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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2024

OR

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

Commission File Number 001-33672

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 officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of 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, 2024 as reported by the Nasdaq Capital Market on such date, was approximately $4.3 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 19, 2025, the registrant had 4,396,646 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, (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended, (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:

- *the results of our preclinical and clinical trials;*
- *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 to be realized;*
- *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 build a commercial infrastructure in the U.S. and other markets;*
- *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*
- *our ability to attract collaborators and partners.*

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 Product Candidates

- Our business depends on the successful clinical development, regulatory approval, and commercialization of our therapeutic compounds, including our lead asset PALI-2108.
- There are substantial risks in drug development, and, as a result, we may not be able to successfully develop any product candidate, including our lead product candidate, PALI-2108.
- We depend on our license agreement with Giiant Pharma Inc. ("Giiant") to permit us to use patents and patent applications relating to PALI-2108. Termination of these rights or the failure to comply with our obligations under the license agreement could materially harm our business and prevent us from developing or commercializing PALI-2108, our lead product candidate.
- Clinical drug development is expensive, time-consuming and uncertain.
- We are currently conducting a Phase 1 clinical trial of PALI-2108 in Canada, and the U.S. Food and Drug Administration ("FDA") or applicable foreign regulatory authorities may not accept data from such trials, or any other trial we conduct outside of the U.S.
- We may find it difficult to enroll patients in our clinical trials, which could delay or prevent us from proceeding with clinical trials of our product candidates.
- 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.
- Our product candidates, including our lead product candidate PALI-2108, may cause undesirable side effects or have other unexpected properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in post-approval regulatory action.
- There can be no assurance that our product candidates will obtain regulatory approval.
- If clinical studies of PALI-2108 do not yield successful results, we may discontinue the development of PALI-2108.
- It may take us longer than we estimate to complete clinical trials, and we may not be able to complete them at all.
- 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.
- 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.
- We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for a product candidate and we may need to limit our commercialization.

•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.

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 clinical 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.

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

•We may choose to discontinue the development or commercialization of any of our product candidates, or may choose not to 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.

•Changes in funding for the FDA and, other government agencies or comparable foreign regulatory authorities could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent these agencies or authorities from performing normal business functions on which the operations of our business may rely, which could negatively impact our business.

Risks Related to Our Dependence on Third Parties

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

•We depend on two qualified suppliers for the active pharmaceutical ingredient used in the clinical trials of PALI-2108. Insufficient availability of the API or other raw materials necessary to manufacture PALI-2108, or the inability of our suppliers to manufacture and supply our products on commercially reasonable terms, could adversely impact our business, results of operations and financial condition.

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

•We currently rely 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 operating losses, and we expect to continue to incur net operating 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.
- Our common stock could be delisted from the Nasdaq Stock Market if we are unable to maintain compliance with the Nasdaq Stock Market's continued listing standards.
- 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 ("Board" or "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 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 v*alue 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 preclinical studies also refers to nonclinical studies.

Item 1. Business.

Company Overview

We are a clinical-stage biopharmaceutical company focused on developing and advancing novel therapeutics for patients living with autoimmune, inflammatory, and fibrotic diseases. Our lead product candidate, PALI-2108, is being developed as a treatment for patients living with inflammatory bowel disease ("IBD"), including ulcerative colitis ("UC") and Fibrostenotic Crohn's disease ("FSCD").

Our 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.

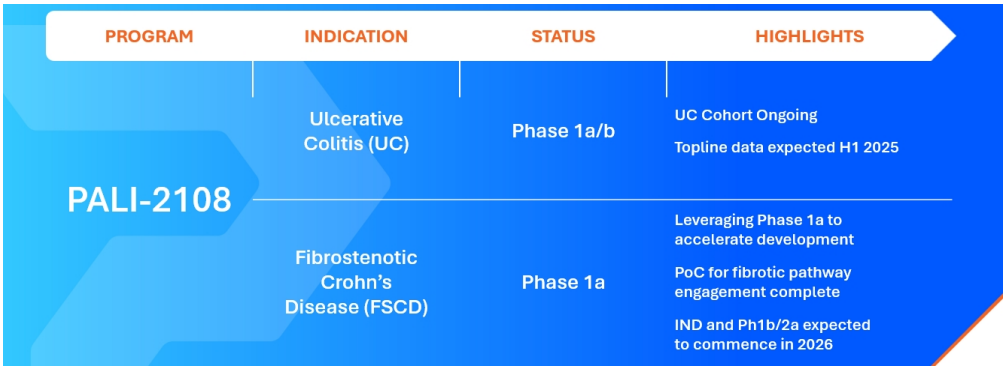
We believe the key elements of our strategy include:

- advancing our lead product candidate, PALI-2108 through human clinical trials;
- 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 Pipeline

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



Our Precision Medicine Approach

We are developing a biomarker-based patient selection approach that we believe may aid clinicians in identifying patients who may better respond to PALI-2108, thereby improving the rate of clinical response previously demonstrated with enzyme phosphodiesterase-4 ("PDE4") inhibitors. Our approach involves the use of clinical and multiomics data from large patient populations to identify PDE4-related biomarkers that are correlated with IBD, its severity, and which are modified with local PDE4-inhibitor therapy in the colon. Based on our research, we have initiated the development of corresponding biomarker assays for these PDE4-related biomarkers that we expect to use in our current and future clinical studies with the aim of developing regulatory approved tests for selecting potential responders to PALI-2108.

PALI-2108

Our lead product candidate, PALI-2108, is a prodrug inhibitor designed to help treat UC and FSCD by targeting the key PDE4 in colon tissues and preventing it from breaking down cyclic Adenosine Monophosphate ("cAMP") molecules which regulate inflammation in the body. By inhibiting PDE4, intracellular cAMP molecule levels become elevated, which may lead to a reduction of inflammatory molecules and an increase of anti-inflammatory molecules within tissues of the colon. Additionally, we believe that PALI-2108 may help prevent the movement of inflammatory cells from the blood into colon tissues, thereby lowering the activity of certain proteins that contribute to fibrosis (a type of tissue scarring).

With a glucuronic-derived sugar moiety, PALI-2108 remains minimally absorbed until activated by the colonic bacterium enzyme β-glucuronidase. We believe that localized bioactivation may help focus the effects of PALI-2108 where it would be most beneficial to a patient suffering from IBD.

PALI-2108 for UC

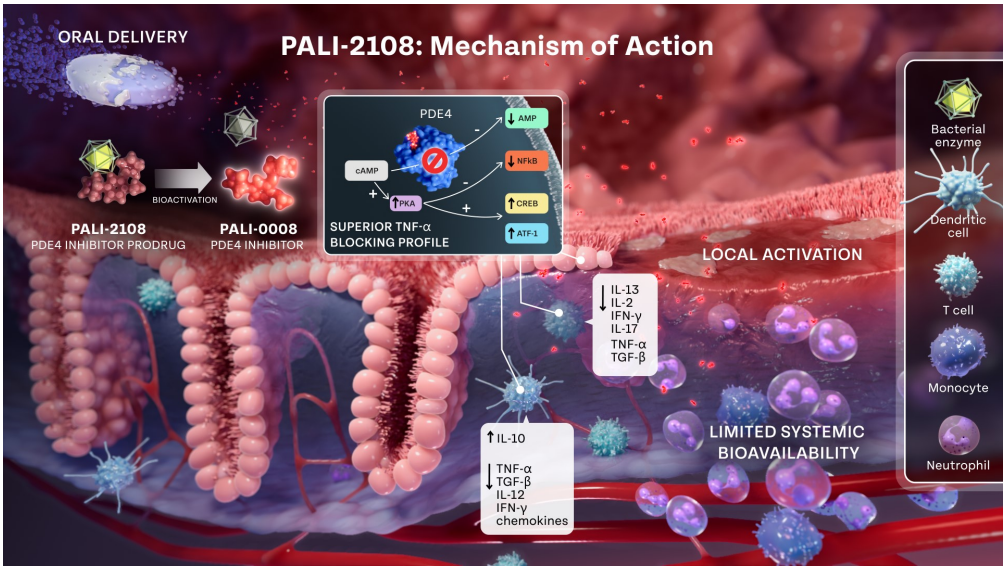
In UC mouse models, we have demonstrated the dose-dependent efficacy of PALI-2108. Specifically, we utilized Dextran Sodium Sulfate ("DSS")-induced UC mouse models and target engagement in oxazolone-induced colitis. Thus, based on the research conducted on these mouse models, we demonstrated that PALI-2108 has preferential colon activation. This preferential colon activation offers a unique approach to delivering the PDE4 inhibitor locally within the colon. The local bioactivation of PALI-2108 prodrug is designed to prevent the systemic toxicity inherent with immunosuppression and avoid the known tolerability issues of PDE4 inhibitors.

PALI-2108 for FSCD

Studies have shown that patients with intestinal fibrosis exhibit elevated PDE4 B and D enzyme levels in intestinal tissues. Also, preclinical research using a chronic DSS-induced mouse model of intestinal fibrosis shows similarly decreased PDE4 enzyme levels and demonstrated that systemic administration of PDE4 inhibitors improve clinical symptoms and reduce known biomarkers of fibrosis associated with FSCD. In these studies, systemically delivered PDE4 inhibitors significantly improved clinical outcomes, including body weight, disease activity, colon length, and key biomarkers of intestinal fibrosis, such as α-SMA and MMPs, with these markers returning to baseline levels upon treatment. Additionally, PDE4 inhibition was found to prevent the breakdown of cAMP, which in turn inhibits fibroblast functions, including tissue remodeling. Further research indicates that TGF-beta, a key driver of fibrosis, modulates cAMP levels, and PDE4 inhibition exerts particularly strong anti-fibrotic effects when TGF-beta-induced fibroblast stimulation is present.

We conducted a study evaluating the anti-inflammatory and anti-fibrotic effects of PALI-2108, a locally bioactivated PDE4 inhibitor, in an acute DSS-induced mouse model. Treatment with PALI-2108 resulted in dose-dependent improvements in clinical outcomes, including disease activity and colon length. Additionally, PDE4B expression in colon tissues was reduced in a dose-dependent manner, intracellular cAMP levels increased, and TNF-alpha levels in colon tissues were normalized in most of the mice treated.

Bioinformatics analysis of colon biopsy gene expression data (RNA-seq) further supports the effects of PALI-2108. The analysis reveals a dose-dependent modulation of 187 genes associated with four major fibrotic pathways in IBD. Furthermore, the treatment shows a dose-dependent improvement in fibrosis enrichment scores for FSCD markers. These findings suggest that PALI-2108 is a promising dual-acting drug candidate, with both anti-inflammatory and anti-fibrotic properties, for the treatment of FSCD.



Phase 1 Clinical Study of PALI-2108

The Phase 1 clinical study of PALI-2108 is a single-center, randomized, double-blinded, placebo-controlled clinical study focused on safety, tolerability, and pharmacokinetics ("PK") in both healthy volunteers and UC patients. The clinical study includes an open-label UC patient cohort with multiple dosing arms in which we will evaluate the pharmacodynamics of PALI-2108 in healthy volunteers. We plan to complete enrollment of approximately 90 subjects across several arms of this Phase 1 clinical study including, (i) at five subject cohorts receiving a Single Ascending Dose ("SAD") with a crossover to evaluate food effects ("FE"), (ii) three or more subject cohorts receiving a Multiple

Ascending Dose (“MAD”), and (iii) at least one multiple dose in a UC patient cohort. The primary objective of the study is to assess the safety and tolerability of single (healthy subjects) and repeated (healthy subjects and UC patients) oral doses of PALI-2108. Secondary objectives include determining plasma, urine, colon tissue, and fecal (MAD healthy subjects and UC patients only) PK, as well as the FE of PALI-2108 and its metabolites following a single oral dose in healthy subjects and repeated oral doses in both healthy subjects and UC patients. We anticipate announcing topline data from this study during the second quarter of 2025. If the trial meets its primary objectives, we plan to initiate a Phase 1b/2a clinical studies in UC patients and FSCD patients in the first quarter of 2026.

Phase I Clinical Study of PALI-2108 in Canada

On October 9, 2024, Health Canada issued a No Objection Letter for our Phase 1 human clinical study of PALI-2108 for the treatment of UC. We officially began studying on November 7, 2024. As of the date of this report, we have dosed five subject cohorts in a SAD study, two subject cohorts in a crossover study to evaluate FE, and four subject cohorts in a MAD study. Each of the SAD and MAD cohorts consisted of eight subjects, with six subjects receiving the drug and two subjects receiving a placebo. The FE study included two cohorts each of six subjects, of which one cohort was in a fasted state and the other cohort in a fed state. Finally, we have initiated the dosing of a cohort of UC patients, of which one patient has completed the study to date.

Planned Clinical Trial of PALI-2108 in the U.S.

In addition to conducting clinical studies in Canada, we anticipate submitting an Investigational New Drug Application (“IND”) with the FDA during 2025. If our IND is approved, we anticipate commencing clinical trials of PALI-2108 in the U.S. during the first quarter of 2026.

Market

We believe that if developed and approved for marketing, PALI-2108 could be an effective treatment for IBD. Our initial indications for PALI-2108 are:

Ulcerative Colitis

UC is a chronic IBD that primarily affects the colon and rectum, leading to long-lasting inflammation and ulcers in the digestive tract. Common symptoms include abdominal pain, diarrhea, and rectal bleeding. The prevalence of UC is estimated to range from 156 to 291 cases per 100,000 people globally. In the eight major markets (“8MM”), diagnosed incident cases of UC are projected to increase from 160,122 cases in 2021 to 168,467 cases by 2031, reflecting an annual growth rate (“AGR”) of 0.52%. The U.S. is expected to have the highest number of diagnosed incident cases in 2031, totaling 104,795, while France will have the fewest at 2,972 cases. Additionally, diagnosed prevalent cases are anticipated to rise from 1,946,428 in 2021 to 2,069,770 in 2031, with an AGR of 0.63%. The U.S. is again projected to lead in prevalence in 2031 with 655,317 cases, whereas Canada is projected to report the lowest with 91,186 cases. This growth in diagnosed cases is largely attributed to changes in population dynamics across these markets. The market for 8MM for UC treatments was valued at approximately $7.3 billion in 2021 and is expected to grow to over $9.5 billion in 2031 at a compound annual growth rate ("CAGR") of approximately 2.78%. Market expansion is driven by the increasing prevalence of the disease, advancements in diagnostic techniques, and the development of more effective and targeted therapies.

Fibrostenotic Crohn’s Disease

Crohn’s disease ("CD") is an IBD that can affect any part of the gastrointestinal tract, from the mouth to the anus. It is characterized by inflammation that can penetrate deep into the layers of the affected bowel tissue, leading to a range of symptoms including abdominal pain, severe diarrhea, fatigue, weight loss, and malnutrition. In the 8MM, diagnosed incident cases of CD are expected to increase from 118,885 cases in 2022 to 122,175 cases by 2032, reflecting an AGR of 0.28%. The U.S. is projected to have the highest number of diagnosed incident cases of CD in 2032, with 68,815 cases, while France is projected to report the fewest at 4,560 cases. Additionally, diagnosed prevalent cases of CD are anticipated to rise from 1,626,752 in 2022 to 1,695,580 in 2032, with an AGR of 0.42%. The U.S. is again projected to lead in prevalence in 2032, with 755,802 cases, whereas Japan is projected to have the fewest diagnosed prevalent cases of CD at 44,732. These increases in diagnosed cases are attributed to changes in population dynamics across these markets. The global market for CD treatments was valued at $13.9 billion in 2022 and is projected to grow to approximately $25.5 billion in 2032 at a CAGR of approximately 6%. This market growth is fueled by the rising prevalence of the disease, improved diagnostic techniques, and ongoing advancements in research and development activities for new drug therapies.

FSCD, a severe form of CD, is characterized by the formation of fibrotic tissue, or strictures, in the bowel, which can result in obstruction and significant complications. Approximately half of CD patients will develop stricture formation within the first 10 years of diagnosis. Currently, treatment options for FSCD are limited, with no approved therapies specifically addressing this indication. Existing treatment approaches are primarily invasive, including balloon dilation, strictureplasty, and, in more severe cases, bowel resection. These procedures, while necessary, pose significant risks and can greatly impact the quality of life.

Given the lack of effective treatment options, we believe PALI-2108 has the potential to provide a much needed first-in-class therapy for these patients. PDE4 inhibitors are a clinically and commercially proven dual-acting anti-inflammatory and anti-fibrotic candidate, offering a unique approach to addressing both the inflammatory and fibrotic components of CD. With its innovative mechanism of action, PALI-2108 has the potential to transform the lives of individuals suffering from FSCD by providing a less invasive and more effective treatment alternative.

