022, respectively. We expect that our operating losses will continue for the foreseeable future as it continues our drug development and discovery efforts. To achieve profitability, we must, either directly or through licensing and/or partnering relationships, meet certain milestones, successfully develop and obtain regulatory approval for one or more drug candidates and effectively manufacture, market and sell any drugs we successfully develop. Even if we are able to successfully commercialize product candidates that receive regulatory approval, it may not be able to realize revenues at a level that would allow it to achieve or sustain profitability. Accordingly, we may never generate significant revenue and, even if it does generate significant revenue, it may never achieve profitability.

Failure to remediate a material weakness in internal controls over financial reporting could result in material misstatements in our consolidated financial statements.

Our management has identified a material weakness in our internal control over financial reporting. The material weakness was due to a lack of controls in the financial closing and reporting process, including a lack of segregation of duties and the documentation and design of formalized processes and procedures surrounding the creation and posting of journal entries and account reconciliations.

If our remaining material weakness, which management concluded is still present as of the date of these financial statements, is not remediated, or if we identify further material weaknesses in our internal controls, our failure to establish and maintain effective disclosure controls and procedures and internal control over financial reporting could result in material misstatements in our consolidated financial statements and a failure to meet our reporting and financial obligations.

Changing circumstances and market conditions, some of which may be beyond our control, could impair our ability to access our existing cash and cash equivalents and investments and to timely pay key vendors and others.

Changing circumstances and market conditions, some of which may be beyond our control, could impair our ability to access our existing cash and cash equivalents and investments and to timely pay key vendors and others. For example, on March 10, 2023, Silicon Valley Bank ("SVB") was placed into receivership with the Federal Deposit Insurance Corporation ("FDIC"), which resulted in all funds held at SVB being temporarily inaccessible by SVB's customers. Although we do not have any funds at SVB, if other banks and financial institutions with whom we have banking relationships enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, we may be unable to access, and we may lose, some or all of our existing cash and cash equivalents to the extent those funds are not insured or otherwise protected by the FDIC. In addition, in

such circumstances we might not be able to timely pay key vendors and others. We regularly maintain cash balances that are not insured or are in excess of the FDIC's insurance limit. Any delay in our ability to access our cash and cash equivalents (or the loss of some or all of such funds) or to timely pay key vendors and others could have a material adverse effect on our operations and cause it to need to seek additional capital sooner than planned.

Risks Related to Our Intellectual Property

We may not be able to obtain, maintain or enforce global patent rights or other intellectual property rights that cover our product candidates and technologies that are of sufficient breadth to prevent third parties from competing against us.

Our success with respect to our current and future product candidates will depend, in part, on our ability to obtain and maintain patent protection in both the U.S. and other countries, to preserve our trade secrets and to prevent third parties from infringing on our proprietary rights. Our ability to protect our product candidates from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents around the world.

The patent application process, also known as patent prosecution, is expensive and time-consuming, and we and our current or future licensors and licensees may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner in all the countries that are desirable. It is also possible that we or our current licensors, or any future licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Moreover, our competitors independently may develop equivalent knowledge, methods and know-how or discover workarounds to our patents that would not constitute infringement. Any of these outcomes could impair our ability to enforce the exclusivity of any issued or pending patents we may have, which may have an adverse impact on our business, financial condition and operating results.

Our ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions especially across countries. Accordingly, rights under any existing patents or any patents we might obtain or license may not cover our product candidates or may not provide us with sufficient protection for our product candidates to afford a sustainable commercial advantage against competitive products or processes, including those from branded, generic and over-the-counter pharmaceutical companies. In addition, we cannot guarantee that any patents or other intellectual property rights will be issued from any pending or future patent or other similar applications owned by or licensed to us. Even if patents or other intellectual property rights have issued or will issue, we cannot guarantee that the claims of these patents and other rights are or will be held valid or enforceable by the courts, through injunction or otherwise, or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us in every country of commercial significance that we may target.

Our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. We do not have outstanding issued patents covering all of the recent developments in our technology and are unsure of the patent protection that we will be successful in obtaining, if any. Even if the patents do successfully issue, third parties may design around or challenge the validity, enforceability or scope of such issued patents or any other issued patents we own or license, which may result in such patents being narrowed, invalidated or held unenforceable. If the breadth or strength of protection provided by the patents we hold or pursue with respect to our product candidates are challenged, it could dissuade companies from collaborating with us to develop or threaten our ability to commercialize or finance our product candidates.

The laws of some foreign jurisdictions do not provide intellectual property rights to the same extent or duration as in the U.S., and many companies have encountered significant difficulties in acquiring, maintaining, protecting, defending and especially enforcing such rights in foreign jurisdictions. If we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property in foreign jurisdictions, our business prospects could be substantially harmed, especially internationally.

Proprietary trade secrets and unpatented know-how are also very important to our business. Although we have taken steps to protect our trade secrets and unpatented know-how by entering into confidentiality agreements with third parties, and intellectual property protection agreements with officers, directors, employees, and certain consultants and advisors, there can be no assurance that binding agreements will not be breached or enforced by courts, that we would have adequate remedies for any breach, including injunctive and other equitable relief, or that our trade secrets

and unpatented know-how will not otherwise become known, inadvertently disclosed by us or our agents and representatives, or be independently discovered by our competitors. If our trade secrets are independently discovered, we would not be able to prevent their use and if we or our agents or representatives inadvertently disclose trade secrets and/or unpatented know-how, we may not be allowed to retrieve these trade secrets and/or unpatented know-how and maintain the exclusivity it previously held.

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

Filing, prosecuting and defending patents on our product candidates does not guarantee exclusivity. The requirements for patentability differ in certain countries, particularly developing countries. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States, especially when it comes to granting use and other kinds of patents and what kind of enforcement rights will be allowed, especially injunctive relief in a civil infringement proceeding. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States and even in launching an identical version of our product notwithstanding we have a valid patent in that country. Competitors may use our technologies in jurisdictions where we have not obtained patent protection, or produce copy products, and, further, may export otherwise infringing products to territories where we have patent protection but enforcement on infringing activities is inadequate or where we have no patents. These products may compete with our products, and our patents or other intellectual property rights may not prevent them from competing.

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 non-compliance with these requirements.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the U.S. Patent and Trade Office ("USPTO") and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedures, including certain documentary, fee payment and other similar provisions during the patent application process. 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 just for failure to know about and/or timely pay a prosecution fee. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees in prescribed time periods, and failure to properly legalize and submit formal documents in the format and style the country requires. If we or our licensors fail to maintain the patents and patent applications covering our product candidates for any reason, our competitors might be able to enter the market, which would have an adverse effect on our business.

If we fail to comply with our obligations under our intellectual property license agreements, we could lose license rights that are important to our business.

We have entered into an in-license agreement with respect to our lead product candidate, PALI-2108. This license agreement imposes various diligence, milestone, royalty, insurance and other obligations on us. If we fail to comply with these obligations, the licensor may terminate the license. The loss of such rights would materially adversely affect our business, financial condition, operating results and prospects.

We may be subject to patent infringement claims, which could result in substantial costs, liabilities and prevent us from commercializing our potential products.

Because the intellectual property landscape in the fields in which we participate is rapidly evolving and interdisciplinary, it is difficult to conclusively assess our freedom to operate without infringing on third-party rights. If any patent infringement claims are brought against us, whether successful, we may incur significant expenses and divert the attention of our management and key personnel from other business concerns. This could negatively affect our results of operations and prospects. We cannot be certain that patents owned or licensed by us will not be challenged, potentially successfully, by others.

In addition, if our product candidates are found to infringe the intellectual property rights of third parties, these third parties may assert infringement claims against our customers, licensees and other parties with whom we have business relationships, and we may be required to indemnify those parties for any damages they suffer as a result of such claims. The claims may require us to initiate or defend protracted and costly litigation on behalf of customers, licensees, and

other parties regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of those parties or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, we may be unable to continue selling such products.

We may be subject to claims that our officers, directors, employees, consultants or independent contractors have wrongfully used or disclosed to us alleged trade secrets of their former employers or their former or current customers.

As is common in the biotechnology and pharmaceutical industries, certain of our employees were formerly employed by other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Moreover, we engage the services of consultants to assist us in the development of our product candidates, many of whom were previously employed at, or may have previously been or are currently providing consulting services to, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that our employees or consultants have inadvertently or otherwise wrongfully used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims. Even if we are successful in defending against any such claims, any such litigation could be protracted, expensive, a distraction to our management team, not viewed favorably by investors and other third parties, and may potentially result in an unfavorable outcome.

Other Risks Related to Our Securities

We will need to raise additional financing in the future to fund our operations, which may not be available to us on favorable terms or at all.

We will require substantial additional capital to fund our operations and conduct the costly and time-consuming research and development, pre-clinical studies, and clinical work necessary to pursue regulatory approval of product candidates. Our future capital requirements will depend upon a number of factors, including: the number and timing of product candidates in the pipeline; progress with and results from pre-clinical testing and clinical trials; the ability to manufacture sufficient drug supplies to complete pre-clinical and clinical trials; the costs involved in preparing, filing, acquiring, prosecuting, maintaining and enforcing patent and other intellectual property claims; and the time and costs involved in obtaining regulatory approvals and favorable reimbursement or formulary acceptance. Raising additional capital may be costly or difficult to obtain and could significantly dilute stockholders' ownership interests or inhibit our ability to achieve our business objectives. If we raise additional funds through public or private equity sales of our securities, the terms of these securities may include liquidation or other preferences that adversely impact the rights of our common stockholders. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, our stockholders' ownership percentage will be decreased. In addition, any debt financing may subject us to fixed payment obligations and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish certain valuable intellectual property or other rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. Even if we obtain additional funding, there can be no assurance that it will be available on terms acceptable to us or our stockholders.

Our common stock price may be highly volatile.

Since the completion of the merger with Seneca Biopharma, Inc., on April 27, 2021, our stock price has been subject to significant fluctuation. Market prices for securities of biotechnology and other life sciences companies historically have been particularly volatile and may be subject to large daily price swings. Some of the factors that may cause the market price of our shares to fluctuate include, but are not limited to:

- failure of our product candidates to show safety and/or efficacy in our pre-clinical or clinical trials;
- our ability to obtain timely regulatory approvals for our product candidates, and delays or failures to obtain such approvals;
- the results of pre-clinical or clinical trials, including our decision to pause or terminate any such trials;
- failure of our product candidates, if approved, to achieve commercial success;

- the entry into, or termination of, or breach by partners of key agreements, including the Giiant License Agreement;
- the initiation of, material developments in, or conclusion of any litigation to enforce or defend any intellectual property rights or defend against the intellectual property rights of others;
- announcements of any financings;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack of, significant contracts, commercial relationships or capital commitments;
- failure to elicit meaningful stock analyst coverage and downgrades of our stock by analysts; and
- the loss of key personnel.

Moreover, the stock markets in general have experienced substantial volatility in the biotechnology industry that has often been unrelated to the operating performance of individual companies or a certain industry segment. These broad market fluctuations may also adversely affect the trading price of our shares. In the past, following periods of volatility in the market price of a company's securities, shareholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

We take advantage of reduced disclosure and governance requirements applicable to smaller reporting companies, which could result in our common stock being less attractive to investors.

As of June 30, 2023, the last business day of our most recently completed second fiscal quarter, our public float is less than $250 million and therefore, we qualify as a smaller reporting company under SEC rules. As a smaller reporting company, we can take advantage of reduced disclosure requirements, such as simplified executive compensation disclosures and reduced financial statement disclosure requirements in our SEC filings. Such reduced disclosures in our SEC filings may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of the reporting exemptions applicable to a smaller reporting company until we are no longer a smaller reporting company, which status would end once we have a public float greater than $250 million. In that event, we could still be a smaller reporting company if our annual revenues are below $100 million and we have a public float of less than $700 million.

We do not anticipate paying any dividends in the foreseeable future.

The current expectation is that we will retain our future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our shares will be your sole source of gain, if any, for the foreseeable future.

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

The trading market for our common stock is and will be influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event it does have equity research analyst coverage, we will not have any control over the analysts, or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline.

Future sales of substantial amounts of our common stock, or the possibility that such sales could occur, could adversely affect the market price of our common stock.

Future sales in the public market of shares of our common stock, including shares issued upon exercise of our outstanding stock options or warrants, or the perception by the market that these sales could occur, could lower the market price of our common stock or make it difficult for it to raise additional capital.

Our business could be negatively affected as a result of the actions of activist stockholders, and such activism could impact the trading value of our securities.

Stockholders may, from time to time, engage in proxy solicitations or advance stockholder proposals, or otherwise attempt to effect changes and assert influence on our Board and management. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our Board could have an adverse effect on our operating results and financial condition. A proxy contest would require us to incur significant legal and advisory fees, proxy solicitation expenses and administrative and associated costs and require significant time and attention by our Board and management, diverting their attention from the pursuit of our business strategy. Any perceived uncertainties as to our future direction and control, our ability to execute on our strategy, or changes to the composition of our Board or senior management team arising from a proxy contest could lead to the perception of a change in the direction of our business or instability, which may result in the loss of potential business opportunities, make it more difficult to pursue our strategic initiatives, or limit our ability to attract and retain qualified personnel and business partners, any of which could adversely affect our business and operating results. If individuals are ultimately elected to our Board with a specific agenda, it may adversely affect our ability to effectively implement our business strategy and create additional value for our stockholders. We may choose to initiate, or may become subject to, litigation as a result of the proxy contest or matters arising from the proxy contest, which would serve as a further distraction to our Board and management and would require us to incur significant additional costs. In addition, actions such as those described above could cause significant fluctuations in our stock price based upon temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business.

Securities class action litigation could divert our management's attention and harm our business and could subject us to significant liabilities.

The stock markets have from time-to-time experienced significant price and volume fluctuations that have affected the market prices for the equity securities of life sciences and biotechnology companies. These broad market fluctuations may cause the market price of our common shares to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. Even if we are successful in defending claims that may be brought in the future, such litigation could result in substantial costs and may be a distraction to our management and may lead to an unfavorable outcome that could adversely impact our financial condition and prospects.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our management.

Provisions in our certificate of incorporation and bylaws may delay or prevent an acquisition or a change in management. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the DGCL, which prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our Board, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the Board, which is responsible for appointing the members of management.

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

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. This has required that we incur substantial professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. We may experience difficulty in meeting these reporting requirements in a timely manner.

Our management identified a material weakness in our internal control over financial reporting. If we do not remediate this material weakness, or if we identify further material weaknesses in our internal controls, our failure to establish

and maintain effective internal financial and accounting controls and procedures could result in material misstatements in our consolidated financial statements and a failure to meet our reporting and financial obligations.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate consolidated financial statements. If that were to happen, the market price of our common stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

Our Board of Directors has broad discretion to issue additional securities, which might dilute the net tangible book value per share of our common stock for existing stockholders.

We are entitled under our certificate of incorporation to issue up to 280,000,000 shares of common stock and 7,000,000 "blank check" shares of preferred stock. Shares of our blank check preferred stock provide our Board with broad authority to determine voting, dividend, conversion, and other rights. As of December 31, 2023, we had outstanding, common stock or securities convertible into common stock, totaling 9,270,894 shares. As a result, we are authorized to issue up to an additional 270,729,106 shares of common stock or common stock equivalents under our certificate of incorporation as amended. Additionally, pursuant to the initial issuance of (i) 1,000,000 shares of Series A 4.5% Convertible Preferred Stock, of which 200,000 shares are outstanding and (ii) 1,460 shares of Series B Convertible Preferred Stock, of which no shares are outstanding, we are authorized to issue up to an additional 6,800,000 shares of preferred stock. We expect that significant additional capital may be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our existing shareholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing shareholders, and new investors could gain rights superior to existing shareholders. Pursuant to our equity incentive plans and employee stock purchase plan, management is authorized to grant stock options, restricted stock units and other equity-based awards to employees, directors and consultants, and to sell common stock to employees, respectively. Any increase in the number of shares outstanding as a result of the exercise of outstanding options, the vesting or settlement of outstanding stock awards, or the purchase of shares pursuant to the employee stock purchase plan will cause shareholders to experience additional dilution, which could cause our stock price to fall.

General Risk Factors

Our business could be adversely affected by the effects of health pandemics or epidemics, such as the COVID-19 pandemic, which could cause significant disruptions in our operations and those of our current or future CMOs, CROs, and other third parties upon whom we rely.

Health pandemics or epidemics, such as the COVID-19 pandemic, have in the past and could again in the future result in quarantines, stay-at-home orders, remote work policies, or other similar events that may disrupt businesses, delay our research and development programs and timelines, negatively impact productivity and increase risks associated with cybersecurity, the future magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations. More specifically, these types of events may negatively impact personnel at third-party manufacturing facilities or the availability or cost of materials, which could disrupt our supply chain. Moreover, our trials may be negatively affected. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources. Some patients may not be able or willing to comply with trial protocols if quarantines impede patient movement or interrupt healthcare services. Our ability to recruit and retain patients, principal investigators, and site staff (who as healthcare providers may have heightened exposure) may be hindered, which would adversely affect our trial operations. Disruptions or restrictions on our ability to travel to monitor data from our trials, or to conduct trials, or the ability of patients enrolled in our trials or staff at trial sites to travel, as well as temporary closures of our trial partners and CMOs' facilities, would negatively impact our trial activities. In addition, we rely on independent clinical investigators, CROs, and other third-party service providers to assist us in managing, monitoring, and otherwise carrying out certain of our preclinical studies and clinical trials, including the collection of data from our trials, and the effects of health pandemics or epidemics, such as the COVID-19 pandemic, may affect their ability to devote sufficient time and resources to our programs or to travel to sites to perform work for us. Similarly, our trials could be delayed and/or disrupted. As a result, the expected timeline for data readouts, including incompleteness in data collection and analysis and other related activities, and certain regulatory filings may be negatively impacted, which would adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses, and adversely affect our business, financial condition, results of

operations, and prospects. In addition, impact on the operations of the FDA or comparable foreign regulatory authorities could negatively affect our planned trials and approval processes. Finally, economic conditions and business activity may be negatively impacted and may not recover as quickly as anticipated.

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

Global economic and business activities continue to face widespread uncertainties, and global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, rising inflation and monetary supply shifts, rising interest rates, bank failures, labor shortages, declines in consumer confidence, declines in economic growth, increases in unemployment rates, recession risks, and uncertainty about economic and geopolitical stability (for example, related to the ongoing Russia-Ukraine and Israel-Hamas conflict). The financial institutions in which we hold our cash and cash equivalents are subject to risk of failure. For example, recent events surrounding certain banks, including Silicon Valley Bank, First Republic Bank, and Signature Bank, created temporary uncertainty on their customers' cash deposits in excess of Federal Deposit Insurance Corporation limits prior to actions taken by governmental entities. While we do not expect any developments with any such banks to have a material impact on our cash and cash equivalents balance, expected results of operations, or financial performance for the foreseeable future, if further failures in financial institutions occur where we hold deposits, we could experience additional risk. Any such loss or limitation on our cash and cash equivalents would adversely affect our business.

The extent of the impact of these conditions on our operational and financial performance, including our ability to execute our business strategies and initiatives in the expected timeframe, as well as that of third parties upon whom we rely, will depend on future developments which are uncertain and cannot be predicted. There can be no assurance that further deterioration in economic or market conditions will not occur, or how long these challenges will persist. If the current equity and credit markets further deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

If our information systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences.

In the ordinary course of our business, it may process, as defined above, proprietary, confidential, and sensitive data, including personal data (such as health-related patient data), intellectual property, and trade secrets (collectively, sensitive information). We may rely upon third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, third-party providers of cloud-based infrastructure, employee email, CROs, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. We may share or receive sensitive information with or from third parties.

The risk of a security breach or disruption, particularly through cyber-attacks, cyber-intrusion, malicious internet-based activity, and online and offline fraud, are prevalent and have generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. These threats are becoming increasingly difficult to detect and come from a variety of sources, including traditional computer hackers, threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including cyber-attacks that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our products.

We and the third parties upon which we rely may be subject to a variety of evolving threats, including but not limited to social engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, natural disasters, terrorism, war, and telecommunication and electrical failures. Ransomware attacks, including by organized

criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Similarly, supply-chain attacks have increased in frequency and severity.

Furthermore, our remote workforce poses increased risks to our information technology systems and data, as most of our employees work from home, utilizing network connections outside our premises.

Any of the previously identified or similar threats could cause a security breach or disruption. While we have not experienced any such security breach or other disruption to date, if such an event were to occur, it could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information and cause interruptions in our operations, including material disruptions of our development programs and business operations.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security breaches and disruptions. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and sensitive information. While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security breach or disruption has occurred. Despite our efforts to identify and remediate vulnerabilities, if any, in our information technology systems, our efforts may not be successful. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of certain security breaches and disruptions. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom it relies) experience a security breach or other disruption, or are perceived to have experienced such events, we may experience adverse consequences, including: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. In particular, since we sponsor clinical trials, any breach or disruption that compromises patient data and identities could generate significant reputational damage, which may affect trust in us and our ability to recruit for future clinical trials. Additionally, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. Furthermore, we cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

Our business and operations would suffer in the event of system failures, cyber-attacks or a deficiency in our cybersecurity.

Despite the implementation of security measures, our internal computer systems, and those of our current and future CROs and other contractors and consultants, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Although we have not suffered any material incidents to date, the risk of a security breach or disruption, particularly through cyber-attacks or cyber-intrusion, including by computer hackers, foreign governments, and cyber-terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. In addition, since we sponsor clinical trials, any breach that compromises patient data

and identities causing a breach of privacy could generate significant reputational damage and legal liabilities and costs to recover and repair, including affecting trust in us to recruit for future clinical trials. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our products and product candidates could be delayed.

Item 1B. Unresolved Staff Comments.

None

Item 1C. Cybersecurity.

In the ordinary course of our business, we may process proprietary, confidential, and sensitive data, including personal data (such as health-related patient data), intellectual property, and trade secrets (collectively, "sensitive information"). We rely upon third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, third-party providers of cloud-based infrastructure, employee email, CROs, and other functions. The secure maintenance of this sensitive information and our information technology systems is important to our operations. To this end, we have processes designed to assess, identify, and manage risks from potential unauthorized occurrences on or through our information technology systems that may result in adverse effects on the confidentiality, integrity, and availability of these systems and the data residing therein. These processes are managed and monitored by our third-party information technology consultants and include mechanisms, controls, technologies, systems, and other processes designed to prevent or mitigate data loss, theft, misuse, or other security incidents or vulnerabilities affecting the data and maintain a stable information technology environment.

We are planning to establish an appropriate confidentiality framework and document management system in order to safeguard sensitive information in addition to the safeguards provided by our third-party service providers. Such confidentiality framework may include the use of third-party information technology experts to manage and oversee our sensitive information and to work directly with our management in overseeing cybersecurity risks and appropriate responses thereto. In addition, we plan to consult with outside advisors and experts, when appropriate, to assist with assessing and identifying cybersecurity risks, including to anticipate future threats and trends, and their impact on our risk environment.

In the last fiscal year, we have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected us, but we face certain ongoing cybersecurity risks threats that, if realized, are reasonably likely to materially affect us. Additional information on cybersecurity risks faced by us are discussed in Part I, Item 1A, “Risk Factors,” under the headings “*If our information systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences*” and “*Our business and operations would suffer in the event of system failures, cyber-attacks or a deficiency in our cybersecurity.*”

Our Board, as a whole and at the committee level, has oversight for the most significant risks facing us and for our processes to identify, prioritize, assess, manage, and mitigate those risks. The Audit Committee, which is comprised solely of independent directors, has been designated by our Board to oversee cybersecurity risks. The Audit Committee receives updates, as needed, on cybersecurity and information technology matters and related risk exposures.

Item 2. Properties.

We lease office space for our corporate headquarters under a non-cancelable facility operating lease for 2,747 square feet located in Carlsbad, California. The initial contractual term is for 39-months commencing on June 1, 2022 and expiring on August 31, 2025. We have the option to renew the lease for an additional 36-month period at the prevailing market rent upon completion of the initial lease term. We do not expect to renew the lease upon its expiration.

For additional information regarding our lease agreements, see Note 9 of the consolidated financial statements included in this Annual Report on Form 10-K.

Item 3. Legal Proceedings.

We are not a party to any material legal proceedings at this time. From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, we do not believe we are a party to any claim or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock trades on the Nasdaq Capital Market under the symbol "PALI." On March 21, 2024, the last reported sale price our common stock on the Nasdaq Capital Market was $0.39 per share.

Holders

As of March 21, 2024 there were 158 holders of record of our common stock, which does not include stockholders who hold shares in street name or stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our Board of Directors and will depend on, among other factors, our financial condition, operating results, capital requirements, contractual restrictions, general business conditions and other factors that our Board of Directors may deem relevant.

Recent Sales of Unregistered Equity Securities

On November 21, 2023, we granted J.D. Finley, our Chief Executive Officer, on a conditional basis until such time as there are sufficient shares available under the 2021 Equity Incentive Plan: (i) options to purchase 45,000 shares of common stock with a term of ten (10) years and an exercise price of $0.59 per share, valued at $22,114 on the grant date and (ii) 38,000 restricted stock units valued at $22,420. Each of the options and restricted stock units granted to Mr. Finley vest in 12 equal installments on a quarterly basis over three years.

On November 21, 2023, we granted Mitchell Jones, M.D., Ph.D., our Chief Medical Officer, on a conditional basis until such time as there are sufficient shares available under the 2021 Equity Incentive Plan: (i) options to purchase 33,160 shares of common stock with a term of ten years and an exercise price of $0.59 per share, valued at $16,296 on the grant date and (ii) 28,000 restricted stock units valued at $16,520. Each of the options and restricted stock units granted to Dr. Jones vest in 12 equal installments on a quarterly basis over three years.

The offers, sales and issuances of the securities described herein were deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act or Rule 506 of D promulgated under the Securities Act as transactions by an issuer not involving a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited investor within the meaning of Rule 501 of Regulation D under the Securities Act and had adequate access, through employment, business or other relationships, to information about the Company.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. Reserved.

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

You should read the following discussion and analysis of financial condition and results of operations together with our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion and other parts of this Annual Report on Form 10-K contain forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, expectations and intentions. Our actual results, performance or achievements could differ materially from any future results, performance or achievements discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section titled "Risk Factors."

As used in this Annual Report on Form 10-K, unless the context indicates or otherwise requires, "Palisade," "Palisade Bio," "the Company," "we," "us," and "our" or similar designations in this report refer to Palisade Bio, Inc., a Delaware Corporation, and its subsidiaries. Any reference to "common shares" or "common stock," refers to our $0.01 par value common stock. Any reference to "Series A Preferred Stock" refers to our Series A 4.5% Convertible Preferred Stock. Any reference to "Leading Biosciences, Inc." or "LBS" refers to our operations prior to the completion of our merger with Seneca Biopharma, Inc. ("Seneca") on April 27, 2021 (the "Merger"). Any technology that we currently own or may acquire the rights to in the future is referred to by us as either a "product candidate" or "product candidates". Additionally, any reference herein that refers to pre-clinical studies also refers to nonclinical studies.

OVERVIEW

On September 1, 2023, we entered into a research collaboration and license agreement for substantially all of Giiant Pharma, Inc.'s ("Giiant") current and future proposed products ("Giiant License Agreement"). Under the terms of the Giiant License Agreement, we obtained the rights to develop, manufacture, and commercialize all compounds from Giiant, existing now and in the future, and any product containing or delivering any licensed compound, in any formulation or dosage for all human and non-human therapeutic uses for any and all indications worldwide, including those technologies that are the basis of PALI-2108. Pursuant to the terms of the Giiant License Agreement, pre-clinical development PALI-2108 will be jointly undertaken by us and Giiant with a portion of development costs being paid by Giiant's current grants. Upon the first approval of either an investigational new drug application ("IND") or a Canadian Clinical Trial Application ("CTA"), we will assume all development, manufacturing, regulatory and commercialization costs.

On August 9, 2023, we announced that the topline data from our U.S Phase 2 PROFILE study of LB1148 did not meet its primary endpoint. Based on the results of the efficacy and safety value results of the U.S. Phase 2 PROFILE study, we terminated the development of LB1148.

As a result of our entering into the Giiant Licensing Agreement, we have significantly reshaped the business into a pre-clinical stage biotechnology company focused on developing and advancing novel therapies for patients living with autoimmune, inflammatory, and fibrotic diseases. Our lead product candidate, PALI-2108, is being developed as a therapeutic for patients living with inflammatory bowel disease ("IBD"), including ulcerative colitis and Crohn's disease.

Financial Results

Our operating loss for the year ended December 31, 2023 was approximately $13.1 million, which consisted of research and development expense and general and administrative expense of approximately $6.9 million and $6.2 million, respectively, and restructuring costs of approximately $0.2 million, partially offset by license revenue of approximately $0.3 million. Net cash used in operating activities was approximately $11.1 million for the year ended December 31, 2023, which includes a $12.3 million net loss adjusted for $0.4 million of net cash inflows related to changes in operating assets and liabilities and certain non-cash items impacting the net loss. Net cash provided by financing activities was approximately $11.2 million for the year ended December 31, 2023.

Recent Financings

In January 2023, we completed a registered direct offering and concurrent private placement of common stock and warrants to purchase common stock for net cash proceeds of $2.2 million consisting of gross cash proceeds of $2.5 million less cash equity issuance costs of approximately $0.3 million.

In April 2023, we completed a registered direct offering and concurrent private placement of common stock and warrants to purchase common stock for net cash proceeds of approximately $5.3 million consisting of gross cash proceeds of $6.0 million, less cash equity issuance costs of approximately $0.7 million.

In September 2023, we completed a registered direct equity offering of common stock for net cash proceeds of approximately $1.7 million consisting of gross cash proceeds of $2.0 million, less cash equity issuance costs of approximately $0.3 million.

In February 2024, we completed a warrant inducement transaction for net cash proceeds of approximately $2.2 million consisting of gross cash proceeds of $2.5 million, less cash equity issuance costs of approximately $0.3 million.

We intend to use the net proceeds from these recent financings for working capital and general corporate purposes, including the development of PALI-2108 for the treatment of IBD. Based on our cash and cash equivalents balance of $12.4 million as of December 31, 2023 and additional net cash proceeds of approximately $2.2 million from the warrant inducement transaction completed in February 2024, we believe we have sufficient cash to fund our currently planned operations into the first quarter of 2025, including the anticipated commencement of a Phase 1 clinical trial of our lead drug candidate, PALI-2108.

FINANCIAL OVERVIEW

License Revenue

We generated no revenues from the sale of our product candidates for any of the periods presented. For the year ended December 31, 2023, we recognized license revenue of approximately $0.3 million from the co-development and distribution agreement with Newsoara, a joint venture established with Biolead Medical Technology Limited, as amended, (the "Newsoara Co-Development Agreement"). For the year ended December 31, 2022, we recognized no licensing revenue.

Research and Development Expenses

Research and development expenses have historically consisted primarily of costs incurred for the clinical development of our product candidate LB1148. On August 9, 2023, based on the results of the efficacy and safety data of the U.S. Phase 2 PROFILE study, we terminated the development of LB1148. The research and development costs included:

- salaries and employee-related costs, including stock-based compensation;
- laboratory and vendor expenses related to the execution of pre-clinical and clinical trials;
- expenses under agreements with third-party contract research organizations, investigative clinical trial sites that conduct research and development activities on our behalf, and consultants;
- costs related to develop and manufacture pre-clinical study and clinical trial material; and
- regulatory expenses.

While we have made the decision to no longer pursue the clinical development of LB1148, we continued to incur expenses related to its development in the year ended December 31, 2023. We do not expect to incur any additional costs in 2024 or beyond related to the closing down of the associated clinical trials. Although the nature of our research and development expenses is expected to shift from clinical activities to those pre-clinical activities associated with the development of PALI-2108, we expect our overall net research and development expenses to remain consistent with prior periods.

Our direct research and development expenses are tracked by product candidate and consist primarily of external costs, such as fees paid under third-party license agreements and to outside consultants, Contract Research Organizations ("CROs"), clinical site, contract manufacturing organizations (“CMOs”) and research laboratories in connection with our pre-clinical development, process development, manufacturing, clinical development, and regulatory activities. We do not allocate employee costs and costs associated with our discovery efforts, laboratory supplies and facilities, including other indirect costs, to specific product candidates because these costs are deployed across multiple programs and, as such, are not separately classified. As needed, we manage third parties that are engaged to conduct our (i) research activities, (ii) pre-clinical, clinical and translational science development activities, and (iii) process development. Pursuant to situations whereby we perform any research and development or manufacturing activities under a co-development agreement, we record the expense reimbursement from the co-development partner as a reduction to research and development expense once the reimbursement amount is approved for payment by the co-development partner. Pursuant to agreements where we perform research and development activities under a joint development plan, such as our collaboration with Giiant, qualifying development costs pursuant to the terms of the Giiant License Agreement are expensed as research and development costs as incurred.

General and Administrative Expenses

General and administrative expenses consist primarily of salary and employee-related costs and benefits, professional fees for legal, intellectual property, investor and public relations, accounting and audit services, insurance costs, director fees and stipends, and general corporate expenses.

Restructuring Costs

In order to better utilize our resources on the implementation of our refocused business plans and corporate strategy, we committed to a cost-reduction plan on September 9, 2022 (the "2022 Cost-Reduction Plan") and a reduction-in-workforce on October 27, 2023 (the "2023 RIF"). The 2022 Cost-Reduction Plan consisted primarily of a 20% reduction in our employee workforce to better align our resources with our proposed business plan. The 2023 RIF consisted of a 25% reduction in our employee workforce, specifically research and development employees that were no longer deemed critical for our development of PALI-2108.

Going Concern

We believe we have sufficient cash to fund our currently planned operations into the first quarter of 2025. Notwithstanding, our management has evaluated all conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that these financial statements are issued, including: (i) the probability that significant changes to our anticipated level of operations, due to factors that are within or outside of our control, would cause our available cash as of the date of this filing to not be sufficient to fund our anticipated level of operations for the next 12 months, and (ii) the uncertainties of the cost and timing of our efforts to in-license or acquire additional product candidates. In the opinion of management, these factors, among others, raise substantial doubt about our ability to continue as a going concern as of the filing date of this Annual Report on Form 10-K and for one year from the issuance of the consolidated financial statements.

Reverse Stock Split

On November 15, 2022, we effected a 1-for-50 reverse stock split of our issued and outstanding common stock (the "Reverse Stock Split"). As a result of the Reverse Stock Split, each of our shareholders received one new share of our common stock for every 50 shares such shareholder held immediately prior to the effective time of the Reverse Stock Split. Unless otherwise noted, all common stock shares, common stock per share data and shares of common stock underlying convertible preferred stock, stock options and common stock warrants included in these consolidated financial statements, including the exercise price of such equity instruments, as applicable, have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented.

Results of Operations

The following table summarizes our results of operations for the year ended December 31, 2023 and 2022 (in thousands):

	Year Ended December 31,		Change	
	2023	2022	$	%
License revenue	$ 250	$ —	$ 250	n/a
Operating expenses				
Research and development	6,893	6,547	346	5 %
General and administrative	6,202	8,764	(2,562)	(29)%
Restructuring costs	225	410	(185)	(45)%
Total operating expenses	13,320	15,721	(2,401)	(15)%
Loss from operations	(13,070)	(15,721)	2,651	(17)%
Other income (expense):				
Interest expense	(15)	(13)	(2)	15 %
Other income	785	2,584	(1,799)	(70)%
Loss on issuance of warrants	—	(1,110)	1,110	n/a
Total other income, net	770	1,461	(691)	(47)%
Net loss	$ (12,300)	$ (14,260)	$ 1,960	(14)%

License revenue

During the year ended December 31, 2023, we recognized license revenue of approximately $0.3 million earned upon the achievement of a milestone under the Newsoara Co-Development Agreement. During the year ended December 31, 2022, we recognized no license revenue.

Research and Development Expenses

Research and development expenses were approximately $6.9 million for the year ended December 31, 2023. The $0.3 million, or 5%, increase in research and development expenses compared to the year ended December 31, 2022 is attributable to increased costs associated with the Giiant License Agreement, which we entered into on September 1, 2023, as well an increase in employee-related costs and employee recruiting costs, which were partially offset by a decrease in costs directly related to our development of LB1148, which we ceased in August of 2023.

For the year ended December 31, 2023, we recognized expenses associated with the Giiant License Agreement of approximately $1.1 million. Of these expenses, approximately $0.7 million relate directly to the joint development of our new lead asset being licensed under the Giiant License Agreement, PALI-2108. We expect these costs, which were primarily recognized in the fourth quarter of 2023, to increase as our pre-clinical activity around the development of PALI-2108 increases. Also, in conjunction with our entry into the Giiant License Agreement, we recognized non-cash expenses of approximately $0.4 million for the year ended December 31, 2023, consisting of the initial recognition and subsequent remeasurement of the fair value of the contingent consideration milestone payment obligation incurred in the transaction in the amount of $0.2 million, and transaction-related costs in the amount of $0.2 million.

Research and development employee compensation-related costs increased by approximately $0.1 million for the year ended December 31, 2023 compared to the year ended December 31, 2022, primarily due to increased year-over-year headcount through most of 2023 compared to 2022. Research and development employee recruiting costs for the year ended December 31, 2023 compared to the year ended December 31, 2022 increased by approximately $0.2 million in conjunction with our hiring of our Chief Medical Officer on September 5, 2023. On October 27, 2023, the 2023 RIF resulted in a 25% reduction-in-workforce, consisting entirely of research and development employees that were no longer deemed critical for our development of PALI-2108.

In August 2023, we made the decision to no longer pursue the clinical development of LB1148, including our U.S. Phase 2 PROFILE study and U.S. Phase 3 Return of Bowel Function study, and we ceased all directly related research and development activities. Accordingly, direct clinical trial-related costs, including clinical trial vendor fees, investigator site fees, and clinical trial consultant and contractor fees decreased by approximately $0.7 million for the year ended December 31, 2023 compared to the year ended December 31, 2022. Similarly, drug manufacturing costs

decreased by approximately $0.9 million and costs associated with regulatory activity decreased approximately $0.3 million for the year ended December 31, 2023 compared to the year ended December 31, 2022. Partially offsetting these decreases was an approximately $0.8 million increase in translational research costs associated with LB1148 for the year ended December 31, 2023, of which there were none of these costs in 2022.

General and Administrative Expenses

General and administrative expenses decreased by approximately $2.6 million, or 29%, from approximately $8.8 million for the year ended December 31, 2022 to approximately $6.2 million for the year ended December 31, 2023, primarily as a result of cost-saving initiatives implemented by us in the third and fourth quarters of 2022, including those associated with the 2022 Cost-Reduction Plan. Compared to the year ended December 31, 2022, general and administrative employee compensation costs for the year ended December 31, 2023 decreased by approximately $1.4 million primarily due to an approximately $0.9 million decrease in salaries and benefits and an approximately $0.5 million decrease in stock-based compensation expense. Other decreases in general and administrative expenses for the year ended December 31, 2023 compared to last year include: (i) an approximately $0.3 million decrease in professional fees, including accounting and legal fees and financial printing costs, (ii) an approximately $0.3 million decrease in investor and public relations costs and shareholder services costs, (iii) an approximately $0.2 million decrease in consultants and contract labor costs, (iv) an approximately $0.2 million decrease in general and administrative employee recruiting costs, and (v) an approximately $0.2 million decrease in insurance costs.

Restructuring Expenses

Associated with the 2023 RIF and the 2022 Cost-Reduction Plan, we recognized restructuring expenses of approximately $0.2 million and approximately $0.4 million for the years ended December 31, 2023 and December 31, 2022, respectively, consisting of severance and benefits payments pursuant to employment agreements and the execution of severance and release agreements. We do not expect to incur any other significant costs associated with either the 2022 Cost-Reduction Plan or the 2023 RIF.

Other income (expense)

Other income, net, of approximately $0.8 million for the year ended December 31, 2023 includes primarily dividend income of approximately $0.7 million from our short-term investments of excess cash in money market funds with maturities of three months or less, and a non-cash gain of approximately $0.1 million associated with the revaluation of our liability-classified warrants in the year.

Other income, net, of approximately $1.5 million for the year ended December 31, 2022 includes an approximately $2.4 million non-cash gain associated with the revaluation of our liability-classified warrants in the period and dividend income of approximately $0.2 million, which was partially offset by a $1.1 million non-cash loss on the issuance of warrants. On January 31, 2022, we issued 45,000 common stock warrants to certain investors as consideration for the waiver of certain rights pursuant to the underlying warrant agreements (the "January 2022 Warrants"). As a result of this issuance, we recognized an approximately $1.1 million non-cash loss upon the issuance of the January 2022 Warrants, which represents the fair value of the warrants on the date of issuance.

Liquidity and Capital Resources

Since our inception, we have financed our operations through the sales of our securities, issuance of long-term debt, the exercise of investor common stock warrants, and to a lesser degree, grants and research contracts as well as the licensing of our intellectual property to third parties. Refer to the paragraph under the heading "Going Concern" in the Financial Overview section above for management's assessment of our ability to continue as a going concern.

Sources of Liquidity

We expect to incur substantial operating losses for the foreseeable future. We will need to raise additional capital through a combination of equity offerings, debt financings, collaborations, and other similar arrangements. Our ability to raise additional capital may be adversely impacted by: (i) general political or economic conditions, (ii) inflation, (iii) rising interest rates, (iv) ongoing supply chain disruptions, (v) the ongoing global conflicts, including those in the Ukraine and Middle East, (vi) limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry, (vii) or a resurgence of COVID-19, COVID-19 variants, or another pandemic. In the event the we are unable to access additional capital, we may need to curtail or greatly reduce our operations, which could have a materially adverse impact on our business, financial condition, and results of operations.

Recent Equity Offerings

On September 11, 2023, we completed a registered direct offering of common stock pursuant to an effective shelf registration statement on Form S-3 filed with the SEC (the "September 2023 Offering"). Gross cash proceeds from the September 2023 Offering were $2.0 million and net cash proceeds were $1.7 million after deducting cash equity issuance costs of approximately $0.3 million.

On April 3, 2023, we completed a registered direct offering and concurrent private placement of common stock and warrants to purchase common stock (the "April 2023 Offering"). Gross cash proceeds from the April 2023 Offering were $6.0 million and net cash proceeds were $5.3 million after deducting cash equity issuance costs of approximately $0.7 million.

On January 4, 2023, we completed a registered direct offering and concurrent private placement of common stock and warrants to purchase common stock (the "January 2023 Offering"). Gross cash proceeds from the January 2023 Offering were $2.5 million and net cash proceeds were approximately $2.2 million after deducting cash equity issuance costs of approximately $0.3 million.

On August 16, 2022, we completed a registered public offering (the "August 2022 Offering"). Gross cash proceeds from the August 2022 Offering, including the full exercise of the underwriter overallotment option, were $13.8 million and net cash proceeds were approximately $12.0 million after deducting cash equity issuance costs of approximately $1.8 million.

On May 10, 2022, we completed a registered direct offering and concurrent private placement of common stock and warrants to purchase common stock (the “May 2022 Offering”). Gross cash proceeds from the May 2022 Offering were $2.0 million and net cash proceeds were approximately $1.4 million after deducting cash equity issuance costs of approximately $0.6 million.

Refer to Note 6, *Stockholders' Equity* in Part II Item 8 of this Annual Report on Form 10-K for further details of our recent equity transactions.

Warrant Exercises

During the year ended December 31, 2023, we received gross cash proceeds of approximately $2.8 million from common stock warrant exercises, approximately $1.4 million of which related to common stock warrant exercises on December 30, 2022 for which the related cash was received by us in January 2023. During the year ended December 31, 2022, we received gross cash proceeds of approximately $2.3 million for the exercise of outstanding common stock warrants.

On January 30, 2024, we entered into warrant inducement agreements (the “Warrant Inducement Agreements”) with certain accredited and institutional holders (collectively, the “Warrant Holders”) of certain of our remaining outstanding common stock purchase warrants issued pursuant to: (i) the May 2022 Offering, (ii) the January 2023 Offering, and (iii) the April 2023 Offering, as well as certain outstanding common stock purchase warrants outstanding from the August 2022 Offering (the "August 2022 Warrants") (collectively, the “Existing Warrants”). Pursuant to the Warrant Inducement Agreements, the exercise price of each Existing Warrant was reduced to $0.7313 per share. Each of the Warrant Holders that exercised their Existing Warrants pursuant to the Warrant Inducement Agreements received one replacement warrant for each Existing Warrant exercised with each such replacement warrant having a term of five years from issuance and an exercise price per share of $0.7313.

The Warrant Holders collectively exercised an aggregate of 3,422,286 Existing Warrants. As a result of the exercises, we issued an aggregate of 3,422,286 shares of our common stock. The transaction closed on February 1, 2024 with us receiving net cash proceeds of approximately $2.2 million consisting of gross cash proceeds of $2.5 million, less transaction-related expenses and placement agent fees of approximately $0.3 million.

Refer to Note 13, *Subsequent Events* in Part II Item 8 of this Annual Report on Form 10-K for further details of our warrant inducement transaction.

Cash Flows

As of December 31, 2023, we had $12.5 million in cash, cash equivalents and restricted cash. The following table shows a summary of our cash flows for the years ended December 31, 2023 and 2022 (in thousands):

	Year Ended December 31,	
	2023	2022
Net cash used in operating activities	$ (11,133)	$ (13,360)
Net cash used in investing activities	(4)	(10)
Net cash provided by financing activities	11,186	15,258

Net Cash Used in Operating Activities

Cash used in operating activities was $11.1 million for the year ended December 31, 2023, which reflects a $12.3 million net loss adjusted for $0.4 million of net cash inflows related to changes in operating assets and liabilities and certain non-cash items impacting the net loss, consisting primarily of a $0.6 million non-cash expense recognized for stock-based compensation and related charges, and a non-cash expense of $0.2 million related to the recognition of the fair value of the contingent consideration obligation incurred pursuant to the Giiant Licensing Agreement transaction. The net cash inflow from operating assets and liabilities was driven by (i) a $0.7 million cash inflow from the decrease in prepaids and other current assets and other noncurrent assets, which was primarily attributable to the amortization of the current and non-current portions of our prepaid insurance policies, and (ii) a $0.3 million cash inflow from an increase in accrued compensation and benefits, partially offset by (i) a $0.5 million cash outflow for accounts payable and accrued liabilities due to the timing of payments, and (ii) a $0.1 million cash outflow related to payments of our operating lease.

Cash used in operating activities of $13.4 million for the year ended December 31, 2022 reflects a $14.3 million net loss adjusted for $1.3 million of net cash inflows related to changes in operating assets and liabilities, and certain non-cash items including: (i) a $1.1 million loss recognized from the issuance of the January 2022 Warrants, (ii) a $2.4 million gain recognized for the change in the fair market value of the warrant liabilities in the period, and (iii) a $1.0 million non-cash expense recognized for stock-based compensation.

Net Cash Used in Investing Activities

Cash used in investing activities for the years ended December 31, 2023 and December 31, 2022 consists of payments for leasehold improvements.

Net Cash Provided by Financing Activities

For the year ended December 31, 2023, cash provided by financing activities of $11.2 million was primarily attributable to net cash proceeds of $9.4 million from the January 2023 Offering, the April 2023 Offering, and the September 2023 Offering. Also contributing to the cash provided by financing activities in the year was $2.8 million from the exercise of common stock purchase warrants, which includes the receipt in early January 2023 of a $1.4 million other receivable from warrant exercises on December 30, 2022, partially offset by payments of equity issuance costs of $0.6 million and payments of $0.4 million for our insurance financing arrangement.

For the year ended December 31, 2022, cash provided by financing activities of $15.3 million was attributable to cash proceeds of $1.8 million from the May 2022 Offering and $12.6 million from the August 2022 Offering and cash

proceeds of $2.3 million from the exercise of common stock purchase warrants, partially offset by payments of equity issuance costs of $0.6 million during the year and payments of $0.8 million for our insurance financing arrangements.

Contractual Obligations

Office Lease

On May 12, 2022, we entered a new, non-cancelable facility operating lease (the "Corporate Office Lease") of office space for our corporate headquarters, replacing our existing corporate headquarters lease that expired on July 31, 2022. The Corporate Office Lease is for 2,747 square feet of an office building in Carlsbad, California. The initial contractual term is for 39-months commencing on June 1, 2022 and expiring on August 31, 2025. We have the option to renew the Corporate Office Lease for an additional 36-month period at the prevailing market rent upon completion of the initial lease term. We have determined that it is not likely we will exercise this renewal option.

Commencing on June 1, 2022, we are subject to contractual monthly lease payments of $10,850, plus certain utilities, for the first 12 months with 3 percent escalations at the first, second and third lease commencement anniversaries. As of December 31, 2023, the total remaining future minimum lease payments associated with the Corporate Office Lease of approximately $229,000, including imputed interest of $18,000 calculated using a discount rate of 10.75%, will be paid over the remaining lease term of approximately 1.7 years.

Insurance Financing Arrangement

Consistent with past practice, in June 2023, we entered into an agreement to finance an insurance policy that renewed in May 2023. The financing arrangement entered into in June 2023 has a stated annual interest rate of 7.92% and is payable over a 9-month period with the first payment commencing June 30, 2023. The insurance financing arrangement is secured by the associated insurance policy. As of December 31, 2023, the aggregate remaining balance under our insurance financing arrangement was $158,000.

Other than the remaining insurance financing arrangement payments due in 2024, as of December 31, 2023 we have no other minimum debt payments required in 2024 or thereafter.

Reduction in Workforce

Associated with the 2023 RIF, we recognized restructuring costs of approximately $0.2 million for the year ended December 31, 2023 consisting of severance and benefits payments pursuant to employment agreements and the execution of severance and release agreements, of which a remaining amount of approximately $0.1 million is expected to be paid in cash during the first half of 2024.

Board Resignations

In December of 2023, based on their annual self-assessment, our Board of Directors ("Board") determined that based on our stage of development and number of employees a reduction in the size of our Board was appropriate. In the first quarter of 2024, five directors voluntarily resigned from our Board. We do not expect to recognize any significant expense or cash payments associated with the Board resignations. We expect that the reduction in the size of our Board will result in significant cost savings in future periods.

Future Liquidity Needs

We have incurred significant operating losses and negative cash flows from operations since our inception. To date, we have not been able to generate significant revenues nor achieve operating profitability. Based upon our cash and cash equivalents balance of $12.4 million as of December 31, 2023, we believe we have sufficient cash to fund our currently planned operations into the first quarter of 2025. Notwithstanding, should our anticipated level of operations significantly change, we may require additional financing sooner than the first quarter of 2025. Further, beyond the first quarter of 2025 we will require additional financing to continue at our expected level of operations. If we fail to obtain the needed capital, we will be forced to delay, scale back, or eliminate some or all of our development activities, or potentially cease our operations.

Critical Accounting Policies and Estimates

Our consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP"). The preparation of financial statements in conformity with U.S. GAAP requires us to make estimates, judgments, and assumptions that impact the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the date of the balance sheet and the reported amounts of expenses during the reporting period. Our estimates are based on historical experience, known trends, events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. In making estimates and judgments, management employs critical accounting policies.

Our significant accounting policies used in the preparation of the consolidated financial statements are described in more detail in Note 2 in Part II, Item 8. "Financial Statement and Supplemental Data" of this Annual Report on Form 10-K. We believe that the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations:

Accrued research and development expenses

We required to make estimates of our accrued expenses resulting from our obligations under contracts or agreements with, as applicable, research and development collaboration partners, CROs, pre-clinical and clinical sites, manufacturers, vendors, and consultants in connection with conducting research and development activities, including those related to joint drug development that are advanced or reimbursed to Giiant pursuant to the terms of the Giiant License Agreement. This process involves reviewing open contracts and purchase requisitions, communicating with our personnel, consultants, and research and development collaboration partners to identify services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost.

Pursuant to the terms of the Giiant License Agreement, we are invoiced by Giiant on or about the 1st and 15th of each calendar month for any qualifying costs or expenses incurred or to be incurred under the agreed upon joint development plan. The financial terms of the contracts entered into by Giiant with CROs, pre-clinical sites, manufacturers, vendors and consultants are subject to negotiation and vary from contract to contract. Often, this will result in payment flows that do not match the periods over which services are provided or milestones are met under the joint development plan. We recognize research and development expenses associated with the Giiant License Agreement only when the qualifying expenses are incurred by matching those expenses with the period in which we estimate services and efforts are expended or other aspects of the drug development or related activities are achieved, examples of which may include authorization of a study, the commencement of a study, the submission of study results milestones. In instances where the expense determined to be recognized under the joint development plan exceeds the payments made to Giiant, we recognize an accrual of the joint development expenses. In addition, there may be instances in which payments made to Giiant will exceed the level of services provided, which results in a prepayment of the joint development expenses.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period.

Contingent Consideration Obligations

Pursuant to the Giiant License Agreement, we incurred a contingent consideration obligation consisting of milestone payments. Because the contingent consideration associated with the milestone payments may be settled in shares of our common stock solely at the election of the Company, we have determined it should be accounted for under Accounting Standards Codification ("ASC") 480, *Distinguishing Liabilities from Equity* ("ASC 480") and accordingly we have recognized it as a liability measured at its estimated fair value. As of September 1, 2023, the date the contingent consideration obligation was incurred, the fair value of the liability was determined to be approximately $0.2 million.

At the end of each reporting period, we re-measure the contingent consideration obligation to its estimated fair value and any resulting change is recognized in research and development expenses in the consolidated statements of operations. The fair value of the contingent consideration obligation is determined using a probability-based model that estimates the likelihood of success in achieving each of the defined milestones which is then discounted to present value using our incremental borrowing rate. The fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement as defined in ASC 820, *Fair Value Measurements and Disclosures*. As of December 31, 2023, approximately $143,000 of the contingent consideration obligation was recognized in accrued liabilities at the consolidated balance sheet as it is expected to be settled within one-year of the balance sheet date. The remaining amount of the contingent consideration liability of approximately $61,000 was recognized as a noncurrent liability in the consolidated balance sheet as of December 31, 2023. The initial fair value of the contingent consideration liability and an insignificant change in the fair value of the contingent consideration liability for the year ended December 31, 2023 is recognized in research and development expenses in the consolidated statements of operations.

Derivative Financial Instruments

We do not use derivative instruments to hedge exposures to cash flow, market, or foreign currency risks. We evaluate our financial instruments, including our common stock warrants, to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. We determine the fair value of our derivatives using the Black-Scholes option pricing model or, when a variety of future events and outcomes is required to be factored into the valuation based on the terms of the underlying derivative instrument, the Monte-Carlo simulation model. Derivative instruments are valued at inception, upon events such as an exercise of the underlying financial instrument, and at subsequent reporting periods. The classification of derivative instruments, including whether such instruments should be recorded as liabilities, is re-assessed at the end of each reporting period.

We review the terms of debt instruments, equity instruments, and other financing arrangements to determine whether there are embedded derivative features, including embedded conversion options that are required to be bifurcated and accounted for separately as a derivative financial instrument. Additionally, in connection with the issuance of financing instruments, we may issue freestanding options and common stock warrants.

We account for our common stock warrants in accordance with ASC 480 and ASC 815, *Derivatives and Hedging* ("ASC 815"). Based upon the provisions of ASC 480 and ASC 815, we account for our common stock warrants as liabilities if the common stock warrant requires net cash settlement or it gives the holder the option of net cash settlement, or if it fails the equity classification criteria. We account for our common stock warrants as equity if the contract requires physical settlement or net physical settlement or if we have the option of physical settlement or net physical settlement and the common stock warrants meet the requirements to be classified as equity. Common stock warrants classified as liabilities are initially recorded at fair value on the grant date and remeasured at fair value at each balance sheet date with the offsetting adjustments recorded in change in fair value of warrant liability within the consolidated statements of operations. If the terms of a common stock warrant previously classified as a liability are amended and pursuant to such amendment meet the requirements to be classified as equity, the common stock warrants are reclassified to equity at the fair value on the date of the amendment and are not subsequently remeasured. Common stock warrants classified as equity are recorded on a relative fair value basis when they are issued with other equity classified financial instruments.

As of December 31, 2023, the fair value of our liability-classified warrants outstanding was determined using a Black-Scholes option pricing model valuation model to be insignificant due to the low market price of our common stock at the date of valuation relative to the exercise price of the underlying common stock warrants outstanding. As of December 31, 2022, our liability-classified warrants had an estimated fair value of approximately $0.1 million. For the years ended December 31, 2023 and 2022, we recognized gains associated with the change in fair value of liability-classified warrants of approximately $0.1 million and $2.4 million, respectively. We expect any gains or losses from the change in the fair value of our liability-classified warrants to remain insignificant in future periods.

Recently Issued and Adopted Accounting Pronouncements

See Note 2 to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

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

As a smaller reporting company, we are not required to provide the information required by this Item.

Item 8. Financial Statements and Supplementary Data.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of Palisade Bio, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Palisade Bio, Inc. (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of operations, convertible preferred stock and stockholders' equity, and cash flows, for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As described in Note 1 to the consolidated financial statements, the Company has suffered losses and negative cash flows from operations, and has an accumulated deficit as of December 31, 2023, that raises substantial doubt about its ability to continue as a going concern. Management's plans in regards to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

Our audits included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated 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 consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Accounting for Complex Financial Instruments

Critical Audit Matter Description

As described in Notes 4 and 6 to the consolidated financial statements, the Company executed several transactions during the year that included the issuance of common stock and warrants.

We identified the accounting for these complex financial instruments as a critical audit matter. This includes both the evaluation of the various features as potential derivative instruments and the determination of the respective fair value of the instruments. The application of the accounting guidance applicable to the transactions is complex, and therefore, applying such guidance to the contract terms is complex and requires significant auditor judgment.

How the Critical Audit Matter was Addressed in the Audit

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included, among others:

- Inspecting the agreements associated with the transactions and evaluating the completeness and accuracy of the Company's technical accounting analysis, including the identification of features that were relevant to the classification determination.
- Utilizing personnel with specialized knowledge and skills in technical accounting matters to assist in assessing management's analysis of the transactions, including (i) evaluating the contracts to identify relevant terms that affect the recognition of the financial instruments in the consolidated financial statements, and (ii) assessing the appropriateness of conclusions reached by management.

Accounting for Research Collaboration and License Agreement

Critical Audit Matter Description

As described in Notes 5 and 8 to the consolidated financial statements, the Company entered into a research collaboration and license agreement (“Agreement”) with Giiant Pharma, Inc. (“Giiant”) (“Giiant Transaction).
We identified the accounting for the Giiant Transaction as a critical audit matter. This includes both the evaluation of the various terms of the Agreement and the determination of the fair value of the contingent consideration obligation on the future milestone payments. The application of the accounting guidance applicable to the Giiant Transaction is complex, and therefore, applying such guidance to the contract terms is complex, and requires significant auditor judgment.

How the Critical Audit Matter was Addressed in the Audit

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included, among others:

- Inspecting the Agreement and evaluating the completeness and accuracy of the Company's technical accounting analysis and the application of the relevant accounting literature.
- Utilizing personnel with specialized knowledge and skills in technical accounting matters and in the determination of fair value of the contingent consideration to assist in assessing management's analysis of the transaction, including:
    - Evaluating the contract to identify relevant terms that affect the recognition in the consolidated financial statements;
    - Assessing the appropriateness and reasonableness of the valuation methodologies and the significant assumptions in the discounted cash flow analysis, including estimates of the discount rate and discrete execution risk associated with the clinical probability of successfully achieving each phase of clinical development, which would trigger a contractually defined milestone payments;

- Evaluating and testing the source information underlying the assumptions and, where necessary, included an evaluation of available information that either corroborated or contradicted management’s conclusions;
- Testing the calculations employed to estimate the fair value of the contingent considerations; and
- Assessing the appropriateness of conclusions reached by management.

/s/ Baker Tilly US, LLP

We have served as the Company's auditor since 2022.
Tewksbury, Massachusetts

March 26, 2024

Palisade Bio, Inc.
Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	December 31,	
	2023	2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,432	$ 12,383
Prepaid expenses and other current assets	896	2,350
Total current assets	13,328	14,733
Restricted cash	26	26
Property and equipment, net	10	10
Operating lease right-of-use asset	198	300
Other noncurrent assets	490	694
Total assets	$ 14,052	$ 15,763
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 698	$ 1,759
Accrued liabilities	831	574
Accrued compensation and benefits	778	486
Current portion of operating lease liability	121	105
Insurance financing debt	158	88
Total current liabilities	2,586	3,012
Warrant liability	2	61
Contingent consideration obligation	61	—
Operating lease liability, net of current portion	90	211
Total liabilities	2,739	3,284
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Series A Convertible Preferred Stock, $0.01 par value, 7,000,000 shares authorized; 200,000 issued and outstanding at December 31, 2023 and December 31, 2022	2	2
Common stock, $0.01 par value; 280,000,000 shares authorized; 9,270,894 and 2,944,306 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	93	30
Additional paid-in capital	132,724	121,637
Accumulated deficit	(121,506)	(109,190)
Total stockholders' equity	11,313	12,479
Total liabilities and stockholders' equity	$ 14,052	$ 15,763

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

Palisade Bio, Inc.
Consolidated Statements of Operations
(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2023	2022
License revenue	$ 250	$ —
Operating expenses:		
Research and development	6,893	6,547
General and administrative	6,202	8,764
Restructuring costs (Note 9)	225	410
Total operating expenses	13,320	15,721
Loss from operations	(13,070)	(15,721)
Other income (expense):		
Interest expense	(15)	(13)
Other income	785	2,584
Loss on issuance of warrants	—	(1,110)
Total other income, net	770	1,461
Net loss	$ (12,300)	$ (14,260)
Net loss available to common stockholders	$ (12,316)	$ (14,548)
Basic and diluted weighted average shares used in computing basic and diluted net loss per common share	6,840,213	880,311
Basic and diluted net loss per common share	$ (1.80)	$ (16.53)

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

Palisade Bio, Inc.
Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity
(in thousands, except share amounts)

	Year Ended December 31, 2023								
	Series B Convertible Preferred Stock		Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, December 31, 2022	—	$ —	200,000	$ 2	2,944,306	$ 30	$ 121,637	$ (109,190)	$ 12,479
Net loss	—	—	—	—	—	—	—	(12,300)	(12,300)
Stock-based compensation expense and related charges	—	—	—	—	—	—	624	—	624
Issuance of common stock for vesting of restricted stock units	—	—	—	—	61,120	1	(1)	—	—
Issuance of common stock for Employee Stock Purchase Plan	—	—	—	—	33,676	—	17	—	17
Issuance of common stock upon warrant exercises	—	—	—	—	2,203,993	22	1,328	—	1,350
Issuance of common stock and warrants in January 2023 Offering, net of issuance costs of $507 (Note 6)	—	—	—	—	476,842	5	2,161	—	2,166
Issuance of common stock and warrants in April 2023 Offering, net of issuance costs of $854 (Note 6)	—	—	—	—	1,211,559	12	5,289	—	5,301
Issuance of common stock in September 2023 Offering, net of issuance costs of $345 (Note 6)	—	—	—	—	2,339,398	23	1,653	—	1,676
Adjustment to record the impact of exercise price reset on outstanding warrants related to down round provisions	—	—	—	—	—	—	16	(16)	—
Balance, December 31, 2023	—	$ —	200,000	$ 2	9,270,894	$ 93	$ 132,724	$ (121,506)	$ 11,313

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

Palisade Bio, Inc.
Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity
(in thousands, except share amounts)

	Year Ended December 31, 2022								
	Series B Convertible Preferred Stock		Preferred Stock		Common Stock		Additional Paid-in Capital*	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares*	Amount*			
Balance, December 31, 2021	—	$ —	200,000	$ 2	284,780	$ 3	$ 102,002	$ (94,642)	$ 7,365
Net loss	—	—	—	—	—	—	—	(14,260)	(14,260)
Stock-based compensation expense and related charges	—	—	—	—	—	—	1,032	—	1,032
Issuance of common stock upon warrant exercises	—	—	—	—	1,482,684	15	4,941	—	4,956
Issuance of common stock and warrants in May 2022 Offering, net of issuance costs of $634 (Note 6)	—	—	—	—	72,933	1	1,426	—	1,427
Issuance of Class A Units and Class B Units in August 2022 Offering, net of issuance costs of $2,293 (Note 6)	1,460	—	—	—	987,200	10	11,949	—	11,959
Issuance of common stock upon conversion of Series B Convertible Preferred Stock	(1,460)	—	—	—	116,800	1	(1)	—	—
Reverse stock split fractional share settlement	—	—	—	—	(91)	—	—	—	—
Adjustment to record the impact of exercise price reset on outstanding warrants related to down round provisions	—	—	—	—	—	—	288	(288)	—
Balance, December 31, 2022	—	$ —	200,000	$ 2	2,944,306	$ 30	$ 121,637	$ (109,190)	$ 12,479

(*) Adjusted to reflect the 1-for-50 reverse stock split effected on November 16, 2022.

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

Palisade Bio, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2023	**2022**
Net loss	$ (12,300)	$ (14,260)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	4	3
Noncash operating lease expense	102	164
Loss on issuance of warrants	—	1,110
Fair value of contingent consideration obligation	204	—
Change in fair value of warrant liabilities	(59)	(2,426)
Stock-based compensation and related charges	624	1,032
Other	(108)	(233)
Changes in operating assets and liabilities:		
Prepaid and other current assets and other noncurrent assets	705	1,027
Accounts payable and accrued liabilities	(492)	399
Accrued compensation	292	(25)
Operating lease liabilities	(105)	(151)
Net cash used in operating activities	(11,133)	(13,360)
Cash flows from investing activities:		
Purchases of property and equipment	(4)	(10)
Net cash used in investing activities	(4)	(10)
Cash flows from financing activities:		
Payments on insurance financing debt	(391)	(790)
Proceeds from issuance of common stock and warrants	9,419	14,401
Proceeds from the exercise of warrants	2,758	2,274
Payment of equity issuance costs	(617)	(627)
Proceeds from issuance of common stock under Employee Stock Purchase Plan	17	—
Net cash provided by financing activities	11,186	15,258
Net increase in cash, cash equivalents and restricted cash	49	1,888
Cash, cash equivalents and restricted cash, beginning of year	12,409	10,521
Cash, cash equivalents and restricted cash, end of year	$ 12,458	$ 12,409
Reconciliation of cash, cash equivalents and restricted cash to the balance sheets:		
Cash and cash equivalents	$ 12,432	$ 12,383
Restricted cash	26	26
Total cash, cash equivalents and restricted cash	$ 12,458	$ 12,409
Supplemental disclosures of cash flow information:		
Interest paid	$ 14	$ 12
Operating right-of-use assets obtained in exchange for operating lease liabilities	—	355
Supplemental disclosures of non-cash investing and financing activities:		
Equity issuance costs included in accounts payable and accrued liabilities	$ —	$ 388
Non cash impact of exercise price reset on outstanding warrants related to down round provisions	16	288
Issuance of common stock for the cashless exercise of warrants	—	1,274
Fair value of warrants issued to placement agent	384	55
Fair value of warrants issued to underwriter agent	—	459
Deferred equity issuance costs recognized as a reduction in additional paid-in capital from financing activities	6	—
Cash receivable for exercises of warrants included in prepaid and other current assets	—	1,408
Issuance of common stock upon conversion of Series B Convertible Preferred Stock	—	1
Insurance financing debt included in prepaid and other current assets and other noncurrent assets	461	784

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

1. Organization and Business

As used in this Annual Report on Form 10-K, unless the context indicates or otherwise requires, "Palisade," "Palisade Bio," "the Company," "we," "us," and "our" or similar designations in this report refer to Palisade Bio, Inc., a Delaware Corporation, and its subsidiaries. Any reference to "common shares" or "common stock," refers to the Company's $0.01 par value common stock. Any reference to "Series A Preferred Stock" refers to the Company's Series A 4.5% Convertible Preferred Stock. Any reference to "Leading Biosciences, Inc." or "LBS" refers to the Company's operations prior to the completion of its merger with Seneca Biopharma, Inc. ("Seneca") on April 27, 2021 (the "Merger"). Any reference herein that refers to pre-clinical studies also refers to nonclinical studies.