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

Strategic Agreements and Collaborations

Giiant License Agreement

On September 1, 2023, we entered into a research collaboration and license agreement (the "Giiant License Agreement") with Giiant. 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, preclinical development of PALI-2108 was jointly undertaken by us and representatives of Giiant. Pursuant to the Giiant License Agreement, we paid, or reimbursed or advanced to Giiant, a portion of the joint development costs. Additionally, per the terms of the Giiant License Agreement, we will pay (i) certain milestone payments (in cash or our common stock at our sole election) (the "Giiant Milestone Payments") and (ii) royalty payments upon sales or sublicenses to third parties, with such Giiant Milestone Payments and royalty payments (the "Giiant License Payments") subject to a payment cap.

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.

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 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 related to LB1148. 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, 2024, 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 U.S. 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 our clinical supply of our API used in PALI-2108 and to supply the Newsoara Licensed Products to Newsoara.

As we progress through the research and clinical trials 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 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 current Good Manufacturing Practice ("cGMP") regulations 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 the necessary 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.

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 to supply us with the Newsoara Licensed Product as required under the Newsoara Co-Development Agreement. The agreement with ThermoFisher Scientific is a non-specific master services agreement that allows us to alter the scope of services as needed.

Competition

As a clinical biopharmaceutical 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, preclinical 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; and in acquiring technologies complementary to, or necessary for, our programs. Smaller or earlier-stage companies may also prove to be significant competitors, particularly if they establish collaborative arrangements with larger 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, most have demonstrated dose-limiting toxicity. Also, precision medicine has been successfully applied in oncology and its adoption in IBD remains an unmet need. Our competitors include established biopharmaceutical companies, emerging biopharmaceutical 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, we are not aware of other PDE4 inhibitors in development for UC or FSCD. Emerging biotech companies have similar agility and focus to us allowing them to explore novel approaches. We compete with these emerging companies 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. We believe that by using a precision medicine approach, we can differentiate our PDE4 inhibitor from generic alternatives, although we are not currently aware of any 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 they 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.

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 U.S., 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.

We have also completed a provisional patent application No. 63/733,390 (Personalized Methods of Administering PDE4 inhibitors) relating to personalized PALI-2108 treatment.

Our success will depend in part on our ability to obtain and maintain patent and other intellectual property protection in the U.S. 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 U.S. 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 U.S., 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.

U.S. Government Regulation and Product Approval

In the U.S., 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 U.S. 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 U.S. generally involves the following:

- Completion of preclinical 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 an NDA for marketing approval that includes substantial evidence of safety and efficacy from results of preclinical 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 cGMP regulations 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 preclinical and clinical trial sites that generated the data supporting 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 preclinical testing. Preclinical tests 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 preclinical tests must comply with federal regulations and requirements including GLPs regulations.

Concurrent with clinical trials, companies usually must complete some long-term preclinical 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 regulations. 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 preclinical 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 preclinical 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 in the U.S. 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 additional 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 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 Regulations

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 regulations 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 regulations and adequate to assure consistent production of the product within required specification.

Concurrent with clinical trials, companies usually complete additional preclinical 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 regulations. 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 regulations and other regulatory rules that are implemented nationally.

U.S. FDA Review and Approval Process

Assuming successful completion of the required clinical and preclinical testing, the results of the preclinical 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 regulations 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 regulations 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.

U.S. 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 preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to both the product and the specific indication for which it is being studied. The sponsor 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.

U.S. 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 regulations. Manufacturers are required to comply with applicable 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 U.S. and between states.

Other post-approval requirements applicable to pharmaceutical products include reporting of deviations from cGMP regulations 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 cGMP regulations 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 cGMP regulations. 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 U.S. 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 API, 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 preclinical 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 preclinical 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 U.S., or more than 200,000 individuals in the U.S. but for which there is no reasonable expectation that the cost of developing and making the product available in the U.S. 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 U.S. 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 need not 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 U.S. 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 U.S. 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 U.S. and include specific requirements for the transfer of personal data outside the EU to the U.S. 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 U.S. 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 U.S. 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 U.S., 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 U.S. 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 U.S. 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 U.S. 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 U.S., 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 U.S., 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 U.S. 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 U.S., 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 U.S. 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 U.S. 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 U.S., 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.

Canadian Government Regulation and Product Approval

In Canada, our product candidates and our research and development activities are primarily regulated by the Food and Drugs Act and the rules and regulations thereunder, which are enforced by Health Canada (including its Biologic and Radio-pharmaceutical Drugs Directorate). Health Canada's regulatory process for review, approval and regulatory oversight of products is similar to the regulatory process conducted by the FDA. To initiate clinical testing of a drug candidate in human subjects in Canada, a Clinical Trial Application ("CTA") must be filed with and approved by Health Canada. In addition, all federally regulated trials must be approved and monitored by research ethics boards. The review boards study and approve study-related documents and monitor trial data.

Prior to being given market authorization for a drug product, a manufacturer must present substantive scientific evidence of a product's safety, efficacy and quality as required by the Food and Drugs Act (Canada) and its associated regulations, including the Food and Drug Regulations. This information is usually submitted in the form of a New Drug Submission ("NDS"). Health Canada reviews the submitted information, sometimes using external consultants and advisory committees, to evaluate the potential benefits and risks of a drug. If after the review, the conclusion is that the patient benefits outweigh the risks associated with the drug, the drug is issued a Drug Identification Number ("DIN"), followed by a Notice of Compliance ("NOC"), which permits the market authorization holder (i.e., the NOC and DIN holder) to market the drug in Canada. Drugs granted an NOC may be subject to additional post-market surveillance and reporting requirements.

The principal steps required for drug approval in Canada are as follows:

Preclinical Toxicology Studies

Non-clinical studies are conducted in vitro and in animals to evaluate pharmacokinetics, metabolism and possible toxic effects to provide evidence of the safety of the drug candidate prior to its administration to humans in clinical studies and throughout development. Such studies are conducted in accordance with applicable laws and GLP.

Initiation of Human Testing

In Canada, the process of conducting human clinical with a new drug cannot begin until a CTA has been submitted, and the required number of days has lapsed without objection from Health Canada. Similar regulations apply in Canada to a CTA as to an IND in the United States. If the CTA is deemed by Health Canada to be acceptable, a No

Objection Letter is issued. A Not Satisfactory Notice will be issued by Health Canada if significant deficiencies are identified or if timely responses to information requested have not been received.

Clinical Trials

Similar regulations apply in Canada regarding clinical trials as in the U.S. In Canada, Research Ethics Boards, or REBs, instead of IRBs, are used to review and approve clinical trial plans. Clinical trials involve the administration of an investigational new drug to human subjects under the supervision of qualified investigators, in most cases a physician, in accordance with current Good Clinical Practices, or cGCP, requirements, which include review and approval by REBs. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the trial procedures, the parameters to be used in monitoring safety and the efficacy criteria to be evaluated and a statistical analysis plan. Similar to in the U.S., human clinical trials for new drugs are typically conducted in three sequential phases, Phase 1, Phase 2 and Phase 3.

The manufacture of investigational drugs for the conduct of human clinical trials is subject to cGMP requirements. Investigational drugs and active pharmaceutical ingredients imported into Canada are also subject to regulation by Health Canada relating to their labeling and distribution. Progress reports detailing the results of the clinical trials must be submitted at least annually to Health Canada and the applicable REBs, and more frequently if serious adverse events occur. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, in Canada, Health Canada or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an REB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the REB's requirements or if the drug has been associated with unexpected serious harm to subjects. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group regularly reviews accumulated data and advises the study sponsor regarding the continuing safety of trial subjects, potential trial subjects and the continuing validity and scientific merit of the clinical trial. A sponsor may also suspend or terminate a clinical trial based on evolving business objectives or competitive climate.

New Drug Submission

Upon successful completion of Phase 3 clinical trials in Canada, the company sponsoring a new drug then assembles all the preclinical and clinical data and other testing relating to the product's pharmacology, chemistry, manufacture, and controls, and submits it to Health Canada as part of a New Drug Submission, or NDS. The NDS is then reviewed by Health Canada for approval to market the drug.

As part of the approval process, Health Canada will inspect the facility or the facilities at which the drug is manufactured. Health Canada will not approve the product unless compliance with cGMP is satisfactory and the NDS contains data that provide substantial evidence that the drug is safe and effective in the indication studied. In addition, before approving an NDS, Health Canada will typically inspect one or more clinical sites to assure compliance with GCP.

Even if Health Canada approves a product candidate, it may limit the approved indications for use of the product candidate, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms.

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, 2024, Suzhou has no employees or other operations. We are currently in the process of dissolving the Suzhou subsidiary. Our other subsidiary is LBS, 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.

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 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 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 us under the ATA, including the upfront payment and all potential milestones and transaction-related payments, will not exceed $5.0 million.

On October 22, 2024, Alto announced that its Phase 2b study of ALTO-100 in patients with major depressive disorder (MDD) did not meet its primary endpoint. Notwithstanding, ALTO-100 is being evaluated as an adjunctive treatment in a Phase 2b study in bipolar depression with topline data expected in 2026. Upon the enrollment of a patient in a Phase 3 clinical trial of ALTO-100, if it occurs, a milestone payment of $1.5 million will be due from Alto to us 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, 2024, we had eight full-time employees and no part-time employees. Of the full-time employees, three 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 consultants to assist with finance, operations, human resources, legal, investor relations and information technology functions, as well as, to the extent needed, our clinical operations. We have no collective bargaining agreements with our employees, and we have not experienced any work stoppages.

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 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 on Form 10-K, 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 on Form 10-K should be considered carefully when evaluating us, our business and the value of our securities.

Risks Related to Our Development, Commercialization and Regulatory Approval of Our Product Candidates

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

On October 9, 2024, Health Canada approved our Canadian Clinical Trial Application ("CTA") to commence a Phase 1 clinical trial for PALI-2108 in Canada. On November 7, 2024, we commenced the Phase 1 clinical trial of PALI-2108. Our success depends on the development and clinical success of PALI-2108, which is subject to a number of risks, including:

- the continued enforceability of our research collaboration and license agreement with Giiant;
- timely and successful completion of required clinical trials, which may be significantly slower or costlier than we anticipate and/or produces results that do not achieve the primary or secondary endpoints of the trial(s);
- our ability to develop and implement clinical trial designs and protocols;
- the successful initiation and completion of our current planned clinical trials and any additionally required preclinical studies, if any;
- our ability to retain third-party CROs on terms acceptable to us for the conduct and oversight of our anticipated clinical trials, including our Phase 1 clinical trial for PALI-2108;
- our ability to fund the development costs related to PALI-2108's clinical development;
- the approval by Health Canada or other regulatory authorities 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 clinical trial supplies and any additional required preclinical studies;
- 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 regulations;
- 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 candidates. For example, we are currently enrolling and dosing subjects in our initial Phase 1 clinical trial of PALI-2108 in Canada. We may experience delays or difficulties in finding suitable trial subjects, or in completing enrollment. Such delays may result in increased costs and the failure to complete the Phase 1 clinical trial of PALI-2108 in Canada in a timely manner. Even if successfully completed, we must complete a number of additional clinical trials prior to obtaining regulatory approval to 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 in drug development, and, as a result, we may not be able to successfully develop any product candidate. including our lead product candidate, PALI-2108.

We have initiated a Phase 1 clinical trial of PALI-2108 in our target indication of IBD. Drug development requires a significant amount of capital and can take a long time to reach commercial viability, if it can be achieved at all. During the 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, including our lead product candidate, PALI-2108, 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 our obligations under the license agreement could materially harm our business and prevent us from developing or commercializing PALI-2108, our lead product candidate.

We are a party to the Giiant License Agreement 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 patents, and patent applications that cover PALI-2108. Our rights to PALI-2108 are subject to the continuation of, and our compliance with, the terms of the Giiant License Agreement. If we fail to comply with any of our obligations under the Giiant License Agreement, Giiant may have the right to terminate the Giiant License agreement, in which event we would not be able to continue the development or our proposed commercialization of PALI-2108. Additionally, disputes may arise under the Giiant License Agreement regarding the intellectual property that is subject to such 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, including the Giiant License Agreement, on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates and technologies.

Clinical drug development is expensive, time-consuming and uncertain.

The 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 generate sufficient revenue to cover their costs of development. In addition, we, any partner with which we may collaborate, Health Canada, any similar regulatory authority, state and local agencies, counterpart agencies in foreign countries, or the applicable Institutional Review Board ("IRB") at our trial sites, may suspend, delay, require modifications to or terminate our clinical trials, once begun, at any time.

We are currently conducting a Phase 1 clinical trial of PALI-2108 in Canada, and the FDA or applicable foreign regulatory authorities may not accept data from such trials, or any other trial we conduct outside of the U.S.

We have commenced a Phase 1 clinical trial for ulcerative colitis in Canada. However, we have not received approval from the FDA to commence any clinical trials in the U.S., and there is no guarantee that we will be able to obtain such approval in a timely manner, if at all. If our Phase 1 clinical trial is successful and we seek to initiate a Phase 2 clinical trial in the U.S, there is no certainty that the FDA will accept the data generated from our Canadian trial. The FDA's acceptance of foreign clinical data is subject to certain conditions, including whether the trial was conducted in accordance with good clinical practices ("GCP") and whether the FDA can validate the trial data through on-site inspections or other means. Moreover, the FDA will assess whether the trial design, patient population, endpoints, and other factors meet the standards expected for clinical trials conducted within the U.S.

In addition, regulatory approval for clinical trials and eventual drug approval in the U.S. is a complex process, influenced by several factors, including:

- the adequacy and relevance of the Phase 1 trial data in supporting progression to Phase 2, as evaluated by the FDA;
- the ability of the trial to meet safety, efficacy, and other scientific requirements set by the FDA, which may differ from those of Health Canada;
- whether the foreign clinical trial was conducted under an FDA-recognized regulatory authority, and whether FDA oversight is possible through monitoring or inspection of clinical sites; and
- the FDA's consideration of the risk-benefit ratio for continuing clinical development in the U.S., particularly based on data from a non-U.S. population.

Furthermore, while the FDA does have the ability to approve drugs that have undergone clinical trials in foreign jurisdictions, including Canada, approval is generally contingent on demonstrating that the trial data align with FDA standards and regulatory expectations. It is also possible that we may be required to conduct additional trials in the U.S. to address any concerns regarding the applicability of the foreign trial data to the U.S. population or regulatory environment. There can be no assurance that we will successfully obtain FDA approval to initiate a Phase 1 clinical trial in the U.S. or that if our Canadian trial is successful, a subsequent Phase 2 trial.

We may find it difficult to enroll patients in our clinical trials, which could delay or prevent us from proceeding with clinical trials of our product candidates.

We are currently enrolling subjects in the Phase 1 clinical trial of PALI-2108 in Canada. Identifying and qualifying subjects to participate in our current and anticipated future clinical trials is critical to our success. Our inability to enroll patients in our clinical trials on a timely basis could result in the trials being delayed or never completed.

Patient enrollment and trial completion are affected by numerous additional factors, including the:

- process for identifying patients;
- design of the trial protocol;
- eligibility and exclusion criteria;
- perceived risks and benefits of the product candidate under study;
- availability of competing therapies and clinical trials;
- severity of the disease under investigation;
- proximity and availability of clinical trial sites for prospective patients;
- ability to obtain and maintain patients' consents;
- risk that enrolled patients will drop out before completion of the clinical trial;
- patient referral practices of physicians; and,
- ability to monitor patients adequately during and after treatment.

If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business, financial condition, results of operations and prospects. There can be no assurances that we will be able to complete enrollment for our anticipated Phase 1 clinical trial for PALI-2108, and if we fail to do so, we may not be able to complete the trial on a timely basis, or at all.

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 business plan, we do not have adequate capital to fund our anticipated operations through the completion of the development of PALI-2108. As a result, we will need to secure additional funding. If we are not able to obtain additional capital in the future or on acceptable terms, we may need to curtail our anticipated clinical trials as well as our operations.

Our product candidates, including our lead product candidate, PALI-2108, may cause undesirable side effects or have other unexpected properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in post-approval regulatory action.

Unforeseen side effects from PALI-2108 could arise either during clinical development or, if approved, after it has been marketed. Undesirable side effects could cause us, any partners with which we may collaborate, or regulatory authorities to interrupt, extend, modify, delay or halt clinical trials and could result in a more restrictive or narrower label or the delay or denial of regulatory approval by Health Canada, or comparable regulatory authorities like the FDA.