Description of Business

On September 1, 2023, the Company entered into the Giiant License Agreement. Under the terms of the Giiant License Agreement, the Company obtained the rights to develop, manufacture, and commercialize all compounds from Giiant, existing now and in the future, and any product containing or delivering any licensed compound, in any formulation or dosage for all human and non-human therapeutic uses for any and all indications worldwide, including those technologies that are the basis of the Company's lead product candidate, PALI-2108. Pursuant to the terms of the Giiant License Agreement, pre-clinical development PALI-2108 will be jointly undertaken by Giiant and the Company with a portion of development costs being paid by Giiant's current grants. Upon the first approval of either an IND or CTA, the Company will assume all development, manufacturing, regulatory and commercialization costs.

On August 9, 2023, the Company announced that the topline data from its U.S Phase 2 PROFILE study of LB1148 did not meet its primary endpoint. Based on the results of the efficacy and safety value results of the U.S. Phase 2 PROFILE study, the Company terminated the development of LB1148.

As a result of the Company entering into the Giiant Licensing Agreement, the Company has significantly reshaped its business into a pre-clinical stage biotechnology company focused on developing and advancing novel therapies for patients living with autoimmune, inflammatory, and fibrotic diseases. The Company is developing PALI-2108 as a therapeutic for patients living with inflammatory bowel disease, including ulcerative colitis and Crohn's disease.

Liquidity and Going Concern

The Company has a limited operating history, and the sales and income potential of the Company's business and market are unproven. The Company has experienced losses and negative cash flows from operations since its inception. As of December 31, 2023, the Company had an accumulated deficit of approximately $121.5 million and cash and cash equivalents of approximately $12.4 million. The Company expects to continue to incur losses into the foreseeable future. The successful transition to attaining profitable operations is dependent upon achieving a level of revenues adequate to support the Company's cost structure.

Based on the Company's current working capital, anticipated operating expenses, and anticipated net operating losses, there is substantial doubt about the Company's ability to continue as a going concern for a period of one year following the date that these consolidated financial statements are issued. The consolidated financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments for the recovery and classification of assets or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

Historically, the Company has funded its operations primarily through a combination of debt and equity financings. The Company plans to continue to fund its operations through cash and cash equivalents on hand, as well as through future equity offerings, debt financings, other third-party funding, and potential licensing or collaboration arrangements. Refer to Note 6, Stockholders' Equity and Note 13, Subsequent Events, for discussion of the recent financings undertaken by the Company. There can be no assurance that additional funds will be available when needed from any source or, if available, will be available on terms that are acceptable to the Company. Even if the Company

raises additional capital, it may also be required to modify, delay or abandon some of its plans, which could have a material adverse effect on the Company's business, operating results and financial condition and the Company's ability to achieve its intended business objectives. Any of these actions could materially harm the Company's business, results of operations and future prospects.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP"). Dollar amounts contained in these consolidated financial statements are in whole numbers, unless otherwise indicated.

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, LBS and Suzhou Neuralstem Biopharmaceutical Co., Ltd. All the entities are consolidated in the Company's consolidated financial statements and all intercompany activity and transactions, if any, have been eliminated.

Reverse Stock Split

On November 15, 2022, the Company effected a 1-for-50 reverse stock split of its issued and outstanding common stock (the "Reverse Stock Split"). As a result of the Reverse Stock Split, each of the Company's shareholders received one new share of common stock for every 50 shares such shareholder held immediately prior to the effective time of the Reverse Stock Split. The Reverse Stock Split affected all the Company's issued and outstanding shares of common stock equally. The par value and authorized shares of the Company's common stock was not adjusted as a result of the Reverse Stock Split. The Reverse Split also affected the Company's outstanding stock options, common stock warrants, and other exercisable or convertible securities and resulted in the shares underlying such instruments being reduced and the exercise price being increased proportionately. Unless otherwise noted, all common stock shares, common stock per share data and shares of common stock underlying convertible preferred stock, stock options and common stock warrants included in these consolidated financial statements, including the exercise price of such equity instruments, as applicable, have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires the Company to make estimates, judgments, and assumptions that impact the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the date of the balance sheet, and the reported amounts of expenses during the reporting period. The most significant estimates in the Company's consolidated financial statements relate to pre-clinical and clinical trial accruals, contingent consideration liabilities, and its derivative financial instruments. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may materially differ from these estimates and assumptions.

Segment Information

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

Cash and Cash Equivalents

Cash and cash equivalents represent cash available in readily available checking and money market accounts. The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents.

Restricted Cash

As of December 31, 2023 and December 31, 2022, the Company held restricted cash of approximately $26,000, in a separate restricted bank account as collateral for the Company's corporate credit card program. The Company has classified these deposits as long-term restricted cash on its consolidated balance sheets.

Deferred Equity Issuance Costs

Deferred equity issuance costs consist of the legal, accounting and other direct and incremental costs incurred by the Company related to its equity offerings (refer to Note 13, Subsequent Events) or shelf registration statements. As of December 31, 2023 and December 31, 2022, deferred equity issuance costs of approximately $112,000 and $114,000, respectively, were included in prepaid expenses and other current assets in the consolidated balance sheets. These costs will be netted against additional paid-in capital as a cost of the future equity issuances to which they relate. During the year ended December 31, 2023, the Company netted previously deferred equity issuance costs associated with its shelf registration statement of approximately $6,000 against the additional paid-in capital recognized in conjunction with the September 2023 Offering (see Note 6, Stockholders' Equity).

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to concentration of credit risk, consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions and in money market accounts, and at times balances may exceed federally insured limits. Management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held and historically the Company has not experienced any losses in such accounts.

Fair Value of Financial Instruments

The Company's financial instruments consist principally of cash and cash equivalents, restricted cash, other current receivables, accounts payable, accrued liabilities, insurance financing debt, liability-classified warrants and contingent consideration obligations. The carrying amounts of financial instruments such as cash and cash equivalents, restricted cash, other current receivables, accounts payable, and accrued liabilities approximate their related fair values due to the short-term nature of these instruments. The Company invests its excess cash in money market funds that are classified as level 1 in the fair value hierarchy defined below, due to their short-term maturity, and measured the fair value based on quoted prices in active markets for identical assets. The carrying value of the Company's insurance financing debt approximates its fair value due to the market rate of interest, which is based on level 2 inputs. The Company's derivative financial instruments, consisting of its liability-classified warrants, and its contingent consideration obligation, are carried at fair value based on level 3 inputs as defined below. None of the Company's non-financial assets or liabilities are recorded at fair value on a nonrecurring basis.

The Company follows Accounting Standards Codification ("ASC") 820, *Fair Value Measurements and Disclosures*, which among other things, defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement determined based on assumptions that market participants would use in pricing an asset or liability.

As a basis for considering such assumptions, a three-tier fair value hierarchy has been established, which prioritizes the inputs used in measuring fair value as follows:

1) Level 1: observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities;
2) Level 2: inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and
3) Level 3: unobservable inputs for which there is little or no market data, which require the reporting entity to develop its own assumptions, which reflect those that a market participant would use.

Further information on the fair value of the Company's liability-classified financial warrants can be found at Note 5, Fair Value Measurements.

Derivative Financial Instruments

The Company does not use derivative instruments to hedge exposures to cash flow, market, or foreign currency risks. The Company evaluates its financial instruments, including warrants, to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. The Company values its derivatives using the Black-Scholes option pricing model or other acceptable valuation models, including the Monte-Carlo simulation model. Derivative instruments are valued at inception, upon events such as an exercise of the underlying financial instrument, and at subsequent reporting periods. The classification of derivative instruments, including whether such instruments should be recorded as liabilities, is reassessed at the end of each reporting period.

The Company reviews the terms of debt instruments, equity instruments, and other financing arrangements to determine whether there are embedded derivative features, including embedded conversion options that are required to be bifurcated and accounted for separately as a derivative financial instrument. Additionally, in connection with the issuance of financing instruments, the Company may issue freestanding options and warrants.

The Company accounts for its common stock warrants in accordance with ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480") and ASC 815, *Derivatives and Hedging* ("ASC 815"). Based upon the provisions of ASC 480 and ASC 815, the Company accounts for common stock warrants as liabilities if the warrant requires net cash settlement or gives the holder the option of net cash settlement, or if it fails the equity classification criteria. The Company accounts for common stock warrants as equity if the contract requires physical settlement or net physical settlement or if the Company has the option of physical settlement or net physical settlement and the warrants meet the requirements to be classified as equity. Common stock warrants classified as liabilities are initially recorded at fair value on the grant date and remeasured at fair value at each balance sheet date with the offsetting adjustments recorded in change in fair value of warrant liability within the consolidated statements of operations. If the terms of a common stock warrant previously classified as a liability are amended and pursuant to such amendment meet the requirements to be classified as equity, the common stock warrants are reclassified to equity at the fair value on the date of the amendment and are not subsequently remeasured. Common stock warrants classified as equity are recorded on a relative fair value basis when they are issued with other equity-classified financial instruments.

Leases

In accordance with ASC 842, *Leases*, the Company assesses contracts for lease arrangements at inception. Operating right-of-use ("ROU") assets and liabilities are recognized at the lease commencement date equal to the present value of future lease payments using the implicit, if readily available, or incremental borrowing rate based on the information readily available at the commencement date. ROU assets include any lease payments as of commencement and initial direct costs but exclude any lease incentives. Lease and non-lease components are generally accounted for separately and the Company recognizes operating lease expense straight-line over the term of the lease.

License Revenue

The Company uses the revenue recognition guidance established by ASC 606, *Revenue From Contracts With Customers* ("ASC 606"). When an agreement falls under the scope of other standards, such as ASC 808, *Collaborative Arrangements*, the Company will apply the recognition, measurement, presentation, and disclosure guidance in ASC 606 to the performance obligations in the agreements if those performance obligations are with a customer. The Company currently does not have any collaborative arrangements with counterparties that are also considered customers. For arrangements that include amounts to be paid to the Company upon the achievement of certain development milestones of technology licensed by the Company, the Company recognizes such license revenue using the most likely method. At the end of each reporting period, the Company re-evaluates the probability or achievement of any potential milestones and any related constraints, and if necessary, adjusts its estimates of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue in the period of adjustment.

Contingent Consideration Obligation

Pursuant to the Giiant License Agreement, the Company incurred a contingent consideration obligation consisting of milestone payments, which are recognized as a liability measured at fair value, and ongoing royalty payments of five percent of the adjusted gross proceeds, as defined in the Giiant License Agreement, upon the sales or sublicenses third parties of any products developed from the assets licensed under the Giiant License Agreement (See Note 8, Collaborations and License Agreements). Because the contingent consideration associated with the milestone payments may be settled in shares of the Company's common stock solely at the election of the Company, the Company has determined it should be accounted for under ASC 480 and accordingly the Company has recognized it as a liability measured at its estimated fair value. At the end of each reporting period, the Company re-measures the contingent consideration obligation to its estimated fair value and any resulting change is recognized in research and development expenses in the consolidated statements of operations. The Company has determined that the contingent consideration associated with the royalty payments should be recognized as a liability when they are probable and estimable, in accordance with ASC 450, *Contingencies*.

Research and Development Costs

Research and development expenses consist primarily of salaries and other personnel related expenses including stock-based compensation costs, and, to the extent applicable, may include pre-clinical costs, clinical trial costs, costs related to acquiring and manufacturing clinical trial materials, and contract services. All research and development costs are expensed as incurred. Pursuant to situations whereby the Company performs any research and development or manufacturing activities under a co-development agreement, the Company records the expense reimbursements from the co-development partner as a reduction to research and development expense once the reimbursement amount is approved for payment by the co-development partner. Expense payments made to Giiant pursuant to the terms of the Giiant License Agreement for qualifying development costs are expensed only as the associated research and development costs are incurred or other aspects of the drug development or related activities are achieved. In instances where the expense determined to be recognized exceeds the payments made to the Giiant, the Company recognizes an accrual of joint development expenses. In addition, there may be instances in which payments made to Giiant will temporarily exceed the level of services provided, which results in a prepayment of the joint development expenses.

Patent Costs

Costs related to filing and pursuing patent applications (including direct application fees, and the legal and consulting expenses related to making such applications) are expensed as incurred, as recoverability of such expenditures is uncertain. These costs are included in general and administrative expenses in the consolidated statements of operations.

Income Taxes

The Company follows ASC 740, *Income Taxes* (“ASC 740”) in reporting deferred income taxes. ASC 740 requires a company to recognize deferred tax assets and liabilities for expected future income tax consequences of events that have been recognized in the Company’s consolidated financial statements. Under this method, deferred tax assets and liabilities are determined based on temporary differences between financial statement carrying amounts and the tax basis of assets and liabilities using enacted tax rates in the years in which the temporary differences are expected to reverse. Valuation allowances are provided if, based on the weight of available evidence, it is more likely than not that some of or all the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions pursuant to ASC 740, which prescribes a recognition threshold and measurement process for financial statement recognition of uncertain tax positions taken or expected to be taken in a tax return. If the tax position meets this threshold, the benefit to be recognized is measured as the tax benefit having the highest likelihood of being realized upon ultimate settlement with the taxing authority. The Company recognizes interest accrued related to unrecognized tax benefits and penalties in the provision for income taxes.

Stock-Based Compensation

The Company's stock-based compensation expense generally includes service-based restricted stock units ("RSUs"), stock options, and market-based performance RSUs ("PSUs"). The Company accounts for forfeitures as they occur for each type of award as a reduction of expense. Stock-based compensation expense related to service-based RSUs is based on the market value of the underlying stock on the date of grant and the related expense is recognized ratably over the requisite service period, which is usually the vesting period. The Company estimates the fair value of employee and non-employee stock option grants using the Black-Scholes option pricing model. The determination of the fair value of stock-based payment awards on the date of grant using the Black-Scholes option pricing model is affected by the Company's stock price as well as assumptions, which include the expected term of the award, the expected stock price volatility, risk-free interest rate, and expected dividends over the expected term of the award. Stock-based compensation expense represents the cost of the estimated grant date fair value of employee and non-employee stock option grants recognized ratably over the requisite service period of the awards, which is usually the vesting period. For PSUs with vesting subject to market conditions, the fair value of the award is determined at grant date using the Monte Carlo simulation model, and expense is recognized ratably over the derived service period regardless of whether the market condition is satisfied. The Monte Carlo simulation model considers a variety of potential future scenarios under the market condition vesting criteria, including but not limited to share prices for the Company and its peer companies in a selected market index.

The Company does not recognize any share-based compensation expense related to conditional RSUs, stock options, or PSUs that are subject to shareholder approval. When and if approval is obtained, the Company recognizes share-based compensation expense related to the conditional equity grants ratably to the vesting of shares over the remaining requisite service period.

Basic and Diluted Net Loss Per Common Share

Basic net loss per common share is computed by dividing net loss available to common stockholders by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share is calculated by dividing the net loss available to common stockholders by the weighted-average number of shares of common stock outstanding during the period, plus potentially dilutive common shares, consisting of stock-based awards and equivalents, and common stock warrants. For purposes of this calculation, stock-based awards and equivalents and common stock warrants are considered to be potential common shares and are only included in the calculation of diluted net loss per common share when their effect is dilutive.

The Company's Series A Convertible Preferred Stock and certain of the Company's outstanding common stock warrants contain non-forfeitable rights to dividends with the common stockholders, and therefore are considered to be participating securities. The Series A Convertible Preferred Stock and the common stock warrants do not have a contractual obligation to fund the losses of the Company; therefore, the application of the two-class method is not required when the Company is in a net loss position but is required if the Company is in a net income position. When in a net income position, diluted net earnings per common share is computed using the more dilutive of the two-class method or the if-converted and treasury stock methods.

As the Company was in a net loss position for both years presented, basic and diluted net loss per common share for the years ended December 31, 2023 and December 31, 2022 were calculated under the if-converted and treasury stock methods. For the years ended December 31, 2023 and December 31, 2022, basic and diluted net loss per common share were the same as all common stock equivalents were anti-dilutive for both years.

In computing both the basic and diluted net loss available to common stockholders for the years ended December 31, 2023 and December 31, 2022, the Company has deducted the value of the effect of the down round feature on equity classified warrants that was triggered in each year as each was determined to be anti-dilutive.

The following table presents the calculation of weighted average shares used to calculate basic and diluted net loss per common share (in thousands, except share and per share amounts):

	Year Ended December 31,	
	2023	2022
Basic and diluted net loss per common share:		
Net loss	$ (12,300)	$ (14,260)
Adjustment to record the impact of exercise price reset on outstanding warrants related to down round provisions	(16)	(288)
Net loss available to common stockholders - basic and diluted	$ (12,316)	$ (14,548)
Weighted average shares used in calculating basic and diluted net loss per common share	6,840,213	880,311
Basic and diluted net loss per common share	$ (1.80)	$ (16.53)

The following potentially dilutive securities were excluded from the calculation of diluted net loss per share because their effects would be anti-dilutive:

	December 31,	
	2023	2022
Stock options	665,472	43,658
Restricted stock units	425,124	—
Warrants for common stock	4,080,876	1,055,672
Series A Convertible Preferred Stock	129	129
Total	5,171,601	1,099,459

Comprehensive Loss

Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. The Company's comprehensive loss was the same as its reported net loss for all years presented.

Reclassifications

Certain prior year amounts have been reclassified to conform to the current year presentation. During the fourth quarter of 2023, the Company reclassified the fair value of the contingent consideration milestone payment obligation associated with the Giiant License Agreement, including transaction related costs, from In-process research and development expenses to Research and development expenses at the consolidated statement of operations, which impacted amounts previously reported for the three and nine months ended September 30, 2023. Amounts reported for the year ended December 31, 2022 were not impacted by this reclassification.

Recently Adopted Accounting Pronouncements

In August 2020, FASB issued Accounting Standards Update ("ASU") 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40) — Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* ("ASU- 2020-06"), which, among other things, provides guidance on how to account for contracts on an entity's own equity. This ASU simplifies the accounting for certain financial instruments with characteristics of liabilities and equity. Specifically, the ASU eliminated the need for the Company to assess whether a contract on the entity's own equity (1) permits settlement in unregistered shares, (2) whether counterparty rights rank higher stockholder's rights, and (3) whether collateral is required. In addition, the ASU requires incremental disclosure related to contracts on the entity's own equity and clarifies the treatment of certain financial instruments accounted for under this ASU on earnings per share. This ASU may be applied on a full retrospective of modified retrospective basis. For smaller reporting companies, this ASU is effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption of the ASU is permitted for fiscal years beginning after December 15, 2020, including interim periods within

those fiscal years. The Company early adopted this standard on January 1, 2022 and determined that it had no impact on the accounting for its liability-classified warrants as of the date of adoption.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments — Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). The ASU introduced a new credit loss methodology, the Current Expected Credit Losses ("CECL") methodology, which requires earlier recognition of credit losses, while also providing additional transparency about credit risk. The CECL methodology utilizes a lifetime "expected credit loss" measurement objective for the recognition of credit losses for loans, held-to maturity debt securities, trade receivables and other receivables measured at amortized cost at the time the financial asset is originated or acquired. After the issuance of ASU 2016-13, the FASB issued several additional ASUs to clarify implementation guidance, provide narrow-scope improvements and provide additional disclosure guidance. In November 2019, the FASB issued an amendment making this ASU effective for fiscal years beginning after December 15, 2022 for smaller reporting companies. The Company adopted this standard as of January 1, 2023 and determined it did not have a material impact on its consolidated financial statements and related disclosures for the year ended December 31, 2023.

Recently Issued Accounting Pronouncements

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 720): Improvements to Income Tax Disclosures* ("ASU 2023-09"), which prescribes standard categories for the components of the effective tax rate reconciliation and requires disclosure of additional information for reconciling items meeting certain quantitative thresholds, requires disclosure of disaggregated income taxes paid, and modifies certain other income tax-related disclosures. ASU No. 2023-09 is effective for annual periods beginning after December 15, 2024 and allows for adoption on a prospective basis, with a retrospective option. The Company is currently evaluating the potential impact of the adoption of ASU 2023-09. The Company expects any potential impact of ASU 2023-09 to only relate to disclosures with no impact to its results of operations, cash flows, and financial condition.

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, ("ASU 2023-07"), which is intended to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. The disclosure requirements included in ASU No. 2023-07 are required for all public entities, including those with a single reportable segment. ASU No. 2023-07 is effective for annual periods beginning after December 15, 2024, on a retrospective basis, and early adoption is permitted. The Company expects any potential impact of ASU 2023-07 to only relate to disclosures with no impact to its results of operations, cash flows, and financial condition.

3. Balance Sheet Details

Prepaid expenses and other current assets consisted of the following (in thousands):

	December 31,	
	2023	2022
Prepaid insurance	$ 428	$ 581
Other receivables	148	1,438
Prepaid subscriptions and fees	138	157
Prepaid software licenses	64	54
Deferred equity issuance costs	112	114
Prepaid other	6	6
	$ 896	$ 2,350

Other receivables as of December 31, 2022 includes a $1.4 million receivable for the cash exercise price of common stock purchase warrants that had been exercised but the cash had not yet been received by the Company as of December 31, 2022. The entire amount of this receivable was received by the Company in January of 2023. There was no such receivable as of December 31, 2023.

Other noncurrent assets consisted of the following (in thousands):

	December 31,	
	2023	2022
Prepaid insurance, less current portion	$ 478	$ 682
Other noncurrent assets	12	12
	$ 490	$ 694

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2023	2022
Accrued accounts payable	$ 166	$ 69
Accrued clinical trial expenses	20	184
Accrued director stipends	106	141
Accrued severance and benefits (Note 9)	131	180
Accrued joint development expenses (Note 8)	98	—
Current portion of contingent consideration obligation (Note 5)	143	—
Accrued other	167	—
	$ 831	$ 574

4. Common Stock Warrants

The Company's outstanding common stock warrants that are classified as equity warrants are included as a component of stockholders' equity based on their relative fair value on their date of issuance. Common stock warrants accounted for as liabilities in accordance with the authoritative accounting guidance are included in noncurrent liabilities. The Company had common stock warrants outstanding of 4,080,876 and 1,055,672 at December 31, 2023 and December 31, 2022, respectively. Of the Company's common stock warrants exercisable at December 31, 2023, (i) 205,201 common stock warrants have an exercise price of $0.84, (ii) 1,012,631 common stock warrants have an exercise price of $2.375, (iii) 2,272,723 common stock warrants have an exercise price of $2.64, (iv) 136,363 common stock warrants have an exercise price of $3.30, (v) 63,158 common stock warrants have an exercise price of $2.9668, (vi) 140,364 common stock warrants have an exercise price of $1.05, and (vii) the remaining 250,436 common stock warrants have a weighted-average exercise price of $103.52. Only the 205,201 common stock warrants outstanding that have an exercise price of $0.84 are subject to down round price reset provisions.

Liability-Classified Warrants

January 2022 Warrants

On January 31, 2022, the Company and an investor entered into an agreement to irrevocably waive any adjustment to the exercise price of the Senior Secured Promissory Note Warrants (defined below) and the May 2021 Warrants (defined below) held by the investor from and after January 31, 2022 for the Company's issuances of equity or equity-linked securities at a price below the exercise price of the warrants (the "January 2022 Waiver Agreement"). The waiver of any adjustments to the exercise price of the Senior Secured Promissory Note Warrants and the May 2021 Warrants was considered a modification to those warrants. The modification was determined to have no impact on the valuation of the warrants.

As consideration for the foregoing, pursuant to the January 2022 Waiver Agreement, the Company issued the investor additional warrants to purchase shares of the Company's common stock (the "January 2022 Warrants"). The initial fair value of the January 2022 Warrants was determined to be $1.1 million and is included in loss on issuance of warrants in the consolidated statements of operations for the year ended December 31, 2023.

The January 2022 Warrants expire five and a half years from the date of issuance, or July 31, 2027. As of December 31, 2023, the January 2022 Warrants outstanding were exercisable for 45,000 shares of the Company's common stock at an exercise price of $55.00 per common stock warrant.

July 2021 Warrants

On July 21, 2021, the Company and an investor entered into an agreement to waive certain provisions of the previous Security Purchase Agreement (defined below) (the "July 2021 Waiver Agreement"). As consideration for the July 2021 Waiver Agreement, the Company issued the investor additional warrants to purchase shares of the Company's common stock (the "July 2021 Warrants"). The July 2021 Warrants expire five years from the date of registration of the warrants, or August 19, 2026. As of December 31, 2023, the July 2021 Warrants outstanding were exercisable for 22,000 shares of the Company's common stock at an exercise price of $181.50 per common stock warrant.

Senior Secured Promissory Note Warrants

On December 16, 2020, the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") with an investor pursuant to which, among other things, the Company agreed to issue warrants to purchase shares of the Company's common stock ("Senior Secured Promissory Note Warrants"). The Senior Secured Promissory Note Warrants expire five years from the date of registration of the warrants, or August 10, 2026. As of December 31, 2023, the Senior Secured Promissory Note Warrants outstanding were exercisable for 17,177 shares of the Company's common stock at an exercise price of $194.00 per common stock warrant.

Equity-Classified Warrants

The Company accounts for the majority of its warrants as equity-classified in accordance with ASC 480 and ASC 815.

September 2023 Offering

In connection with the September 2023 Offering (see Note 6, Stockholders' Equity), on September 11, 2023 the Company issued 140,364 warrants to purchase shares of the Company's common stock to the offering placement agent at an exercise price of $1.05 per share and a term of five years and are immediately exercisable from issuance (the "September 2023 Placement Agent Warrants"). The fair value of the September 2023 Placement Agent Warrants was recognized by the Company as an equity issuance cost, which reduced the additional paid-in capital recognized from the September 2023 Offering. The September 2023 Placement Agent Warrants are not subject to any exercise price reset or down round provisions.

April 2023 Registered Direct Offering and Private Placement Warrants

In connection with the April 2023 Offering (see Note 6, Stockholders' Equity), on April 3, 2023 the Company issued (i) 1,061,164 pre-funded warrants to purchase shares of the Company's common stock at a purchase price of $2.6399, with such warrants having an exercise price of $0.0001 per share and a perpetual term, (ii) 2,272,723 warrants to purchase shares of the Company's common stock at an exercise price of $2.64 per share and a term of five years from the date of issuance (the "April 2023 Warrants"), and (iii) 136,363 warrants to purchase shares of the Company's common stock to the offering placement agent at an exercise price of $3.30 per share and a term of five years. As of December 31, 2023, all of the pre-funded warrants issued with the April 2023 Offering have been exercised for shares of the Company's common stock. None of the warrants issued with the April 2023 Offering are subject to any exercise price reset or down round provisions.

January 2023 Registered Direct Offering and Private Placement Warrants

In connection with the January 2023 Offering (see Note 6, Stockholders' Equity), on January 4, 2023 the Company issued (i) 37,000 pre-funded warrants to purchase shares of the Company's common stock at a purchase price of $2.3749 per warrant, with such warrants having an exercise price of $0.0001 per warrant and a perpetual term (ii) 538,789 pre-funded warrants to purchase shares of the Company's common stock at a purchase price of $2.3749 per

warrant, with such warrants having an exercise price of $0.0001 per warrant and a perpetual term; (iii) 1,052,631 warrants to purchase shares of the Company's common stock at an exercise price of $2.375 per share and a term of five years (the "January 2023 Warrants"), and (iv) 63,158 warrants to purchase shares of the Company's common stock to the offering placement agent at an exercise price of $2.9688 per share and a term of five years. As of December 31, 2023, all of the pre-funded warrants issued with the January 2023 Offering have been exercised for shares of the Company's common stock and 40,000 warrants issued with the January 2023 Offering have been exercised for shares of the Company's common stock. None of the warrants issued with the January 2023 Offering are subject to any exercise price reset or down round provisions.

August 2022 Offering Warrants

In connection with the August 2022 Offering (see Note 6, Stockholders' Equity), on August 16, 2022 the Company issued warrants exercisable for 1,104,000 shares of the Company's common stock that expired one year from the date of issuance (the "Series 1 Warrants") and warrants exercisable for 1,104,000 shares of the Company's common stock that expire five years from the date of issuance (the "Series 2 Warrants"). Both the Series 1 Warrants and the Series 2 Warrants became exercisable beginning on the date of stockholder approval of the exercisability of the warrants, which was received on October 6, 2022. The original exercise price of the Series 1 Warrants and Series 2 Warrants was $12.50. Per the terms of the underlying warrant agreements, the exercise price of the Series 1 Warrants and Series 2 Warrants was adjusted to $2.81, based upon the five day volume weighted average price of the Company's common stock immediately following the effective date of the Reverse Stock Split. Concurrent with the August 2022 Offering, the Company issued the underwriter warrants to purchase 66,240 shares of the Company's common stock at an exercise price of $15.63 (the "Underwriter Warrants"). The Underwriter Warrants expire five years from the date of issuance.

The exercise price of the Series 1 Warrants and Series 2 Warrants can be further adjusted in the event of issuances of the Company's common stock at a price lower than the exercise price of the Series 1 Warrants and Series 2 Warrants then in effect (the “Down Round Feature”). During the year ended December 31, 2022, the Down Round Feature was triggered due to the December 30, 2022 announcement of the January 2023 Offering (See Note 6) (the "December 2022 Down Round"). As a result of the triggering of the December 2022 Down Round, the exercise price of any outstanding Series 1 Warrants or Series 2 Warrants was adjusted down to $2.38, which represents the price per share of the equity being offered in the January 2023 Offering. During the year ended December 31, 2023, the Down Round Feature was again triggered on 205,201 of the Company's outstanding equity-classified Series 2 Warrants due to the September 7, 2023 announcement of the September 2023 Offering (See Note 6) (the "September 2023 Down Round"). As a result of the triggering of the September 2023 Down Round, the exercise price of any outstanding Series 2 warrants including the Down Round Feature was adjusted down to $0.84, which represents the price per share of the equity being offered in September 2023 Offering. None of the Series 1 Warrants were impacted by September 2023 Down Round as all had expired. As of December 31, 2023, Series 2 Warrants outstanding were exercisable for 205,201 shares of the Company’s common stock, each at an exercise price of $0.84. All of the Underwriter Warrants are outstanding as of December 31, 2023 at an exercise price of $15.63, and are not subject to any exercise price reset or down round provisions.

The Company calculated the value of the effect of Down Round Feature in both the December 2022 Down Round and the September 2023 Down Round as the difference between the fair of the warrants impacted, using a Monte Carlo valuation model, immediately before and immediately after the Down Round Feature was triggered using the existing exercise price and the new exercise price. The difference in fair value of the effect of the December 2022 Down Round of $288,000 and was recognized as a deduction from the loss available to common shareholders for the year ended December 31, 2022. The difference in fair value of the effect of the September 2023 Down Round of $16,000 and was recognized as a deduction from the loss available to common shareholders the year ended December 31, 2023. The exercise price of any outstanding Series 2 warrants subject to down round price reset provisions will continue to be adjusted in the event the Company issues additional shares of common stock below the current exercise price, in accordance with the terms of the warrants. Only 205,201 common stock warrants outstanding as of December 31, 2023 are subject to down round price reset provisions.

May 2022 Registered Direct Offering Warrants

In connection with the May 2022 Offering (see Note 6, Stockholders' Equity), on May 10, 2022 the Company issued the warrants to purchase 72,935 shares of the Company's common stock at an exercise price of $35.53 (the "May 2022 Warrants"). The May 2022 Warrants were not exercisable until six months following the date of issuance and expire five and a half years from the date of issuance. Concurrently, the Company issued common stock warrants to purchase 4,376 shares of the Company's common stock at an exercise price of $35.53 to the offering placement agent (the "May 2022 Placement Agent Warrants"). The May 2022 Placement Agent Warrants are not exercisable until six months following the date of issuance and expire five years from the date of issuance. None of the warrants issued with the May 2022 Offering are subject to any exercise price reset or down round provisions.

The following table summarizes all common stock warrant activity for the year ended December 31, 2023:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)
Warrants outstanding, December 31, 2022	1,055,672	$ 26.48	3.32
Granted	5,302,192	1.75	4.64
Exercised	(2,203,993)	0.61	0.73
Forfeited, expired or cancelled	(72,995)	4.86	—
Warrants outstanding, December 31, 2023	4,080,876	8.63	4.12

For the years ended December 31, 2023 and 2022, the Company received gross cash proceeds of approximately $2.8 million and approximately $2.3 million, respectively, from exercises of common stock warrants. Of the gross cash proceeds received for the year ended December 31, 2023, $1.4 million related to common stock warrants exercised on December 30, 2022 for which the related cash exercise price was receivable to the Company as of December 31, 2022. The related cash payment was received by the Company in January 2023.

On January 30, 2024, the Company entered into warrant inducement agreements with certain accredited and institutional holders, which resulted in the exercise of an aggregate of 3,422,286 of the Company's equity-classified warrants outstanding as of December 31, 2023. Refer to Note 13, Subsequent Events, for further details.

5. Fair Value Measurements

Contingent Consideration Obligations

Pursuant to the Giiant License Agreement entered into on September 1, 2023, the Company incurred a contingent consideration obligation related to future milestone payments. The Company has an obligation to make contingent consideration payments to Giiant, in either cash or shares of the Company's common stock solely at the Company's election, upon the achievement of development milestones (as set forth in the Giiant License Agreement). Because the contingent consideration may be settled in shares of the Company's common stock, the Company has determined it should be accounted for under ASC 480, *Distinguishing Liabilities from Equity*, and accordingly has recognized it as a liability measured at its estimated fair value.

At the end of each reporting period, the Company re-measures the contingent consideration obligation to its estimated fair value and any resulting change is recognized in research and development expenses in the consolidated statements of operations. The fair value of the contingent consideration obligation is determined using a probability-based model that estimates the likelihood of success in achieving each of the defined milestones which is then discounted to present value using the Company's incremental borrowing rate. The fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement as defined in fair value measurement accounting. The significant assumptions used in the calculation of the fair value as of December 31, 2023 included a discount rate of 13.5% and management's updated projections of the likelihood of success in achieving each of the defined milestones based on reputable, published industry data.

As of September 1, 2023, the date the contingent consideration obligation was incurred, the initial fair value of the liability was determined to be approximately $0.2 million. The following table summarizes the activity of the Company's Level 3 contingent consideration obligations, which are fair valued on a recurring basis (in thousands):

Contingent Consideration Obligations	Year Ended December 31, 2023
Fair value at beginning of year	$ —
Initial fair value at the original issuance date	212
Change in fair value during the year	(8)
Fair value at end of year	$ 204

As of December 31, 2023, approximately $143,000 of the contingent consideration obligation was recognized in accrued liabilities at the consolidated balance sheet as it is expected to be settled within one-year of the balance sheet date. The remaining amount of the contingent consideration liability of approximately $61,000 was recognized as a noncurrent liability in the consolidated balance sheet as of December 31, 2023. The initial fair value of the contingent consideration liability of $0.2 million, transaction-related costs of approximately $0.1 million, and the change in the fair value of the contingent consideration liability for the year ended December 31, 2023 is recognized in research and development expenses in the consolidated statements of operations.

Liability-Classified Warrants

The Company has issued warrants that are accounted for as liabilities based upon the guidance of with ASC 480 and ASC 815. Estimating fair values of liability-classified financial instruments requires the development of estimates that may, and are likely to, change over the duration of the instrument with related changes in internal and external market factors. Changes in fair value of the liability-classified warrants are recognized as a component of other income in the consolidated statement of operations.

As of December 31, 2023, the fair value of the Company's liability-classified warrants outstanding was determined using a Black-Scholes option pricing model valuation model to be insignificant due to the low market price of the Company's stock at the date of valuation relative to the exercise price of the underlying warrants outstanding.

The following table summarizes the activity of the Company's Level 3 liability-classified warrants, which are fair valued on a recurring basis (in thousands):

Warrant Liabilities	Year Ended December 31, 2023	Year Ended December 31, 2022
Fair value at beginning of year	$ 61	$ 2,651
Initial fair value at the original issuance date	—	1,110
Change in fair value during the period	(59)	(2,426)
Fair value of liability classified warrants exercised	—	(1,274)
Fair value at end of year	$ 2	$ 61

6. Stockholders' Equity

Classes of Stock

Common Stock

As of December 31, 2023, the Company was authorized to issue 280,000,000 shares of $0.01 par value common stock. Each share of common stock entitles the holder thereof to one vote on each matter submitted to a vote at a meeting of stockholders.

On November 15, 2022, the Company effected the Reverse Stock Split. Accordingly, each of the Company's shareholders received one new share of the Company's common stock for every 50 shares of the Company's common

stock such shareholder held immediately prior to the effective time of the Reverse Stock Split. The Reverse Stock Split affected all of the Company's issued and outstanding shares of the Company's common stock equally. The Reverse Stock Split also affected the Company's outstanding stock options, warrants and other exercisable or convertible securities and resulted in the shares underlying such instruments being reduced and the exercise price being increased proportionately to the Reverse Stock Split ratio. No fractional shares were issued as a result of the Reverse Stock Split with any fractional shares that would have otherwise resulted from the Reverse Stock Split paid in cash, at an amount equal to the resulting fractional interest in one share of the Company's common stock to which the shareholder would otherwise be entitled, multiplied by the closing trading price of the Company's common stock on November 15, 2022. The amount of cash paid for fractional shares was insignificant.

As a result of the Reverse Stock Split, the number of issued and outstanding shares of the Company's common stock was adjusted from 77,080,169 shares to approximately 1,541,508 shares. Each share of the Company's common stock entitles the holder thereof to one vote on each matter submitted to a vote at a meeting of stockholders.

Preferred Stock

As of December 31, 2023, the Company was authorized to issue 7,000,000 shares of $0.01 par value preferred stock of which 1,000,000 shares have been designated as Series A 4.5% Convertible Preferred Stock ("Series A Convertible Preferred Stock") and 200,000 of which are issued and outstanding. As of December 31, 2023, the Company's Series A Convertible Preferred Stock issued in the amount of 200,000 preferred stock shares is convertible into 129 shares of common stock.

In connection with the August 2022 Offering (see below), the Company's Board of Directors ("Board") designated 1,460 shares of the Company's preferred stock as $0.01 par value Series B Convertible Preferred Stock. Each share of Series B Convertible Preferred Stock will be convertible at any time at the holder's option into one share of the Company's common stock, which conversion ratio will be subject to adjustment for stock splits, stock dividends, distributions, subdivisions and combinations. Subject to certain limitations, if the volume weighted average price of the Company's stock during any 30 consecutive trading day period exceeds 300% of the conversion price, the average daily dollar trading volume for such 30 consecutive trading period $500,000 per trading day and the holder is not in possession of any material non-public information, the Company may force each holder of Series B Convertible Preferred Stock to convert all of their shares of Series B Convertible Preferred Stock. The Series B Convertible Preferred Stock carries no voting rights and is not eligible for any dividends paid by the Company on shares of the Company's common stock, other than dividends in the form of the Company's common stock. The Series B Convertible Preferred Stock was classified as permanent equity as of the date of issuance, in accordance with authoritative guidance of ASC 480-10-S99 for the classification and measurement of potentially redeemable securities. As of December 31, 2022, all of the shares of the Series B Convertible Preferred stock issued in connection with the August 2022 Offering (see below) have been converted into shares of the Company's common stock and there were no shares of the Series B Convertible Preferred Stock issued or outstanding.

September 2023 Offering

On September 7, 2023, the Company entered into securities purchase agreements with certain institutional investors, pursuant to which the Company agreed to sell and issue in a registered direct offering an aggregate of 2,339,398 shares of the Company's common stock, par value $0.01 per share, at a purchase price per share of $0.84 (the "September 2023 Offering"). The shares of the Company's common stock offered in the September 2023 Offering were offered and sold by the Company pursuant to a shelf registration statement on Form S-3, including a base prospectus, previously filed with and declared effective by the SEC on April 26, 2022. The September 2023 Offering closed on September 11, 2023.

Gross cash proceeds from the September 2023 Offering were approximately $2.0 million and net cash proceeds were approximately $1.7 million after deducting cash equity issuance costs of approximately $0.3 million, which excludes the grant date fair value of the September 2023 Placement Agent Warrants of approximately $0.1 million. The fair value of the September 2023 Placement Agent Warrants was recognized by the Company as an equity issuance cost.

April 2023 Registered Direct Offering and Private Placement

On April 3, 2023, the Company entered into securities purchase agreements with certain institutional and accredited investors pursuant to which the Company agreed to sell and issue, in a registered direct offering (the "April 2023

Registered Offering"), an aggregate of 756,317 shares of the Company's common stock, at a purchase price per share of $2.64. Additionally, in a concurrent private placement, the Company also agreed to sell and issue to such purchasers, an aggregate of (i) 455,242 unregistered shares of the Company's common stock, at a purchase price per share of $2.64, (ii) 1,061,164 prefunded warrants to purchase shares of the Company's common stock at a purchase price of $2.6399 per prefunded warrant, with such warrants having an exercise price of $0.0001 per share and a perpetual term; and (iii) 2,272,723 common stock warrants to purchase shares of the Company's common stock at an exercise price of $2.64 per share and a term of five years from the date of issuance (the "April 2023 Private Placement") (collectively, April 2023 Registered Offering and April 2023 Private Placement are referred to as the "April 2023 Offering"). All of the warrants issued in the April 2023 Offering are immediately exercisable from their date of issuance.

Pursuant to a placement agency agreement dated as of April 3, 2023, the Company engaged Ladenburg Thalmann & Co. Inc. (the "April 2023 Placement Agent"), to act as the exclusive placement agent in connection with the April 2023 Offering. The Company issued warrants to the April 2023 Placement Agent to purchase an aggregate of 136,363 shares of the Company's common stock (the "April 2023 Offering Placement Agent Warrants"). The April 2023 Offering Placement Agent Warrants have an exercise price of $3.30 per share and a term of five years and are immediately exercisable from their date of issuance. The fair value of the April 2023 Offering Placement Agent Warrants was recognized by the Company as an equity issuance cost which reduced the additional paid-in capital recognized from the April 2023 Offering.

Gross cash proceeds from the April 2023 Offering were approximately $6.0 million and net cash proceeds were approximately $5.3 million after deducting cash equity issuance costs of approximately $0.7 million, which excludes the grant date fair value of the April 2023 Placement Agent Warrants of approximately $0.2 million.

January 2023 Registered Direct Offering and Private Placement

On January 4, 2023, the Company closed on an agreement with certain institutional and accredited investors pursuant to which it agreed to sell and issue, in a registered direct offering (the "January 2023 Registered Offering"), an aggregate of (i) 476,842 shares of the Company's common stock, par value $0.01 per share, at a purchase price per share of $2.375, and (ii) 37,000 pre-funded warrants to purchase shares of the Company's common stock at a purchase price of $2.3749, with such warrants having an exercise price of $0.0001 per share and a perpetual term. Additionally, in a concurrent private placement, the Company also agreed to sell and issue to such purchasers, an aggregate of (i) 538,789 pre-funded warrants to purchase shares of the Company's common stock at a purchase price of $2.3749, with such warrants having an exercise price of $0.0001 per share and a perpetual term; and (ii) 1,052,631 warrants to purchase shares of the Company's common stock at an exercise price of $2.375 per share and a term of five years from the date of issuance (the "January 2023 Private Placement") (collectively, the January 2023 Registered Offering and the January 2023 Private Placement are referred to as the "January 2023 Offering"). All the warrants issued in the January 2023 Offering are immediately exercisable from their date of issuance.

Pursuant to a placement agency agreement dated as of December 30, 2022, the Company engaged Ladenburg Thalmann & Co. Inc. (the "January 2023 Placement Agent"), to act as the exclusive placement agent in connection with the January 2023 Offering. The Company issued warrants to the January 2023 Placement Agent to purchase an aggregate of 63,158 shares of the Company's common stock (the "January 2023 Placement Agent Warrants"). The January 2023 Placement Agent Warrants have an exercise price of $2.9688 per share and a term of five years. The January 2023 Placement Agent Warrants are immediately exercisable from issuance. The fair value of the January 2023 Placement Agent Warrants was recognized by the Company as an equity issuance cost, which reduced the additional paid-in capital recognized from the January 2023 Offering.

Gross cash proceeds from the January 2023 Offering were approximately $2.5 million and net cash proceeds were approximately $2.2 million after deducting cash equity issuance costs of approximately $0.3 million, which excludes the grant date fair value of the January 2023 Placement Agent Warrants of approximately $0.2 million.

August 2022 Offering

On August 16, 2022, the Company closed on a registered public offering pursuant to which the Company agreed to issue and sell (i) 987,200 shares of the Company's common stock, par value $0.01 per share, (ii) 1,460 shares of Series B Convertible Preferred Stock, of which each share is convertible into 80 shares of the Company's common stock, (iii) 1,104,000 Series 1 warrants with a term of one year from the date of issuance ("Series 1 Warrant") to purchase one share of the Company's common stock, and (iv) 1,104,000 Series 2 warrants with a term of five years from the date of issuance ("Series 2 Warrant") to purchase one share of the Company's common stock (the "August 2022 Offering"). The warrants became exercisable beginning on the date of stockholder approval of the exercisability of the warrants, which was received on October 6, 2022. Gross proceeds from the August 2022 Offering, including the full exercise of the underwriter overallotment option, were $13.8 million and net proceeds were approximately $11.5 million after deducting equity issuance costs of $2.3 million, which includes the underwriter discount, professional fees, and the fair value of the warrants issued to the underwriter of the August 2022 Offering, Ladenburg Thalmann & Co. Inc. All shares of the Series B Convertible Preferred Stock have been converted into shares of the Company's common stock, and any remaining, unexercised Series 1 Warrants have expired as of December 31, 2023.

May 2022 Registered Direct Offering

On May 6, 2022, the Company entered into securities purchase agreements with certain investors pursuant to which it agreed to sell and issue, in a registered direct offering (the "May 2022 Offering"), an aggregate of 72,935 shares of its common stock, par value $0.01 per share, and, in a concurrent private placement, also agreed to sell and issue to such purchasers warrants (the "May 2022 Purchase Warrants") to purchase up to 72,935 shares of the Company's common stock.

In connection with the May 2022 Offering and concurrent private placement transaction, the Company engaged a placement agent. The Company issued placement agent warrants ("May 2022 Placement Agent Warrants") to purchase an aggregate of 4,376 shares of its common stock. The May 2022 Placement Agent Warrants and the May 2022 Purchase Warrants are referred to collectively as the May 2022 Warrants.

The net proceeds from the May 2022 Offering of $1.4 million consisted of gross proceeds of $2.0 million less equity issuance costs of approximately $0.6 million. The fair value of the May 2022 Placement Agent Warrants was recognized as an equity issuance cost.

The shares of common stock (but not the warrants or the shares of common stock underlying such warrants) offered in the May 2022 Offering were offered and sold by the Company pursuant to a shelf registration statement on Form S-3, including a base prospectus, previously filed with and declared effective by the SEC on April 26, 2022.

7. Equity Incentive Plans

In 2013, LBS adopted the 2013 Employee, Director, and Consultant Equity Incentive Plan, (as amended and restated, the "2013 Plan"). No further awards will be made under the 2013 Plan.

In April 2021, the Company's shareholders approved the Palisade Bio, Inc. 2021 Equity Incentive Plan (the "2021 EIP Plan"). In June 2023, the Company's shareholders approved amendments to the 2021 EIP Plan to increase (i) the number of shares of common stock issuable under the plan by 708,072 shares and (ii) the annual evergreen share increase amount from 4% to 7.5% of the outstanding shares of common stock on January 1 of each year. As of December 31, 2023, there were 4,947 shares of the Company's common stock reserved for future issuance as equity-based awards under the 2021 EIP Plan, which excludes a total of 144,160 shares of the Company's common stock issuable upon exercise of outstanding stock options and outstanding restricted stock units that were conditionally granted to the Company's Chief Executive Officer and Chief Medical Officer on November 21, 2023 subject to sufficient shares being available under the 2021 EIP Plan, as well as any subsequent evergreen share increases in the number of shares of common stock reserved for issuance under the 2021 EIP Plan.

Also in April 2021, the Company's shareholder approved the Palisade Bio, Inc. 2021 Employee Stock Purchase Plan (the "2021 ESPP"). In June 2023, the Company's shareholders approved amendments to the 2021 ESPP to increase (i) the number of shares of common stock authorized under the plan by 109,944 shares and (ii) the annual evergreen share increase amount from 1% to 2.5% of the outstanding shares of common stock on January 1 of each year.

All employees are eligible to participate in the 2021 ESPP while employed by the Company. The 2021 ESPP permits eligible employees to purchase common stock through payroll deductions, which may not exceed $25,000 or 10,000 shares of the Company's shares of common stock each offering period, as defined in the 2021 ESPP, at a price equal to 85% of the fair value of the Company's common stock at the beginning or end of the offering period, whichever is lower. The 2021 ESPP is intended to qualify under Section 423 of the Internal Revenue Code. The first offering period under the plan commenced on July 1, 2023 and ended on November 20, 2023, at which time a second 6-month offering period commenced. As of December 31, 2023, there have been 33,676 shares of the Company's common stock issued under the 2021 ESPP. As of December 31, 2023, there were 110,871 shares of the Company's common stock reserved for future issuance under the 2021 ESPP, which excludes any subsequent evergreen share increases in the number of shares of common stock reserved for future issuance under the 2021 ESPP.

The Company estimates the fair value of grants from the 2021 ESPP on their grant date using the Black-Scholes option pricing model. The estimated fair value of the grants from the 2021 ESPP are amortized on a straight-line basis over the requisite service period of the grants. The Company reviews, and when deemed appropriate, updates the assumptions used on a periodic basis. The Company utilizes its estimated volatility in the Black-Scholes option pricing model to determine the fair value of 2021 ESPP grants. Compensation expense associated with the 2021 ESPP for the year ended December 31, 2023 was approximately $18,000.

In November 2021, the Company's compensation committee of the Company's Board adopted the Palisade Bio, Inc. 2021 Inducement Award Plan (the "2021 Inducement Plan"). The 2021 Inducement Plan was adopted in order to grant equity-based awards to individuals not previously employed by the Company, as an inducement to join the Company. On August 7, 2023, the Company's compensation committee of the Board approved an increase in the shares of the Company's common stock authorized and available for issuance to 1,000,000 shares. As of December 31, 2023, there were 863,214 shares of the Company's common stock reserved for future issuance as equity-based awards under the 2021 Inducement Plan.

Stock Options

The Company believes that stock options align the interests of its employees and directors with the interests of its stockholders. Stock option awards are generally granted with an exercise price equal to the market price of Company’s stock at the date the grants are awarded and a term as determined by the Company's Board but generally not to exceed ten-years. Stock option awards to employees vest in equal proportions each quarter over three years and stock option awards to directors of the Company's Board cliff vest after a period of one year. Vesting could be accelerated in the event of retirement, disability, or death of a participant, or change in control of the Company, as defined in the individual stock option agreements or employment agreements. Stock-based awards are valued as of the measurement date, which is the grant date, and are generally amortized on a straight-line basis over the requisite vesting period for all awards. The Company's equity incentive plans allow for the issuance of both incentive stock options and non-statutory stock options.

The fair value of options granted during the years ended December 31, 2023 and December 31, 2022 is estimated as of the grant date using the Black-Scholes option pricing model using the assumptions in the following table:

	Year Ended December 31,	
	2023	2022
Weighted-average exercise price per share	$ 1.39	$ 40.32
Weighted-average expected term (years)	5.66	5.81
Weighted-average risk-free interest rate	4.08%	2.30%
Weighted-average expected dividend yield	—	—
Weighted-average volatility	78.35%	73.66%

Risk-free interest rate. The Company bases the risk-free interest rate assumption on observed interest rates appropriate for the expected term of the stock option grants.

Expected dividend yield. The Company bases the expected dividend yield assumption on the fact that it has never paid cash dividends and has no present intention to pay cash dividends.

Expected volatility. Due to the Company's limited operating history and lack of company-specific historical or implied volatility, the expected volatility assumption is based on historical volatilities of a peer group of similar companies whose share prices are publicly available. The peer group was developed based on companies in the biotechnology industry.

Expected term. The expected term represents the period of time that options are expected to be outstanding. As the Company does not have sufficient historical exercise behavior, it determines the expected life assumption using the simplified method, which is an average of the contractual term of the option and its vesting period.

The following table summarizes stock option activity and related information under the 2013 Plan, the 2021 EIP Plan and the 2021 Inducement Plan for the year ended December 31, 2023:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2022	43,658	$ 311.74	6.08	$ —
Granted	669,180	1.39	9.57	—
Exercised	—	—	—	—
Forfeited, expired or cancelled	(47,366)	57.98	—	—
Outstanding at December 31, 2023	665,472	17.60	9.37	1
Vested and expected to vest at December 31, 2023	665,472	17.60	9.37	1
Exercisable at December 31, 2023	97,981	108.57	8.18	—

Included in the stock options granted for the year ended December 31, 2023 are a total of 78,160 stock options that were conditionally granted to the Company's Chief Executive Officer and Chief Medical Officer on November 21, 2023, subject to sufficient shares being available under the 2021 EIP Plan, which occurred upon the annual evergreen share increase on January 1, 2024.

The weighted-average grant date fair value of options granted during the years ended December 31, 2023 and December 31, 2022 was $0.82 per share and $26.15 per share, respectively. The fair value of the options vested during each the years ended December 31, 2023 and December 31, 2022 was approximately $0.3 million and $1.0 million, respectively.

Restricted Stock Units

During the year ended December 31, 2023, the Company granted RSUs to employees under the 2021 EIP Plan and 2021 Inducement Plan. The RSUs generally vest proportionally each quarter over a term of one or three years.

The following table summarizes RSU activity and related information under the 2021 EIP Plan and the 2021 Inducement Plan for the year ended December 31, 2023:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value Per Share	Weighted Average Remaining Contractual Life (Years)
Non-vested at December 31, 2022	—	$ —	—
Granted	445,742	1.35	—
Vested	(61,120)	2.33	—
Forfeited	(21,698)	1.88	—
Non-vested at December 31, 2023	362,924	1.15	2.17

Included in the RSUs granted for the year ended December 31, 2023 are a total of 66,000 RSUs that were conditionally granted to the Company's Chief Executive Officer and Chief Medical Officer on November 21, 2023, subject to

sufficient shares being available under the 2021 EIP Plan, which occurred upon the annual evergreen share increase on January 1, 2024.

The fair value of the RSUs vested during the year ended December 31, 2023 was approximately $70,000.

Performance Based Stock Units

On February 6, 2023, the Company granted to certain members of management a total of 68,700 market-based PSUs, which vest (a) 50% when the volume weighted average price of the Company's common stock over 20 consecutive trading days is $3.20 or greater ("vesting Tranche 1"), and (b) 50% when such volume weighted average price of the Company's common stock over 20 consecutive trading days is $4.25 or greater ("vesting Tranche 2"). The PSUs were conditional subject to shareholder approval, which such approval was received at the Company's annual shareholder meeting held on June 8, 2023. The fair value of each of the market-based vesting tranches of the PSUs was determined using a Monte Carlo simulation model that considered a variety of potential share prices for the Company's common stock. The weighted-average grant date fair value per share of vesting Tranche 1 and vesting Tranche 2 of the PSUs was $1.50 per award share and $1.47 per award share, respectively, and was determined using the following key assumptions: (i) a risk-free interest rate of 3.74%, (ii) expected stock price volatility of 76.6%, (iii) a cost of equity of 27.99%, and (iv) an expected contractual life of 9.66 years. As shareholder approval of the PSUs was received, the Company is recognizing the share-based compensation expense associated with the PSUs ratably over the derived service period of 1.75 years for vesting Tranche 1 and 2.48 years for vesting Tranche 2, regardless of whether the market condition for vesting is satisfied. None of the PSUs vested during the year ended December 31, 2023 and 6,500 PSUs were forfeited during the year. As of December 31, 2023, a total of 62,200 PSUs remain unvested and outstanding.

Share-Based Compensation Expense

On February 6, 2023, the Company granted to certain members of management a total of 81,500 stock options and 59,500 RSUs that were conditional subject to shareholder approval (the "Conditional Equity Awards"), which such approval was received at the Company's annual shareholder meeting held on June 8, 2023. Accordingly, the Company began to recognize share-based compensation expense related to the Conditional Equity Awards during the year ended December 31, 2023 ratably to the vesting of the awards.

The allocation of stock-based compensation for all stock awards is as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Research and development expense	$ 240	$ 182
General and administrative expense	366	850
Total	$ 606	$ 1,032

As of December 31, 2023, the unrecognized compensation cost related to outstanding options was $0.6 million, which is expected to be recognized over a weighted-average period of approximately 1.80 years and the unrecognized compensation cost related to outstanding service-based and performance-based RSUs was $0.4 million, which is expected to be recognized over a weighted average period of approximately 2.08 years.

8. Collaborations and License Agreements

Research Collaboration and License Agreement with Giiant

On September 1, 2023 (the "Effective Date"), the Company entered into the Giiant License Agreement whereby the Company has received an exclusive, worldwide license (with the right to sublicense in multiple tiers) to develop, manufacture, and commercialize substantially all of the assets of Giiant, including: (i) the PALI-2108 (formerly GT-2108) compound, and (ii) the PALI-1908 (formerly GT-1908) compound and the associated intellectual property around each of the foregoing (the "Giiant Licensed Assets"). The Giiant License Agreement has a perpetual term.

Pursuant to the Giiant License Agreement, the Company and Giiant have established a joint development committee (“JDC”), consisting of one Giiant appointee and two Company appointees. The JDC will be responsible for: (i) overseeing the day-to-day development of the Giiant Licensed Assets through Proof of Concept (as defined below), and (ii) creation and implementation of the development plan and development budget for such development (the “Giiant Development Plan”) and any amendments or updates thereto.

Prior to receiving regulatory approval to commence a Phase 1 clinical trial (as such term is defined in the Giiant License Agreement) (the “Proof of Concept”), each of the Company and Giiant shall be solely responsible for all costs and expenses incurred by such party for the joint development of the Giiant Licensed Assets, except as set forth in the Giiant Development Plan. Prior to reaching the Proof of Concept, the Company will reimburse or advance Giiant up to an amount in the low seven-digit range for costs and expenses incurred by them, subject to increase upon unanimous consent of all members of the JDC, and provided that the costs and expenses are included in the Giiant Development Plan budget and are approved by the JDC. Upon reaching the Proof of Concept, the Company will be solely responsible for all costs and expenses incurred for the development, manufacturing, regulatory and commercialization of the Giiant Licensed Assets. For the year ended December 31, 2023, the Company has recognized expenses related to the joint development plan with Giiant in the amount of approximately $0.7 million, which are included in research and development expenses in the consolidated statements of operations. At December 31, 2023, the Company has accrued joint development expenses of approximately $98,000 in Accrued expenses at the consolidated balance sheets.

As consideration for the Giiant Licensed Assets, the Company will (i) make payments between the mid six-digit range and low seven-digit range upon the achievement of development milestones (as set forth in the Giiant License Agreement), in either cash or shares of the Company’s common stock, at the Company’s election (“ Giiant Milestone Payments”), and (ii) pay ongoing royalty payments of five percent of the adjusted gross proceeds, as defined in the Giiant License Agreement, upon the sales or sublicenses of any products developed from the Giiant Licensed Assets to third parties (“Giiant Royalty Payments”) (collectively, the Giiant Milestone Payments and the Giiant Royalty Payments are referred to as the “Giiant License Payments”). The Giiant License Payments are subject to a maximum payment cap in the very low eight-digit range, which will be increased or decreased on a dollar-for-dollar basis based on a formula related to the aggregate of development costs incurred by the parties (“Payment Cap”). The Company made no Giiant License Payments since the commencement of the Giiant License Agreement.

In the event that Giiant desires to sell or assign any rights to receive the Giiant License Payments, it will be required to notify the Company of such offer or proposal (“Offer Notice”). The Company will then have a right of first refusal for thirty days from the receipt of such Offer Notice, to acquire the rights and obligations contained in such Offer Notice on the same terms.

The Company may unilaterally terminate the Giiant License Agreement for: (i) convenience ("Company Convenience Termination"), (ii) the failure to achieve Proof of Concept within eighteen months of September 1, 2023, subject to extension upon the occurrence of certain event (“Proof-of-Concept Termination”), or (iii) a material breach by Giiant, that is not cured within ninety days of written notice (“Giiant Material Breach Termination”).

In the event of a Company Convenience Termination, the Giiant License Agreement will be terminated and Giiant will retain unencumbered ownership of the Giiant Licensed Assets and no further License Payments will be required of the Company.

In the event of a Proof-of-Concept Termination or Giiant Material Breach Termination, the Company may elect to terminate the Giiant License Agreement. In such instance, the Company will remain obligated to continue making the Giiant License Payments, if any, if and when they become due.

Giiant may unilaterally terminate the Giiant License Agreement only for a material breach by Company that is not cured within ninety days of written notice (“Company Material Breach Termination”) provided however that upon the Payment Cap being achieved, that right will terminate and the Giiant License Agreement will become perpetual. In the event of a Company Material Breach Termination, the Giiant License Agreement, including the License will be terminated and Giiant will retain unencumbered ownership of the Giiant Licensed Assets, including any improvements made up until such termination and the Company will be under no further obligations.

Co-Development and Distribution Agreement with Newsoara

LBS entered into a co-development and distribution agreement with Newsoara, a joint venture established with Biolead Medical Technology Limited, as amended, (the “Newsoara Co-Development Agreement”). Pursuant to the Newsoara Co-Development Agreement (and subsequent assignment agreement), LBS granted or licensed Newsoara

an exclusive right under certain patents to develop, use, sell, offer to sell, import, and otherwise commercialize licensed products (the "Newsoara Licensed Products") for any and all indications in the People's Republic of China, including the regions of Hong Kong and Macao, but excluding Taiwan (the "Territory"). The Newsoara Licensed Products only include the drug asset referred to as LB1148. The right includes the right to grant sublicenses to third parties, subject to LBS' written consent, provided that both parties agreed that Newsoara would be permitted to use a certain partner for development purposes. The Newsoara Co-Development Agreement obligates Newsoara to initially use LBS as the exclusive supplier for all Newsoara's requirements for Newsoara Licensed Products in the Territory. During the term of the Newsoara Co-Development Agreement, Newsoara may request to manufacture the Newsoara Licensed Products in the Territory, subject to satisfying certain conditions to LBS' reasonable satisfaction. LBS is obligated to approve Newsoara manufacturing rights without undue refusal or delay. Where the Company performs any research and development or manufacturing activities under the Newsoara Co-Development Agreement, the Company records the expense reimbursement from Newsoara as a reduction to research and development expense.

In consideration of the rights granted to Newsoara under the Newsoara Co-Development Agreement, Newsoara paid LBS a one-time upfront fee of $1.0 million. In addition, Newsoara is obligated to make (i) payments of up to $6.75 million in the aggregate upon achievement of certain regulatory and commercial milestones, (ii) payments in the low six-digit range per licensed product upon achievement of a regulatory milestone, and (iii) tiered royalty payments ranging from the mid-single-digit to low-double-digit percentage range on annual net sales of Licensed Products, subject to adjustment to the royalty percentage in certain events, including a change of control, the expiration of certain patents rights, and royalties paid by Newsoara third parties. To date, Newsoara has met all of its payment obligations under the Newsoara Co-Development Agreement.

During the year ended December 31, 2023, the Company recognized license revenue of $0.3 million earned upon Newsoara's achievement of a development milestone under the Newsoara Co-Development Agreement during the first quarter of 2023. During the year ended December 31, 2022, the Company recognized no license revenue from Newsoara under the Newsoara Co-Development Agreement.

The Newsoara Co-Development Agreement will expire upon the later of the expiration date of the last valid claim of any licensed patent covering the Newsoara Licensed Products in the Territory. In addition, the Newsoara Co-Development Agreement can be terminated (i) by either party for the other party's material breach that remains uncured for a specified time period after written notice or for events related to the other party's insolvency, (ii) by LBS if Newsoara challenges or attempts to interfere with any licensed patent rights and, (iii) by Newsoara for any reason upon specified prior written notice.

License Agreements with the Regents of the University of California

The Company has entered into three license agreements, as amended, with the Regents of the University of California ("Regents") for exclusive commercial rights to certain patents, technology and know-how. Concurrent with the Company's decision to terminate the development of LB1148, on October 20, 2023 the Company terminated two of its license agreements with Regents. As of December 31, 2023, the only license agreement remaining with Regents is that entered into with LBS in August 2015, as amended in December 2019 and September 2022 (the "2015 UC License"). The 2015 UC License was retained for the sole purpose of maintaining the Newsoara Co-Development Agreement under which the Company may receive future milestone or royalty payments through the term of the license. Accordingly, pursuant to the 2015 UC License, the Company is obligated to pay a percentage of non-royalty licensing revenue it receives from Newsoara under the Newsoara Co-Development Agreement to Regents ranging from 30 percent to 35 percent of one-third of the upfront payment and milestone payments received from Newsoara. During the year ended December 31, 2023, the Company recognized approximately $25,000 in sublicense fees and approximately $21,000 in license maintenance fees due to Regents in research and development expenses in the consolidated statements of operations. During the year ended December 31, 2022, there were no sublicense fees recognized and approximately $17,000 in license maintenance fees due to Regents recognized in research and development expenses in the consolidated statements of operations.

The 2015 UC License will expire upon the expiration date of the longest-lived patent right licensed under the 2015 UC License. The Regents may terminate the 2015 UC License if: (i) a material breach by us is not cured within 60 days, (ii) we file a claim asserting the Regents licensed patent rights are invalid or unenforceable, or (iii) we file for bankruptcy. We also have the right to terminate the 2015 UC License at any time upon at least 90 days' written notice.