Results of clinical trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, trials could be suspended or terminated, and Health Canada or comparable regulatory authorities, like the FDA, could order us to cease further development of or deny approval of a product candidate for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in product liability claims. Any of these occurrences may have an adverse material effect on our business, financial condition, operating results and prospects.

Additionally, if we or others identify undesirable side effects, or other previously unknown problems, caused by a product after obtaining regulatory approval, a number of potentially negative consequences could result, which could prevent us or our potential partners from achieving or maintaining market acceptance of the product and could substantially increase the costs of commercializing such product.

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:

- preclinical 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, preclinical and clinical data; and
- adherence to cGMP regulations during production and storage.

PALI-2108 will require significant development, clinical testing, possibly additional preclinical studies, and the investment of significant funds to gain regulatory approval before it can be commercialized. Although we commenced a Phase 1 clinical trial in Canada, there can be no assurances that gaining regulatory approval in Canada will result in regulatory approval from any other regulatory agency, including the FDA of the U.S. The results of our human clinical testing of PALI-2108 may not meet applicable regulatory requirements. If approved in a jurisdiction, PALI-2108 may also require the completion of post-market studies. The process of completing 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.

On June 28, 2024, the U.S. Supreme Court issued an opinion holding that courts reviewing agency action pursuant to the Administrative Procedure Act "must exercise their independent judgment" and "may not defer to an agency interpretation of the law simply because a statute is ambiguous." The decision will have a significant impact on how lower courts evaluate challenges to agency interpretations of law, including those by the FDA and other agencies with significant oversight of the biopharmaceutical industry. The new framework is likely to increase both the frequency of such challenges and their odds of success by eliminating one way in which the government previously prevailed in such cases. As a result, significant regulatory policies will be subject to increased litigation and judicial scrutiny.

If we fail to obtain regulatory approvals, or if there are significant changes in regulatory policies that result in increased litigation and judicial scrutiny leading to unexpected delays and increased cost, we may not be able to market PALI-2108 and our operations will be adversely affected.

If clinical studies of PALI-2108 do not yield successful results, we may discontinue the development of PALI-2108.

We must demonstrate that PALI-2108 is safe and efficacious in humans through extensive clinical testing. 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 preclinical studies that we have completed may not be indicative of results that will be obtained in human clinical trials;
- safety and efficacy results attained in preclinical studies may not be indicative of results that are obtained in our clinical trials;
- after reviewing early clinical trial results, we may abandon projects that we 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 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 clinical trials; a number of factors, including scheduling conflicts with participating researchers and/or CROs, clinicians and research or clinical institutions, and difficulties in identifying or enrolling patients who meet trial eligibility criteria, may cause significant delays. Even if we were to commence and complete our clinical trials involving PALI-2108 as currently contemplated, they may not be successful.

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 market and commercialize 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.

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 in the applicable jurisdiction, including, for example, Medicare and Medicaid in the U.S., 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 U.S. 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, is 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, we may incur substantial liability for a product candidate and we may need 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, we 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 us for all expenses or losses we 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 us 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 approved labeling;
- any requirement of an authoritative regulatory body 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.

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. While we were initially formed in 2001, our operations, to date, have been limited to business planning, raising capital and other research and development activities related to our product candidates. We additionally adopted a new business plan in September 2023 upon entering into the Giiant License Agreement. Since that time, we have not yet demonstrated an ability to successfully complete any clinical trials and have never completed the development of any product candidate, nor have we ever generated any revenue from product sales. 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 we 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 clinical 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 only have a limited history upon which we can evaluate our ability to develop PALI-2108. We commenced our initial Phase 1 clinical trial of PALI-2108 in November of 2024. Thus, we have limited experience and have not yet demonstrated an 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 approval from Health Canada and/or approval from similar foreign regulatory bodies, such as the FDA;
- Retain qualified CROs to oversee and manage our Phase 1 clinical trial for PALI-2108 and future clinical trials;
- 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 preclinical 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.

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. 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, we may be unable to execute our business plan in a timely manner, if at all.

We may choose to discontinue development or commercialization any of our product candidates, or may choose not to 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 competing product(s) 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, we may be dependent on pharmaceutical companies, academic or government scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly on our ability to identify and select promising pharmaceutical product candidates and approved 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 approved products or product candidates on terms that we find acceptable, or at all.

Further, any product candidate that we acquire or license may require additional development efforts prior to commercial sale, including preclinical or clinical testing and approval by the applicable 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 we acquire will be manufactured or sold profitably or achieve market acceptance.

Changes in funding for the FDA and, other government agencies or comparable foreign regulatory authorities could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent these agencies or authorities from performing normal business functions on which the operations of our business may rely, which could negatively impact our business.

The ability of the FDA or comparable foreign regulatory authorities to review and approve new products, to provide feedback on clinical trials and development programs, to meet with sponsors and to otherwise review regulatory submissions can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key leadership and other personnel, the sufficiency of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies or comparable foreign regulatory authorities on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other, other government agencies or comparable foreign regulatory authorities may also slow the time necessary for new drugs to be reviewed or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to Our Dependence on Third Parties

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

We have retained a CRO to oversee our Phase 1 clinical trial for PALI-2108 in Canada. We are likely to rely on third-party CROs to conduct and oversee our other anticipated 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 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 any additionally required preclinical 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 GLP regulations, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities, such as Health Canada, with respect to our Phase 1 clinical trial for PALI-2108. Regulatory authorities enforce these GCP or GLP regulations 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 regulations, 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 any of our clinical trials comply with applicable GCP or GLP regulations. 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 us to repeat clinical trials, which would be costly and delay the regulatory approval process. In the event that we are unable to retain a qualified CRO for our Phase 1 clinical trial for PALI-2108, or any other anticipated clinical trial, it would delay planned clinical operations and result in additional cost and expense. Additionally, if our current CRO for our Phase 1 clinical trial in Canada or if any of our CROs that we retain in the future 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.

We depend on two qualified suppliers for the active pharmaceutical ingredient used in the clinical trials of PALI-2108. Insufficient availability of the API or other raw materials necessary to manufacture PALI-2108, or the inability of our suppliers to manufacture and supply our products on commercially reasonable terms, could adversely impact our business, results of operations and financial condition.

We have two qualified suppliers for the API used in PALI-2108. We do not have, and we do not intend to establish in the foreseeable future, internal manufacturing capabilities. Instead, we intend to use the facilities of third-party manufacturers to produce the materials used in our clinical trials. Our dependence on third parties for the supply and manufacture of PALI-2108 and any future product candidates may adversely affect our ability to obtain our products in a timely or competitive manner, if at all.

Any supply shortages, quality concerns, or failure to obtain sufficient API, excipients, or components from our suppliers, including disruptions caused by, among other things, supply chain delays, public health emergencies, climate events, or political unrest would adversely affect our business, results of operations and financial condition. In particular, our suppliers may be impacted by epidemics, pandemics or other disease outbreaks or public health emergencies and general macroeconomic conditions, including inflationary pressures, economic slowdown or

recession, relatively high interest rates, imposed tariffs, changes in monetary policy, potential U.S. federal government shutdowns, geopolitical conflicts and financial institution instability, all of which may result in supply delays and cost increases.

The manufacturing process for pharmaceutical products is highly regulated, and regulatory agencies may from time to time shut down facilities that they believe do not comply with regulations. Our third-party manufacturers and suppliers are subject to numerous FDA and Health Canada regulations, including those governing manufacturing processes, stability testing, record keeping, product serialization, and quality standards. Similar regulations apply in other jurisdictions where we may conduct business. Our third-party manufacturers and suppliers are independent entities who are subject to their own operational and financial risks which are out of our control.

If we, our third-party manufacturers, or our suppliers fail to comply with these regulations, our ability to deliver adequate supplies of PALI-2108 for clinical trials in a timely and cost-effective manner may be adversely affected. Should any of these risks materialize and adversely affect such third-party manufacturers' and/or suppliers' performance obligations to us, and we are unable to secure sufficient of the API used in the manufacture of PALI-2108 on commercially acceptable terms, or if we encounter delays and difficulties in our relationships with manufacturers or suppliers, our business, results of operations and financial condition could be adversely affected.

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

We currently rely on and expect to continue 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 currently rely on third-party contractors to supply, manufacture and distribute clinical drug supplies for our product candidates.

We do not currently have, nor do we currently plan to acquire, the infrastructure or capability to supply, store, manufacture or distribute clinical or commercial quantities of drug substances or products. Although we have entered into a commercial supply agreement to provide us with such drug substances or products for our current Phase 1 clinical trial, our future 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 preclinical 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 regulations 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 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. Furthermore, the manufacturing facilities of our suppliers are located outside of the U.S. This may give rise to difficulties in importing our products or product candidates or their components into the U.S. or other countries.

We currently have agreements in place with foreign third parties in China and other countries to provide the necessary clinical supply of our API. Termination of or limitations on our relationships with foreign third parties that manufacture the API used in PALI-2108 may arise if U.S. legislation, tariffs, sanctions, trade restrictions, or other U.S. and foreign regulatory requirements, or prohibitions restrict our ability to engage with these foreign third parties. Further, any such actions could adversely impact our current and future arrangements with our foreign suppliers, including our current Chinese drug manufacturer, which could increase the cost or reduce the supply of material available to us or delay the procurement or supply of such material used in our clinical trial.

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 Annual Report on Form 10-K. 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 consolidated financial statements are issued, including our available cash as of the date of this filing, which is not sufficient to fund our anticipated level of operations for the next 12 months. 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 we 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 $14.4 million and $12.3 million for the years ended December 31, 2024 and December 31, 2023, respectively. We expect that our operating losses will continue for the foreseeable future as we continue 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, we may not be able to realize revenues at a level that would allow us to achieve or sustain profitability. Accordingly, we may never generate significant revenue and, even if we generate significant revenue, we 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.

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 in certain countries.

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, or future licensors and 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 or the ability to obtain future patent protections, which may have an adverse impact on our business, financial condition and operating results.

Our ability to obtain, maintain and/or enforce patents is uncertain and involves complex legal and factual questions, especially across varying 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 prior art make it patentable. We do not have outstanding issued patents covering all of the recent developments in our technology and we are unsure of the patent protection that we will be successful in obtaining, if any. Even if the patents are successfully issued, 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 assignment and protection agreements with officers, directors, employees, and certain consultants and advisors, there can be no assurance that such 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 we 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 vary between countries, particularly developing nations. In addition, the laws of some countries do not protect intellectual property rights to the same extent as the laws of all other countries or jurisdictions, especially when it comes to granting use and other types 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 using our inventions or even in launching an identical version of our product even if we hold a valid patent. Competitors may use our technologies in jurisdictions where we have not obtained patent protection, or they may produce copy products, and, further, may export otherwise infringing products to territories where we have patent protection but enforcement against such activities is inadequate or where we have no patents. These products could compete with ours, 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 applicable patent agencies, which require compliance with a number of procedures, including certain documentary, fee payment and other similar provisions during the patent application process. 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. 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. 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.

The Giiant License Agreement pursuant to which we license PALI-2108, and other assets of Giiant, contains certain requirements related to diligence, milestone, royalty, insurance, expense reimbursement, and other obligations. If we fail to comply with these obligations, Giiant may have the ability to terminate the license, subject to certain requirements as more fully set forth in the Giiant License Agreement. If the license granted thereunder were to be terminated, our business, financial condition, operating results, and prospects would be materially adversely affected.

We may be subject to patent infringement claims, which could result in substantial costs and liabilities, and could 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, regardless of 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, the related litigation could be protracted, expensive, a distraction to our management team, and not viewed favorably by investors and other third parties.

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 have used and we intend to use the proceeds from our previous offerings and any future offerings, to, among other uses, advance PALI-2108 through clinical development, advancing the remainder of the existing portfolio through preclinical studies and into INDs or their equivalent in foreign jurisdictions, our research and development activities and for general working capital needs. We will require substantial additional capital to fund our operations and conduct the costly and time-consuming research and development 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 preclinical testing and clinical trials; the ability to manufacture sufficient drug supplies to complete clinical trials or any additional preclinical studies required; 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, which could inhibit our ability to achieve our business objectives. Given our limited cash reserves and the significant amount of capital that we will likely need to fund our operations and business plan, our stockholders will likely experience significant dilution to their ownership interests. 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 need 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 on April 27, 2021, the price of our common stock 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 clinical trials;
- our ability to obtain timely regulatory approvals for our product candidates, and delays or failures to obtain such approvals;

- the results of our 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, and employment agreements with our named executive officers;
- 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, particularly in the micro-cap and nano-cap companies, 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, stockholders 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.

Our common stock could be delisted from the Nasdaq Stock Market if we are unable to maintain compliance with the Nasdaq Stock Market's continued listing standards.

Our common stock is listed on the Nasdaq Stock Market. There are a number of continued listing requirements that we must satisfy in order to maintain our listing on The Nasdaq Stock Market, including the requirement to maintain a minimum bid price of at least $1.00 (the "Bid Price Rule"). Although we are currently in compliance with the Bid Price Rule, we have been unable to comply with this rule in the past. For example, in October 2023, we were notified that we were no longer in compliance with the Bid Price Rule and had 180 days to cure such deficiency. On April 5, 2024, we effected a 1-for-15 reverse stock split and we were notified by the Nasdaq Stock Market that as of April 19, 2024, we were back in compliance with the Bid Price Rule. Although we are in compliance with the Bid Price Rule as of the date of this Annual Report on Form 10-K, on March 17, 2025, our stock price began trading below $1.00. Notwithstanding our current compliance with the Bid Price Rule, in the event that our common stock trades below $1.00 for 30 consecutive business days, Nasdaq may notify us that we are no longer in compliance with the Bid Price Rule and may have 180 days to cure such deficiency. If we are unable to cure such deficiency, we may be subject to delisting. If we fail to comply with the Bid Price Rule in the future, or any of the other continued listing requirements, there can be no assurance that we will be able to regain compliance. The delisting of our common stock would likely adversely affect the market liquidity and market price of our common stock and our ability to obtain financing for the continuation of our operations and/or result in the loss of confidence by investors.

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, 2024, the last business day of our most recently completed second fiscal quarter, our public float was 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.

We do not anticipate paying any dividends in the foreseeable future. We currently plan to retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our shares will likely be the sole source of gain, if any, for our stockholders 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 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 we do have equity research analyst coverage, we will not have any control over the analysts, or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrades our stock or issues 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 us to raise additional capital.

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, as amended ("Certificate of Incorporation"), and bylaws, as amended ("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 Delaware General Corporation Law, 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 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 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 of such preferred stock. As of December 31, 2024, we had outstanding, common stock or securities convertible into common stock, totaling 9,567,496 shares. As a result, we are authorized to issue up to an additional 270,432,507 shares of common stock or common stock equivalents under our Certificate of Incorporation. 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 will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our existing stockholders will likely 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 that we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors will likely be materially diluted by the initial and subsequent sales. Additionally, new investors may gain rights superior to existing stockholders, depending on the terms of such transactions and types of securities. 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 stockholders 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 conflicts). 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, we 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. 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 parties 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 we rely) 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.

Risk Management and Strategy

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.*"

Governance

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 8, *Commitments and Contingencies*, 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 20, 2025, the last reported sale price our common stock on the Nasdaq Capital Market was $0.78 per share.

Holders

As of March 20, 2025 there were 137 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 October 1, 2024, we issued 3,000 restricted common shares to a consultant. The common stock shares were fully vested on the grant date and valued at $3.45 per share on the date of issuance.

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 the above transaction(s) 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.

Statements in this Annual Report on Form 10-K that are not strictly historical are "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (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 which 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. You can identify these forward-looking statements because they involve our expectations, intentions, beliefs, plans, projections, anticipations, or other characterizations of future events or circumstances. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that may cause actual results to differ materially from those in the forward-looking statements as a result of any number of factors. Some of these factors are more fully discussed in the section of this Annual Report on Form 10-K entitled "Risk Factors" and elsewhere herein. We do not undertake to update any of these forward-looking statements or announce the results of any revisions to these forward-looking statements except as required by law.

We recommend investors read this entire Annual Report on Form 10-K, including the "Risk Factors" section, the consolidated financial statements, and related notes thereto. 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 "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 preclinical studies also refers to nonclinical studies.

OVERVIEW

We are a clinical-stage biopharmaceutical company focused on developing and advancing novel therapeutics for patients living with autoimmune, inflammatory, and fibrotic diseases. Our lead product candidate, PALI-2108, is being developed as a treatment for patients living with inflammatory bowel disease ("IBD"), including ulcerative colitis ("UC") and Fibrostenotic Crohn's disease ("FSCD").

We are currently conducting a Phase 1 human clinical trial of our lead product candidate, PALI-2108, for the treatment of UC. The Phase 1 clinical trial is being conducted in Canada. We anticipate announcing topline data from this study during the second quarter of 2025. Assuming the trial meets its primary objectives, we plan to initiate a Phase 1b/2a clinical study in UC patients in the first quarter of 2026.

In addition to conducting clinical studies in Canada, we anticipate filing an Investigational New Drug Application ("IND") with the United States Food and Drug Administration ("FDA") during 2025. If our IND is approved, we anticipate commencing clinical trials of PALI-2108 in the United States ("U.S.") during the first quarter of 2026.

Financial Results

Our operating loss for the year ended December 31, 2024 was approximately $14.9 million, which consisted of research and development expense and general and administrative expense of approximately $9.1 million and $5.8 million, respectively. Net cash used in operating activities was approximately $12.2 million for the year ended December 31, 2024, which includes a $14.4 million net loss adjusted for $1.4 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 $9.6 million for the year ended December 31, 2024.

Recent Financings

In December 2024, we completed an underwritten public offering for net cash proceeds of $4.1 million consisting of gross cash proceeds of $5.0 million less cash equity issuance costs of approximately $0.9 million.

In May 2024, we completed a private placement for net cash proceeds of approximately $3.5 million consisting of gross cash proceeds of $4.0 million, less cash equity issuance costs of approximately $0.5 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 $9.8 million as of December 31, 2024, we believe we have sufficient cash to fund our currently planned operations through the fourth quarter of 2025.

Giiant License Agreement

On September 1, 2023, we entered into a research collaboration and license agreement (the "Giiant License Agreement") with Giiant Pharma Inc. (“Giiant”). 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, preclinical development of PALI-2108 was jointly undertaken by us and representatives of Giiant. Pursuant to the Giiant License Agreement, we paid, or reimbursed or advanced to Giiant, a portion of the joint development costs. Additionally, per the terms of the Giiant License Agreement, we will pay (i) certain milestone payments (in cash or stock at our sole election) (the "Giiant Milestone Payments") and (ii) royalty payments upon sales or sublicenses to third parties, with such milestone and royalty payments (the "Giiant License Payments") subject to a payment cap (the "Payment Cap").

On August 2, 2024, we entered into an amendment to the Giiant License Agreement with Giiant (the "Giiant License Agreement Amendment"). Pursuant to the Giiant License Agreement Amendment, we agreed to increase the amount of joint development costs we would reimburse or advance to Giiant pursuant to the Giiant License Agreement. As consideration for the increase, Giiant agreed to (i) a reduction in the Giiant Milestone Payments that would be due to them upon the achievement of certain development milestones, and (ii) a decrease to the Payment Cap applied to future Giiant License Payments, as set forth in the original Giiant License Agreement. There were no other changes to the terms of the original Giiant License Agreement as a result of the Giiant License Agreement Amendment that would have a material impact on our results of operations, financial position or future cash flows.

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, 2024, we recognized no license revenue.

Research and Development Expenses

The research and development expenses include:

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

Research and development expenses recognized in the year ended December 31, 2023 consisted primarily of costs directly incurred for the clinical development of our legacy 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 of LB 1148, we terminated the development of LB1148. Through the first nine months of 2024, the nature of our research and development expenses

incurred related primarily to the preclinical activities associated with our joint development of PALI-2108 with our collaboration partner, Giiant. With the approval to commence the Phase 1 clinical trial of PALI-2108, which we received from Health Canada on October 9, 2024, pursuant to the Giiant License Agreement we have assumed all development, manufacturing, regulatory and commercialization activities and costs of PALI-2108. Therefore, we expect our clinical research and development costs directly attributable to the clinical trials of PALI-2108 to continue to increase in 2025, offset by a decrease in joint development costs associated with the Giiant License Agreement.

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, CROs, clinical site, contract manufacturing organizations ("CMOs") and research laboratories in connection with our preclinical 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) preclinical, clinical and translational science development activities, and (iii) process development. When 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 research and collaboration with Giiant, qualifying development costs are expensed as research and development costs as incurred. We recognize expense payments from Giiant, if any, as a reduction to research and development expense once the expense payments are realized or realizable, which is when we receive the cash or we have an undisputed claim to the cash that is probable of collection.

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 and committee fees, 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 reduction-in-workforce on October 27, 2023 (the "2023 RIF"). 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. We have outsourced to a third-party CRO many of the clinical trial activities related to our Phase 1 clinical trial of PALI-2108, which commenced in November of 2024.

Going Concern

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) our available cash as of the date of this filing will not be sufficient to fund our anticipated level of operations for the next 12 months; (ii) we will require additional financing by the end of 2025 to continue at our expected level of operations; and (iii) 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 perhaps cease operations. 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 April 5, 2024, we effected a 1-for-15 reverse stock split of our issued and outstanding common stock (the "Reverse Stock Split"). As a result of the Reverse Stock Split, our stockholders received one share of our common stock for every 15 shares each stockholder 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-based awards and common stock warrants included in this Annual Report on Form 10-K, including the exercise or conversion price of such equity instruments, as applicable, have been retrospectively adjusted to reflect the Reverse Stock Split.

Results of Operations

The following table summarizes our results of operations for the year ended December 31, 2024 and 2023 (in thousands):

	Year Ended December 31,		Change	
	2024	2023	$	%
License revenue	$ —	$ 250	$ (250)	n/a
Operating expenses:				
Research and development	9,063	6,893	2,170	31%
General and administrative	5,796	6,202	(406)	(7)%
Restructuring costs	—	225	(225)	n/a
Total operating expenses	14,859	13,320	1,539	12%
Loss from operations	(14,859)	(13,070)	(1,789)	14%
Other (expense) income:				
Interest expense	(12)	(15)	3	(20)%
Other income, net	433	785	(352)	(45)%
Total other income, net	421	770	(349)	(45)%
Net loss	$ (14,438)	$ (12,300)	$ (2,138)	17%

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, 2024, we recognized no license revenue.

Research and Development Expenses

Research and development expenses increased by approximately $2.2 million, or 31%, from approximately $6.9 million for the year ended December 31, 2023 to approximately $9.1 million for the year ended December 31, 2024, primarily due to (i) an increase in joint development expenses directly related to PALI-2108 of approximately $3.6 million, from approximately $0.7 million for the year ended December 31, 2023 to approximately $4.3 million for the year ended December 31, 2024, and (ii) an approximately $1.0 million increase in drug manufacturing costs for the preclinical and clinical trials of PALI-2108. Partially offsetting these increases in joint development expenses and drug manufacturing costs was a decrease in clinical trial-related expenses of approximately $1.3 million for the year ended December 31, 2024, compared to the year ended December 31, 2023. Associated with our clinical trials of LB1148, which we ceased developing in August of 2023, we recognized clinical vendor costs, translational research costs, investigator site fees and regulatory activity costs of approximately $2.5 million for the year ended December 31, 2023, compared to costs specific to the clinical trials of PALI-2108 of approximately $1.2 million for the year ended December 31, 2024. With the commencement of our clinical trials of PALI-2108 in November of 2024, in 2025 we expect an increase in costs directly associated with the clinical trials of PALI-2108.

Also, for the year ended December 31, 2024 compared to the year ended December 31, 2023, employee-related costs decreased by approximately $0.6 million as a result of a 25% reduction in our employee workforce in October 2023 and a decrease in fees associated with the hiring of our CMO in September of 2023.

Finally, associated with the Giiant License Agreement entered into on September 1, 2023, the year ended December 31, 2023 included transaction costs of approximately $0.2 million and non-cash expense of approximately $0.2 million for the initial recording of the fair value of the contingent consideration obligation, compared to a small non-cash gain recognized for a decrease in the fair value of the contingent consideration obligation in the year ended December 31, 2024, resulting in a net favorable impact year-over-year of approximately $0.4 million. The non-cash gain of less than $0.1 million for the year ended December 31, 2024 was due to a decrease in the fair value of the Giiant Milestone Payment primarily as a result of the Giiant License Agreement Amendment.

General and Administrative Expenses

General and administrative expenses decreased by approximately $0.4 million, or 7%, from approximately $6.2 million for the year ended December 31, 2023 to approximately $5.8 million for the year ended December 31, 2024,

primarily driven by (i) a decrease insurance costs of approximately $0.2 million, due to lower insurance premiums, (ii) a decrease in our Board and Board committee fees of approximately $0.2 million, due to reduction in the size of our Board and Board committee membership in the first quarter of 2024, (iii) a decrease of approximately $0.2 million related to patent costs, license and maintenance fees, and subscription fees recognized in 2023 that did not repeat in 2024, and (iii) a decrease in professional fees, primarily accounting fees, of approximately $0.5 million for the year ended December 31, 2024, compared to the for the year ended December 31, 2023. These increases were partially offset by an approximately $0.6 million increase in consultants and contract labor in the year ended December 31, 2024, compared to the year ended December 31, 2023, and a $0.1 million increase in shareholders services fees due to the special meeting of our shareholders held on March 25, 2024 to approve the Reverse Stock Split.

Restructuring Expenses

Associated with the 2023 RIF, we recognized restructuring expenses of approximately $0.2 million and 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. We recognized no restructuring expenses for the year ended December 31, 2024. We do not expect to incur any other significant costs associated with the 2023 RIF.

Other income (expense)

Other income, net, of approximately $0.4 million for the year ended December 31, 2024 includes dividend income of approximately $0.5 million from our short-term investments of excess cash in money market funds with maturities of three months or less, partially offset by other non-cash losses of less than $0.1 million associated primarily with the write-off of certain other receivable balances.

Other income, net, of approximately $0.8 million for the year ended December 31, 2023 includes dividend income of approximately $0.7 million from our short-term investments, and a non-cash gain of approximately $0.1 million associated with the revaluation of our liability-classified warrants in the year.

Liquidity and Capital Resources

Since our inception, we have financed our operations through the sales of our securities, issuance of debt, the exercise of 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 the Middle East, and (vi) limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry. In the event that 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 December 13, 2024, we completed an underwritten public offering of common stock, prefunded warrants to purchase common stock and warrants to purchase common stock (the "December 2024 Offering"). Gross cash proceeds from the December 2024 Offering were approximately $5.0 million and net cash proceeds were $4.1 million after deducting cash equity issuance costs of approximately $0.9 million.

On May 6, 2024, we completed a private placement of common stock, prefunded warrants to purchase common stock and warrants to purchase common stock (the "May 2024 Offering"). Gross cash proceeds from the May 2024 Offering were $4.0 million and net cash proceeds were approximately $3.5 million after deducting cash equity issuance costs of approximately $0.5 million.

On September 11, 2023, we completed a registered direct offering of common stock (the "September 2023 Offering"). 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.

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 approximately $6.0 million and net cash proceeds were approximately $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 approximately $2.5 million and net cash proceeds were approximately $2.2 million after deducting cash equity issuance costs of approximately $0.3 million.

Refer to Note 5, *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, 2024, we received gross cash proceeds of approximately $2.5 million for the exercise of outstanding common stock warrants. 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.

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 $10.97 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 $10.97 (in its entirety, the "February 2024 Warrant Inducement").

The Warrant Holders collectively exercised an aggregate of 228,162 Existing Warrants. As a result of the exercises of the Existing Warrants, we issued an aggregate of 228,162 shares of our common stock and 228,162 Replacement Warrants. The February 2024 Warrant Inducement closed on February 1, 2024 for net cash proceeds of approximately $2.2 million consisting of gross cash proceeds of approximately $2.5 million, less cash equity issuance costs of approximately $0.3 million.

Cash Flows

As of December 31, 2024, we had $9.8 million in cash, cash equivalents and restricted cash. The following table shows a summary of our cash flows for the years ended December 31, 2024 and 2023 (in thousands):

	Year Ended December 31,	
	2024	2023
Net cash used in operating activities	$ (12,193)	$ (11,133)
Net cash used in investing activities	—	(4)
Net cash provided by financing activities	9,582	11,186

Net Cash Used in Operating Activities

Cash used in operations increased by approximately $1.1 million for the year ended December 31, 2024 compared to the year ended December 31, 2023 primarily due to an increase in net loss, partially offset by favorable changes in operating assets and liabilities.

Cash used in operating activities was approximately $12.2 million for the year ended December 31, 2024, which reflects a $14.4 million net loss adjusted for (i) approximately $1.4 million of net cash inflows related to changes in operating assets and liabilities, and (ii) certain non-cash items impacting the net loss, consisting primarily of (a) an approximately $0.7 million non-cash expense recognized for stock-based compensation and related charges, (b) an approximately $0.1 million non-cash expense associated with the issuance of our common stock as payment for vendor services provided, (c) an approximately $0.1 million non-cash expense related to the amortization of our operating lease right of use asset, and (d) an approximately $0.2 million non-cash gain recognized for the remeasurement of the contingent consideration liability associated with the Giiant Milestone Payments. The net cash inflow from operating assets and liabilities was primarily attributable to an approximately $0.1 million cash outflow related to payments of our operating lease that was more than offset by approximately $1.6 million cash inflow from (i) an approximately $0.8 million 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) an approximately $0.8 million increase in accounts payable and accrued liabilities, which was primarily due to additional drug manufacturing accruals associated with the clinical trials of PALI-2108 and an increase in accrued joint development expenses associated with the Giiant License Agreement. These increases in accounts payable and accrued liabilities were partially offset by a decrease in accrued severance payments and lower accrued Board and Board committee fees.

Cash used in operating activities was approximately $11.1 million or the year ended December 31, 2023, which reflects an approximately $12.3 million net loss adjusted for (i) approximately $0.4 million of net cash inflows related to changes in operating assets and liabilities, and (ii) certain non-cash items impacting the net loss, consisting primarily of (a) a $0.6 million non-cash expense recognized for stock-based compensation and related charges, (b) a $0.1 million non-cash expense related to the amortization of our operating lease right of use asset, and (c) a non-cash expense of $0.2 million related to the remeasurement of certain liabilities recorded at fair value. The net cash inflow from operating assets and liabilities was primarily attributable to (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.

Net Cash Used in Investing Activities

Cash used in investing activities for the year ended December 31, 2023 consists of payments for leasehold improvements. There was no cash used in or provided by investing activities for the year ended December 31, 2024.

Net Cash Provided by Financing Activities

For the year ended December 31, 2024, cash provided by financing activities of approximately $9.6 million was attributable to net cash proceeds of approximately $2.2 million from the exercise of common stock warrants in conjunction with the February 2024 Warrant Inducement and net cash proceeds of approximately $7.9 million from the May 2024 Offering and December 2024 Offering, partially offset by payments made on our insurance financing arrangements of approximately $0.4 million.

For the year ended December 31, 2023, cash provided by financing activities of approximately $11.2 million was primarily attributable to net cash proceeds of approximately $8.8 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 approximately $2.8 million from the exercise of common stock purchase warrants, which includes the receipt in early January 2023 of an approximately $1.4 million other receivable from warrant exercises on December 30, 2022, partially offset by payments of approximately $0.4 million for our insurance financing arrangement.

Contractual Obligations

Office Lease

We are party a to non-cancelable facility operating lease (the "Corporate Office Lease") of office space for our corporate headquarters. 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, 2024, the total remaining future minimum lease payments associated with the Corporate Office Lease of approximately $93,000, including imputed interest of $3,000 calculated using a discount rate of 10.75%, will be paid over the remaining lease term of approximately 0.7 years.

Insurance Financing Arrangement

In June 2024, we entered into an agreement to finance an insurance policy that renewed in May 2024. The insurance financing arrangement is payable over a 9-month period with the first payment having been payable on June 30, 2024. As of December 31, 2024, the aggregate remaining balance under our insurance financing arrangement was $79,000.

Other than the remaining insurance financing arrangement payments due in 2025, as of December 31, 2024 we have no other minimum debt payments required in 2025 or thereafter.