Contingent Value Right

Immediately prior to the closing of the Merger, Seneca issued each share of its common stock held by Seneca stockholders of record, one contingent value right (“CVR”). The CVR entitled the holder (the “CVR Holder”) to receive, pro rata with the other CVR Holders, 80% of the net proceeds, if any and subject to certain minimum distribution limitations (“CVR Payment Amount”), received from the sale or licensing of the intellectual property owned, licensed or controlled by Seneca immediately prior to the closing of the Merger (the “Legacy Technology”); provided however that the CVR Holders are only entitled to receive such CVR Payment Amount if the sale or licensing of such Legacy Technology occurred on or before October 27, 2022 (“Legacy Monetization”). Pursuant to the terms of the CVR agreement (“CVR Agreement”), CVR Holders are only entitled to receive CVR Payment Amounts received within 48-months following the closing of the Merger. The CVR Agreement also provides that no distributions will be made to the CVR Holders in the event such distribution is less than $0.3 million.

NSI-189 – Exclusive License and Subsequent Exercise of Purchase Option

Prior to the Merger, Seneca exclusively licensed certain patents and technologies, including a sublicense covering a synthetic intermediate, of the Company's NSI-189 assets (“189 License”), along with a purchase option through December 16, 2023 (“Purchase Option”). On October 22, 2021, Alto Neuroscience ("Alto") agreed to terms of an early exercise of the Purchase Option under the 189 License and entered into an asset transfer agreement ("ATA"). Alto is a U.S. based public, clinical-stage biopharmaceutical company with a mission to redefine psychiatry by leveraging neurobiology to develop personalized and highly effective treatment options.

Pursuant to the terms of the CVR Agreement, no distribution was required to be made to the CVR Holders as the CVR Payment Amount after deducting costs and expenses required to maintain the 189 License was less than $0.3 million. In accordance with the terms of the CVR Agreement, the net proceeds from the sale of the NSI-189 assets, less any applicable transaction costs and expenses, were deposited into the CVR escrow to be used to pay costs and expenses associated with the monetization of the Company's other Legacy Technologies.

In addition, Alto will be required to pay the Company up to an aggregate of $4.5 million upon the achievement of certain development and regulatory approval milestones for NSI-189 (or a product containing or otherwise derived from NSI-189), which is now known as ALTO-100. If Alto sells or grants to a third party a license to the patents and other rights specific to ALTO-100 prior to the achievement of a specified clinical development milestone, Alto will be required to pay to the Company a low-double digit percentage of any consideration received by Alto from such license or sale, provided that the maximum aggregate consideration Alto will be required to pay to the Company under the ATA, including the upfront payment and all potential milestones and transaction-related payments, will not exceed $5.0 million.

Alto has successfully completed a Phase 2a clinical trial of ALTO-100 and is currently enrolling a Phase 2b clinical trial from which topline data is expected in the second half of 2024. Upon the enrollment of a patient in a Phase 3 clinical trial of ALTO-100, a milestone payment of $1.5 million will be due from Alto under the ATA. If this occurs within 48-months of the closing of the Merger, the CVR Holders will be entitled to a CVR Payment Amount, with the remaining 20% of the net proceeds deposited into the CVR escrow. If the milestone is met after 48-months of the closing of the Merger, all the net proceeds will be paid to the Company. There can be no assurance that CVR holders will receive CVR Payment Amounts from the sale of the NSI-189 assets.

NSI-532.IGF-1

On October 27, 2022, the Company entered an agreement to license NSI-532.IGF-1 to the Regents of the University of Michigan ("University of Michigan") for maintaining NSI-532.IGF-1 cell lines, continued development, maintaining patent protection, and seeking licensees. The Company received no upfront fees for the license. NSI-532.IGF-1 is a pre-clinical cell therapy being investigated as a potential therapy for prevention and treatment of Alzheimer’s disease. The University of Michigan shall bear 100% of the costs for patent filing, prosecution, maintenance, and enforcement of the patent rights. The Company will receive 50% of net revenues received by the University of Michigan from the licensing of patent rights through the last-to-expire patent in patent rights, unless otherwise earlier terminated, less all reasonable and actual out-of-pocket costs incurred in the litigation of patent rights.

There can be no assurance that NSI-532.IGF-1 will ever be successfully monetized or that CVR holders will receive CVR Payment Amounts from the sale of the NSI-532.IGF-1 assets.

9. Commitments and Contingencies

Corporate Office Lease

On May 12, 2022, the Company entered a new, non-cancelable facility operating lease (the "Corporate Office Lease") of office space for its corporate headquarters, replacing its existing corporate headquarters lease that expired on July 31, 2022. The Corporate Office Lease is for 2,747 square feet of an office building in Carlsbad, California. The initial contractual term is for 39-months commencing on June 1, 2022 and expiring on August 31, 2025. The Company has the option to renew the Corporate Office Lease for an additional 36-month period at the prevailing market rent upon completion of the initial lease term. The Company has determined it is not likely that it will exercise this renewal option.

Commencing on June 1, 2022, the Company is subject to contractual monthly lease payments of $10,850, plus certain utilities, for the first 12 months with 3 percent escalations at the first, second and third lease commencement anniversaries. The Corporate Office Lease is subject to conditional abatement of fifty percent (50%) of such base rent during the second, third and fourth full calendar months of the initial lease term, as set forth in the lease agreement, as well as a $28,000 tenant improvement allowance.

The Corporate Office Lease is also subject to additional variable charges for common area maintenance, insurance, taxes and other operating costs. This additional variable rent expense is not estimable at lease inception. Therefore, it is excluded from the Company’s straight-line expense calculation at lease inception and is expensed as incurred.

As of December 31, 2023, the Company recognized an operating right-of-use asset related to the Corporate Office Lease in the amount of $198,000, which included in Operating lease right-of-use asset in the consolidated balance sheets. As of December 31, 2023, the Company recognized a current and noncurrent operating lease liability related to the Corporate Office Lease of $121,000 and $90,000, respectively, which is included in Current portion of operating lease liability and Operating lease liability, net of current portion, respectively, in the consolidated balance sheets. As of December 31, 2023, the total remaining future minimum lease payments associated with the Corporate Office Lease of approximately $229,000, including imputed interest of $18,000 calculated using a discount rate of 10.75%, will be paid over the remaining lease term of approximately 1.7 years.

Maturities of the Company's operating lease liabilities as of December 31, 2023 are as follows (in thousands):

Year ending December 31,	
2024	$ 136
2025	93
Total operating lease payments	229
Less: imputed interest	(18)
Total operating lease obligations	$ 211

The Company recognized operating lease expense associated with its Corporate Office Lease and its predecessor corporate headquarters lease of approximately $130,000 and $189,000 for the years ended December 31, 2023 and December 31, 2022, respectively.

Insurance Financing Arrangement

Consistent with past practice, in June 2023, the Company entered an agreement to finance an insurance policy that renewed in May 2023. The financing arrangement entered in June 2023 has a stated annual interest rate of 7.92% and is payable over a 9-month period with the first payment commencing June 30, 2023. The insurance financing

arrangement is secured by the associated insurance policy. As of December 31, 2023 and December 31, 2022, the aggregate remaining balance under the Company's insurance financing arrangement was $158,000 and $88,000, respectively, and is included in Insurance financing debt in the consolidated balance sheets.

Other than the remaining insurance financing arrangement payments due in 2024, as of December 31, 2023, the Company has no other minimum debt payments required in 2024 or thereafter.

Restructuring Costs

In order to better utilize the Company's resources on the implementation of its refocused business plans and corporate strategy, the Company committed to a cost-reduction plan on September 9, 2022 (the "2022 Cost-Reduction Plan") and a reduction-in-workforce on October 27, 2023 (the "2023 RIF"). The 2022 Cost-Reduction Plan consisted primarily of a 20% reduction in the Company's employee workforce to better align the Company's resources with its proposed business plan. The 2023 RIF consisted of a 25% reduction in the Company's employee workforce, specifically research and development employees that were no longer deemed critical for the Company's development of PALI-2108.

Associated with the 2023 RIF and the 2022 Cost-Reduction Plan, the Company has recognized restructuring costs of approximately $0.2 million and $0.4 million in the consolidated statements of operations for the years ended December 31, 2023 and December 31, 2022, respectively, consisting of severance and benefits payments pursuant to employment agreements and the execution of severance and release agreements. The Company does not expect to incur any other significant costs associated with either the 2022 Cost-Reduction Plan or the 2023 RIF.

The following table summarizes the change in the Company's accrued restructuring liabilities under both the 2022 Cost-Reduction Plan and the 2023 RIF, which consisted solely of employee compensation and benefits and is classified within Accrued liabilities in the consolidated balance sheets as of each year shown (in thousands):

	Year Ended December 31,	
	2023	2022
Balance as of the beginning of year	$ 180	$ —
Net accrual additions	225	410
Cash paid	(274)	(230)
Balance as of the end of year	$ 131	$ 180

Legal Proceedings

From time to time, the Company may be involved in various lawsuits, legal proceedings, or claims that arise in the ordinary course of business. Management believes there are no claims or actions pending against the Company through December 31, 2023, which will have, individually or in the aggregate, a material adverse effect on its business, liquidity, financial position, or results of operations. Litigation, however, is subject to inherent uncertainties, and an adverse result in such matters may arise from time to time that may harm the Company's business.

Indemnification

In accordance with the Company's certificate of incorporation, as amended, and amended and restated bylaws, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving in such capacity. There have been no claims to date, and the Company has a directors and officers liability insurance policy that may enable it to recover a portion of any amounts paid for future claims.

10. Related Party Transactions

Director stipends

Unpaid cash stipends owed to the Company's directors for their annual board service are recorded on the Company's consolidated balance sheets within accrued liabilities. These liabilities were $105,625 and $141,250 as of December 31, 2023, and December 31, 2022, respectively.

Consultancy agreement with former Chief Operating Officer

Effective May 15, 2023, the Company's former Chief Operating Officer ("COO") resigned his position as COO and transitioned to an executive strategic consultant with the Company. In conjunction with the transition, the former COO received monthly compensation of $4,000. The consultancy agreement ended on January 15, 2024, upon mutual agreement of both parties. Total consultancy fees earned by the former COO during the year ended December 31, 2023 were approximately $28,000.

Separation agreement with former Chief Executive Officer

On October 11, 2022, the Company entered into a separation agreement with its former Chief Executive Officer whereby the parties agreed to a mutual release of claims. Subsequent to paying an aggregate of $22,000 pursuant to the terms of the separation agreement, the Company determined that it is not probable that any additional compensation would be due to the former Chief Executive Officer and therefore, the Company has not recognized any accrual related to compensation or benefits owed pursuant to the separation agreement as of December 31, 2023.

11. Employee Benefits

The Company participates in a defined contribution 401(k) plan adopted by LBS effective June 20, 2016. All employees are eligible to participate in the plan beginning on the first day of employment. Under the terms of the plan, employees may make voluntary contributions as a percent of compensation. No matching contributions have been made by the Company since the adoption of the 401(k) plan.

12. Income Taxes

The Company has no current or deferred income taxes as of December 31, 2023 and December 31, 2022.

Income taxes vary from the statutory federal income tax rate applied to loss before income taxes as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Statutory federal income tax rate of 21 percent applied to loss before income taxes	$ (2,583)	$ (2,995)
State taxes - net of federal benefit	(810)	(1,040)
Meals and entertainment	3	—
Warrants	(12)	(276)
Stock-based compensation	522	60
Other non-deductible expenses	(89)	71
Expiration of tax attributes	484	484
Change in tax rate	207	(157)
Valuation allowance	2,278	3,853
	$ —	$ —

Deferred income tax assets and liabilities arising from differences between accounting for financial statement purposes and tax purposes, less valuation reserves at year end are as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Deferred tax assets:		
Accrued expenses	$ 128	$ 91
Depreciation	245	192
Lease accounting	55	87
Net operating loss carryforwards	24,703	22,681
Stock compensation	1,470	1,955
Capitalized research and development costs	2,515	1,912
Total deferred tax assets	29,116	26,918
Deferred tax liabilities:		
Operating right-of-use asset	52	83
Prepaid expense	112	160
Total deferred tax liabilities	164	243
Net deferred tax asset	28,952	26,675
Valuation allowance	(28,952)	(26,675)
Net deferred taxes	$ —	$ —

Deferred tax assets and liabilities are recognized for temporary differences and unused tax losses to the extent that realization of the related tax benefits is more-likely-than-not. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods when the deferred tax assets become deductible. After considering the history of operating losses and uncertainty regarding its ability to generate positive pre-tax income in 2024 and beyond, the Company has concluded that it is not-more-likely-than-not that its deferred tax assets will be realized, and therefore maintains a full valuation allowance on all deferred tax assets.

As of December 31, 2023, the Company had federal net operating loss ("NOL") carryforwards of approximately $100.5 million and state NOL carryforwards of approximately $51.5 million. Of the total amount of federal NOL carryforwards, approximately $68.0 million arose in tax years beginning after December 31, 2017 and will carry forward indefinitely. The federal NOL carryforwards arising in tax years beginning before January 1, 2018 of approximately $32.5 million will begin to expire in 2024 unless previously utilized. The Company’s state NOL carryforwards as of December 31, 2023 may be carried forward for 20 years, and will expire at various dates between 2027 and 2043.

Pursuant to the provisions of the Internal Revenue Code ("IRC"), the Company’s NOL and tax credit carryforwards and certain other attributes are subject to review and possible adjustment by the Internal Revenue Service ("IRS") and state tax authorities. NOL and tax credit carryforwards may be subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50 percent, as defined under Sections 382 and 383 of the IRC, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Including the recently completed Merger, the Company has completed several equity offerings since its inception, which may have resulted in a change in control as defined by Sections 382 and 383 of the IRC, or could result in a change in control in the future. The Company has not completed an IRC Section 382 and 383 analysis for all relevant tax years regarding the limitation of net operating losses. The NOL deferred tax asset does reflect the limitation resulting from the Merger; however, there could be further limitations due to prior changes in control. Due to the existence of a full valuation allowance, however, changes in the NOLs included as deferred tax assets on the Company’s consolidated balance sheets would have no impact on the Company's effective tax rate.

The Company files income tax returns in the U.S. federal jurisdiction and various states. Because of the NOLs, the Company is subject to U.S. federal examinations for tax years 2005 and forward, and for examinations from state taxing authorities for tax years 2009 and forward.

The Company accounts for taxation under ASC 740, which clarifies the accounting for uncertain tax positions. ASC 740 requires that the Company recognize the impact of a tax position in its consolidated financial statements if the position is more-likely-than-not to be sustained upon examination based on the technical merits of the position. The Company did not have any uncertain income tax positions as of December 31, 2023 and 2022.

ASC 740 requires the Company to accrue interest and penalties where there is an underpayment of taxes based on the Company's best estimate of the amount to ultimately be paid. The Company identified no unrecorded material uncertain tax positions as of December 31, 2023 and 2022, consequently no interest or penalties have been accrued by the Company in either period. The Company does not anticipate a significant change to its unrecognized tax benefits within the next 12 months.

On December 22, 2017, the United States enacted the Tax Cuts and Jobs Act (the "TCJA"). The TCJA contains certain provisions that went into effect on January 1, 2022, including a provision impacting Section 174 of the IRC whereby for tax years beginning on or after January 1, 2022, taxpayers are required to capitalize and amortize rather than deduct research and development expenses. Section 174 research and development expenses must be amortized over five years for research performed in the U.S. and 15 years for research performed outside the U.S., beginning with the midpoint in the year in which the expenses were incurred. Further, software development costs were specifically included in the definition of a Section 174 expenditure, and therefore must be capitalized and amortized over five (or 15 years). Finally, if a research project is abandoned or disposed of, the taxpayer cannot recover costs earlier than the end of the required amortization period. Beginning in 2022, the Company capitalized and amortized its research and development expenses pursuant to Section 174. Due to the Company’s prior and current year losses and its full valuation allowance, the change pursuant to Section 174 did not have a material impact to the Company's tax provision or cash flows.

The Inflation Reduction Act (“IRA”) was enacted in the U.S. on August 16, 2022, containing revenue-raising provisions that include a book-income alternative minimum tax and an excise tax on stock buybacks, among other provisions. Based on the thresholds detailed in the IRA and a review of the Company’s transactions during the year, these changes do not have an impact on the Company’s income tax provision for the year ended December 31, 2022.

13. Subsequent Events

Warrant Inducement Transaction

On January 30, 2024, the Company entered into warrant inducement agreements (the “Warrant Inducement Agreements”) with certain accredited and institutional holders (collectively, the “Warrant Holders”) of certain of the Company’s remaining outstanding May 2022 Warrants, (ii) January 2023 Warrants, and (iii) April 2023 Warrants, as well as certain outstanding Series 2 Warrants (collectively, the “Existing Warrants”). Pursuant to the Warrant Inducement Agreements, the exercise price of each Existing Warrant exercised was reduced to $0.7313 per share. Each of the Warrant Holders that exercised its Existing Warrants pursuant to the Warrant Inducement Agreements, received one replacement warrant (the “Replacement Warrants”) for each Existing Warrant exercised.

The Replacement Warrants are exercisable immediately, have an exercise price per share of $0.7313, and expire five years from the date of issuance. The Replacement Warrants are subject to adjustment in the event of stock splits, dividends, subsequent rights offerings, pro rata distributions, and certain fundamental transactions, as more fully described in the Replacement Warrants. The Replacement Warrants contain standard anti-dilution provisions but do not contain any price protection provisions with respect to future securities offerings of the Company.

The Warrant Holders collectively exercised an aggregate of 3,422,286 Existing Warrants consisting of: (i) 72,932 May 2022 Warrants, (ii) 64,000 Series 2 Warrants, (iii) 1,012,631 January 2023 Warrants, and (iv) 2,272,723 April 2023 Warrants. As a result of the exercises, the Company issued an aggregate of 3,422,286 shares of its common stock. The transaction closed on February 1, 2024 with the Company receiving net cash proceeds of approximately $2.2 million consisting of gross cash proceeds of $2.5 million, less transaction-related expenses and placement agent fees of approximately $0.3 million.

Ladenburg Thalmann & Co. Inc. acted as the exclusive placement agent for the transaction. The placement agent fees associated with the transaction consisted of: (i) a cash fee equal to 7.75% of the gross proceeds received by the

Company in the transaction, (ii) a common stock purchase warrant to purchase such number of shares of common stock equal to 6% of the aggregate number shares issued pursuant to the exercise of Existing Warrants by the Warrant Holders with an exercise price of $0.7313 per share, and a term of five years from issuance, and (iii) $35,000 of out-of-pocket expenses.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our management, with the participation of our Chief Executive Officer, who is also our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2023. Based upon the evaluation, our Chief Executive Officer concluded that, as of December 31, 2023, our disclosure controls and procedures were not effective at a reasonable assurance level as a result of the material weakness that existed in our internal control over financial reporting, as described below.

However, our management, including our Chief Executive Officer, has concluded that, notwithstanding the identified material weakness in our internal control over financial reporting, the consolidated financial statements in this Annual Report on Form 10-K fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with U.S. GAAP.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term as defined in Exchange Act Rule 13a-15(f). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer, who is also our principal financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

Material Weakness in Internal Control over Financial Reporting and Fair Value Calculations

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

As previously disclosed, during the quarter ended June 30, 2021, the Company identified a material weakness in our internal controls over financial reporting due to a lack of controls in the financial closing and reporting process, including a lack of segregation of duties and the documentation and design of formalized processes and procedures surrounding the creation and posting of journal entries and account reconciliations. This material weakness contributed to a material weakness in our control activities based on the criteria set forth in the 2013 Framework. If not remediated, or if the Company identifies further material weaknesses in its internal controls, the Company's failure to establish and maintain effective disclosure controls and procedures and internal control over financial reporting could result in material misstatements in its consolidated financial statements and a failure to meet its reporting and financial obligations.

As described below, management has begun designing the plan and executing the remediation actions to address the material weakness and further actions are ongoing as of December 31, 2023. The material weakness continues to be present as of December 31, 2023.

Remediation Efforts related to the Material Weakness

Management, with oversight from the Audit Committee of the Board of Directors of the Company, is actively engaged in remediation efforts to address the material weaknesses identified in the management's evaluation of internal controls and procedures. The remediation efforts summarized below, which have been or are in the process of being implemented, are intended to address the identified material weakness.

(i) The Company will continue to hire additional finance, accounting and information technology employees with appropriate experience, certification, education and training.

(ii) The Company has implemented new accounting and finance management software effective July 1, 2022, which is intended to eliminate some of the existing deficiencies in the Company's internal control environment. The information technology general controls implemented with the new accounting and finance management software will be documented and tested for operating effectiveness.

(iii) The Company is in the process of updating its formal accounting policies, procedures and controls, including preparation and review of account reconciliations, review of journal entries, and controls over period end financial reporting.

(iv) The Company is developing a comprehensive plan to identify and remediate all segregation of duties deficiencies in its current control environment.

(v) The Company is in the process of implementing additional key internal controls designed to address the potential risks identified in its key business processes.

(vi) The Company engaged a third-party service provider to assist with the development, implementation and testing of its information technology general computer controls.

The Company believes that the implementation of the above steps will allow it to make progress on addressing a number of the deficient controls within its internal control environment, which will help facilitate the remediation of the material weakness identified above. As the Company continues to evaluate and work to improve its internal control over financial reporting, it will take additional measures to address control deficiencies, or it may modify certain of the remediation measures described above. However, the Company requires additional time to complete the design and implementation of its remediation plans and demonstrate the operating effectiveness of our remediation efforts. The material weakness cannot be considered remediated until the applicable remedial controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

Changes in Internal Control Over Financial Reporting

There were no changes in the Company's internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) during the quarter ended December 31, 2023 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Item 9B. Other Information.

Not applicable.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The names of our directors and executive officers and their ages, positions, and biographies as of March 26, 2024 are set forth below. There are no family relationships among any of our directors or executive officers.

Name	Position	Age	Position Since
Named Executive Officers			
J.D. Finley	CFO, CEO, Director	65	2021
Mitchell Jones, MD	Chief Medical Officer	46	2023
Independent Directors			
Donald Williams	Director	65	2021
Binxian Wei	Director (Series A Preferred)	54	2019

J.D. Finley, has served as the Company's Chief Financial Officer since April 2021. Previously, Mr. Finley served as Leading Biosciences, Inc's (the Company's wholly owned subsidiary and predecessor company) Chief Financial Officer since January 2017 and as a member of the board of directors of Leading Biosciences, Inc. (the "LBS Board") since December 2014. Prior to joining Leading Biosciences, Inc., Mr. Finley was Chief Executive Officer of PointAcross, Inc., a marketing company, from January 2016 to January 2017. Mr. Finley previously co-founded Proteus Capital Partners, Inc., a firm specializing in providing financing for a variety of businesses, and was CFO at Phillips Capital, a broker/dealer firm specializing in private debt and equity capital raises. From March 2011 to June 2012 Mr. Finley was Executive Vice President, and from June 2012 to April 2014, Mr. Finley was President of Goldmail. Mr. Finley received a B.A. in business administration from Boise State University and an M.S. in Taxation from the University of Denver. The Company's Board of Directors (the "Board") believes Mr. Finley's experience and familiarity with the Company, its operations, and the life science industry qualify him to serve on the Board.

Mitchell Jones, M.D., Ph.D., has served as the Company's Chief Medical Officer since September 2023. Dr. Jones has over 16 years of medical and pharmaceutical experience directing translational and clinical activities for therapeutic product candidates in inflammatory bowel disease, metabolic disease, hepatic infectious disease, and oncology. During his career, Dr. Jones has served in a number of positions related to the strategy and development of novel therapies. From November 2022 until joining the Company, Dr. Jones served as VP, Corporate Development and Strategy for Chemomab, Inc. (Nasdaq: CMMB), a clinical stage biotechnology company focused on fibro-inflammatory diseases. Additionally, from November 2022 to September 2023, Dr. Jones served as a consultant for Novome Biotechnologies, Inc. and xBiome, Inc., both with development programs in inflammatory bowel disease. Additionally, from August 2020 through November 2022, Dr. Jones served as VP, Clinical Discovery and Development for Finch Therapeutics Group, Inc. (Nasdaq: FNCH), a company focused on developing immune modulating therapies including for serious GI infection and inflammatory bowel disease. From May 2015 through July 2020, Dr. Jones served as VP, Translational and Clinical Development for Biora Therapeutics, Inc. (Nasdaq: BIOR), a company focused on the development of targeted and local acting immune modulating therapies for the treatment of inflammatory bowel disease, where he assisted in securing over $100 million in investor capital. Dr. Jones holds a BS in Physiology, a Master of Biomedical Engineering, a Doctor of Medicine, and a Doctor of Biomedical Philosophy, all from McGill University in Canada.

Donald Williams, has served as a member of the Board since April 2021. Previously, Mr. Williams served on the LBS Board since May 2019. Mr. Williams has served as a member of the board of directors of Akari Therapeutics PLC since June 2016, a member of the board of directors of Forte Biosciences, Inc. since 2020, and a member of the board of directors of ImpediMed, Inc. since 2017. From 2014 to 2019, Mr. Williams was a member of the board of directors of Adhera Therapeutics, Inc. From 2015 to 2021, Mr. Williams served as a member of the board of directors of Alphatec Spine, Inc. From 2007 to 2014, Mr. Williams was a Partner and the National Life Sciences Leader for Grant Thornton LLP, and spent over 20 years as a partner at Ernst & Young LLP. From 2001 to 2014, Mr. Williams served on the board of directors of the San Diego Venture Group, during which time he also served as the group's president and chairman. Mr. Williams was also a founding member of the Young VCs of Southern California. Mr. Williams received a B.A. in accountancy from Southern Illinois University and completed the director education and certification program at the University of California, Los Angeles Anderson School of Business. The Board believes

Mr. Williams' experience as a board member and public accountant in the life science industry qualifies him to serve on the Board.

Binxian Wei, has served as a member of the Board since February 2019. Mr. Wei has been the V.P. of Darsheng Trade & Tech. Development Co, Ltd. (a subsidiary to Tianjin Tiayo Pharmaceutical Co., Ltd.) since 2015. Mr. Wei is responsible for Active Pharmaceutical Ingredient ("API") and finished dosage marketing for Chinese pharmaceutical companies. From 2008 through 2010, he worked as a business development manager for Sakai Trading. Mr. Wei received a master's degree in mathematical and computer sciences from Colorado School of Mines, and a master's degree and B.S. in chemical engineering from Tianjin University in China. Binxian Wei was appointed as the director representative of the Series A 4.5% Convertible Preferred Stock by Tianjin Pharmaceuticals Group International Holdings Co., LTD, the sole holder of our outstanding Series A 4.5% Convertible Preferred Stock. The Board believes Mr. Wei's experience as a board member and pharmaceutical experience qualify him to serve on the Board.

Board of Directors

Vacancies on the Board may be filled only by persons elected by a majority of the remaining directors. A director elected by the Board to fill a vacancy in a class, including vacancies created by an increase in the number of directors, shall serve for the remainder of the full term of that class and until the director's successor is duly elected and qualified. The holder of our Series A 4.5% Convertible Preferred Stock has the right to appoint one member to the Board.

The Board presently has three (3) members. Effective February 29, 2024, we amended our bylaws to remove the classified board structure. Accordingly, all of our directors' terms, except for the director appointed by the Series A preferred stock, expire at our 2024 annual meeting of shareholders and thereafter on an annual basis. Our business, property and affairs are managed under the direction of the Board. Members of the Board are kept informed of our business through discussions with our Chief Executive Officer and other officers, by reviewing materials provided to them and by participating in meetings of the Board and its committees.

Our Board is responsible for establishing broad corporate policies and for overseeing our overall management. In addition to considering various matters which require its approval, the Board provides advice and counsel to, and ultimately monitors the performance of, our senior management.

Independent Directors

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

Consistent with these considerations, after review of all relevant identified transactions or relationships between each director, or any of their family members, and the Company, its senior management and its independent auditors, the Board has affirmatively determined that each of (i) Mr. Williams and (ii) Mr. Wei are independent directors within the meaning of the applicable Nasdaq listing standards. In making this determination, the Board found that none of these directors had a material or other disqualifying relationship with the Company.

Role of the Board in Risk Oversight

One of the Board's key functions is informed oversight of our risk management process. The Board does not have a standing risk management committee, but rather administers this oversight function directly through the Board as a whole, as well as through various Board standing committees that address risks inherent in their respective areas of oversight. In particular, our Board is responsible for monitoring and assessing strategic risk exposure, including a determination of the nature and level of risk appropriate for the Company. Our Audit Committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The Audit Committee also monitors compliance with legal and regulatory requirements. Audit Committee responsibilities also include oversight of cybersecurity risk management. Our Governance and Nominating Committee monitors the effectiveness of our corporate governance guidelines, including whether they are successful in preventing illegal or improper liability-creating conduct. Our Compensation Committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking. It is the responsibility of the committee chairs to report findings regarding material risk exposures to the Board as quickly as possible. The Board has delegated to the Board's lead independent director the responsibility of

coordinating between the Board and management with regard to the determination and implementation of responses to any problematic risk management issues.

Code of Ethics

We have adopted the Palisade Bio, Inc. Code of Business Conduct and Ethics, or Ethics Code, that applies to all of our officers, directors and employees. The Ethics Code is available on our website at www.palisadebio.com by clicking on "Investors & News", then clicking "Corporate Governance" then "Governance Documents". The information on our website is not incorporated by reference into this Annual Report on Form 10-K.. If we make any substantive amendments to the Code of Business Conduct and Ethics or grant any waiver from a provision of the code to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website.

Stockholder Communications with the Board of Directors

We have adopted a formal process for stockholder communications with our independent directors. Individuals wanting to communicate with our directors are invited to communicate with the non-management members of the Board by sending correspondence to the Board, c/o Corporate Secretary, Palisade Bio, Inc., 7750 El Camino Real, Suite 2A, Carlsbad, CA 92009. These communications will be reviewed by the Secretary of Palisade, who will determine whether the communication is appropriate for presentation to the Board or the relevant director. The purpose of this screening is to allow the Board to avoid having to consider irrelevant or inappropriate communications (such as advertisements, solicitations and hostile communications). The screening procedures have been approved by a majority of the independent directors. All communications directed to the Audit Committee in accordance with our Code of Business Conduct and Ethics policy or reported or on our Ethics Point whistleblower hotline that relate to questionable accounting or auditing matters will be promptly and directly forwarded to the Audit Committee, at the discretion of our compliance officer.

Information Regarding Committees of the Board of Directors

The Board has three committees: an Audit Committee, a Compensation Committee, and a Governance and Nominating Committee. The following table provides, as of March 26, 2024, membership for each of our Board committees:

Director	Audit Committee	Compensation Committee	Governance and Nominating Committee
Donald A. Williams	C	C	C
Binxian Wei	X	X	X
J.D. Finley (not Independent)			

X = Current member of committee
C = Current member and chairperson of the committee

Audit Committee

The Audit Committee of the Board was established by the Board in accordance with Section 3(a)(58)(A) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), to oversee our corporate accounting and financial reporting processes and audits of our financial statements. For this purpose, the Audit Committee performs several functions. The Audit Committee evaluates the performance of and assesses the qualifications of the independent auditors; determines and approves the engagement of the independent auditors; determines whether to retain or terminate the existing independent auditors or to appoint and engage new independent auditors; reviews and approves the retention of the independent auditors to perform any proposed permissible non-audit services; monitors the rotation of partners of the independent auditors on our audit engagement team as required by law; reviews and approves or rejects transactions between the Company and any related persons; confers with management and the independent auditors regarding the effectiveness of internal control over financial reporting; establishes procedures, as required under applicable law, for the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls or auditing matters and the confidential and anonymous submission by employees of concerns regarding questionable accounting or auditing matters; reviews and assesses our cyber security risks and assessments; and meets to review our annual audited financial statements and quarterly financial statements with management and the independent auditor, including a review of our disclosures under "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Subsequent to the resignation of certain directors during the first quarter of 2024, the Audit Committee is currently composed of two directors: Mr. Williams (Chair) and Mr. Wei. The Board has adopted a written Audit Committee charter that is available to stockholders on our website at www.palisadebio.com under the section entitled "Governance Documents" under the Investors & News and Corporate Governance tabs. The information on our website is not incorporated by reference into this Annual Report on Form 10-K.

The Board reviews the Nasdaq listing standards definition of independence for Audit Committee members on an annual basis and has determined that all members of our Audit Committee are independent (as independence is currently defined in Rule 5605(c)(2)(A)(i) and (ii) of the Nasdaq listing standards).

The Board has also determined that Mr. Williams qualifies as an "audit committee financial expert," as defined in applicable SEC rules. The Board made a qualitative assessment of Mr. Williams' level of knowledge and experience based on a number of factors, including his formal education and his tenure as a partner at Grant Thornton LLP and his tenure as a partner at Ernst & Young LLP.

Pursuant to Rule 5605 of the Nasdaq Listing Rules (the "Nasdaq Rules"), all listed companies' audit committees must be comprised of at least three independent directors. As of the date of this Annual Report on Form 10-K, we currently have only two audit committee members. Nasdaq Rule 5605(c)(4) provides that we will have until the earlier of the next annual shareholders meeting or one year from the occurrence of the event that caused the failure to comply with this requirement; provided, however, that if the annual shareholders meeting occurs no later than 180 days following the event that caused the vacancy, we shall instead have 180 days from such event to regain compliance. On March 22, 2024, we received a notice from Nasdaq ("the Notice") stating that pursuant to the recent resignation of certain members of our Board, we became noncompliant with the requirements set forth in Nasdaq Listing Rule 5605(c)(2)(A). The Notice states that, consistent with Nasdaq Listing Rule 5605(c)(4), Nasdaq will provide us with a cure period in order to regain compliance (i) until the earlier of our next annual shareholders' meeting or March 4, 2025, or (ii) if our next annual shareholders' meeting is held before September 3, 2024, then we must evidence compliance no later than September 3, 2024.