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 $9.8 million as of December 31, 2024, we believe we have sufficient cash to fund our currently planned operations through the fourth quarter of 2025. Notwithstanding, should our anticipated level of operations significantly change, we may require additional financing sooner than anticipated. Further, beyond the fourth 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 U.S. (“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 expense research and development costs as incurred pursuant to Accounting Standards Codification ("ASC") 730, *Research and Development Costs*. We are 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, clinical sites, manufacturers, vendors, and consultants in connection with conducting research and development activities, including those related to our ongoing clinical operations. The financial terms of these contract arrangements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows that do not match the periods over which services are provided or milestones are met under the associated research and development contract. Payments under some of these contracts depend on factors such as the successful enrollment of patients, site initiation and the completion of clinical milestones. We make estimates of our accrued research and development expenses as of each balance sheet date based on facts and circumstances known at that time. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each

period. If the actual timing of the performance of services or the level of effort varies from its estimate, we adjust the accrual or prepaid expense balance accordingly.

Our process around estimating accrued research and development expenses 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.

We accrue for research and development expenses, including manufacturing and clinical trial costs, for which the estimated services have been provided but we have not yet been invoiced as of the balance sheet date. There may be instances in which payments made to our service providers will temporarily exceed the level of services provided and result in a prepayment of the research and development expenses.

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, we recognize 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. We record expense payments from Giiant, if any, as a reduction to research and development expense once the expense payments are realized or realizable, which is when Company receives the cash or has an undisputed claim to the cash that is probable of collection, pursuant to the terms of the Giiant License Agreement and the principles of ASC 450, *Gain Contingencies*.

Although we do not expect our estimates of research and development expenses 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 Obligation

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 ASC 480, *Distinguishing Liabilities from Equity* 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 initial 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*. The significant assumptions used in the calculation of the fair value as of December 31, 2024 included a discount rate of 9.29% and management's updated projections of the likelihood of success in achieving each of the defined milestones based on empirical, published industry data.

As of December 31, 2024, the entire amount of contingent consideration obligation was classified as a noncurrent liability in the consolidated balance sheet as none of it is expected to be settled within one-year of the balance sheet date. As of December 31, 2023, approximately $143,000 of the contingent consideration obligation was classified in accrued liabilities in the consolidated balance sheets as it was expected to be settled within one-year of the balance sheet date and the remaining obligation of approximately $61,000 was classified as a noncurrent liability in the consolidated balance sheet.

The change in the fair value of the contingent consideration obligation of approximately $54,000 for the year ended December 31, 2024 was primarily due to the reduction in the milestone payments that would be due to Giiant upon the achievement of certain development milestones pursuant to the amendment to the Giiant License Agreement, partially offset by an increase in management's projected likelihood of success in achieving each of the defined milestones as a result of our commencement of a Phase 1 trial in November of 2024. The change in the revaluation of

the liability in the years ended December 31, 2024 and December 31, 2023 is recognized in research and development expenses in the consolidated statements of operations. In addition, the initial fair value of the contingent consideration liability of $0.2 million and transaction-related costs of approximately $0.1 million for the year ended December 31, 2023 is recognized in research and development expenses in the consolidated statements of operations.

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.

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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, 2024 and 2023, the related consolidated statements of operations, stockholders' equity, and cash flows, for each of the two years in the period ended December 31, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, 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, 2024, 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

Critical audit matters 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 judgements. We determined that there are no critical audit matters.

/s/ Baker Tilly US, LLP

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

New York, New York

March 24, 2025

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

	December 31, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 9,821	$ 12,432
Prepaid expenses and other current assets	673	896
Total current assets	10,494	13,328
Restricted cash	26	26
Property and equipment, net	3	10
Operating lease right-of-use asset	84	198
Other noncurrent assets	273	490
Total assets	$ 10,880	$ 14,052
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,105	$ 698
Accrued liabilities	1,240	831
Accrued compensation and benefits	722	778
Current portion of operating lease liability	90	121
Insurance financing debt	79	158
Total current liabilities	3,236	2,586
Warrant liability	2	2
Contingent consideration obligation, net of current portion	150	61
Operating lease liability, net of current portion	—	90
Total liabilities	3,388	2,739
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Series A Convertible Preferred Stock, $0.01 par value, 7,000,000 shares authorized; 200,000 issued and outstanding at December 31, 2024 and December 31, 2023	2	2
Common stock, $0.01 par value; 280,000,000 shares authorized; 2,768,646 and 618,056 shares issued and outstanding at December 31, 2024 and December 31, 2023, respectively	27	6
Additional paid-in capital	143,407	132,811
Accumulated deficit	(135,944)	(121,506)
Total stockholders' equity	7,492	11,313
Total liabilities and stockholders' equity	$ 10,880	$ 14,052

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,	
	2024	**2023**
License revenue	$ —	$ 250
Operating expenses:		
Research and development	9,063	6,893
General and administrative	5,796	6,202
Restructuring costs (Note 8)	—	225
Total operating expenses	14,859	13,320
Loss from operations	(14,859)	(13,070)
Other (expense) income:		
Interest expense	(12)	(15)
Other income, net	433	785
Total other income, net	421	770
Net loss	$ (14,438)	$ (12,300)
Net loss available to common stockholders	$ (14,438)	$ (12,316)
Basic and diluted weighted average shares used in computing basic and diluted net loss per common share*	1,416,471	456,014
Basic and diluted net loss per common share*	$ (10.19)	$ (27.01)

(*) Basic and diluted loss per common share and basic and diluted weighted average share used in computing basic and diluted loss per common share for the year ended December 31, 2023 has been adjusted to reflect the 1-for-15 reverse stock split effected on April 5, 2024.

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

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

	Year Ended December 31, 2024						
	Preferred Stock		Common Stock		Additional Paid-in Capital*	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares*	Amount*			
Balance, December 31, 2023	200,000	$ 2	618,056	$ 6	$ 132,811	$ (121,506)	$ 11,313
Net loss	—	—	—	—	—	(14,438)	(14,438)
Stock-based compensation expense and related charges	—	—	—	—	652	—	652
Issuance of common stock to vendors	—	—	32,632	—	135	—	135
Issuance of common stock for vesting of restricted stock units, net of employee withholding tax liability	—	—	18,046	—	(25)	—	(25)
Issuance of common stock in connection with exercise of warrants	—	—	1,626,496	16	(13)	—	3
Issuance of common stock under Employee Stock Purchase Plan	—	—	2,256	—	11	—	11
Issuance of common stock in connection with warrant inducement, net of issuance costs of $2,412 (Note 5)	—	—	228,162	2	2,158	—	2,160
Issuance of common stock and warrants in May 2024 Offering, net of issuance costs of $705 (Note 5)	—	—	85,100	1	3,543	—	3,544
Issuance of common stock and warrants in December 2024 Offering, net of issuance costs of $1,403 (Note 5)	—	—	158,000	2	4,135		4,137
Reverse stock split fractional share settlement	—	—	(102)	—	—	—	—
Balance, December 31, 2024	200,000	$ 2	2,768,646	$ 27	$ 143,407	$ (135,944)	$ 7,492

(*) Adjusted to reflect the 1-for-15 reverse stock split effected on April 5, 2024.

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

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

	Year Ended December 31, 2023						
	Preferred Stock		Common Stock		Additional Paid-in Capital*	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares*	Amount*			
Balance, December 31, 2022	200,000	$ 2	196,287	$ 2	$ 121,665	$ (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, net of employee withholding tax liability	—	—	4,074	—	—	—	—
Issuance of common stock under Employee Stock Purchase Plan	—	—	2,245	—	17	—	17
Issuance of common stock in connection with exercise of warrants	—	—	146,932	1	1,349	—	1,350
Issuance of common stock and warrants in January 2023 Offering, net of issuance costs of $507	—	—	31,789	—	2,166	—	2,166
Issuance of common stock and warrants in April 2023 Offering, net of issuance costs of $854	—	—	80,770	1	5,300	—	5,301
Issuance of common stock and warrants in September 2023 Offering, net of issuance costs of $345	—	—	155,959	2	1,674	—	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	618,056	$ 6	$ 132,811	$ (121,506)	$ 11,313

(*) Adjusted to reflect the 1-for-15 reverse stock split effected on April 5, 2024.

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, 2024	2023
Net loss	$ (14,438)	$ (12,300)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	3	4
Non-cash operating lease expense	114	102
Recurring fair value measurements of liabilities	(54)	145
Issuance of common stock to vendors	135	—
Loss on disposal of property and equipment	4	—
Stock-based compensation and related charges	652	624
Other	—	(108)
Changes in operating assets and liabilities:		
Prepaid and other current assets and other noncurrent assets	750	705
Accounts payable and accrued liabilities	818	(492)
Accrued compensation and benefits	(56)	292
Operating lease liabilities	(121)	(105)
Net cash used in operating activities	(12,193)	(11,133)
Cash flows from investing activities:		
Purchases of property and equipment	—	(4)
Net cash used in investing activities	—	(4)
Cash flows from financing activities:		
Payments on insurance financing debt	(426)	(391)
Proceeds from issuance of common stock and warrants	8,435	9,419
Proceeds from the exercise of warrants	2,506	2,758
Payment of warrant inducement issuance costs	(343)	—
Payment of equity issuance costs	(576)	(617)
Proceeds from issuance of common stock under Employee Stock Purchase Plan	11	17
Shares withheld for payment of employee withholding tax liability	(25)	—
Net cash provided by financing activities	9,582	11,186
Net (decrease) increase in cash, cash equivalents and restricted cash	(2,611)	49
Cash, cash equivalents and restricted cash, beginning of year	12,458	12,409
Cash, cash equivalents and restricted cash, end of period	$ 9,847	$ 12,458
Reconciliation of cash, cash equivalents and restricted cash to the balance sheets:		
Cash and cash equivalents	$ 9,821	$ 12,432
Restricted cash	26	26
Total cash, cash equivalents and restricted cash	$ 9,847	$ 12,458
Supplemental disclosures of cash flow information:		
Interest paid	$ 14	$ 14
Supplemental disclosures of non-cash investing and financing activities:		
Warrant inducement and equity issuance costs included in accounts payable and accrued liabilities	$ 176	$ —
Non-cash impact of exercise price reset on outstanding warrants related to down round provisions	—	16
Fair value of warrants issued to solicitation agent	94	—
Fair value of warrants issued to placement agents	249	384
Fair value of warrants issued to representatives of underwriter	278	—
Deferred equity issuance costs recognized as a reduction in additional paid-in capital from financing activities	37	6
Insurance financing debt included in prepaid and other current assets and other noncurrent assets	347	461
Incremental fair value of modified warrants (Note 5)	2,237	—

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

Palisade Bio, Inc.
Notes To Consolidated Financial Statements

1. Organization and Business

Unless the context indicates or otherwise requires, "Palisade," "Palisade Bio," "the Company," "we," "us," and "our" or similar designations in this Annual Report on Form 10-K 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 "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 preclinical studies also refers to nonclinical studies.

Description of Business

The Company is a clinical-stage biopharmaceutical company focused on developing and advancing novel therapeutics for patients living with autoimmune, inflammatory, and fibrotic diseases. The Company's lead product candidate, PALI-2108, is being developed as a treatment for patients living with inflammatory bowel disease, or IBD, including ulcerative colitis and fibrostenotic 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 net losses and negative cash flows from operations since its inception. As of December 31, 2024, the Company had an accumulated deficit of approximately $135.9 million and cash and cash equivalents of approximately $9.8 million. The Company expects to continue to incur losses into the foreseeable future. The successful transition to achieving profitability is dependent upon achieving a level of revenues adequate to support the Company's costs. There can be no assurances that such profitability will ever be achieved.

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 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 5, *Stockholders' Equity*, 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 is successful in raising 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 April 5, 2024, the Company effected a 1-for-15 reverse stock split of its issued and outstanding common stock (the "Reverse Stock Split"). As a result of the Reverse Stock Split, the Company's stockholders received one share of common stock for every 15 shares each stockholder 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 were not adjusted as a result of the Reverse Stock Split. The Reverse Stock Split also affected the Company's outstanding stock-based awards, common stock warrants, and other exercisable or convertible securities and resulted in the shares underlying such instruments being reduced and the exercise price or conversion 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-based award and common stock warrants included in these consolidated financial statements, including the exercise price or conversion price of such equity instruments, as applicable, have been retrospectively adjusted to reflect 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 accrued research and development expenses and its contingent consideration obligation. 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.

Cash and Cash Equivalents

Cash and cash equivalents represent cash 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, 2024 and December 31, 2023, 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, if not yet finalized as of the balance sheet date, or shelf registration statement. As of December 31, 2024 and December 31, 2023, deferred equity issuance costs of approximately $75,000 and $112,000, 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, 2024, the Company netted previously deferred equity issuance costs of approximately $37,000 against the additional paid-in capital recognized in conjunction with the February 2024 Warrant Inducement. During the year ended December 31, 2023, the Company netted previously deferred equity issuance costs of approximately $6,000 associated with its shelf registration statement against the additional paid-in capital recognized in conjunction with the September 2023 Offering (see Note 5, 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 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 financial assets and liabilities can be found at Note 4, *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 common stock 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, if any, 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 common stock 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

On September 1, 2023, the Company and Giiant Pharma, Inc. ("Giiant") entered into a research collaboration and license agreement (the "Giiant License Agreement") (see Note 7, *Collaborations and License Agreements*). 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 a mid-single-digit percentage 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. 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 Expenses

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 preclinical 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 ASC 730, *Research and Development Costs*. Pursuant to situations whereby the Company performs any research and development or manufacturing activities under a co-development agreement, and the co-development partner is not considered a customer under ASC 606, 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. The Company records expense payments from Giiant, if any, as a reduction to research and development expense once the expense payments are realized or realizable, which is when Company receives the cash or has an undisputed claim to the cash that is probable of collection, pursuant to the terms of the Giiant License

Agreement and the principles of ASC 450, *Gain Contingencies* ("ASC 450"). The Company has determined that Giiant is not considered a customer under ASC 606.

Clinical Trial Expenses

Expenses related to clinical studies are based on estimates of the services received and efforts expended pursuant to the Company's contract arrangements. The financial terms of these contract arrangements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients, site initiation and the completion of clinical milestones. The Company makes estimates of its accrued expenses as of each balance sheet date in its consolidated financial statements based on facts and circumstances known at that time. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from its estimate, the Company adjusts the accrual or prepaid expense balance accordingly.

The Company accrues for clinical trial expenses for which the estimated services have been provided but the Company has not yet been invoiced as of the balance sheet date. There may be instances in which payments made to the Company's service providers will temporarily exceed the level of services provided and result in a prepayment of the clinical trial expenses. Clinical trial expenses are included in research and development 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 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.

The Company offers to its employees an opportunity to participate in its shareholder approved Palisade Bio, Inc. 2021 Employee Stock Purchase Plan (the "2021 ESPP"). The Company estimates the fair value of 2021 ESPP awards on the first day of the offering period using the Black-Scholes option pricing model. The estimated fair value of 2021 ESPP awards is amortized on a straight-line basis over the requisite service period of the award. 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 awards.

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.

Recently Adopted Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board ("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 fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 31, 2024 on a retrospective basis, with early adoption permitted. The Company adopted ASU 2023-07 in the fourth quarter of 2024. The adoption of this guidance resulted in additional financial statement disclosures and had no impact on the Company's results of operations and financial condition. See Note 12, *Segment Information*, for disclosures resulting from the adoption of ASU 2023-07.

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 may be applied either on a prospective or retrospective basis, and early adoption is permitted. The Company is currently evaluating the potential impact of the adoption of ASC 2023-09 on its consolidated financial statement disclosures.

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* ("ASU 2024-03"), which is intended to improve disclosures about a public business entity's expenses by requiring disaggregated disclosure, in the notes to the financial statements, of certain categories of expenses included in the financial statements. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. ASU 2024-03 may be applied either on a prospective or retrospective basis, and early adoption is permitted. The Company is currently evaluating the potential impact of the adoption of ASU 2024-03 on its consolidated financial statement disclosures.

3. Balance Sheet Details

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

	December 31,	
	2024	2023
Prepaid insurance	$ 384	$ 428
Other receivables	24	148
Prepaid subscriptions and fees	116	138
Prepaid software licenses	57	64
Deposits	12	—
Deferred equity issuance costs	75	112
Prepaid other	5	6
	$ 673	$ 896

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

	December 31,	
	2024	2023
Prepaid insurance, less current portion	$ 273	$ 478
Other noncurrent assets	—	12
	$ 273	$ 490

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2024	2023
Accrued accounts payable	$ 109	$ 146
Accrued clinical trial expenses	-	20
Accrued chemistry, manufacturing and controls ("CMC") expenses	606	5
Accrued director stipends	59	106
Accrued severance and benefits (Note 8)	—	131
Accrued joint development expenses (Note 7)	223	98
Current portion of contingent consideration obligation (Note 4)	—	143
Accrued other	243	182
	$ 1,240	$ 831

4. Fair Value Measurements

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 a contingent consideration obligation. The carrying amounts of financial instruments such as 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 carrying value of the Company's insurance financing debt approximates its fair value as of December 31, 2024 and December 31, 2023 due to the market rate of interest, which is based on level 2 inputs. The Company's liability-classified warrants and its contingent consideration obligation are carried at fair value based on level 3 inputs. None of the Company's non-financial assets or liabilities are recorded at fair value on a nonrecurring basis.