Compensation Committee

The Compensation Committee is currently composed of two directors: Mr. Williams (Chair) and Mr. Wei. The Board has determined that each member of the Compensation Committee is independent (as independence is currently defined in Rule 5605(d)(2) of the Nasdaq Rules), a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act, and an "outside director" as that term is defined in Section 162(m) of the Internal Revenue Code of 1986, as amended. The Board has adopted a written Compensation Committee charter that is available to stockholders on our website at www.palisadebio.com under the section entitled "Governance Documents." The information on our website is not incorporated by reference into this Annual Report on Form 10-K.

The Compensation Committee of the Board acts on behalf of the Board to review, modify (as needed) or approve (or, if it deems appropriate, making recommendations to the Board regarding) our overall compensation strategy and policies for, including, among other things:

- reviewing and approving (or, if it deems appropriate, making recommendations to the Board regarding) corporate performance goals and objectives, which shall support and reinforce our long-term strategic goals, relevant to our compensation plans and programs;

- evaluating and approving (or, if it deems appropriate, making recommendations to the Board regarding) our compensation plans and programs, as well as the modification or termination of existing plans and programs;

- evaluating (including, if it deems appropriate, with the input of some or all of the other members of the Board) risks associated with and potential consequences of our compensation policies and practices, as applicable to all our employees, and assessing whether risks and consequences arising from our compensation policies and practices for our employees, as may be mitigated by any other compensation policies and practices, are reasonably likely to have a material adverse effect on the Company;

- establishing policies with respect to equity compensation arrangements, with the objective of appropriately balancing the perceived value of equity compensation and the dilutive and other costs of that compensation to the Company; and

- evaluating the efficacy of our compensation policy and strategy in achieving expected benefits to the Company and otherwise furthering the Committee's policies.

Compensation Committee Processes and Procedures

Typically, the Compensation Committee meets at least once annually and with greater frequency if necessary. The agenda for each meeting is usually developed by the Chair of the Compensation Committee, in consultation with management. The Compensation Committee meets regularly in executive session. However, from time to time, various members of management and other employees as well as outside advisors or consultants may be invited by the Compensation Committee to make presentations, to provide financial or other background information or advice or to otherwise participate in Compensation Committee meetings. Our Chief Executive Officer does not participate in and is not present during any deliberations or determinations of the Compensation Committee regarding his compensation or individual performance objectives. The charter of the Compensation Committee grants the Compensation Committee full access to all books, records, facilities and personnel of the Company. In addition, under its charter, the Compensation Committee has the authority to obtain, at the expense of the Company, advice and assistance from compensation consultants and internal and external legal, accounting or other advisors and other external resources that the Compensation Committee considers necessary or appropriate in the performance of its duties. The Compensation Committee has direct responsibility for the oversight of the work of any consultants or advisers engaged for the purpose of advising the Compensation Committee. In particular, the Compensation Committee has the sole authority to retain, in its sole discretion, compensation consultants to assist in its evaluation of executive and director compensation, including the authority to approve the consultant's reasonable fees and other retention terms. Under its charter, to the extent required by the SEC and Nasdaq rules, the Compensation Committee may select, or receive advice from, a compensation consultant, legal counsel or other adviser to the compensation committee, other than in-house legal counsel and certain other types of advisers, only after taking into consideration six factors, prescribed by the SEC and Nasdaq, that bear upon the adviser's independence; however, there is no requirement that any adviser be independent.

During the year ended December 31, 2023, after taking into consideration the guidance from the SEC and Nasdaq described above, the Compensation Committee engaged Compensia Inc. ("Compensia") as its compensation consultant. The Compensation Committee identified Compensia based on its general reputation in the industry and experience providing similar services to companies similar to us. The Compensation Committee requested that Compensia:

- evaluate the efficacy of our existing compensation strategy and practices in supporting and reinforcing our long-term strategic goals (including through a peer group analysis); and

- assist in refining our compensation strategy and in developing and implementing executive and non-employee director compensation programs to execute that strategy.

In addition, under its charter, the Compensation Committee may form and delegate authority to subcommittees as appropriate.

The Compensation Committee holds one or more meetings during the first quarter of the year to discuss and make recommendations to the Board for annual base salary compensation adjustments, annual bonuses, annual equity awards, and current year corporate performance objectives. However, the Compensation Committee also considers matters related to individual compensation, such as compensation for new executive hires, as well as high-level strategic issues, such as the efficacy of our compensation strategy, potential modifications to that strategy and new trends, plans or approaches to compensation, at various meetings throughout the year. Generally, the Compensation Committee's process comprises two related elements: the determination of compensation levels and the establishment of performance objectives for the current year. For executives other than the Chief Executive Officer, the Compensation Committee solicits and considers evaluations and recommendations submitted to the Compensation Committee by our Chief Executive Officer. In the case of our Chief Executive Officer, the evaluation of his performance is conducted by the Compensation Committee, which determines recommendations to the Board regarding any adjustments to his compensation as well as equity awards to be granted. For all executives and directors as part of its deliberations, the Compensation Committee may review and consider, as appropriate, materials such as financial reports and projections, operational data, executive and director stock ownership information, company stock

performance data, analyses of historical executive compensation levels and current Company-wide compensation levels, compensation data from comparative companies, compensation surveys, and recommendations of any compensation consultant, if applicable. The Compensation Committee considered the peer-group analysis from Compensia when making compensation decisions. Based on this analysis, the overall average of the 2023 cash compensation for our named executive officers approximated the 25th percentile of the peer group.

Governance and Nominating Committee

The Governance and Nominating Committee of the Board is responsible for identifying, reviewing and evaluating candidates to serve as directors of the Company (consistent with criteria approved by the Board), reviewing and evaluating incumbent directors, selecting or recommending to the Board for selection candidates for election to the Board, making recommendations to the Board regarding the membership of the committees of the Board, assessing the performance of the Board, and developing a set of corporate governance principles for the Company.

The Governance and Nominating Committee is currently composed of two directors: Mr. Williams (Chair) and Mr. Wei. Each member of the Governance and Nominating Committee is independent (as independence is currently defined in Rule 5605(a)(2) of the Nasdaq listing standards), a non-employee director and free from any relationship that would interfere with the exercise of their independent judgment. The Board has adopted a written Governance and Nominating Committee charter that is available to stockholders on our website at www.palisadebio.com under the section entitled "Governance Documents." The information on our website is not incorporated by reference into this Annual Report on Form 10-K.

The responsibilities of the Governance and Nominating Committee include, among other things:

- identifying and evaluating candidates, including the nomination of incumbent directors for reelection and nominees recommended by stockholders, to serve on the Board;
- considering and making recommendations to the Board regarding the composition and chairmanship of the committees of the Board;
- considering the need for and, if necessary, developing and instituting plans or programs for the continuing education of the Board; and
- developing corporate governance principles to be applicable to the Company.

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

The Governance and Nominating Committee appreciates the value of thoughtful Board refreshment, and regularly identifies and considers qualities, skills and other director attributes that would enhance the composition of the Board. In the case of incumbent directors whose terms of office are set to expire, the Governance and Nominating Committee reviews these directors' overall service to the Company during their terms, including the number of meetings attended, level of participation, quality of performance and any other relationships and transactions that might impair the directors' independence. The Governance and Nominating Committee also takes into account the results of the Board's self-evaluation, conducted annually on a group and individual basis. In the case of new director candidates, the Governance and Nominating Committee also determines whether the nominee is independent for Nasdaq purposes, which determination is based upon applicable Nasdaq listing standards, applicable SEC rules and regulations and the advice of counsel, if necessary. The Governance and Nominating Committee then uses its network of contacts to

compile a list of potential candidates, but may also engage, if it deems appropriate, a professional search firm. The Governance and Nominating Committee conducts any appropriate and necessary inquiries into the backgrounds and qualifications of possible candidates after considering the function and needs of the Board. The Governance and Nominating Committee meets to discuss and consider the candidates' qualifications and then selects candidates for recommendation to the Board by majority vote.

Our Governance and Nominating Committee does not have a formal policy regarding Board diversity. Diversity is one of a number of factors, however, that the committee takes into account in identifying nominees, and the Governance and Nominating Committee believes that it is essential that the Board members represent diverse viewpoints.

The Governance and Nominating Committee will consider director candidates recommended by our stockholders. The Governance and Nominating Committee does not intend to alter the manner in which it evaluates candidates, including the minimum criteria set forth above, based on whether or not the candidate was recommended by a stockholder. Stockholders who wish to recommend individuals for consideration by the Governance and Nominating Committee to become nominees for election to the Board may do so by delivering a written recommendation to the Governance and Nominating Committee at the following address: Palisade Bio, Inc., Attn: Corporate Secretary, 7750 El Camino Suite 2A, Carlsbad, California 92009, no later than the close of business on the 90th day nor earlier than the close of business on the 120th day prior to the first anniversary of the preceding year's annual meeting of stockholders. Submissions must include, among other things, the name and address of the stockholder on whose behalf the submission is made; the number of our common stock shares that are owned beneficially by such stockholder as of the date of the submission; the full name of the proposed candidate; a description of the proposed candidate's business experience for at least the previous five years; complete biographical information for the proposed candidate; and a description of the proposed candidate's qualifications as a director. Any such submission must be accompanied by the written consent of the proposed nominee to be named as a nominee and to serve as a director if elected.

Item 11. Executive Compensation.

EXECUTIVE COMPENSATION

Our named executive officers for the year ended December 31, 2023, consisting of our current principal executive officer and financial officer, our the next two most highly compensated executive officers as of December 31, 2023, and two additional individuals for whom disclosure would have been required to be provided under applicable SEC rules but for the fact that the individuals were not serving as an executive officer at December 31, 2023, were:

- Thomas Hallam, Ph.D., our former Chief Executive Officer;
- J.D. Finley, our current Chief Executive Officer and Chief Financial Officer;
- Michael Dawson, M.D., our former Chief Medical Officer;
- Mitchell Jones, M.D., Ph.D. our current Chief Medical Officer; and
- Robert McRae, our former Chief Operating Officer.

The following table presents all of the compensation awarded to or earned by or paid to our named executive officers during the fiscal years ended December 31, 2023 and 2022.

Summary Compensation Table

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards [1] ($)	Non-Equity Incentive Plan Compensation [2] ($)	All Other Compensation ($)	Total ($)
Thomas Hallam, Ph.D.	2023	—	—	—	—	—	—	—
Former Chief Executive Officer [3]	2022	415,167	—	—	96,572 [4]	—	22,083	533,822
J.D. Finley	2023	520,333	—	264,541 [6]	221,226 [7]	271,000	—	1,277,100
Chief Executive Officer and Chief Financial Officer [5]	2022	440,500	—	—	39,961 [8]	133,100	—	613,561
Mitchell Jones, M.D., Ph.D.	2023	135,189	—	54,247 [10]	49,563 [11]	166,000	53,025 [12]	458,024
Chief Medical Officer [9]	2022	—	—	—	—	—	—	—
Michael Dawson	2023	—	—	—	—	—	—	—
Former Chief Medical Officer [13]	2022	94,501	—	—	19,981 [14]	—	74,698	189,180
Robert McRae	2023	145,833	—	24,850 [16]	739 [17]	—	28,000 [18]	199,422
Chief Operating Officer [15]	2022	350,000	—	—	61,067 [19]	89,420	—	500,487

(1) In accordance with SEC rules, amount reflects the aggregate grant date fair value of stock options granted to our named executive officers during fiscal years ended December 31, 2022 and 2023 under the 2021 Inducement Pan and the 2021 Equity Incentive Plan, as determined in accordance with the provisions of FASB ASC Topic 718. The valuation assumptions used in calculating the fair value of the stock options are included in Note 9 to our audited consolidated financial statements included in the Company's Annual Report on Form 10-K filed with the SEC on March 22, 2023 with respect to grants in 2022. With respect to the grants in the 2023, those valuation assumptions were as follow: (i) a weighted-average exercise price of $1.39, (ii) a weighted-average expected term of 5.66 years, (iii) a weighted-average risk-free interest rate of 4.08%, (iv) a weighted-average expected dividend yield of 0%, and (v) a weighted-average volatility of 78.35%. These amounts do not reflect the actual economic value that may be realized by the named executive officer upon the vesting of the stock options, the exercise of the stock options, or the sale of the common stock underlying such stock options.

(2) Amounts reflect non-equity discretionary cash incentive plan bonuses paid.

(3) Dr. Hallam ceased to serve as our Chief Executive Officer and as a member of the Board effective October 11, 2022.

(4) Amount includes an option grant to purchase 1,296 shares under the 2021 Equity Incentive Plan. The options were issued on February 17, 2022 and have an exercise price of $47.71 per share.

(5) Mr. Finley was appointed Chief Executive Officer on October 11, 2022. Mr. Finley's salary was increased to $490,000 effective October 1, 2022. Effective June 1, 2023, Mr. Finley's salary was increased to 542,000 and his target cash bonus from 45% to 50% of his base salary.

(6) Amount includes: (i) 5,236 restricted stock units issued on January 3, 2023, (ii) 41,700 restricted stock units issued on February 6, 2023, (iii) 66,700 restricted stock units issued on June 11, 2023, (iv) 38,000 restricted stock units issued on November 21, 2023, and (v) 32,500 restricted performance stock units issued on February 6, 2023. All the grants were issued under the 2021 Equity Incentive Plan.

(7) Amount includes: (i) an option grant issued on February 6, 2023 to purchase 57,200 shares at an exercise price of $2.40 per share, (ii) an option grant issued on June 11, 2023 to purchase 148,500 shares at an exercise price of $1.60 per share, and (iii) an option grant issued on November 11, 2023 to purchase 45,000 shares at an exercise price of $0.59 per share. All the grants were issued under the 2021 Equity Incentive Plan.

(8) Amount includes an option grant to purchase 3,132 shares under the 2021 Equity Incentive Plan. The options were issued on February 17, 2022 and have an exercise price of $47.71 per share.

(9) Mitchell Jones was appointed Chief Medical Officer effective September 5, 2023 with a base salary of $415,000.

(10) Amount includes 54,700 restricted stock units issued on September 5, 2023 under the 2021 Inducement Plan and 28,000 restricted stock units issued on November 21, 2023 under the 2021 Equity Incentive Plan.

(11) Amount includes 75,000 option grants issued on September 5, 2023 under the 2021 Inducement Plan at an exercise price of $0.6897 per share and 33,160 options grants issued on November 21, 2023 under the 2021 Equity Incentive Plan at an exercise price of $0.59 per share.

(12) Amounts reflect payment made to Dr. Jones as a consultant of the Company prior to becoming the Chief Medical Officer on September 5, 2023.

(13) Dr. Dawson ceased to serve as our Chief Medical Officer effective October 11, 2022.

(14) Amount includes an option grant to purchase 1,800 shares under the 2021 Equity Incentive Plan. The options were issued on February 9, 2022 and have an exercise price of $52.50 per share.

(15) Mr. McRae served as our chief operating officer from February 2, 2023 through May 15, 2023. Mr. McRae continued to provide consulting services to the Company through January 15, 2024.

(16) Amount includes: (i) 2,618 restricted stock units issued on January 1, 2023, (ii) 8,000 restricted stock units issued on February 6, 2023, and (iii) 17,900 restricted performance stock units issued on February 6, 2023. All of the grants were issued under the 2021 Equity Incentive Plan.

(17) Amount includes an option grant to purchase 12,000 shares under the 2021 Equity Incentive Plan. The options were issued on February 6, 2023 and have an exercise price of $2.40 per share.

(18) Represents amounts paid to Mr. McRae for consulting services to the Company after he ceased being Chief Operating Officer on May 15, 2023.

(19) Amount includes an option grant to purchase 1,800 shares under the 2021 Equity Incentive Plan. The options were issued on February 9, 2022 and have an exercise price of $52.50 per share.

Compensation Program Overview

Our compensation program for executive officers is designed to encourage our management team to continually achieve our short-term and long-term corporate objectives while effectively managing business risks and challenges. We provide what we believe is a competitive total compensation package to our management team through a combination of base salary, an annual performance-based bonus and long-term equity-based incentives.

The Compensation Committee shall review, determine and approve (or, if it deems appropriate, recommend to the Board for determination and approval, except as provided below), at their discretion, in light of relevant performance goals and objectives, taking into account such other items as the Compensation Committee deems relevant.

Bonus Opportunity

Named executive officers are eligible to be considered for an annual discretionary cash incentive bonus of up to a percentage of their respective base salary, based on achievement of individual and/or corporate performance targets, metrics and/or objectives to be determined and approved by the Board or the Compensation Committee, including pursuant to an annual incentive plan or similar plan adopted by the Board, if any. Any such bonus would be paid after the close of the fiscal year and after determination by the Board or the Compensation Committee. All annual incentive compensation is discretionary and not guaranteed and, in addition to the other conditions for earning such compensation, each officer must remain an employee in good standing of the Company on the annual incentive compensation payment date in order to be eligible for any annual incentive compensation. The Board (or the Compensation Committee thereof) may review an executive officer’s annual performance bonus amount for adjustment from time to time. The 2023 annual discretionary cash incentive bonus targets were 50% of base salary for Mr. Finley (which amount was increased from 45% effective June 1, 2023) and 40% of base salary for Dr. Jones.

In 2023, the annual cash incentive bonuses paid to Mr. Finley and Dr. Jones were calculated based on achievement of 100% of the corporate performance targets for the year multiplied by their respective bonus target percentages at the time. The corporate performance targets related to clinical and medical development, financial position, and corporate operations and infrastructure during 2023.

Equity Compensation Plans

As of December 31, 2023, we currently have the following equity compensation plans: (i) the Palisade 2021 Equity Incentive Plan, as amended (the "2021 EIP"), (ii) the Palisade 2021 Employee Stock Purchase Plan, as amended (the "Employee Stock Purchase Plan”), (ii) the Leading BioSciences 2013 Amended and Restated Employee, Director,

and Consultant Equity Incentive Plan (the "2013 Plan"), which was assumed by the Company in connection with the merger with Seneca BioPharma, (iii) the Palisade 2021 Inducement Plan, (the "2021 Inducement Plan"), (iv) Seneca's 2019 Equity Incentive Plan (the "Seneca 2019 Plan"), (v) Seneca's 2020 Equity Incentive Plan (the "Seneca 2020 Plan") and (vi) Seneca's Inducement Award Stock Option Plan (the "Seneca Inducement Plan"). As a result of the approval of the 2021 EIP, no future awards may be granted under the 2013 Plan. Additionally, no future awards may be granted under the Seneca 2019 Plan, the Seneca 2020 Plan, or the Seneca Inducement Plan.

Clawback Policy

Effective October 2, 2023, we adopted a clawback policy (the "Clawback Policy"), that is administered by our Compensation Committee. Pursuant to the Clawback Policy, our current and former executive officers are required to reimburse us in the event that any Incentive Compensation (as defined in the Clawback Policy) is awarded to such executive and is determined to be awarded in error subsequent to an accounting restatement resulting from material noncompliance with financial reporting requirements under federal securities laws. Notwithstanding, we have not historically granted Incentive Compensation based on financial metrics that would be subject to a restatement.

FOR ADDITIONAL INFORMATION, PLEASE SEE BELOW UNDER "OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END."

Say-on-Pay

At our 2023 Annual Meeting of Stockholders held on June 8, 2023 (the "2023 Annual Meeting"), we submitted two proposals to our stockholders regarding our executive compensation.

The first is an advisory vote on the compensation awarded to our named executive officers (commonly known as a "say-on-pay" vote). At our 2023 Annual Meeting, excluding broker non-votes, approximately 1,332,108 shares cast votes with regard to the say-on-pay proposal. Of those, or approximately 57.45%, of the shares approved the compensation of our named executive officers. We believe that the outcome of our say-on-pay vote signals our stockholders' support of our compensation approach, specifically our efforts to retain and motivate our named executive officers. In light of this stockholder support, the Compensation Committee determined not to change its approach to compensation. However, even though stockholders demonstrated support for our compensation approach in 2023, the Compensation Committee annually reviews our compensation practices to determine how they might be improved. The Compensation Committee will continue to consider the outcome of say-on-pay votes when making future compensation decisions for our named executive officers.

The second proposal was a vote on the frequency of future stockholder advisory votes regarding compensation awarded to named executive officers (commonly known as a "say-when-on-pay" vote). The frequency of every one (1) year received the highest number of votes cast. Notwithstanding these results, our Board determined that we would hold our next say-on-pay votes at the 2026 Annual Meeting or three (3) years from the 2023 Annual Meeting.

Agreements with Our Named Executive Officers

We are party to (i) an employment agreement with Mr. Finley, our Chief Executive Officer and Chief Financial Officer and (ii) an employment agreement with Mitchell Jones, M.D., Ph.D., our Chief Medical Officer.

Previously, we were a party to (i) an employment agreement entered into with Dr. Hallam in December 2020 (entered into by LBS), and (ii) an employment agreement entered into with Dr. Dawson in December 2020 (entered into by LBS). Employment for both Dr. Hallam and Dr. Dawson terminated on October 11, 2022.

Descriptions of each of the foregoing employment or consulting agreement(s) are described below.

Finley Employment Agreement

Mr. Finley served as our Chief Financial Officer pursuant to his amended and restated employment agreement dated January 22, 2021 ("Finley Employment Agreement"). Additionally, effective October 11, 2022, Mr. Finley was appointed to serve as our interim Chief Executive Officer and effective June 1, 2023, Mr. Finley's title was changed from interim Chief Executive Officer to Chief Executive Officer. Pursuant to the Finley Employment Agreement, Mr. Finley received an annual base salary of $400,000, with an annual target cash bonus of 40% of his base salary. In February 2022, his base salary was increased to $424,000 per annum. Effective October 1, 2022, Mr. Finley's salary was increased to $490,000 and his target cash bonus increased to 45% of his base salary pursuant to his appointment as interim Chief Executive Officer. Effective June 1, 2023, Mr. Finley's base salary was increased to $542,000 per annum and his target cash bonus to 50% of his base salary.

Finley Termination / Change in Control Payments

The Finley Employment Agreement also provided that if the Company terminated Mr. Finley without "Cause" or if Mr. Finley resigned his employment for "Good Reason", each as defined in the Finley Employment Agreement, Mr. Finley would be entitled to receive (i) salary continuation and COBRA reimbursement for twelve (12) months each, up to three (3) months of outplacement assistance, and (iii) 9 months of immediate vesting of equity grants subject to time based vesting. In the case of a termination that occurred during the period beginning three (3) months before and ending twelve (12) months after a "Change in Control", (a) these severance-related periods would also be (12) months, (b) the equity award acceleration will result in full vesting for all time-based awards, and (c) Mr. Finley would receive an additional payment equal to his target bonus.

Upon Mr. Finley's termination for any reason, Mr. Finley will be entitled to receive amounts earned but unpaid during his term of service, including unpaid salary and unused vacation, as applicable.

Mr. Finley received certain stock option grants and restricted stock unit grants under the 2013 Plan and the 2021 EIP that were granted subject to the general terms of the 2013 Plan or the 2021 EIP, as applicable, and the relevant form of stock option or stock award agreement. The specific terms of such grants are described under the heading "Outstanding Equity Awards at Fiscal Year-End."

Jones Employment Agreement

On September 5, 2023, we entered into an at-will employment agreement with Dr. Jones (the "Jones Employment Agreement"). Pursuant to the terms of the Jones Employment Agreement, Dr. Jones (i) receives a base salary of $415,000 per annum and is eligible to receive an annual cash bonus based on the achievement of certain performance goals with a target of 40% of his base salary, and (ii) is eligible to receive an annual market-based stock option grant as determined by the Board or a committee thereof.

Per the Jones Employment Agreement, we issued to Dr. Jones under the 2021 Inducement Plan (i) options to purchase 75,000 shares of our common stock, and (ii) 54,700 restricted stock units. Dr. Jones has also received certain stock option grants and restricted stock unit grants under the 2021 EIP that were granted subject to the general terms of the 2021 EIP, as applicable, and the relevant form of stock option or stock award agreement. The specific terms of such grants are described under the heading "Outstanding Equity Awards at Fiscal Year-End."

Severance Benefits

Pursuant to the terms of the Jones Employment Agreement, if we terminate Dr. Jones' employment without "Cause" or Dr. Jones resigns for "Good Reason," as each term is defined in the Jones Employment Agreement, Dr. Jones will be eligible for the continued payment of his base salary (in accordance with regular payroll practices) and COBRA benefits for nine (9) months following the termination date (collectively, the "Jones Severance Benefits").

Jones Termination / Change in Control Payments

In the event that we terminate Dr. Jones' employment without "Cause" or Dr. Jones resigns for "Good Reason" within three (3) months immediately prior to or twelve (12) months after the effective date of a "Change in Control" as such term is defined in the Jones Employment Agreement (the "Jones Change in Control Period"), then in lieu of the Jones Severance Benefits described above, Dr. Jones will be eligible for (i) a lump sum payment equal to the sum of (x) twelve (12) months of base salary plus (y) 100% of the target bonus in effect at the time of termination, (ii) the continued payment of COBRA benefits for twelve (12) months, and (iii) the immediately and full acceleration of 100% of outstanding equity awards that are subject to time-based vesting. The foregoing benefits are contingent on Dr. Jones entering into a release of claims satisfactory to the Company.

McRae Employment

Effective February 2, 2022, Robert McRae was appointed our Chief Operating Officer. Pursuant to Mr. McRae's appointment, the Board agreed to pay Mr. McRae a base salary of $400,000 per annum and set his target bonus at 40% of his base salary. We did not enter into a formal employment agreement with Mr. McRae. Effective May 15, 2023, Mr. McRae transitioned from the Company's COO to an executive strategic consultant. For his services as a consultant, Mr. McRae received monthly compensation of $4,000. Mr. McRae's service to the Company as a consultant terminated on January 15, 2024.

Mr. McRae received certain stock option grants and restricted stock unit grants under the 2021 EIP and the 2021 Inducement Plan that were granted subject to the general terms of the 2021 EIP and 2021 Inducement Plan, as

applicable, and the relevant form of stock option or stock award agreement. The specific terms of such grants are described under the heading "Outstanding Equity Awards at Fiscal Year-End."

Hallam Employment Agreement

Dr. Hallam served as our Chief Executive Officer pursuant to his employment agreement dated December 16, 2022 ("Hallam Employment Agreement") until October 11, 2022. Pursuant to the Hallam Employment Agreement, Dr. Hallam received an annual base salary of $490,000, with an annual target cash bonus of 50% of his base salary. Dr. Hallam also received a one-time payment of $285,000, consisting of (i) $73,500 for the 2019 performance bonus, which had been voluntarily deferred (ii) $164,937 for the amount of 2020 salary that had been voluntarily deferred, (iii) a bonus equal to 10% of the 2020 salary that had been voluntarily deferred and (iv) a discretionary bonus of $30,000 awarded for the successful close of the merger with Seneca. In February 2022, Dr. Hallam's base salary was increased to $530,000 per annum.

Hallam Termination / Change in Control Payments

The Hallam Employment Agreement also provided that if we terminated Dr. Hallam without "Cause" or if Dr. Hallam resigned his employment for "Good Reason", each as defined in the Hallam Employment Agreement, Dr. Hallam would be entitled to receive (i) salary continuation and COBRA reimbursement for twelve (12) months each, up to three (3) months of outplacement assistance, and (iii) 12 months of immediate vesting of equity grants subject to time based vesting. In the case of a termination that occurred during the period beginning three (3) months before and ending twelve (12) months after a "Change in Control", (a) these severance-related periods would have increased to eighteen (18) months, (b) the equity award acceleration will result in full vesting for all time-based awards, and (c) Dr. Hallam would receive an additional payment equal to his target bonus.

Upon Dr. Hallam's termination, Dr. Hallam received amounts earned but unpaid during his term of service, including unpaid salary and unused vacation, as applicable.

Pursuant to his service, Dr. Hallam received certain stock option grants under the 2013 Plan and the 2021 EIP that were granted subject to the general terms of the 2013 Plan or 2021 EIP, as applicable, and the relevant form of stock option agreement. The specific terms of such grants are described under the heading "Outstanding Equity Awards at Fiscal Year-End."

Termination of Employment of Dr. Hallam

On October 11, 2022, the Company entered into a separation agreement with Thomas Hallam, Ph.D., its former chief executive officer and member of its board of directors whereby the Company and Dr. Hallam agreed to a mutual release of claims in exchange for (i) the payment of an aggregate of $530,000 payable in twelve equal monthly installments, (ii) up to twelve (12) months of continued COBRA coverage, (iii) twelve (12) months of immediate vesting of his outstanding equity grants subject to time based vesting, and (iv) up to six (6) months of virtual job replacement services valued at $3,100. Subsequent to entering into the separation agreement, certain facts and conduct by Dr. Hallam were discovered that excused the Company's performance under the settlement agreement. As a result, subsequent to paying Dr. Hallam an aggregate of $22,000, the Company determined that it is not probable that any additional compensation would be due to Dr. Hallam.

Dawson Employment Agreement

Dr. Dawson served as our Chief Medical Officer pursuant to his employment agreement dated December 16, 2020 ("Dawson Employment Agreement") until October 11, 2022. Pursuant to the Dawson Employment Agreement, Dr. Dawson received an annual base salary of $115,900, with an annual target cash bonus of 40% of his base salary. Dr. Dawson also received a one-time payment of $66,000, consisting of (i) $7,500 for the 2019 performance bonus, which had been voluntarily deferred (ii) $52,515 for the amount of 2020 salary that had been voluntarily deferred, and (iii) a bonus equal to 10% of the 2020 salary that had been voluntarily deferred. In February 2022, Dr. Dawson's base salary was increased to $240,000 per annum.

Dawson Termination / Change in Control Payments

The Dawson Employment Agreement also provided that if we terminated Dr. Dawson without "Cause" or if Dr. Dawson resigned his employment for "Good Reason", each as defined in the Dawson Employment Agreement, Dr. Dawson would be entitled to receive (i) salary continuation and COBRA reimbursement for nine (9) months each, (ii) up to three (3) months of outplacement assistance, and (iii) nine (9) months of immediate vesting of equity grants subject to time based vesting. In the case of a termination that occurred during the period beginning three (3) months before and ending twelve (12) months after a "Change in Control", (a) these severance-related periods would have increased to nine (9) months, (b) the equity award acceleration will result in full vesting for all time-based awards, and (c) Dr. Dawson would receive an additional payment equal to his target bonus.

Upon a termination of service for any reason, Dr. Dawson would have been entitled to receive amounts earned during his term of service, including unpaid salary and unused vacation, as applicable.

As a result of his termination, all of Dr. Dawson's option grants have expired.

Perquisites, Health, Welfare and Retirement Benefits

All of our current named executive officers are eligible to participate in our employee benefit plans, including our medical, dental, vision, life, disability and accidental death and dismemberment insurance plans, in each case on the same basis as all of our other employees. Current named executive officers are eligible to participate in our defined contribution 401(k) plan, on the same basis as all of our other employees, under which they may make voluntary contributions as a percentage of compensation. No matching contributions have been made by us since the adoption of the 401(k) plan.

Outstanding Equity Awards at Fiscal Year-End

			Option Awards [1]					Stock Awards [2]			
Name	Award Type [3]	Grant Date	Number of securities underlying unexercised options - exercisable (#)	Number of securities underlying unexercised options – unexercisable [4] (#)	Equity incentive plan awards: Number of securities underlying unexercised unearned options (#)	Option exercise price [5] ($)	Option expiration date	Number of shares or units of stock that have not vested [6] (#)	Market value of shares of units of stock that have not vested [7] ($)	Equity incentive plan award: Number of unearned shares, units or other rights that have not vested [8] (#)	Equity incentive plan awards: Market or payout value of unearned shares, units or other rights that have not vested [7] ($)
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	(k)	(l)
J.D. Finley	ISO	6/12/2015	155	–		$ 116.00	6/12/2025				
	ISO	11/10/2017	605	–		$ 116.00	11/10/2027				
	ISO	11/18/2021	948	862		$ 116.00	11/18/2031				
	ISO	11/21/2023	–	15,000		$ 0.59	11/21/2033				
	ISO	3/22/2019	36	–		$ 116.00	3/22/2029				
	ISO	2/17/2022	–	108		$ 47.71	2/17/2032				
	ISO	6/11/2023	–	64,844		$ 1.60	6/11/2033				
	ISO	2/6/2023	–	23,833		$ 2.40	2/6/2033				
	ISO	3/22/2019	47	–		$ 116.00	3/22/2029				
	ISO	2/19/2020	107	–		$ 116.00	2/19/2030				
	NQ	12/9/2016	190	–		$ 116.00	12/13/2024				
	NQ	3/22/2019	194	–		$ 116.00	3/22/2029				
	NQ	3/22/2019	66	–		$ 116.00	3/22/2029				
	NQ	4/27/2021	652	–		$ 116.00	4/27/2031				
	NQ	11/18/2021	1,273	478		$ 116.00	11/18/2031				
	NQ	2/6/2023	14,300	19,067		$ 2.40	2/6/2033				
	NQ	6/11/2023	24,750	58,906		$ 1.60	6/11/2033				
	NQ	3/22/2019	380	–		$ 116.00	3/22/2029				
	NQ	11/10/2017	436	–		$ 116.00	11/10/2027				
	NQ	2/19/2020	51	–		$ 116.00	2/19/2030				
	NQ	11/21/2023	–	30,000		$ 0.59	11/21/2033				
	NQ	6/12/2015	53	–		$ 116.00	6/12/2025				
	NQ	3/22/2019	257	–		$ 116.00	3/22/2029				
	NQ	2/17/2022	756	432		$ 47.71	2/17/2032				
	PRSU	2/6/2023								32,500	$ 19,175.00
	RSU	11/21/2023						38,000	$ 22,420		
	RSU	1/3/2023						1,309	$ 772.31		
	RSU	6/11/2023						55,583	$ 32,793.97		
	RSU	2/6/2023						31,275	$ 18,452.25		
Mitchell Jones M.D., Ph.D.	ISO	11/21/2023	–	33,160		$ 0.59	11/21/2033				
	NQ	9/5/2023	6,250	68,750		$ 0.69	9/5/2033				
	RSU	9/5/2023						50,144	$ 29,584.96		
	RSU	11/21/2023						28,000	$ 16,520.00		
Robert McRae	NQ	2/9/2022	1,200	600		$ 52.50	2/9/2032				
	NQ	2/6/2023	3,000	9,000		$ 2.40	2/6/2033				
	PRSU	2/6/2023								17,900	$ 10,561.00
	RSU	2/6/2023						6,000	$ 3,540.00		
	RSU	1/3/2023						654	$ 385.86		

(1) Option awards were granted under the 2013 Plan, the 2021 EIP and the 2021 Inducement Plan.