Cash and Cash Equivalents

The Company invests its excess cash in money market funds that are classified as level 1 in the fair value hierarchy due to their short-term maturity, and measured the fair value based on quoted prices in active markets for identical assets. The fair value of the Company's cash and cash equivalents invested in money market funds was $9.8 million and $12.3 million as of December 31, 2024 and December 31, 2023, respectively.

Contingent Consideration Obligation

Pursuant to the Giiant License Agreement, 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. On August 2, 2024, the Company and Giiant entered into an amendment to the Giiant License Agreement, which among other things, reduced the milestone payments due to Giiant upon the achievement of certain development milestones (see Note 7, *Collaborations and License Agreements*, for further details).

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 that 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, 2024 included a discount rate of 9.29% and management's updated projections of the likelihood of success in achieving each of the defined milestones based on empirical, published industry data.

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):

	Year Ended December 31,	
Contingent Consideration Obligation	**2024**	**2023**
Fair value at beginning of year	$ 204	$ —
Initial fair value at the original issuance date	—	212
Change in fair value during the year	(54)	(8)
Fair value at end of year	$ 150	$ 204

As of December 31, 2024, the entire amount of contingent consideration obligation of $150,000 was classified as a noncurrent liability in the consolidated balance sheet as none of it is expected to be settled within one-year of the balance sheet date. As of December 31, 2023, approximately $143,000 of the contingent consideration obligation was classified in accrued liabilities in the consolidated balance sheets as it was expected to be settled within one-year of the balance sheet date and the remaining obligation of approximately $61,000 was classified as a noncurrent liability in the consolidated balance sheet.

The change in the fair value of the contingent consideration obligation of approximately $54,000 for the year ended December 31, 2024 was primarily due to the reduction in the milestone payments that would be due to Giiant upon the achievement of certain development milestones pursuant to the amendment to the Giiant License Agreement, partially offset by an increase in management's projected likelihood of success in achieving each of the defined milestones as a result of the Company's commencement of a Phase 1 trial in November of 2024. The change in the revaluation of the liability in the years ended December 31, 2024 and December 31, 2023 is recognized in research and development expenses in the consolidated statements of operations. In addition, the initial fair value of the contingent consideration obligation of $0.2 million and transaction-related costs of approximately $0.1 million 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, net in the consolidated statement of operations.

As of December 31, 2024, 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 during the years ended December 31, 2024 and December 31, 2023 (in thousands):

	Year Ended December 31,	
Warrant Liabilities	**2024**	**2023**
Fair value at beginning of year	$ 2	$ 61
Change in fair value during the period	—	(59)
Fair value at end of year	$ 2	$ 2

5. Stockholders' Equity

Classes of Stock

Common Stock

As of December 31, 2024, 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 April 5, 2024, the Company effected the Reverse Stock Split. Accordingly, the Company's stockholders received one share of the Company's common stock for every 15 shares of the Company's common stock that each stockholder 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-based awards, warrants and other exercisable or convertible securities and resulted in the shares underlying such instruments being reduced and the exercise price or conversion price being increased proportionately by 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 that the stockholder would otherwise be entitled, multiplied by the closing trading price of the Company's common stock on April 5, 2024. The amount of cash paid for fractional shares was immaterial to the Company's financial statements.

As a result of the Reverse Stock Split, on April 5, 2024 the number of issued and outstanding shares of the Company's common stock was adjusted from 12,771,015 shares to approximately 851,302 shares.

Preferred Stock

As of December 31, 2024, 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, 2024, the Company's Series A Convertible Preferred Stock issued in the amount of 200,000 preferred stock shares is convertible into 8 shares of common stock.

Recent Equity Offerings

December 2024 Offering

On December 12, 2024, the Company entered into an Underwriting Agreement (the "Underwriting Agreement") pursuant to which the Company agreed to issue and sell, in an underwritten public offering by the Company (the "December 2024 Offering"), (a) 158,000 Class A Units at a public offering price of $1.525 per Class A Unit (the

“Class A Units”), with each Class A Unit consisting of (i) one share of the Company’s common stock, par value $0.01 per share, and (ii) one warrant to purchase one share of the Company's common stock at an exercise price per share of $1.40 and a term of five years from the date of issuance (“December 2024 Offering Common Stock Warrant”) and (b) 3,120,688 Class B Units at a public offering price of $1.5249 per Class B Unit (the “Class B Units”, and collectively with the Class A Units, the “Units”), with each Class B Unit consisting of (i) one pre-funded warrant to purchase one share of the Company's common stock being immediately exercisable, having an exercise price of $0.0001 per share, and a perpetual term (“December 2024 Offering Pre-funded Common Stock Warrant”) and (ii) one December 2024 Offering Common Stock Warrant. In addition, pursuant to the Underwriting Agreement, the Company granted the sole underwriter a 45-day option (the “Overallotment Option”) to purchase up to 491,803 additional shares of the Company's common stock and/or December 2024 Offering Common Stock Warrants. The Overallotment Option expired and was not exercised by the underwriter.

The Company issued warrants to representatives of the sole underwriter in the December 2024 Offering to purchase an aggregate 196,721 shares of common stock (the “December 2024 Representative Warrants”). The December 2024 Representative Warrants have substantially the same terms as the December 2024 Offering Common Stock Warrants, except that the exercise price of each of the December 2024 Representative Warrants is $2.51625 per share. The fair value of the December 2024 Offering Common Stock Warrants was recognized by the Company as an equity issuance cost which reduced the additional paid-in capital recognized from the December 2024 Offering.

The December 2024 Offering closed on December 13, 2024 for net cash proceeds to the Company of approximately $4.1 million, consisting of gross cash proceeds of $5.0 million less cash equity issuance costs of approximately $0.9 million, which excludes the grant date fair value of the December 2024 Representative Warrants of approximately $0.3 million and the incremental fair value of the Repriced Warrants of approximately $0.3 million, described below.

On December 12, 2024, the Company entered into a warrant amendment agreement (the “Warrant Amendment Agreement”) whereby the Company, contemporaneously with and contingent with the closing of the December 2024 Offering, reduced the exercise price of 1,040,217 outstanding common stock warrants (the “Repriced Warrants”) held by an investor that participated in the December 2024 Offering which expire between July 31, 2027 and May 6, 2031. The Repriced Warrants had their exercise price reduced to $1.40 per share. Other than the reduction in exercise price, the terms of the Repriced Warrants remain the same and unchanged.

The Warrant Amendment Agreement is considered a modification of the Repriced Warrants under the guidance of ASC 815-40. The modification is consistent with the Equity Issuance classification under that guidance as the reason for the Company's repricing of the warrants was to meet a condition of the holder's participation in the December 2024 Offering, which raised equity capital and generated gross cash proceeds for the Company of approximately $5.0 million. As pursuant to the guidance of ASC 480 and ASC 815 the Repriced Warrants were classified as equity instruments before and after the modification, and as the modification is directly attributable to an equity offering, the Company recognized the effect of the modification of approximately $0.3 million as an equity issuance cost netted against the additional paid-in capital recognized in the December 2024 Offering. The amount of the equity issuance cost recognized for the modification of the Repriced Warrants was determined using the Black-Scholes option pricing model as the incremental fair value of the Repriced Warrants as compared to the fair value of the warrants immediately prior to their modification.

May 2024 Offering

On May 1, 2024, the Company entered into a securities purchase agreement with an institutional investor, pursuant to which the Company sold in a private placement, (i) 85,100 shares of common stock at a purchase price per share of $6.5015, (ii) 530,142 pre-funded warrants to purchase shares common stock at a purchase price of $6.5014 per pre-funded warrant, with such pre-funded warrants being immediately exercisable, having an exercise price of $0.0001 per share, and a perpetual term, and (iii) common stock warrants to purchase 922,863 shares of the common stock at an exercise price of $6.314 per share and a term of seven years from the date of issuance (the "May 2024 Warrants") (collectively, the “May 2024 Offering”).

The Company issued warrants to the placement agent in the May 2024 Offering to purchase an aggregate 36,914 shares of common stock (the “May 2024 Placement Agent Warrants”). The May 2024 Placement Agent Warrants have substantially the same terms as the May 2024 Warrants, except that the exercise price of each of the May 2024 Placement Agent Warrants is $10.727 per share and the term is five years from issuance. The fair value of the May 2024 Placement Agent Warrants was recognized by the Company as an equity issuance cost which reduced the additional paid-in capital recognized from the May 2024 Offering.

The May 2024 Offering closed on May 6, 2024 for net cash proceeds to the Company of approximately $3.5 million, consisting of gross cash proceeds of $4.0 million less cash equity issuance costs of approximately $0.5 million, which excludes the grant date fair value of the May 2024 Placement Agent Warrants of approximately $0.2 million.

Other Recent Equity Offerings

On September 11, 2023, the Company completed a registered direct offering of common stock (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, the Company 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, the Company 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.

Common Stock Warrants and Warrant Exercises

February 2024 Warrant Inducement

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 common stock warrants issued on May 10, 2022 (the "May 2022 Warrants"), January 4, 2023 (the "January 2023 Warrants"), and April 5, 2023 (the "April 2023 Warrants"), as well as certain outstanding Series 2 warrants issued on August 16, 2022 (the "Series 2 Warrants") (collectively, the "Existing Warrant(s)"). Pursuant to the Warrant Inducement Agreements, the exercise price of each of the Existing Warrants exercised was reduced to $10.97 per share. Each of the Warrant Holders that exercised its Existing Warrants pursuant to the Warrant Inducement Agreements, received one replacement warrant to purchase one share of the Company's common stock (the "Replacement Warrants") for each Existing Warrant exercised (in its entirety, the "February 2024 Warrant Inducement").

The Replacement Warrants are exercisable immediately, have an exercise price per share of $10.97, and expire five years from the date of issuance, which was February 1, 2024.

The Warrant Holders collectively exercised an aggregate of 228,162 Existing Warrants consisting of: (i) 4,865 May 2022 Warrants, (ii) 4,267 Series 2 Warrants, (iii) 67,511 January 2023 Warrants, and (iv) 151,519 April 2023 Warrants. As a result of the exercises of the Existing Warrants, the Company issued an aggregate of 228,162 shares of its common stock and 228,162 Replacement Warrants. The February 2024 Warrant Inducement 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 cash equity issuance costs of approximately $0.3 million.

The February 2024 Warrant Inducement, which resulted in the lowering of the exercise price of the Existing Warrants and the issuance of the Replacement Warrants, is considered a modification of the Existing Warrants under the guidance of ASC 815-40. The modification is consistent with the Equity Issuance classification under that guidance as the reason for the modification was to induce the holders of the Existing Warrants to cash exercise their Existing Warrants, resulting in the imminent exercise of the Existing Warrants, which raised equity capital and generated gross cash proceeds for the Company of approximately $2.5 million. As pursuant to the guidance of ASC 480 and ASC 815 the Existing Warrants and Replacement Warrants were classified as equity instruments before and after the modification, and as the modification is directly attributable to an equity offering, the Company recognized the effect of the modification of approximately $2.0 million as an equity issuance cost netted against the additional paid-in capital recognized from the associated warrant exercises. The amount of the equity issuance cost recognized for the warrant modification was determined using the Black-Scholes option pricing model as the incremental fair value of the modified Existing Warrants and additional Replacement Warrants issued as compared to the fair value of the original Existing Warrants immediately prior to their modification.

The solicitation agent fees associated with the February 2024 Warrant Inducement consisted of: (i) a cash fee equal to 7.75% of the gross proceeds received by the Company, (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 the Existing Warrants, with an exercise price of $10.97 per share, and a term of five years from issuance (the "Solicitation Agent Warrants"), and (iii) $35,000 of out-of-pocket expenses. The fair value of the Solicitation Agent Warrants was recognized by the Company as an equity issuance cost, which reduced the additional paid-in capital recognized from the issuance of common stock in connection with the exercise of the Existing Warrants.

Total equity issuance costs recognized in the February 2024 Warrant Inducement of $2.4 million include cash equity issuance costs of $0.3 million, non-cash warrant modification costs of approximately $2.0 million, and non-cash issuance costs associated with the Solicitation Agent Warrants of $0.1 million.

Common Stock Warrants Outstanding and Warrant Activity

The Company accounts for the majority of its warrants as equity-classified in accordance with ASC 480 and ASC 815. 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 exercisable common stock warrants outstanding of 6,745,213 and 272,211 at December 31, 2024 and December 31, 2023, respectively.

The following table summarizes the Company's outstanding and exercisable common stock warrants as of December 31, 2024:

Common Stock Warrants	Classification	Number of Warrants Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)
December 2024 Offering Pre-Funded Common Stock Warrants	Equity-classified	2,027,000	$ 0.0001	Perpetual
December 2024 Offering Common Stock Warrants	Equity-classified	3,278,688	1.40	4.95
May 2024 Offering Common Stock Warrants	Equity-classified	922,863	1.40	6.34
February 2024 Warrant Inducement Replacement Common Stock Warrants	Equity-classified	228,158	6.17	4.09
August 2024 Offering Series 2 Common Stock Warrants	Equity-classified	6,748	1.40	2.61
Bridge, January 2021, and July 2021 Common Stock Warrants	Liability-Classified	1,144	58.20	1.75
Placement Agent, Solicitor and Representative Common Stock Warrants	Equity-classified	274,693	10.98	4.66
All Other Common Stock Warrants	Equity-classified	5,919	3,418.56	1.50
Total Warrants Outstanding, December 31, 2024		6,745,213	4.53	5.16 (1)

(1) The pre-funded common stock warrants granted and outstanding during the year ended December 31, 2024 have a perpetual term and are therefore excluded from the calculation of the weighted average remaining contractual life.

Of the outstanding common stock warrants, only the Series 2 Warrants include a down round feature whereby they are subject to price reset provisions in the event future sales of the Company's securities are sold at a price per share less than the exercise price of such warrants.

The following table summarizes all common stock warrant activity for the year ended December 31, 2024:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)
Warrants outstanding, December 31, 2023	272,211	$ 144.78	4.12
Granted	8,327,864	1.68	5.27 (1)
Exercised	(1,854,658)	1.35	—
Forfeited, expired or cancelled	(204)	17,438.12	—
Warrants outstanding, December 31, 2024	6,745,213	4.53	5.16 (1)

(1) The pre-funded common stock warrants granted and outstanding during the year ended December 31, 2024 have a perpetual term and are therefore excluded from the calculation of the weighted average remaining contractual life.

For the years ended December 31, 2024 and 2023, the Company received gross cash proceeds of approximately $2.5 million and approximately $2.8 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.

6. 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"). As of December 31, 2024, there were 37,586 shares of the Company's common stock reserved for future issuance as equity-based awards under the 2021 EIP, which excludes the subsequent evergreen share increase in the number of shares of common stock reserved for issuance under the 2021 EIP that occurred on January 1, 2025.

Also in April 2021, the Company's shareholder approved the ESPP. 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 in a calendar year or 5,000 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. As of December 31, 2024, there have been 4,501 shares of the Company's common stock issued under the 2021 ESPP. As of December 31, 2024, there were 19,086 shares of the Company's common stock reserved for future issuance under the 2021 ESPP, which excludes the subsequent evergreen share increases in the number of shares of common stock reserved for future issuance under the 2021 ESPP that occurred on January 1, 2025.

Compensation expense associated with the 2021 ESPP for the year ended December 31, 2024 and December 31, 2023 was approximately $19,000 and $18,000, respectively.

In November 2021, the Company's compensation committee of the Company's Board of Directors ("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 66,666 shares. As of December 31, 2024, there were 52,941 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, 2024 and December 31, 2023 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,	
	2024	2023
Weighted-average exercise price per share	$ 4.54	$ 20.85
Weighted-average expected term (years)	5.65	5.66
Weighted-average risk-free interest rate	4.03%	4.08%
Weighted-average expected dividend yield	—	—
Weighted-average volatility	111.74%	78.35%

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 biopharmaceutical 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 and the 2021 Inducement Plan for the year ended December 31, 2024:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2023	44,276	$ 233.09	6.08	$ —
Granted	12,300	4.54	—	—
Exercised	—	—	—	—
Forfeited, expired or cancelled	(5,902)	335.18	—	—
Outstanding at December 31, 2024	50,674	166.48	8.75	—
Vested and expected to vest at December 31, 2024	50,674	166.48	8.75	—
Exercisable at December 31, 2024	22,825	349.89	8.44	—

The weighted-average grant date fair value of options granted during the years ended December 31, 2024 and December 31, 2023 was $3.80 per share and $12.33 per share, respectively. The grant date fair value of the options vested during each the years ended December 31, 2024 and December 31, 2023 was approximately $0.4 million and $0.3 million, respectively.

Restricted Stock Units

During the year ended December 31, 2024, the Company granted no RSUs. As of December 31, 2024, there were no RSUs that remained outstanding.

The following table summarizes RSU activity and related information under the 2021 EIP and the 2021 Inducement Plan for the year ended December 31, 2024:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value Per Share	Weighted Average Remaining Contractual Life (Years)
Non-vested at December 31, 2023	24,195	$ 17.30	2.17
Granted	—	—	—
Vested	(23,067)	17.23	—
Forfeited	(1,128)	18.84	—
Non-vested at December 31, 2024	—	—	—

The grant date fair value of the RSUs vested during the years ended December 31, 2024 and December 31, 2023 was approximately $0.1 million in each year.

Performance Based Stock Units

On February 6, 2023, the Company granted to certain members of management a total of 4,580 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 $48.00 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 $63.75 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 $22.50 per award share and $22.05 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. As of December 31, 2023, a total of 4,144 PSUs remained unvested and outstanding. None of the PSUs vested during the year ended December 31, 2024 and 1,192 PSUs were forfeited during the year. As of December 31, 2024, a total of 2,952 PSUs remain unvested and outstanding.

Share-Based Compensation Expense

The allocation of stock-based compensation for all stock option, RSU and PSU awards is as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Research and development expense	$ 263	$ 240
General and administrative expense	370	366
Total	$ 633	$ 606

To reduce the ongoing administrative burden and expense associated with the quarterly vesting of the Company's time-based RSUs, on May 28, 2024, the Company's Board approved the immediate accelerated vesting of all unvested time-based RSUs issued to employees that were outstanding as of that date. The accelerated vesting was accounted for as a Type I modification under ASC 718 and accordingly, in the second quarter of 2024 the Company recognized share-based compensation expense associated with the time-based RSUs subject to immediate vesting of approximately $129,000 in general and administrative expenses and approximately $125,000 in research and development expenses.

As of December 31, 2024, the unrecognized compensation expense related to outstanding options was $0.2 million, which is expected to be recognized over a weighted-average period of approximately 1.49 years. As of December 31, 2024 there is no unrecognized compensation expense related to outstanding service-based RSUs as there are no outstanding non-vested service-based RSUs as of that date and the unrecognized compensation expense related to outstanding PSUs is immaterial.

7. Collaborations and License Agreements

Research Collaboration and License Agreement with Giiant

On September 1, 2023, the Company entered into the Giiant License Agreement whereby the Company 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 compound, and (ii) the PALI-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 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 was 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 reimbursed or advanced Giiant up to an amount in the low seven-digit range for costs and expenses incurred by them. Upon reaching the Proof of Concept, which occurred in October of 2024, the Company became solely responsible for all costs and expenses incurred for the development, manufacturing, regulatory and commercialization of the Giiant Licensed Assets. For the years ended December 31, 2024 and December 31, 2023, the Company recognized expenses related to the joint development plan with Giiant in the amount of approximately $4.3 million and $0.7 million, respectively, which are included in research and development expenses in the consolidated statements of operations. The Company recognized no reductions to its joint development expenses for payments from Giiant for either the years ended December 31, 2024 or December 31, 2023. At December 31, 2024 and December 31, 2023, the Company accrued joint development expenses of approximately $0.2 million and $0.1 million, respectively, in Accrued liabilities in the consolidated balance sheets.

Pursuant to the Giiant License Agreement, as amended (see below), the Company will (i) make certain payments between the mid six-digit range and low seven-digit range upon the achievement of development milestones, as defined 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 a mid-single-digit percentage 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 has made no Giiant License Payments since the commencement of the Giiant License Agreement.

On August 2, 2024, the Company and Giiant entered into an amendment to the Giiant License Agreement (the "Giiant License Agreement Amendment"). Pursuant to the Giiant License Agreement Amendment, the Company agreed to increase the amount it would reimburse or advance to Giiant prior to Proof of Concept under the Giiant Development Plan by an amount in the mid six-digit range. After taking into account such increase, the amount that Company will reimburse or advance Giiant for costs and expenses incurred by them will remain in the low seven-digit range. As consideration for the increase, Giiant agreed to (i) a reduction in the Giiant Milestone Payments that would be due to them upon the achievement of certain development milestones, and (ii) a decrease to the Payment Cap applied to future Giiant License Payments, as set forth in the original Giiant License Agreement. The amount of the reduction in the Giiant Milestone Payment as a result of the Giiant License Agreement Amendment is in the high six-digit range and the decrease in the Payment Cap is in the mid-six digit range. There were no other changes to the terms of the original Giiant License Agreement as a result of the Giiant License Agreement Amendment that would have a material impact on the Company's results of operations, financial position or future cash flows.

In the event that Giiant desires to sell or assign any rights to receive the Giiant License Payments, they 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, or (ii) a material breach by Giiant, that is not cured within the applicable notice period.

Giiant may unilaterally terminate the Giiant License Agreement only for a material breach by Company that is not cured within the applicable notice period provided however that upon the Payment Cap being achieved, that right will terminate and the Giiant License Agreement will become perpetual.

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. The Company records the expense reimbursements from Newsoara for any research and development or manufacturing activities it performs under the Newsoara Co-Development Agreement as a reduction to research and development expenses once the reimbursement amount is approved for payment by Newsoara.

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, 2024, the Company recognized no license revenue from Newsoara under the Newsoara Co-Development Agreement.

The Newsoara Co-Development Agreement will expire upon 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 related to LB1148. 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, 2024, 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, 2024, there were no sublicense fees and approximately $16,000 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 the Company is not cured within 60 days, (ii) the Company files a claim asserting the Regents licensed patent rights are invalid or unenforceable,

or (iii) the Company files for bankruptcy. The Company also has 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.

On October 22, 2024, Alto announced that its Phase 2b study of ALTO-100 in patients with major depressive disorder (MDD) did not meet its primary endpoint. Notwithstanding, ALTO-100 is being evaluated as an adjunctive treatment in a Phase 2b study in bipolar depression with topline data expected in 2026. Upon the enrollment of a patient in a Phase 3 clinical trial of ALTO-100, if it occurs, 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 preclinical 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.

8. Commitments and Contingencies

Corporate Office Lease

The Company is party to a non-cancelable facility operating lease (the "Corporate Office Lease") of office space for its corporate headquarters 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.

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, 2024, the Company recognized an operating right-of-use asset related to the Corporate Office Lease in the amount of $84,000, which included in Operating lease right-of-use asset in the consolidated balance sheets, and an operating lease liability of $90,000, all of which is included in Current portion of operating lease liability in the consolidated balance sheets. As of December 31, 2024, the total remaining future minimum lease payments associated with the Corporate Office Lease of approximately $93,000, including imputed interest of $3,000 calculated using a discount rate of 10.75%, will be paid over the remaining lease term of approximately 0.7 years. Other than the remaining maturities of the operating lease liability due in 2025 related to Corporate Office Lease, as of December 31, 2024 the Company has no maturities of operating lease liabilities in 2025 or thereafter.

The Company recognized operating lease expense associated with its Corporate Office Lease of approximately $130,000 for each of the years ended December 31, 2024 and December 31, 2023, respectively.

Insurance Financing Arrangement

In June 2024, the Company entered an agreement to finance insurance policies that renewed in May 2024. The financing arrangement entered in June 2024 has a stated annual interest rate of 8.42% and is payable over a 9-month period with the first payment payable on June 30, 2024. The insurance financing arrangement is secured by the associated insurance policy. As of December 31, 2024 and December 31, 2023, the aggregate remaining balance under the Company's insurance financing arrangement was approximately $0.1 million and $0.2 million, respectively, and is included in Insurance financing debt in the consolidated balance sheets.

Other than the remaining insurance financing arrangement payments due in 2025, as of December 31, 2024 the Company has no other minimum debt payments required in 2025 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 its lead drug candidate, PALI-2108.

The Company recognized no restructuring expenses related to either the 2022 Cost-Reduction Plan or the 2023 RIF for the year ended December 31, 2024. For the year ended December 31, 2023, the Company recognized restructuring costs of approximately $0.2 million associated with the 2023 RIF, consisting of severance and benefits payments pursuant to employment agreements and the execution of severance and release agreements. Total expenses related to the 2022 Cost-Reduction Plan and the 2023 RIF through December 31, 2024 were approximately $0.4 million and $0.2 million, respectively 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,	
	2024	2023
Balance as of the beginning of year	$ 131	$ 180
Net accrual adjustments	(3)	225
Cash paid	(128)	(274)
Balance as of the end of year	$ —	$ 131

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, 2024, 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.

9. Net Loss Per Share

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 any 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.

Pursuant to the December 2024 Offering the Company issued 3,120,688 prefunded warrants with such prefunded warrants being immediately exercisable, having an exercise price of $0.0001 per share, and a perpetual term (See Note 5, *Stockholders' Equity*). The prefunded warrants were determined to be equity-classified in accordance with ASC 480 and ASC 815. As of December 31, 2024, 2,027,000 of these prefunded warrants remained unexercised. Pursuant to the guidance of ASC 260-10, the Company concluded that because the equity-classified prefunded warrants were immediately exercisable for little or no cash consideration due to the non-substantive stated exercise price, all the necessary conditions for issuance of the underlying common shares had been met when the prefunded warrants were issued. Therefore, the underlying common shares have been included in the denominator for both the calculation of basic and dilutive net loss per common share for the year ended December 31, 2024.

As the Company was in a net loss position for all periods presented, basic and diluted net loss per common share for both the years ended December 31, 2024 and December 31, 2023 was calculated under the if-converted and treasury stock methods. For both the years ended December 31, 2024 and December 31, 2023, basic and diluted net loss per common share were the same as all common stock equivalents other than the prefunded warrants discussed above were anti-dilutive for both years.

In computing the basic and diluted net loss available to common stockholders for the year December 31, 2023, 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 value of the down round feature on equity classified warrants for the year ended December 31, 2024 was determined to be immaterial.

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,	
	2024	2023
Basic and diluted net loss per common share:		
Net loss	$ (14,438)	$ (12,300)
Adjustment to record the impact of exercise price reset on outstanding warrants related to down round provisions	—	(16)
Net loss available to common stockholders - basic and diluted	$ (14,438)	$ (12,316)
Weighted average shares used in calculating basic and diluted net loss per common share	1,416,471	456,014
Basic and diluted net loss per common share	$ (10.19)	$ (27.01)

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,	
	2024	2023
Stock options	50,674	44,276
Restricted stock units and performance stock units	2,952	28,339
Warrants for common stock	4,718,213	272,211
Series A Convertible Preferred Stock	8	8
Total	4,771,847	344,834

10. 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.

11. Income Taxes

The Company has no current or deferred income taxes as of December 31, 2024 and December 31, 2023.

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

	Year Ended December 31,	
	2024	2023
Statutory federal income tax rate of 21 percent applied to loss before income taxes	$ (3,032)	$ (2,583)
State taxes - net of federal benefit	(660)	(810)
Meals and entertainment	1	3
Warrants	—	(12)
Stock-based compensation	371	522
Other non-deductible expenses	16	(89)
Expiration of tax attributes	184	484
Change in tax rate	(346)	207
Other	(49)	—
Valuation allowance	3,515	2,278
	$ —	$ —

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,	
	2024	2023
Deferred tax assets:		
Accrued expenses	$ 122	$ 128
Depreciation	82	245
Lease liability	25	55
Net operating loss carryforwards	27,383	24,703
Stock compensation	1,216	1,470
Capitalized research and development costs	3,771	2,515
Total deferred tax assets	32,599	29,116
Deferred tax liabilities:		
Operating right-of-use asset	23	52
Prepaid expense	108	112
Total deferred tax liabilities	131	164
Net deferred tax asset	32,468	28,952
Valuation allowance	(32,468)	(28,952)
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 2025 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.

The valuation allowance increased $3.5 million during the year ended December 31, 2024 and $2.3 million during the year ended December 31, 2023.

As of December 31, 2024, the Company had federal net operating loss ("NOL") carryforwards of approximately $109.4 million and state NOL carryforwards of approximately $63.0 million. Of the total amount of federal NOL carryforwards, approximately $77.8 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 $31.7 million will begin to expire in 2025 unless previously utilized. The Company's state NOL carryforwards as of December 31, 2024 may be carried forward for 20 years, and will expire at various dates between 2027 and 2044.

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 California. Because of the NOLs, the Company is subject to U.S. federal examinations for tax years 2006 and forward, and for examinations from state taxing authorities for tax years 2008 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, 2024 and 2023.

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, 2024 and 2023, 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.

12. Segment Information

The Company operates as one operating and reportable segment, focused on the research and development of novel therapeutics for patients, including the advancement of PALI-2108 through clinical trials. The Company did not aggregate multiple operating segments into its one operating segment. The Company's chief operating decision maker ("CODM") is its chief executive officer.

The Company's CODM uses Net loss that is reported on the consolidated statements of operations and comprehensive loss for the purposes of assessing performance, allocating resources and planning, monitoring budget versus actual results, and forecasting future periods. The Company's CODM views specific program spend within research and development expenses, research and development spend that is not allocated to specific programs, as well as general and administrative expenses as significant segment expenses. As a pre-product revenue company, the CODM considers budget versus actual results for expenses that are deemed significant and cash forecast models for assessing performance and to decide the level of investment in the Company's operating and capital allocation activities.

In addition to significant expense categories included in Net loss, the Company regularly provides disaggregated significant expense amounts that comprise operating expenses to the CODM to assist when managing the Company's single reporting segment. A reconciliation to consolidated operating expenses as our single segment operating loss for the years ended December 31, 2024 and 2023 is included in the table below (in thousands):

	Year Ended December 31,	
	2024	2023
PALI-2108 program expenses	$ 7,070	$ 736
Legacy program expenses	155	3,303
Other research and development expenses	2,156	2,987
Other general and administrative expenses	5,478	6,069
Restructuring costs	—	225
Total operating expenses	$ 14,859	$ 13,320

PALI-2108 program expenses are those expenses directly related with the development of the Company's only asset currently under development, PALI-2108. Legacy program expenses are those expenses directly related to its legacy assets, primarily LB1148, which the Company ceased developing in August of 2023. Other research and development expenses includes primarily employee-related expenses and research and development facility expenses, which are not allocated to specific programs, and non-cash losses associated with changes in the fair value of the Company's contingent consideration obligation. For the year ended December 31, 2023, Other research and development expenses also includes the initial fair value of the contingent consideration obligation and transaction-related costs related to the Giiant License Agreement (See Note 4, Fair Value Measurements). Other general and administrative expenses consist primarily of salary and employee-related costs and benefits, professional fees for legal, investor and public relations, accounting and audit services, insurance costs, director and committee fees, and general corporate expenses. Excluded from other general and administrative expenses are intellectual property expenses and business development expenses that are allocated to program expenses.

For the years ended December 31, 2024 and 2023, the other segment items that the Company used to aggregate Total operating expenses to arrive at Net Loss as shown on the consolidated statement of operations include, if applicable, License Revenue, Interest expense and Other income, net.

The Company does not provide separate segment asset information to the CODM because the CODM does not review segment assets at a different asset level or category than those shown on the consolidated balance sheets. All of the Company’s assets are located in the U.S.

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, 2024. Based upon the evaluation, our Chief Executive Officer concluded that, as of December 31, 2024, 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 U.S. GAAP.

Material Weakness in Internal Control over Financial Reporting

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, we 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 Committee of Sponsoring Organizations 2013 Framework. If not remediated, or if we identify further material weaknesses in its 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 its reporting and financial obligations.

As described below, management has begun to execute remediation actions to address the material weakness and further actions are ongoing as of December 31, 2024. The material weakness continues to be present as of December 31, 2024.

Remediation Efforts related to the Material Weakness

Management, with oversight from our Audit Committee of the Board, 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)We will continue to hire additional finance and accounting employees with appropriate experience, certification, education and training.