(2) Stock awards were granted under the 2021 EIP and the 2021 Inducement Plan.

(3) The acronym ISO refers to Incentive Stock Options, NQ refers to non—statutory stock options, PRSU to Performance Restricted Stock Units, and RSU to Restricted Stock Units.

(4) Options vest in equal proportions each quarter over three years, generally from the date of grant, except those options specifically granted to Mr. Finley on April 27, 2021, which vested quarterly over one year.

(5) All of the option awards granted under the 2013 Plan were granted with a per share exercise price equal to fair market value of one share of LBS common stock on the date of grant, as determined in good faith by the Board. All of the option awards granted under the 2021 EIP and the 2021 Inducement Plan were granted with a per share exercise price equal to the closing price of our common stock on the grant date.

(6) Restricted stock units vest in equal proportions each quarter over three years, except those restricted stock units granted on January 3, 2023, which vest quarterly over one year.

(7) The values shown are based on $0.59 per share, which was the closing price of our common stock on December 29, 2023, the last day of our most recent fiscal year.

(8) Performance restricted stock units vest (a) 50% when the volume weighted average price of our common stock over 20 consecutive trading days is $3.20, and (b) 50% when such volume weighted average price of our common stock over 20 consecutive trading days is $4.25.

Equity Benefit Plans

The principal features of our equity plans are summarized below.

2021 Equity Incentive Plan

Our board and stockholders approved the 2021 EIP, which became effective in April 2021. On June 8, 2023, our stockholders approved amendments to the 2021 EIP increasing the numbers of shares of common stock issuable under the plan and increasing the annual evergreen share amount. The number of shares of common stock reserved for issuance under the 2021 EIP will automatically increase on January 1 of each calendar year, starting on January 1, 2022 through January 1, 3031, in an amount equal to the lesser of (1) 7.5% (increased from 4.5% pursuant to the approval of stockholders in our 2023 Annual Meeting) of the total number of shares of our common stock outstanding on December 31 of the preceding year, or (2) a lesser number of shares of our common stock determined by the Board prior to the date of the increase. As of December 31, 2023, 4,947 shares of our common stock were authorized for future grants under the 2021 EIP and there were an aggregate of 805,326 outstanding awards issued under the 2021 EIP, excluding 144,160 conditional grants that we made to certain members of management that are subject to sufficient shares available under the 2021 EIP.

Our 2021 EIP provides for the grant of incentive stock options ("ISOs"), within the meaning of Section 422 of the Code to employees, including employees of any parent or subsidiary, and for the grant of nonstatutory stock options ("NSOs"), stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of awards to employees, directors and consultants, including employees and consultants of our affiliates. Our compensation committee has the authority, concurrent with our Board, to administer our 2021 EIP. The Board may also delegate to one or more of our officers certain authority under the terms of the 2021 EIP.

Stock options under the 2021 EIP are generally granted with an exercise price equal to the fair market value of our common stock on the date of grant. Options granted under the 2021 EIP vest at the rate specified in the stock option agreement as determined by the plan administrator. Options may have a term up to a maximum of 10 years. Unless the terms of an optionee's stock option agreement provides otherwise, if an optionee's service relationship with us, or any of our affiliates, ceases for any reason other than disability, death or cause, the optionee may generally exercise any vested options for a period of three months following the cessation of service. If an optionee's service relationship with us, or any of our affiliates, ceases due to disability or death, or an optionee dies within a certain period following cessation of service, the optionee or a beneficiary may generally exercise any vested options for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, options generally terminate immediately upon the termination of the individual. In no event may an option be exercised beyond the expiration of its term.

Our 2021 EIP provides that in the event of certain specified significant corporate transactions (or a change in control, as defined below), unless otherwise provided in an award agreement or other written agreement between us and the award holder, the administrator may take one or more of the following actions with respect to such stock awards:

- arrange for the assumption, continuation, or substitution of a stock award by a successor corporation;
- arrange for the assignment of any reacquisition or repurchase rights held by us to a successor corporation;
- accelerate the vesting, in whole or in part, of the stock award and provide for its termination if not exercised (if applicable) at or before the effective time of the transaction;
- arrange for the lapse, in whole or in part, of any reacquisition or repurchase rights held by us;
- cancel or arrange for the cancellation of the stock award, without the approval of stockholders but with the consent of any materially adversely affected participant, in exchange for other awards, cash, or other consideration, if any, as determined by our Board; or
- make a payment, in the form determined by our Board, equal to the excess, if any, of (i) the per share amount payable to holders of our common stock in connection with the corporate transaction, over (ii) any per share exercise price payable by such holder, if applicable.

Under the 2021 EIP, a corporate transaction is generally the consummation of: (1) a sale of all or substantially all of our assets, (2) the sale or disposition of more than 50% of our outstanding securities, (3) a merger or consolidation where we do not survive the transaction, or (4) a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately before such transaction are converted or exchanged into other property by virtue of the transaction.

If the surviving or acquiring corporation (or its parent company) does not assume, continue or substitute for such stock awards, then (i) with respect to any such stock awards that are held by participants whose continuous service has not terminated prior to the effective time of the corporate transaction, or current participants, the vesting (and exercisability, if applicable) of such stock awards will be accelerated in full (or, in the case of performance awards with multiple vesting levels depending on the level of performance, vesting will accelerate at 100% of the target level) to a date prior to the effective time of the corporate transaction (contingent upon the effectiveness of the corporate transaction), and such stock awards will terminate if not exercised (if applicable) at or prior to the effective time of the corporate transaction, and any reacquisition or repurchase rights held by us with respect to such stock awards will lapse (contingent upon the effectiveness of the corporate transaction), and (ii) any such stock awards that are held by persons other than current participants will terminate if not exercised (if applicable) prior to the effective time of the corporate transaction, except that any reacquisition or repurchase rights held by us with respect to such stock awards will not terminate and may continue to be exercised notwithstanding the corporate transaction. In the event a stock award will terminate if not exercised prior to the effective time of a corporate transaction, our Board may provide, in its sole discretion, that the holder of such stock award may not exercise such stock award but instead will receive a payment equal in value to the excess (if any) of (i) the per share amount payable to holders of common stock in connection with the corporate transaction, over (ii) any per share exercise price payable by such holder, if applicable.

2021 Employee Stock Purchase Plan

Additional long-term equity incentives are provided through the ESPP. On June 8, 2023 our stockholder approved amendments to the ESPP increasing the number of shares of common stock authorized under the ESPP and increasing the annual evergreen share amount. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Code. Our compensation committee has the authority, concurrent with our Board, to administer the ESPP. Under the ESPP, all of our regular employees (including our named executive officers during their employment with us) may participate and may contribute, normally through payroll deductions, up to 15% of their earnings for the purchase of our common stock. The number of shares of common stock reserved for issuance under the ESPP will automatically increase on January 1 of each calendar year, starting on January 1, 2022 through January 1, 3031, in an amount equal to the lesser of (1) 2.5% (increased from 1% pursuant to the approval of stockholders in our 2023 annual meeting of shareholders) of the total number of shares of our common stock outstanding on December 31 of the preceding year, (2) 433,641 shares of our common stock, or (3) such lesser number of shares of our common stock as the Board may designate prior to the date of increase. As of December 31, 2023, 110,871 shares of our common stock were authorized for future grants under the ESPP. A total of 33,676 shares of our common stock were purchased by employees under participation in the ESPP during the year ended December 31, 2023.

The ESPP is implemented through a series of offerings of purchase rights to eligible employees. Under the ESPP, we may specify offerings with a duration of not more than 27 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which our common stock will be purchased for employees participating in the offering. Unless otherwise determined by our compensation committee, shares are purchased for accounts of employees participating in the ESPP at a price per share equal to the lower of (a) 85% of the fair market value of our common stock on the first date of an offering or (b) 85% of the fair market value of our common stock on the date of purchase.

2021 Inducement Plan

The Board adopted the 2021 Inducement Plan in November 2021. The 2021 Inducement Plan was adopted without stockholder approval pursuant to Rule 5635(c) of the Nasdaq Listing Rules. On August 7, 2023, the Board amended the 2021 Inducement Plan to increase the number of common shares authorized under the plan from 15,000 to 1,000,000. The 2021 Inducement Plan provides for the grant of nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance stock awards, performance cash awards and other forms of stock awards.

Stock awards granted under our 2021 Inducement Plan may only be made to individuals who did not previously serve as employees or non-employee directors of the Company or an affiliate of the Company (or following such individuals' bona fide period of non-employment with the Company or an affiliate of the Company), as an inducement material to the individuals' entering into employment with the Company or an affiliate of the Company or in a manner otherwise permitted by Rule 5635(c) of the Nasdaq Listing Rules. In addition, stock awards must be approved by either a majority of our "independent directors" (as such term is defined in Rule 5605(a)(2) of the Nasdaq Listing Rules) or the Compensation Committee, provided such committee comprises solely independent directors. The terms of the 2021 Inducement Plan are otherwise substantially similar to our 2021 EIP (including with respect to the treatment of stock awards upon corporate transactions involving us or certain changes in our capitalization), except stock awards granted under the 2021 Inducement Plan may not be repriced without stockholder approval.

The maximum number of shares of our common stock that may be issued under the 2021 Inducement Plan is 1,000,000 shares. Shares subject to stock awards granted under the 2021 Inducement Plan that expire or terminate without being exercised in full, or that are paid out in cash rather than in shares, do not reduce the number of shares available for issuance under the 2021 Inducement Plan. Additionally, shares become available for future grant under the 2021 Inducement Plan if they were issued under stock awards granted under the 2021 Inducement Plan and we repurchase or reacquire them or they are forfeited. This includes shares used to pay the exercise price of a stock award or to satisfy the tax withholding obligations related to a stock award. As of December 31, 2023, there were 863,214 shares of our common stock authorized and available for issuance as equity-based awards under the 2021 Inducement Plan and there were an aggregate of 132,230 outstanding awards issued under the 2021 Inducement Plan.

Seneca Equity Compensation Plans

Seneca 2019 Plan

Pursuant to the completion of the merger transaction in April 2021, all outstanding awards under the Seneca 2019 Plan were cancelled and no further awards will be granted under the Seneca 2019 Plan.

Seneca Inducement Plan

Pursuant to the completion of the merger transaction in April 2021, all outstanding awards under the Seneca Inducement Plan were cancelled and no further awards will be granted under the Seneca Inducement Plan.

DIRECTOR COMPENSATION

Board Compensation Arrangements

Current Non-employee Director Compensation Policy

Our Compensation Committee amended the Non-employee Director Compensation Policy (the "Current Director Compensation Policy") of the Company on February 22, 2023 that is applicable to each member of our Board who is not also serving as an employee or consultant to the Company. This compensation policy provides that each such non-employee director will receive the following compensation for service on our Board:

Cash Compensation

- an annual cash retainer of $40,000;
- an additional annual cash retainer of $35,000 for service as chairman of our Board;
- an additional annual cash retainer of $20,000, $15,000, $10,000 and $20,000 for service as chair of the Audit Committee, Compensation Committee, the Governance and Nominating Committee and the Strategy and Finance Committee, respectively (the Strategy and Finance Committee was removed as a committee of our Board in February 2024); and
- an additional annual cash retainer of $10,000, $7,500, $5,000 and $10,000 for service as a member (not applicable to committee chairs) of the Audit Committee, Compensation Committee, the Governance and Nominating Committee and the Strategy and Finance Committee, respectively (the Strategy and Finance Committee was removed as a committee of our Board in February 2024).

Equity Compensation

- *Initial Grants For New Eligible Directors* – (i) 13,700 common stock options and (ii) 10,000 restricted stock units, that each vest in equal monthly installments over a three (3) year period; and

- *Annual Grants For Eligible Directors* – (i) 7,000 common stock options and (ii) 5,100 restricted stock units, each subject to the following terms:

    - One (1) year cliff vesting; and
    - Grant date three (3) days after our annual meeting of shareholders based on closing price of our common stock on such date.

We have reimbursed and will continue to reimburse all of our non-employee directors for their reasonable out-of-pocket expenses incurred in attending Board and committee meetings. J.D. Finley was appointed to the Board on February 2, 2023, but will not participate in any of the foregoing director compensation given his service as an executive officer of the Company.

Supplemental Grants

In addition to the foregoing compensation, the Compensation Committee of the Board periodically issues supplemental grants to the independent members of the Board on an ad hoc basis.

Legacy Non-employee Director Compensation Policy

Our Board adopted a Non-employee Director Compensation Policy in November 2021 that was applicable to each member of our Board who was not an employee or consultant to the Company. The policy was substantially the same as the Current Director Compensation Policy described above, except that the equity compensation component of the legacy policy was determined on an ad hoc basis at the discretion of the Board or Compensation Committee.

Compensation During 2023

The following table sets forth in summary form information concerning the compensation that was earned by each of our non-employee directors during the year ended December 31, 2023.

Name	Fees Earned or Paid in Cash ($)	Stock Awards($) *		Option Awards ($) *		Total ($)
James R. Neal [15]	105,000	11,594	[1]	15,635	[2]	132,229
Stephanie C. Diaz [16]	60,833	14,602	[3]	13,030	[4]	88,465
Donald A. Williams	60,000	11,594	[5]	15,635	[6]	87,229
Mary Ann Gray, Ph.D. [17]	60,417	11,594	[7]	15,635	[8]	87,646
Cristina Csimma, PharmD, MHP [16]	47,500	14,602	[9]	13,030	[10]	75,132
Robert Trenschel, D.O. [16]	50,625	11,594	[11]	15,635	[12]	77,854
Binxian Wei	40,000	14,602	[13]	13,030	[14]	67,632

* Each non-employee director received 7,000 common stock options and 5,100 restricted stock units on June 11, 2023 pursuant to the Company's non-employee director compensation policy, each of which is included in the footnotes below. All additional stock awards and option awards described in the footnotes below are supplemental grants in addition to the standard non-employee director compensation policy.

(1) Amount includes (i) 5,100 restricted stock units issued on June 11, 2023 and (ii) 5,820 restricted stock units issued on November 21, 2023. The grants were issued under the 2021 EIP.

(2) Amount includes (i) an option grant to purchase 12,160 common stock shares issued on June 11, 2023 with an exercise price of $1.60 per share and (ii) an option grant to purchase 6,880 common stock shares issued on November 21, 2023, with an exercise price of $0.59 per share. The option grants were each issued under the 2021 EIP, vest fully on the one (1) year anniversary of the respective grant date, and have terms of 10 years from issuance.

(3) Amount includes (i) 6,980 restricted stock units issued on June 11, 2023 and (ii) 5,820 restricted stock units issued on November 21, 2023.

(4) Amount includes (i) an option grant to purchase 9,580 shares issued on June 11, 2023 with an exercise price of $1.60 per share and (ii) an option grant to purchase 6,880 shares issued on November 21, 2023 with an exercise price of $0.59 per share. The option grants were each issued under the 2021 EIP, vest fully on the one (1) year anniversary of the respective grant date, and have terms of 10 years from issuance.

(5) Amount includes (i) 5,100 restricted stock units issued on June 11, 2023 and (ii) 5,820 restricted stock units issued on November 21, 2023.

(6) Amount includes (i) an option grant to purchase 12,160 shares issued on June 11, 2023 with an exercise price of $1.60 per share and (ii) an option grant to purchase 6,880 shares issued on November 21, 2023. with an exercise price of $0.59 per share. The option grants were each issued under the 2021 EIP, vest fully on the one (1) year anniversary of the respective grant date, and have terms of 10 years from issuance.

(7) Amount includes (i) 5,100 restricted stock units issued on June 11, 2023 and (ii) 5,820 restricted stock units issued on November 21, 2023.

(8) Amount includes (i) an option grant to purchase 12,160 shares issued on June 11, 2023 with an exercise price of $1.60 per share and (ii) an option grant to purchase 6,880 shares issued on November 21, 2023. with an exercise price of $0.59 per share. The option grants were each issued under the 2021 EIP, vest fully on the one (1) year anniversary of the respective grant date, and have terms of 10 years from issuance.

(9) Amount includes (i) 6,980 restricted stock units issued on June 11, 2023 and (ii) 5,820 restricted stock units issued on November 21, 2023.

(10) Amount includes (i) an option grant to purchase 9,580 shares issued on June 11, 2023 with an exercise price of $1.60 per share and (ii) an option grant to purchase 6,880 shares issued on November 21, 2023 with an exercise price of $0.59 per share. The option grants were each issued under the 2021 EIP, vest fully on the one (1) year anniversary of the respective grant date, and have terms of 10 years from issuance.

(11) Amount includes (i) 5,100 restricted stock units issued on June 11, 2023 and (ii) 5,820 restricted stock units issued on November 21, 2023.

(12) Amount includes (i) an option grant to purchase 12,160 shares issued on June 11, 2023 with an exercise price of $1.60 per share and (ii) an option grant to purchase 6,880 shares issued on November 21, 2023. with an exercise price of $0.59 per share. The option grants were each issued under the 2021 EIP, vest fully on the one (1) year anniversary of the respective grant date, and have terms of 10 years from issuance.

(13) Amount includes (i) 6,980 restricted stock units issued on June 11, 2023 and (ii) 5,820 restricted stock units issued on November 21, 2023.

(14) Amount includes (i) an option grant to purchase 9,580 shares issued on June 11, 2023 with an exercise price of $1.60 per share and (ii) an option grant to purchase 6,880 shares issued on November 21, 2023 with an exercise price of $0.59 per share. The option grants were each issued under the 2021 EIP, vest fully on the one (1) year anniversary of the respective grant date, and have terms of 10 years from issuance.

(15) Effective February 9, 2024, James R. Neal resigned as a member of our Board.

(16) Effective February 8, 2024, Stephanie C. Diaz, Dr. Cristina Csimma, and Dr. Robert Trenschel resigned as members of our Board.

(17) Effective March 4, 2024, Dr. Mary Ann Gray resigned as a member of our Board.

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

EQUITY COMPENSATION PLAN INFORMATION

The following table sets forth information with respect to our equity compensation plans which have outstanding securities as of December 31, 2023. For the description of these plans, please see below under "Equity Benefit Plans."

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options and Rights (a)	Weighted- Average Exercise Price for Outstanding Options and Rights (b) ($)	Number of Securities Remaining Available for Future Issuance under Equity compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Equity compensation plans approved by security holders			
2021 Equity Incentive Plan [(1)]	949,936 [(2)]	4.21	4,947 [(3)]
2013 Plan [(4)]	8,430	1,054.60	543
ESPP [(5)]	-	-	110,871
Equity compensation plans not approved by security holders			
Palisade 2021 Inducement Plan	132,230	4.90	863,214
Total	1,090,596	17.60	979,575

(1) On January 1 of each calendar year, the number of shares of common stock authorized under the 2021 EIP increases by an amount equal to (i) 7.5% of the total number of shares of common stock outstanding on December 31 of the preceding year, or (ii) a lesser number of shares of common stock determined by our Board prior to the date of the increase.

(2) Includes a total of 78,160 shares of common stock issuable upon exercise of outstanding stock options each with an exercise price of $0.59 and a total of 66,000 restricted stock units that were conditionally granted to our Chief Executive Officer and Chief Medical Officer on November 21, 2023 subject to sufficient shares available under the 2021 EIP, which became available on January 1, 2024.

(3) Excludes the availability of a total of 144,160 shares of common stock issuable upon exercise of outstanding stock options and outstanding restricted stock units that were conditionally granted to our Chief Executive Officer and Chief Medical Officer on November 21, 2023 subject to sufficient shares being available under the 2021 EIP, which became available on January 1, 2024.

(4) Although certain awards under the plan are outstanding, no additional grants will be made pursuant to the 2013 Plam.

(5) On January 1 of each calendar year, the number of shares of common stock authorized under the ESPP increases by (i) 2.5% of the total number of shares of our common stock outstanding on December 31 of the preceding year, (ii) 433,641 shares of common stock, or (3) such lesser number of shares of common stock as our Board may designate prior to the date of increase.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth information regarding beneficial ownership of our capital stock as of March 15, 2024 by:

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

The information in the following table is calculated based on 12,762,944 shares of our common stock outstanding as of March 15, 2024. Beneficial ownership is determined according to the rules of the SEC. Beneficial ownership means that a person has or shares voting or investment power of a security and includes any securities that person or group has the right to acquire within 60 days after the measurement date, including upon the exercise of common stock purchase options or warrants or the conversion of preferred stock.

Name of Beneficial Owner [1]	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
Greater than 5% Stockholders		
	—	— %
Directors and Named Executive Officers		
James R. Neal [2]	31,250	*
Thomas Hallam, Ph.D. [3]	831	*
Stephanie C. Diaz [4]	30,518	*
Donald Williams [5]	31,258	*
Mary Ann Gray, Ph.D. [6]	1,046	*
Cristina Csimma, Pharm.D., MHP [7]	30,270	*
Robert J. Trenschel, D.O. [8]	76,266	*
Binxian Wei [9]	1,006	*
J.D. Finley [10]	177,626	1.38 %
Michael Dawson, M.D. [11]	300	*
Herbert Slade, MD FAAAAI [12]	-	*
Robert McRae [13]	4,568	*
Mitchell Jones, M.D., Ph.D. [14]	29,820	*
All directors and executive officers as a group (13 persons) [15]	414,759	**3.20 %**

* Represents less than one percent

(1) Except as otherwise indicated in the footnotes to this table, this table is based upon information supplied by officers, directors and principal stockholders and Schedules 13D and 13G, and Form 4s, filed with the SEC. Unless otherwise indicated in the footnotes to this table and subject to community property laws where applicable, we believe that each of the stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned. Shares of our common stock underlying options, warrants and convertible securities that are currently exercisable or exercisable within 60 days of March 15, 2024 are deemed to be outstanding for the purpose of computing the number of shares held and the percent of total ownership of the person holding those options, warrants or convertible securities, but are not treated as outstanding for the purpose of computing the percent of total ownership of any other person. Applicable percentages are based on 12,762,944 shares of our common stock outstanding on March 15, 2024, adjusted as required by rules promulgated by the SEC. Unless otherwise indicated, the address of the beneficial owner is c/o Palisade Bio, Inc. 7750 El Camino Real, Suite 2A, Carlsbad, CA 92009.

(2) Includes (i) 10,920 shares of common stock held by Mr. Neal and (ii) 20,330 shares of common stock underlying stock options. On February 9, 2024, Mr. Neal resigned as a member of our Board.

(3) Includes (i) 31 shares of common stock and (ii) 800 shares of common stock underlying common stock purchase warrants. Dr. Hallam ceased to be an officer and director of the Company effective October 11, 2022.

(4) Includes (i) 12,800 shares of common stock held by Ms Diaz and (ii) 17,718 shares of common stock underlying stock options. On February 8, 2024, Ms. Diaz resigned as a member of our Board.

(5) Includes (i) 30,000 shares of common stock held by Mr. Williams and (ii) 1,258 shares of common stock underlying stock options.

(6) Includes (i) 80 shares of common stock and (ii) 966 shares of common stock underlying stock options. On March 4, 2024, Dr. Gray resigned as a member of our Board.

(7) Includes (i) 12,844 shares of common stock held by Dr. Csimma and (ii) 17,426 shares of common stock underlying stock options. On February 8, 2024, Dr. Csimma resigned as a member of our Board.

(8) Includes (i) 10,920 shares of common stock held by Dr. Trenschel, and (ii) 20,322 shares of common stock underlying stock options held by Dr. Trenschel and (ii) (a) 36,287 shares of common stock and (ii) 8,737 shares of common stock that may be acquired within 60 days pursuant to the exercise of outstanding warrants held by Yuma Regional Medical Center. The board of directors of Yuma Regional Medical Center, acting by a majority vote, has the authority to direct the vote and/or disposition of any and all shares of common stock and warrants held by Yuma Regional Medical Center. The address of Yuma Regional Medical Center is 2400 South Avenue A, Yuma, Arizona, 85364. Dr. Trenschel is the President, Chief Executive Officer and member of the board of directors of Yuma Regional Medical Center and shares voting and investment power over the shares held by Yuma Regional Medical Center. Dr. Trenschel also serves on our Board. On February 8, 2024, Dr. Trenschel resigned as a member of our Board.

(9) Includes (i) 40 shares of common stock held by Mr. Wei and (ii) 966 shares of common stock underlying stock options.

(10) Consists of (i)(a) 96,849 shares of common stock held by Mr. Finley, (b) 2,008 shares of common stock that may be acquired pursuant to the exercise of outstanding warrants held by Mr. Finley, (c) 6,641 shares of common stock underlying restricted stock units (RSUs) held by Mr. Finley, (d) 71,318 shares of common stock underlying options held by Mr. Finley, (ii)(a) 777 shares of common stock held by FCW Investments LLC, and (b) 33 shares of common stock underlying warrants held by FCW Investments, LLC. The address for FCW Investments LLC is 19 Cherrymoor Dr, Englewood, CO 80113. Does not include 32,500 PRSUs, which vest based on volume weighted average trading price of our common stock.

(11) Includes 300 shares of common stock. Dr. Dawson ceased to be an officer of the Company effective October 11, 2022.

(12) Dr. Slade was appointed to serve as our Chief Medical Officer on November 17, 2022 and ceased to be our Chief Medical Officer on September 5, 2023.

(13) Includes (i) 4,348 shares of common stock held by Mr. McRae and (ii) 220 shares of common stock that may be acquired pursuant to the exercise of outstanding warrants held by Mr. McRae. Mr. McRae was appointed to serve as our Chief Operating Officer (“COO”) on February 2, 2023. Effective May 15, 2023, Mr. McRae transitioned from the Company’s COO to an executive strategic consultant. For his services as a consultant, Mr. McRae received monthly compensation of $4,000. Mr. McRae’s service to us as a consultant terminated on January 15, 2024

(14) Dr. Jones was appointed to serve as our Chief Operating Officer on September 5, 2023. Includes (i) 7,664 shares of common stock held by Dr. Jones, (ii) 6,893 shares of common stock underlying restricted stock units held by Dr. Jones, and (iii) 15,263 shares of common stock underlying options held by Dr. Jones.

(15) Includes the securities described in footnotes (2)-(14) above.

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

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Related Party Transactions Procedures

In 2021, we adopted a written Related-Person Transactions Policy that sets forth our policies and procedures regarding the identification, review, consideration and approval or ratification of "related persons transactions." For purposes of our policy only, a "related person transaction" is a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we and any "related person" are participants involving an amount that exceeds $120,000. Transactions involving compensation for services provided us as an employee, director, consultant or similar capacity by a related person are not covered by this policy. A related person is any executive officer, director, or more than 5% stockholder of the Company, including any of their immediate family members, and any entity owned or controlled by such persons.

Under the policy, where a transaction has been identified as a related person transaction, management must present information regarding the proposed related person transaction to the Audit Committee (or, where Audit Committee approval would be inappropriate, to another independent body of the Board) for consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to the Company of the transaction and whether any alternative transactions were available. To identify related person transactions in advance, we rely on information supplied by its executive officers, directors and certain significant stockholders. In considering related person transactions, the Audit Committee takes into account the relevant available facts and circumstances including, but not limited to (a) the risks, costs and benefits to the Company, (b) the impact on a director's independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated, (c) the terms of the transaction, (d) the availability of other sources for comparable services or products and (e) the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

Other than compensation arrangements, including employment, termination of employment and change in control arrangements, with our directors and executive officers, and the other transactions discussed in the sections titled "Executive Compensation" and "Director Compensation", the following is a description of each transaction since January 1, 2021 and each currently proposed transaction in which:

(i) the amounts involved exceeded or will exceed the lesser of (a) $120,000 or (b) 1% of the average of our total assets for the fiscal years ended December 31, 2023, 2022 or 2021; and

(ii) any of our directors, executive officers or holders of more than 5% of our capital stock, or any member of the immediate family of, or person sharing the household with, the foregoing persons, had or will have a direct or indirect material interest.

- In April 2021, Dr. Kenneth Carter, Dr. Matthew Kalnik, and Mr. Dane Saglio, and Seneca's senior vice president of research and development agreed to the cancellation of their respective outstanding options to purchase common stock in Seneca immediately prior to the closing of our merger with Seneca in exchange for aggregate consideration of $1,423,012. Dr. Carter, Dr. Kalnik, and Mr. Saglio served as (i) Executive Chairman, (ii) President and Chief Operating Officer, and (iii) Chief Financial Officer of Seneca, respectively, until the closing of our merger with Seneca.

- In July 2021, Altium Growth Fund, LP ("Altium"), a then holder of more than five percent of our common stock, entered into a Waiver and Amendment Agreement with the Company (the "Waiver Agreement"). Pursuant to

the Waiver Agreement, Altium and the Company agreed to waive certain rights, waive the reset provisions with respect to the exercise price and number of shares subject to the outstanding warrants held by Altium, eliminate certain financing restrictions, and accelerate registration rights for the shares underlying the warrants. As consideration for the foregoing, pursuant to the Waiver Agreement, we issued Altium an additional warrant to purchase up to 22,000 shares of our common stock. The Waiver Agreement also provides that we will file a resale registration statement for the shares underlying Altium's warrants, including the additional warrant to purchase up to 22,000 shares of our common stock, before July 31, 2021.

Effective January 31, 2022 (the "2022 Effective Time"), Altium entered into a Waiver and Amendment Agreement with us (the "2022 Waiver Agreement"). Pursuant to the 2022 Waiver Agreement, we agreed with Altium to irrevocably waive any adjustment to the exercise price of the existing warrants held by Altium from and after 2022 Effective Time for our issuances of equity or equity-linked securities at a price below the exercise price of the warrants. The 2022 Waiver Agreement also includes agreement by the parties to, among other things, (i) restrict Altium's ability to sell our securities through a "leak out" provision whereby sales are restricted by applying a volume limitation, (ii) shorten the notice period for Altium's participation rights related to certain future securities offerings, (iii) restrict our ability to conduct a primary offering of its securities for a specified period of time, and (iv) provide registration rights for the shares underlying the January 2022 Warrant (defined below). As consideration for the foregoing, pursuant to the 2022 Waiver Agreement, we issued Altium an additional warrant to purchase up to 45,000 shares of our common stock (the "January 2022 Warrant"). The January 2022 Warrant is exercisable beginning six months following the 2022 Effective Time.

- In August 2021, we and Yuma Regional Medical Center ("Yuma") entered into a Securities Purchase Agreement pursuant to which Yuma purchased 30,197 shares of our common stock and a warrant to purchase up to 7,549 shares of our common stock for a total purchase price of $5.2 million. The warrant is exercisable for five years. Dr. Trenschel does not have any pecuniary interest in these securities and disclaims beneficial ownership of them.

  Pursuant to the purchase agreement, we agreed to file one or more registration statements with the SEC registering the resale of the shares and the shares of our common stock issuable upon exercise of the warrant by Yuma, to have all such registration statements declared effective within the timeframes set forth in the purchase agreement, and to keep such registration statements effective for up to five years.

- In October 2020, we issued and sold to Yuma (i) an unsecured promissory note in the principal amount of $0.5 million with an interest rate of 10% per annum (the "Yuma Notes") and (ii) warrants to purchase 45,000 shares of our common stock at an exercise price of $0.73 per share (the "Old Yuma Warrants"). The Old Yuma Warrants were immediately exercisable and expire ten years from the date of issuance. In May 2021, we entered into an agreement with Yuma to amend the Yuma Notes to extend the maturity date of the Yuma Notes to November 15, 2021 (the "Notes Amendment"). In connection with the Notes Amendment, the Old Yuma Warrants were cancelled and we issued new warrants to purchase 100 shares of our common stock at $300.00 per share to Yuma. Dr. Trenschel is formerly a member of our Board and is the president and chief executive officer of Yuma.

- We determined that the outstanding stock options under the 2013 Plan had an exercise price per share that was significantly higher than the current fair market value of the Company's common stock (the "Underwater Options"). On November 18, 2021, the Compensation Committee resolved that it was in the best interests of the Company and its stockholders to amend the Underwater Options for Dr. Hallam, Mr. Finley and Dr. Dawson, our former Chief Executive Officer, current Chief Executive Officer, and former Chief Medical Officer, respectively, to reduce the exercise price per share to $116.00, the closing per share price of the Company's common stock on November 18, 2021 (the "Repricing"). In accordance with the 2013 Plan requirements, the holders of the Underwater Options identified under the Repricing consented to the modification of their affected awards. All the other terms of the Underwater Options other than the exercise price remained the same, including the number of shares granted, vesting schedule and expiration date. We determined that the Repricing represented a modification of share-based awards under ASC 718. Accordingly, we recognized incremental compensation expense of $0.4 million for the year ended December 31, 2021. Of the incremental compensation expense recognized, $200,939, $147,197 and $37,574 was attributable to shares held by Dr. Hallam, Mr. Finley and Dr. Dawson, respectively.

- During the fiscal year ended December 31, 2021, the Company paid the following compensation to its non-executive directors that served as directors at any time during such year:

    - An aggregate of $492,102 in cash;
    - An aggregate of $36,960 in stock awards consisting of 24,000 restricted stock units awarded to directors by Seneca Biopharma, Inc., prior to the merger with LBS; and
    - An aggregate of $489,489 in value of stock option grants consisting of 966 options granted to 7 directors during 2021, each having an exercise price of $116 per share and a term of 10 years.

- Pursuant to a registered offering in May 2022, we sold an aggregate of 72,930 shares of our common stock, par value $0.01 per share, at a purchase price per share of $27.50 to certain of the selling stockholders. In a concurrent private placement, we also sold purchase warrants to such purchasers to purchase up to 72,930 shares of our common stock at an exercise price of $35.525 per share, the closing bid price of our common stock on May 5, 2022. Altium Growth Fund LP, a holder of greater than 5% of our common stock, purchased 18,000 shares.

  In a concurrent private placement, we also agreed to sell and issue to such purchasers warrants to purchase up to 72,930 shares of common stock at an exercise price of $35.525 per share, the closing bid price of our common stock on May 5, 2022. We issued Altium a warrant to purchase 18,000 shares of our common stock. The warrants are not exercisable until six months following the date of issuance and expire five and a half years from the date of issuance.

- On August 16, 2022, J.D. Finley, our Chief Executive Officer and Chief Financial Officer participated in the Company's underwritten offering. Pursuant to the offering, Mr. Finley invested $25,000 in exchange for 2,000 units at $12.50 per unit consisting of an aggregate of (i) 2,000 Common Shares, (ii) 2,000 Series 1 Common Stock purchase warrants and (iii) 2,000 Series 2 Common Stock purchase warrants. The Series 1 warrants had a term of one year from issuance and expired on August 16, 2023. The Series 2 warrants have a term of five years from issuance. Both Series 1 and Series 2 warrants initially had exercises prices of $12.50 but have been subsequently reduced as a result of adjustments to the exercise prices for future offerings contained in the warrants. As of December 31, 2023, the Series 2 warrants have an exercise price of $0.7313 per share.

- On August 16, 2022, Thomas Hallam, PhD, our former Chief Executive Officer and former member of our Board, participated in the Company's underwritten offering. Pursuant to the offering, Dr. Hallam invested $10,000 in exchange for 800 units at $12.50 per unit consisting of an aggregate of (i) 800 Common Shares, (ii) 800 Series 1 Common Stock purchase warrants and (iii) 800 Series 2 Common Stock purchase warrants. The Series 1 warrants had a term of one year from issuance and expired on August 16, 2023. The Series 2 warrants have a term of five years from issuance. Both Series 1 and Series 2 warrants initially had exercises prices of $12.50 but have been subsequently reduced as a result of adjustments to the exercise prices for future offerings contained in the warrants. As of December 31, 2023, the Series 2 warrants have an exercise price of $0.7313 per share.

- On October 11, 2022, we entered into a separation agreement with Thomas Hallam, Ph.D., its former chief executive officer and member of its Board whereby the Company and Dr. Hallam agreed to a mutual release of claims in exchange for (i) the payment of an aggregate of $530,000 payable in twelve equal monthly installments, (ii) up to twelve (12) months of continued COBRA coverage, (iii) twelve (12) months of immediate vesting of his outstanding equity grants subject to time based vesting, and (iv) up to six (6) months of virtual job replacement services valued at $3,100. Subsequent to entering into the separation agreement, certain facts and conduct by Dr. Hallam were discovered that excused the Company's performance under the settlement agreement. As a result, subsequent to paying Dr. Hallam an aggregate of $22,000, we determined that it is not probable that any additional compensation would be due to Dr. Hallam.

- On January 3, 2023, we granted J.D. Finley, our Chief Executive Officer and Chief Financial Officer, 5,236 restricted stock units valued at $20,000. The restricted stock units vest in 4 equal quarterly installments over the grant year. The restricted stock units were issued from the Company's 2021 EIP.

- On February 6, 2023, we granted J.D. Finley, our Chief Executive Officer and Chief Financial Officer: (i) an option to purchase 57,200 shares of our common stock valued at approximately $87,853, having an exercise price of $2.40 per share, a term of 10 years, and which vests quarterly over a three year period (ii) 41,700 restricted stock units valued at approximately $100,080 which vests in 12 equal installments quarterly over a three year period, and (iii) 32,500 restricted performance stock units valued at approximately $78,000, which vest (a) 50% when the volume weighted average price of our common stock over 20 consecutive trading days is $3.20, and (b) 50% when such volume weighted average price of our common stock over 20 consecutive trading days is $4.25. All of the grants issued to Mr. Finley were issued on a conditional basis, and are subject to the receipt of shareholder approval of the grants, which was received at our annual shareholder meeting held on June 8, 2023

- On February 6, 2023, we granted Robert McRae, our former Chief Operating Officer: (i) an option to purchase 12,000 shares of common stock valued at approximately $18,431, having an exercise price of $2.40 per share, a term of 10 years, and which vests quarterly over three years (ii) 8,800 restricted stock units valued at approximately $21,120 which vests in 12 equal installments quarterly over a three year period, and (iii) 17,900 restricted performance stock units valued at approximately $42,960, which vest (a) 50% when the volume weighted average price of our common stock over 20 consecutive trading days is $3.20, and (b) 50% when such volume weighted average price of our common stock over 20 consecutive trading days is $4.25. All of the grants issued to Mr. McRae were issued on a conditional basis, and are subject to the receipt of shareholder approval of the grants, which was received at our annual shareholder meeting held on June 8, 2023

- On February 22, 2023, the Compensation Committee amended the Company's non-employee director compensation policy. For a full discussion of this policy, see the section of this Proxy Statement entitled "Director Compensation".

- Pursuant to a registered offering in April 2023, we sold an aggregate of 756,317 shares of our common stock at a purchase price per share of $2.64 to certain institutional and accredited investors. In a concurrent private placement, we also sold (i) 455,242 unregistered shares of common stock, (ii) 1,061,164 prefunded warrants to purchase common stock with a perpetual term and exercise price of $0.0001 per share, and (iii) 2,272,723 common stock purchase warrants with a term of five (5) years and an exercise price of $2.64 per share. Armistice Capital LLC, a then holder of greater than 5% of our outstanding common stock pursuant to the ownership of outstanding common stock purchase warrants, purchased (i) 378,160 shares in the registered offering and (ii) in the concurrent private placement: (a) 76,140 unregistered shares of our common stock, (b) 682,063 prefunded warrants, and (c) 1,136,363 warrants to purchase common stock in exchange for an aggregate of $2,999,930.11.

- Effective May 15, 2023, Robert McRae, our then Chief Operating Officer ("COO") transitioned to an executive strategic consultant. Upon the transition, Mr. McRae ceased his duties and responsibilities as COO. For his services, Mr. McRae received ongoing monthly compensation of $4,000 per month until January 15, 2024, when he ceased providing services to the Company his outstanding equity awards ceased vesting

- Effective June 1, 2023, we increased J.D. Finley's base salary from $490,000 to $542,000 contemporaneous with his appointment from interim CEO to CEO. Additionally, Mr. Finley's target cash bonus was increased from 45% to 50% of his base salary. Additionally, on June 11, 2023, we granted Mr. Finley: (i) options to purchase 148,500 shares of our common stock with a term of ten (10) years and an exercise price of $1.60 per share, valued at $151,978 on the grant date and (ii) 66,700 restricted stock units valued at $106,720. Each of the options and restricted stock units granted to Mr. Finley vest in twelve (12) equal installments on a quarterly basis over three (3) years. The equity grants were issued from our 2021 EIP.

- On June 11, 2023, we granted to the non-employee members of the Board of Directors, as supplemental grants, an aggregate of: (i) options to purchase 77,380 shares of common stock with a term of ten (10) years and an exercise price of $1.60 per share and (ii) 36,240 restricted stock units. Each of the grants vests fully on the one (1) year anniversary of the grant date. The aggregate options were valued at $78,136 and the aggregate restricted stock units were valued at $57,984. The equity grants were issued from the 2021 EIP.

- On September 5, 2023, pursuant to his appointment as Chief Medical Officer, the Company issued Mitchell Jones, M.D., Ph.D. (i) options to purchase 75,000 shares of common stock with a term of ten (10) years and an

exercise price of $0.6897 per share and (ii) 54,700 restricted stock units. The options vest quarterly over three (3) years from the grant date and the restricted stock units vest as follows: (a) 4,556 shares on November 6, 2023, and (b) the remaining 51,144 shares vest over eleven (11) equal quarterly periods after the initial vesting date. The options were valued at $33,267 and the restricted stock units were valued at $37,727, respectively from the grant date. The equity grants were issued from our 2021 Inducement Plan.

- On November 21, 2023, we granted J.D. Finley, our CEO, on a conditional basis until such time as there are sufficient shares available under the 2021 EIP, which occurred upon the annual evergreen share increase on January 1, 2024.: (i) options to purchase 45,000 shares of common stock with a term of ten (10) years and an exercise price of $0.59 per share, valued at $22,114 on the grant date and (ii) 38,000 restricted stock units valued at $22,420. Each of the options and restricted stock units granted to Mr. Finley vest in twelve (12) equal installments on a quarterly basis over three (3) years.

- On November 21, 2023, we granted Mitchell Jones, M.D., Ph.D., our Chief Medical Officer, on a conditional basis until such time as there are sufficient shares available under the 2021 EIP, which occurred upon the annual evergreen share increase on January 1, 2024: (i) options to purchase 33,160 shares of common stock with a term of ten (10) years and an exercise price of $0.59 per share, valued at $16,296 on the grant date and (ii) 28,000 restricted stock units valued at $16,520. Each of the options and restricted stock units granted to Dr. Jones vest in twelve (12) equal installments on a quarterly basis over three (3) years.

- On November 21, 2023, we granted to each of the non-employee members of our, as supplemental grants: (i) options to purchase 6,880 shares of our common stock with a term of ten (10) years and an exercise price of $0.59 per share and (ii) 5,820 restricted stock units. Each of the grants vests fully on the one (1) year anniversary of the grant date. The aggregate of all options were valued at $23,494 and the aggregate of all restricted stock units were valued at $24,037. The equity grants were issued from the 2021 EIP.

- Between February 8 and February 9, 2024, James Neal, Stephanie Diaz, Dr. Cristina Csimma, and Dr. Robert Trenschel resigned as members of our Board. Pursuant to their resignation, we agreed to fully vest all of their outstanding equity awards issued on June 11, 2023 and November 21, 2023 and to extend the exercise period of their outstanding options until the expiration of each option. Accordingly, as a result of the vesting, we issued to the former directors, an aggregate of 47,440 of our common stock shares upon vesting of outstanding restricted stock units and extended the exercise period for an aggregate of (i) 43,480 options issued on June 11, 2023 having an exercise price of $1.60 per share and a term of 10 years and (ii) 27,520 options issued on November 21, 2023, having an exercise price of $0.59 per share and a term of 10 years.

Item 14. Principal Accounting Fees and Services.

Our independent registered public accounting firm is Baker Tilly US, LLP, Tewksbury, MA, PCAOB ID #23 (“Baker Tilly”). Baker Tilly was appointed as our independent registered public accounting firm on September 21, 2022. Prior to September 21, 2022, BDO USA, LLP (“BDO”) served as our independent registered public accounting firm.

Principal Accountant Fees and Services

Services Rendered to the Company by Baker Tilly

The following table represents aggregate fees billed to us for services performed beginning September 21, 2022 (the date of appointment) through December 31, 2023 by Baker Tilly.

	Year Ended December 31,	
	2023	2022
Audit Fees [1]	$ 422,000	$ 265,000
Audit-related Fees	—	—
Tax Fees	—	—
All Other Fees	—	—
Total Fees	$ 422,000	$ 265,000

(1) Audit fees consist of fees billed for professional services performed by Baker Tilly for the audit of our annual financial statements, reviews of our financial statements included in our quarterly reports on Form 10-Q (which only included our 10-Q for the quarter ended September 30, 2022) and annual report on Form 10-K, reviews of our current reports on Form 8-K, and related services that are normally provided in connection with regulatory filings or engagements. Baker Tilly was appointed to serve as our independent registered public accounting firm on September 21, 2022.

All fees described above were pre-approved by our Audit Committee.

Services Rendered to the Company by BDO

The following table represents aggregate fees billed to us for the year from January 1, 2022 through September 21, 2022 (the date of dismissal) by BDO, our prior independent registered public accounting firm.

	Year Ended December 31, 2022
Audit Fees [1]	$ 339,609
Audit-related Fees	—
Tax Fees	—
All Other Fees	—
Total Fees	$ 339,609

(1) Audit fees consist of fees billed for professional services performed by BDO for the audit of our annual financial statements, reviews of our financial statements included in our quarterly reports on Form 10-Q and annual report on Form 10-K, services in connection with securities offerings, reviews of our registration statements on Forms S-3 and S-4, reviews of our current reports on Form 8-K, and related services that are normally provided in connection with statutory and regulatory filings or engagements. BDO served as our independent registered public accounting firm through September 21, 2022 (the date of its dismissal).

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a)(1) Financial Statements.

The consolidated financial statements and supplementary data required by this item are set forth under Item 8 above.

(a)(2) Financial Statement Schedules.

All schedules have been omitted because they are not required or because the required information is given in the consolidated financial statements or notes thereto.

(a)(3) Exhibits.

The exhibits listed in the Exhibit Index below are filed or incorporated by reference as part of this Annual Report on Form 10-K.

Exhibit Index

Exhibit Number	Description of document
2.1†	Agreement and Plan of Merger, dated as of December 16, 2020, by and among Seneca Biopharma, Inc., Leading BioSciences, Inc. and Townsgate Acquisition Sub 1, Inc. (Incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on December 21, 2020).
3.1	Amended and Restated Certificate of Incorporation of the Registrant (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 27, 2021).
3.2	Certificate of Designation of Series A 4.5% Convertible Preferred Stock (Incorporated by reference to Exhibit 3.01 to the Registrant's Current Report on Form 8-K, filed with the SEC on December 12, 2016).
3.3	Amended and Restated Bylaws of the Registrant (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on March 6, 2024).
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on August 16, 2022).
3.5	Amendment to Amended and Restated Certificate of Incorporation of Palisade Bio, Inc., effective November 15, 2022 (Incorporated by reference to Exhibit 3.01(i) to the Registrant's Current Report on Form 8-K, filed with the SEC on November 16, 2022).
4.1	Reference is made to Exhibits 3.1, 3.2 and 3.3.
4.2	Description of Securities (incorporated by reference to Exhibit 4.2 to the Registrant's Form 10-K, filed with the SEC on March 17, 2022).
4.3	Specimen Common Stock Certificate. (Incorporated by reference to Exhibit 4.3 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 17, 2022).
4.4	Form of Series A Preferred Stock Certificate (Incorporated by reference to Exhibit 4.01 to the Registrant's Current Report on Form 8-K, filed with the SEC on September 12, 2016).
4.5	Form of Consulting Warrant issued January 2011 and March 2012 (Incorporated by reference to Exhibit 4.01 to the Registrant's Registration Statement on Form S-3 (File No. 333-188859) original filed with the SEC on May 24, 2013
4.6	Form of Common Stock Purchase Warrant from August 2017 Public Offering Dated August 1, 2017 (Incorporated by reference to Exhibit 4.01 to the Registrant's Current Report on Form 8-K, filed with the SEC on July 28, 2017).
4.7	Form of Common Stock Purchase Warrant from October 2018 Offering (Incorporated by reference to Exhibit 4.01 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on October 29, 2018)
4.8	Form of Placement Agent Common Stock Purchase Warrant from October 2018 Offering (Incorporated by reference to Exhibit 4.02 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on October 29, 2018)
4.9	Consultant Warrant for Hibiscus BioVentures, LLC issued January 2019 (Incorporated by reference to Exhibit 4.40 to the Registrant's Form 10-Q, originally filed with the SEC on May 14, 2019)
4.10	Form of Series M and Series N warrant from July 2019 Offering (Incorporated by reference to Exhibit 4.45 to the Registrant's Registration Statement on Form S-1/A (File No. 333-232273), filed with the SEC on July 24, 2019)
4.11	Letter Agreement from January 2020 Offering (Incorporated by reference to Exhibit 10.01 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on January 22, 2020)
4.12	Form of Series O Pre-Funded Warrant from July 2019 Offering (Incorporated by reference to Exhibit 4.45 to the Registrant's Registration Statement on Form S-1/A (File No. 333-232273), filed with the SEC on July 24, 2019)

4.13	Form of Series Q Replacement Warrant issued in January 2020 Offering (Incorporated by reference to Exhibit 4.02 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on January 22, 2020)
4.14	Form of Placement Agent Agreement from January 2020 Offering (Incorporated by reference to Exhibit 10.02 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on January 22, 2020)
4.15	Form of Placement Agent Warrant issued in January 2020 Offering (Incorporated by reference to Exhibit 4.03 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on January 22, 2020)
4.16	Form of Placement Agent Warrant issued in May 2020 Offering (Incorporated by reference to Exhibit 4.01 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on May 27, 2020)
4.17	Form of Securities Purchase Agreement with Investors from May 2020 Offering (Incorporated by reference to Exhibit 10.01 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on May 27, 2020)
4.18	Form of Warrant to Purchase Shares of Common Stock of Leading BioSciences, Inc. (Incorporated by reference to Exhibit 4.30 to the Registrant's Registration Statement on Form S-4 (File No. 333-251659), originally filed with the SEC on December 23, 2020, as amended).
4.19	Form of Bridge Warrant of Leading BioSciences, Inc. (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on December 21, 2020).
4.20	Form of Equity Warrant of Leading BioSciences, Inc. (Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on December 21, 2020).
4.21†	Registration Rights Agreement, by and between Seneca Biopharma, Inc. and the investor party thereto, dated December 16, 2020 (Incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K, filed with the SEC on December 21, 2020).
4.22	Waiver Agreement, dated as of July 21, 2021, by and between Palisade Bio, Inc. and Altium Growth Fund, LP (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on July 22, 2021).
4.23	Warrant, dated as of July 21, 2021, issued to Altium Growth Fund, LP (Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on July 22, 2021).
4.24	Waiver Agreement, dated as of January 31, 2022, by and between Palisade Bio, Inc. and Altium Growth Fund, LP (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on February 21, 2022).
4.25	Warrant, dated as of January 31, 2022, issued to Altium Growth Fund, LP (Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on February 21, 2022).
4.26	Securities Purchase Agreement, dated as of August 19, 2021, by and between Palisade Bio, Inc. and Yuma Regional Medical Center (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on August 24, 2021).
4.27	Warrant, dated as of August 19, 2021, issued to Yuma Regional Medical Center (Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on August 24, 2021).
4.28	Form of Common Stock Purchase Warrant (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on May 6, 2022).
4.29	Form of Placement Agent Warrant (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on May 6, 2022).
4.30	Form of Series 1 Common Stock Warrant (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on August 16, 2022).
4.31	Form of Series 2 Common Stock Warrant (Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on August 16, 2022).

4.32		Warrant Agency Agreement dated August 16, 2022, by and between Palisade Bio, Inc. and American Stock Transfer and Trust Company, LLC. (Incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K, filed with the SEC on August 16, 2022).
4.33		Form of Series B Preferred Stock Certificate of Registrant (Incorporated by reference to Exhibit 4.33 to the Registrant's Registration Statement on Form S-1/A, filed with the SEC on August 9, 2022)
4.34		Form of Underwriter Warrant issued August 16, 2022 (Incorporated by reference to Exhibit 4.33 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 14, 2022).
4.35		Form of Registered Prefunded Warrant issued in January 2023 Registered Offering (Incorporated by reference to Exhibit 4.01 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 4, 2023).
4.36		Form of Prefunded Warrant issued in January 2023 Private Placement (Incorporated by reference to Exhibit 4.02 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 4, 2023).
4.37		Form of Warrant issued in January 2023 Private Placement (Incorporated by reference to Exhibit 4.03 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 4, 2023).
4.38		Form of Placement Agent Warrant issued in January 2023 Private Placement (Incorporated by reference to Exhibit 4.04 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 4, 2023).
4.39		Form of Prefunded Warrant issued in April 2023 Private Placement (Incorporated by Reference to Exhibit 4.01 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 5, 2023).
4.40		Form of Warrant issued in April 2023 Private Placement (Incorporated by Reference to Exhibit 4.02 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 5, 2023).
4.41		Form of Placement Agent Warrant issued in April 2023 Private Placement (Incorporated by reference to Exhibit 4.03 to the Registrant's Current Report on Form 8-K filed with the SEC on April 5, 2023).
4.42		Form of Placement Agent Warrant issued in September 2023 Private Placement (Incorporated by reference to Exhibit 4.01 to the Registrant's Current Report on Form 8-K filed with the SEC on September 11, 2023).
4.43		Form of Replacement Warrant issued in February 2024 Warrant Inducement Transaction (Incorporated by reference to Exhibit 4.01 to the Registrant's Current Report on Form 8-K filed with the SEC on February 1, 2024).
4.44		Form of Placement Agent Warrant issued in February 2024 Warrant Inducement Transaction (Incorporated by reference to Exhibit 4.02 to the Registrant's Current Report on Form 8-K filed with the SEC on February 1, 2024).
10.1+		Seneca Biopharma 2019 Equity Incentive Plan (Incorporated by reference to Appendix A to the Registrant's Definitive Proxy Statement, originally filed with the SEC on April 29, 2019).
10.2+		Form of Restricted Option Grant from 2019 Equity Incentive Plan (Incorporated by reference to Exhibit 4.43 to the Registrant's Registration Statement on Form S-1 (File No. 333-232273), originally filed with the SEC on June 21, 2019, originally filed with the SEC on June 21, 2019).
10.3#		License Agreement, by and between Leading BioSciences, Inc. and The Regents of the University of California, dated August 19, 2015, as amended on December 20, 2019 (Incorporated by reference to Exhibit 10.18 to the Registrant's Registration Statement on Form S-4 (File No. 333-251659), originally filed with the SEC on December 23, 2020, as amended).
10.4#		License Agreement, by and between Leading BioSciences, Inc. and The Regents of the University of California, dated April 1, 2020 (Incorporated by reference to Exhibit 10.19 to the Registrant's Registration Statement on Form S-4 (File No. 333-251659), originally filed with the SEC on December 23, 2020, as amended).
10.5#		License Agreement, by and between Palisade Bio, Inc. and The Regents of the University of California, dated July 6, 2021 (incorporated by reference to Exhibit 10.5 to the Registrant's Form 10-K, filed with the SEC on March 17, 2022).
10.6#		Co-Development and Distribution Agreement, by and between Leading BioSciences, Inc. and Newsoara Biopharma Co., Ltd. (as successor-in-interest to Biolead Medical Technology Limited).

		dated February 17, 2018, as amended on November 27, 2018 (Incorporated by reference to Exhibit 10.20 to the Registrant's Registration Statement on Form S-4 (File No. 333-251659), originally filed with the SEC on December 23, 2020, as amended).
10.7		Form of Seneca Biopharma, Inc. Support Agreement, dated as of December 16, 2020, by and between Leading BioSciences, Inc. and each of the parties named in each agreement therein (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on December 21, 2020).
10.8		Form of Leading BioSciences, Inc. Support Agreement, dated as of December 16, 2020, by and between Seneca Biopharma, Inc. and each of the parties named in each agreement therein(Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on December 21, 2020).
10.9†		Securities Purchase Agreement, by and between Leading BioSciences, Inc. and the investor party thereto, dated December 16, 2020 (Incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K, filed with the SEC on December 21, 2020).
10.10†		Securities Purchase Agreement, by and among Seneca Biopharma, Inc., Leading BioSciences, Inc. and the investor party thereto, dated December 16, 2020 (Incorporated by reference to Exhibit 10.6 to the Registrant's Current Report on Form 8-K, filed with the SEC on December 21, 2020).
10.11		Amendment Agreement to Securities Purchase Agreement by and among, the Company, Leading BioSciences, Inc. and Altium Growth Fund, LP, dated May 3, 2021 (Incorporated by reference to Exhibit 10.03 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 14, 2021).
10.12		Form of Separation Agreement with Seneca Biopharma, Inc. Executives (Incorporated by reference to Exhibit 10.01 to the Registrant's Current Report on Form 8-K, filed with the SEC on March 18, 2021).
10.13†		Contingent Value Rights Agreement, dated as of April 27, 2021, by and among the Company, American Stock Transfer & Trust Company, LLC and Raul Silvestre (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 27, 2021).
10.14+		Form of Indemnification Agreement (incorporated by reference from Exhibit 10.03 to the Registrant's Current Report on Form 8-K filed with the SEC on December 18, 2018).
10.15+		Leading BioSciences, Inc. Amended and Restated 2013 Employee, Director and Consultant Equity Incentive Plan and Forms of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise of Stock Option thereunder (Incorporated by reference to Exhibit 10.24 to the Registrant's Registration Statement on Form S-4 (File No. 333-251659), originally filed with the SEC on December 23, 2020, as amended).
10.16+		Palisade Bio, Inc. 2021 Equity Incentive Plan, as amended (Incorporated by reference to Exhibit 10.01 to the Registrant's Current Report on Form 8-K, filed with the SEC on June 9, 2023).
10.17+		Form of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise under the Palisade Bio, Inc. 2021 Equity Incentive Plan (Incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K, filed with the SEC on November 23, 2021).
10.18+		Form of Non-Employee Director Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise under the Palisade Bio, Inc. 2021 Equity Incentive Plan (Incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K, filed with the SEC on November 23, 2021).
10.19+		Palisade Bio, Inc. Employee Stock Purchase Plan (Incorporated by reference to Exhibit 10.02 to the Registrant's Current Report on Form 8-K, filed with the SEC on June 9, 2023).
10.20+		Palisade Bio, Inc. 2021 Inducement Incentive Plan, as Amended August 7, 2023 (Incorporated by reference to Exhibit 10.20 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on August 10, 2023).
10.21+		Form of Restricted Stock Unit Grant Notice and Award Agreement under the Palisade Bio, Inc. 2021 Inducement Incentive Plan (Incorporated by reference to Exhibit 99.1 to the Registrant's Registration Statement on Form S-8 (File No. 333-261196), filed with the SEC on November 19, 2021).

10.22+		Form of Stock Option Grant Notice and Award Agreement under the Palisade Bio, Inc. 2021 Inducement Incentive Plan (Incorporated by reference to Exhibit 99.2 to the Registrant's Registration Statement on Form S-8 (File No. 333-261196), filed with the SEC on November 19, 2021).
10.23+		Non-Employee Director Compensation Policy (Incorporated by reference to Exhibit 10.35 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 22, 2023).
10.24+		Amended and Restated Executive Employment Agreement, by and between Leading BioSciences, Inc. and JD Finley, dated January 22, 2021(Incorporated by reference to Exhibit 10.23 to the Registrant's Registration Statement on Form S-4 (File No. 333-251659), originally filed with the SEC on December 23, 2020, as amended).
10.25+		Executive Employment Agreement, by and between Leading BioSciences, Inc. and Thomas Hallam, Ph.D., dated December 16, 2020 (Incorporated by reference to Exhibit 10.22 to the Registrant's Registration Statement on Form S-4 (File No. 333-251659), originally filed with the SEC on December 23, 2020, as amended).
10.26		Executive Employment Agreement, by and between Leading BioSciences, Inc. and Michael Dawson, M.D., dated December 16, 2020 (Incorporated by reference to Exhibit 10.21 to the Registrant's Registration Statement on Form S-4 (File No. 333-251659), originally filed with the SEC on December 23, 2020, as amended).
10.27†		Asset Transfer Agreement, by and between Alto Neuroscience, Inc. and Palisade Bio, Inc., dated October 18, 2021 (incorporated by reference to Exhibit 10.27 to the Registrant's Form 10-K, filed with the SEC on March 17, 2022).
10.28		Office Lease Between AP Beacon Carlsbad, LP, and Palisade Bio, Inc., dated May 12, 2022 (Incorporate by reference to Exhibit 10.1 to the Registrant's Form 10-Q filed with the SEC on May 13, 2022).
10.29		First Amendment dated July 14, 2022 to the Office Lease Between AP Beacon Carlsbad, LP, and Palisade Bio, Inc., dated May 12, 2022 (Incorporated by reference to Exhibit 10.2 to the Registrants Form 10-Q filed with the SEC on August 15, 2022).
10.30		Form of Securities Purchase Agreement, dated May 6, 2022, by and among the Company and the purchasers named therein (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on May 6, 2022).
10.31+		Separation Agreement and Release with former Chief Executive Officer (Incorporated by reference to Exhibit 10.01 to the Registrant's Current Report on Form 8-K filed with the SEC on October 14, 2022).
10.32		Form of Securities Purchase Agreement dated December 30, 2022, by and among the Company and the purchasers named therein (Incorporated by Reference to Exhibit 10.01 to the Registrant's Current report on Form 8-K, filed with the SEC on January 4, 2023).
10.33		Form of Registration Rights Agreement, dated December 30, 2022, by and among the Company and signatories named therein (Incorporated by reference to Exhibit 10.02 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 4, 2023).
10.34		Form of Placement Agency Agreement, dated December 30, 2022, by and between the Company and Ladenburg Thalmann & Co Inc. (Incorporated by reference to Exhibit 10.03 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 4, 2023).
10.35+		Form of First Amendment Consulting Agreement dated January 25, 2023 by and between Dr. Herbert Slade and the Company (Incorporated by reference to Exhibit 10.35 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 22, 2023).
10.36+		Form of Consulting Agreement dated April 7, 2023 by and between Dr. Herbert Slade and the Company. (Incorporated by reference to Exhibit 10.36 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 22, 2023).
10.37		Form of Securities Purchase Agreement dated April 3, 2023, by and among the Company and the purchasers named therein (Incorporated by Reference to Exhibit 10.01 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 5, 2023).

10.38		Form of Registration Rights Agreement dated April 3, 2023, by and among the Company and the signatories named therein (Incorporated by Reference to Exhibit 10.02 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 5, 2023).
10.39		Form of Placement Agency Agreement dated April 3, 2023, by and among the Company and Ladenburg Thalmann & Co Inc. (Incorporated by Reference to Exhibit 10.01 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 5, 2023).
10.40#		Form of Research, Collaboration, and License Agreement with Giiant Pharma (Incorporated by reference to Exhibit 10.01 to the Registrant's Current Report on Form 8-K, filed with the SEC on September 8, 2023.
10.41		Form of Securities Purchase Agreement dated September 7, 2023, by and among the Company and the signatories named therein (Incorporated by Reference to Exhibit 10.01 to the Registrant's Current report on Form 8-K, filed with the SEC on September 11, 2023).
10.42		Form of Placement Agency Agreement dated September 7, 2023, by and among the Company and Ladenburg Thalmann & Co Inc. (Incorporated by reference to Exhibit 10.02 to the Registrant's Current Report on Form 8-K, filed with the SEC on September 11, 2023).
10.43		Form of Employment Agreement with Mitchell Jones, dated September 5, 2023 (Incorporated by reference to Exhibit 10.01 to the Registrant's Current Report on Form 8-K, filed with the SEC on September 11, 2023).
10.44		Form of Warrant Inducement Agreement entered into pursuant to February 2024 Warrant Inducement Transaction (Incorporated by reference to Exhibit 10.01 to the Registrant's Current Report on Form 8-K, filed with the SEC on February 1, 2024).
16.1		Letter dated July 8, 2021 from Dixon Hughes Goodman LLP to the Securities and Exchange Commission (incorporated by reference to Exhibit 16.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on July 9, 2021).
16.2		Letter dated September 26, 2022 from BDO USA, LLP to the Securities and Exchange Commission (Incorporated by reference to Exhibit 16.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on September 26, 2022).
19.1		Registrant's Insider Trading Policy (Incorporated by reference to Exhibit 19.1 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 22, 2023).
21.1		Subsidiaries of Registrant (Incorporated by reference to Exhibit 21.1 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 22, 2023).
23.1*		Consent of Baker Tilly US, LLP, Independent Registered Public Accounting Firm
31.1*		Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Exchange Act.
31.2*		Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Exchange Act.
32.1**		Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rules 13a-14(b) or 15d-14(b) of the Exchange Act, and 18 U.S.C. Section 1350.
97.1*		Clawback Policy of the Registrant
101.INS*		Inline XBRL Instance Document-the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document.
101.SCH*		Inline XBRL Taxonomy Extension Schema with Embedded Linkbase Documents
104*		Cover Page Interactive Data File (embedded within the Inline XBRL and contained in Exhibit 101).

* Filed herewith
** Furnished herewith.
+ Indicates management contract or compensatory plan.
# Certain portions of this exhibit (indicated by "[***]") have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

† Schedules and exhibits to the Agreement have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the Securities and Exchange Commission upon request.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

PALISADE BIO, INC.

Date: March 26, 2024

By: /s/ J.D. Finley

J.D. Finley
Chief Executive Officer,
Chief Financial Officer and Director

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints J.D. Finley, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place, and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents, or his or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ J.D. Finley **J.D. Finley**	Chief Executive Officer, Chief Financial Officer and Director (Principal Executive and Financial Officer)	March 26, 2024
/s/ Mitchell Jones, M.D., Ph.D. **Mitchell Jones, M.D., Ph.D.**	Chief Medical Officer	March 26, 2024
/s/ Donald A. Williams **Donald A. Williams**	Chairman of the Board of Directors	March 26, 2024
/s/ Binxian Wei **Binxian Wei**	Director	March 26, 2024