(ii)We have 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 tested for operating effectiveness.

(iii)We are in the process of updating our 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)We have identified and remediated all segregation of duties deficiencies in its current control environment. The controls established to remediate all segregation of duties deficiencies identified will be documented and tested for operating effectiveness.

(v)We are in the process of implementing additional key internal controls designed to address the potential risks identified in its key business processes. Once fully implemented, these controls will be tested for operating effectiveness.

We believe that the implementation and testing of the above steps will allow us to make progress on addressing a number of the deficient controls within our internal control environment, which will help facilitate the remediation of the material weakness identified above. As we continue to evaluate and work to improve our internal control over financial reporting, we will take additional measures to address control deficiencies, or we may modify certain of the remediation measures described above. However, we require additional time to complete the design and implementation of our 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, 2024 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 21, 2025 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	Chief Executive Officer, Chief Financial Officer, and Director	67	2021
Mitchell Jones, MD	Chief Medical Officer	48	2023
Independent Directors			
Donald Williams	Director, Chair	66	2021
Margery Fischbein	Director	69	2024
Binxian Wei	Director (Series A Preferred)	54	2019

J.D. Finley, has served as our Chief Financial Officer since April 2021, and Chief Executive Officer since October 2022. He was appointed to our Board in February 2023. 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 Chief Financial Officer 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, Inc. Mr. Finley received a B.A. in business administration from Boise State University and an M.S. in Taxation from the University of Denver. Our 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 our Board.

Mitchell Jones, M.D., Ph.D., has served as the our Chief Medical Officer since September 2023. Dr. Jones has over 17 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 our Board since April 2021, and became chairman of our Board in February 2024. Previously, Mr. Williams served on the LBS Board since May 2019. Mr. Williams has also served as a member of the board of directors of Akari Therapeutics PLC from 2016 until 2024, a member of the board of directors of Forte Biosciences, Inc. from 2020 until 2024, and a member of the board of directors of ImpediMed, Inc. from 2017 until 2023. 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. Our Board believes Mr. Williams' experience as a board member and public accountant in the life sciences industry qualifies him to serve on the Board.

Margery Fischbein, has served as a member of our Board since May 2024. Ms. Fischbein has been a Managing Director, Healthcare, at Cassel Salpeter & Co., an independent investment banking firm, since January 2020. Previously, from 2017 through 2019, Ms. Fischbein was Managing Director, Healthcare Investment Banking, at Seaport Global. She also serves on the Board of CytoDel Inc., a private biotechnology company. Ms. Fischbein received a BA degree in economics from Harvard University and an MBA from Harvard Business School. She is a Board Member Emeritus of the Harvard Business School Club of New York. Our Board believes that Ms. Fischbein's experience in investment banking and the healthcare industry qualifies her to serve on our Board.

Binxian Wei, has served as a member of our 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 the active pharmaceutical ingredient 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. Mr. 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. Our Board believes Mr. Wei's experience as a board member and pharmaceutical experience qualify him to serve on our Board.

Board Meetings

During 2024, the Board held seven meetings (including regularly scheduled and special meetings) and acted through unanimous written consent nine times. All of our directors, attended at least 75% of all meetings of the general Board and each respective committee on which such director serves during the year ended December 31, 2024. The Board currently holds regularly scheduled meetings and calls for special meetings or acts through unanimous written consents as necessary. Meetings of the Board may be held in-person, virtually or telephonically. Directors are expected to attend all board meetings and meetings of the committees of the board on which they serve and to spend the time needed and meet as frequently as necessary to properly discharge their duties. As required under applicable Nasdaq listing standards, in 2024, our independent directors met four times in scheduled executive sessions at which only independent directors were present. Information with regard to committee meetings and written consent is provided for below in the section of this Annual Report on Form 10-K entitled "Committees." Although attendance of meetings is encouraged, we do not have a formal policy regarding attendance by directors at board and committee meetings.

Attendance at 2024 Annual Meeting

Although we do not have a formal policy regarding attendance by members of our Board at annual meetings of stockholders, we encourage, but do not require, directors and nominees for director to attend. All of our directors attended the annual meeting of stockholders in 2024.

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 of the Board.

The Board presently has four 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 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 the 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 of directors. 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, (ii) Ms. Fischbein and (iii) 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.

Board Leadership Structure

The Board has an independent chair, Mr. Williams, who has authority, among other things, to call and preside over Board meetings, including meetings of the independent directors, to set meeting agendas and to determine materials to be distributed to the Board. Accordingly, the Board Chair has substantial ability to shape the work of the Board. The Company believes that separation of the positions of Board Chair and Chief Executive Officer reinforces the independence of the Board in its oversight of the business and affairs of the Company. In addition, the Company believes that having an independent Board Chair creates an environment that is more conducive to objective evaluation and oversight of management's performance, increasing management accountability and improving the ability of the Board to monitor whether management's actions are in the best interests of the Company and its shareholders. As a result, the Company believes that having an independent Board Chair can enhance the effectiveness of the Board as a whole.

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

Delinquent Section 16(a) Reports

Name of Reporting Person	Type of Report and Number Filed Late	No. of Transactions Reported Late
Stephanie C. Diaz	Form 4	1 [(1)]
Cristina Csimma, PharmD, MHP	Form 4	1 [(1)]
Robert Trenschel, D.O.	Form 4	1 [(1)]

(1)Filed Form 4 on February 13, 2024.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires the Company's directors and executive officers, and persons who own more than ten percent of a registered class of the Company's equity securities, to file with the SEC initial reports of

ownership and reports of changes in ownership of common stock and other equity securities of the Company. Officers, directors and greater than ten percent shareholders are required by SEC regulation to furnish the Company with copies of all Section 16(a) forms they file.

We believe that during the fiscal year ended December 31, 2024, our directors, executive officers, and greater than 10% stockholders complied with all applicable Section 16(a) filing requirements. In making these statements, we have relied upon a review of the copies of Section 16(a) reports furnished to us and the written representations of our directors, executive officers, and greater than 10% stockholders.

Code of Ethics

We have adopted the Palisade Bio, Inc. Code of Business Conduct and Ethics (the "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 Ethics Code or grant any waiver from a provision of the Ethics Code to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website.

Insider Trading Policy

We have adopted an Insider Trading Policy governing the purchase, sale, and/or other dispositions of our securities by directors, officers, employees, and the Company itself that is reasonably designed to promote compliance with insider trading laws, rules and regulations, and any listing standards applicable to the Company. A copy of the policy can be found as Exhibit 19.1 to this Annual Report on Form 10-K.

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 standing committees: an Audit Committee, a Compensation Committee, and a Governance and Nominating Committee. The following table provides, as of March 21, 2025, membership for each of the Board committees:

Director	Audit Committee	Compensation Committee	Governance and Nominating Committee
Donald A. Williams	C	X	C
Margery Fischbein	X	C	X
Binxian Wei	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 the Company's accounting and

financial reporting processes and audits of its 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 the Company's 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 the Company's cyber security risks and assessments; and meets to review the Company's annual audited financial statements and quarterly financial statements with management and the independent auditor, including a review of the Company's disclosures under "Management's Discussion and Analysis of Financial Condition and Results of Operations."

The Audit Committee is currently composed of three directors: Mr. Williams (Chair), Ms. Fischbein, and Mr. Wei. The Audit Committee met five times and acted through unanimous written consent one time during the year ended December 31, 2024. The Board has adopted a written Audit Committee charter that is available to stockholders on our website at www.palisadebio.com by clicking on "Investors & News", the clicking "Corporate Governance", then "Governance Documents." 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 the Company's 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.

Compensation Committee

The Compensation Committee is currently composed of two directors: Ms. Fischbein (Chair) and Mr. Williams. 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 listing standards), 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 Compensation Committee met two times and acted through unanimous written consent five times during the year ended December 31, 2024. The Board has adopted a written Compensation Committee charter that is available to stockholders on our website at www.palisadebio.com by clicking on "Investors & News," the clicking "Corporate Governance," then "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) the overall compensation strategy and policies for the Company, 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 the Company's long-term strategic goals, relevant to the Company's compensation plans and programs;
- evaluating and approving (or, if it deems appropriate, making recommendations to the Board regarding) the Company's 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 the Company's compensation policies and practices, as applicable, to all the Company's employees, and assessing whether risks and consequences arising from the

Company's compensation policies and practices for the Company's 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 the Company's 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 Company's 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. The 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, 2024, 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 the Company's existing compensation strategy and practices in supporting and reinforcing our long-term strategic goals (including through a peer group analysis); and

- assist in refining the Company's 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 fourth quarter of the year and the first quarter of the following 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 2024 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 three directors: Mr. Williams (Chair), Ms. Fischbein, 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 his or her independent judgment. The Governance and Nominating Committee met one time and acted through unanimous written consent two times during the year ended December 31, 2024. The Board has adopted a written Governance and Nominating Committee charter that is available to stockholders 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.

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 the Company's 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, the operating requirements of the Company and the long-term interests of 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 the Company's 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 the Company's 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 fiscal year ended December 31, 2024, were as follows:

- J.D. Finley, our Chief Executive Officer and Chief Financial Officer; and
- Mitchell Jones, M.D., Ph.D., our Chief Medical 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, 2024 and 2023.

Summary Compensation Table

Name and Principal Position	Year	Salary ($)	Stock Awards [1] ($)	Option Awards [1] ($)	Non-Equity Incentive Plan Compensation [2] ($)	All Other Compensation ($)	Total ($)
J.D. Finley	2024	542,000	— [3]	— [3]	271,000	—	813,000
Chief Executive Officer and Chief Financial Officer	2023	520,333	264,541	221,226	271,000	—	1,277,100
Mitchell Jones, M.D., Ph.D.	2024	415,000	— [3]	— [3]	166,000	—	581,000
Chief Medical Officer	2023	135,189	54,247	49,563	166,000	53,025 [4]	458,024

(2)In accordance with SEC rules, reflects the aggregate grant date fair value of stock awards and option awards granted to our named executive officers in the applicable fiscal years, as determined in accordance with the provisions of FASB ASC Topic 718. See Note 6 of the notes to our audited consolidated financial statements included in the Company's Annual Report on Form 10-K filed with the SEC on March 26, 2024 with respect to grants in 2023.

(3)The amounts in this column reflect annual cash bonuses paid with respect to the applicable fiscal year, based on corporate and individual performance.

(4)The RSU and option awards granted to each named executive officer in November 2023 were intended to provide retention and compensation for service in 2024; however, because the grants were approved in November 2023, no amounts are disclosed for 2024 RSU or option awards for the named executive officers.

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

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 our 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.

Base Salary

The base salaries of our named executive officers are reviewed from time to time and adjusted when our Board or compensation committee determines an adjustment is appropriate. The base salaries of Mr. Finley and Dr. Jones were $542,000 per annum and $415,000 annum, respectively, in 2024. Prior to 2024, Mr. Finley's base salary in 2023 was $490,000 per annum, and increased to $542,000 per annum effective June 1, 2023 with his appointment to our Chief

Executive Officer. Dr. Jones was appointed Chief Medical Officer effective September 5, 2023 with a base salary of $415,000.

Bonus Opportunity

Our 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 our Board or the Compensation Committee, including pursuant to an annual incentive plan or similar plan adopted by our Board, if any. Any such bonus would be paid after the close of the fiscal year and after determination by our 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. Our Board (or the Compensation Committee thereof) may review an executive officer's annual performance bonus amount for adjustment from time to time. The 2024 annual discretionary cash incentive bonus targets were 50% of base salary for Mr. Finley and 40% of base salary for Dr. Jones.

In 2024, 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 2024.

Equity Compensation

We offer stock options and RSUs to our employees, including our named executive officers, as the long-term equity-based incentive component of our compensation program. Our stock options allow our employees to purchase shares of our common stock at a price equal to the fair market value of our common stock on the date of grant. Our Board or the Compensation Committee determines the fair market value of our common stock based on the closing price of our common stock. Generally, our stock options and RSUs granted to our named executive officers vest in equal amounts on a quarterly basis over three years from the date of grant, subject to continuous service.

The grants to our current named executive officers also provide for accelerated vesting of all unvested option shares and RSUs in the event we undergo a change in control and the named executive officer is subject to an involuntary termination without cause within 12 months thereafter.

Previously, we granted to Mr. Finley 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 $48.00 or greater, and (b) 50% when such volume weighted average price of the Company's common stock over 20 consecutive trading days is $63.75 or greater. The market-based PSUs remain unvested.

For additional information regarding the equity awards currently held by our named executive officers, please see below under "Outstanding Equity Awards at Fiscal Year-End."

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.

Descriptions of each of the foregoing employment agreements are described below.

Finley Employment Agreement

Mr. Finley was appointed as our Chief Financial Officer in January 2021 pursuant to his amended and restated employment agreement dated January 22, 2021 ("Finley Employment Agreement"). Pursuant to the Finley Employment Agreement, Mr. Finley originally received an annual base salary of $400,000, with an annual target cash bonus of 40% of his base salary. Mr. Finley's base salary and annual target cash bonus have been increased several times since Mr. Finley was original appointed as our Chief Financial Officer, including in connection with his promotion to Chief Executive Officer, including most recently in June 2023, when his base salary was increased to $542,000 per annum and his annual target cash bonus was increased to 50% of his base salary. On September 25, 2024, we entered into an executive employment agreement (the "Amended Finley Employment Agreement"), which amended and restated the terms of the Finley Employment Agreement.

The Amended Finley Employment Agreement provides that if we terminate Mr. Finley without "Cause" or if Mr. Finley resigns for "Good Reason", each as defined in the Amended Finley Employment Agreement, except during the Change in Control Period (as defined below) Mr. Finley will be entitled to receive the following, subject to Mr. Finley signing and not revoking a general release of claims against us: (i) salary continuation and COBRA reimbursement for 12 months each and (ii) 12 months of vesting acceleration of equity grants subject to time based vesting.

In the event that we terminate Mr. Finley without "Cause" or if Mr. Finley resigns for "Good Reason" during the period beginning three months before and ending 12 months after a "Change in Control", as defined in the Amended Finley Employment Agreement (such period, the "Change in Control Period"), Mr. Finley will be entitled to receive the following, subject to Mr. Finley signing and not revoking a general release of claims against us: (i) salary continuation and COBRA reimbursement for 18 months each , (ii) full acceleration of all time-based equity awards, and (iii)an additional severance payment equal to his target bonus.

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.

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 months following the termination date.

In the event that we terminate Dr. Jones' employment without "Cause" or Dr. Jones resigns for "Good Reason" within the Change in Control Period, then Dr. Jones will be eligible to receive the following: (i) a lump sum payment equal to the sum of (x) 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 12 months, and (iii) 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.

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.

Equity Grant Policy

Equity awards are discretionary and are generally granted to our named executive officers the second month of the applicable fiscal year. In certain circumstances, our Compensation Committee may approve grants to be effective at other times. The Compensation Committee does not grant equity awards in anticipation of the release of material nonpublic information and we do not time the release of material nonpublic information based on equity award grant dates. No equity awards were granted to our named executive officers in 2024, as the equity awards granted in

November 2023 to our named executive officers were intended to provide retention and compensation for service in 2024.

Clawback Policy

Effective October 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. A copy of the Clawback Policy is included as Exhibit 97.1 to this our Annual Report on Form 10-K filed with the SEC on March 26, 2024.

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	Market value of shares of units of stock that have not vested	Equity incentive plan award: Number of unearned shares, units or other rights that have not vested [6]	Equity incentive plan awards: Market or payout value of unearned shares, units or other rights that have not vested [6]
			(#)	(#)	(#)	($)		(#)	($)	(#)	($)
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	(k)	(l)
J.D. Finley	ISO	6/12/2015	10	–		$ 1740.00	6/12/2025				
	ISO	11/10/2017	38	–		$ 1740.00	11/10/2027				
	ISO	11/18/2021	113	–		$ 1740.00	11/18/2031				
	ISO	11/21/2023	–	1,000		$ 8.85	11/21/2033				
	ISO	3/22/2019	4	–		$ 1740.00	3/22/2029				
	ISO	2/17/2022	–	7		$ 715.65	2/17/2032				
	ISO	6/11/2023	–	4,328		$ 24.00	6/11/2033				
	ISO	2/6/2023	–	1,588		$ 36.00	2/6/2033				
	ISO	3/22/2019	2	–		$ 1740.00	3/22/2029				
	ISO	2/19/2020	7	–		$ 1740.00	2/19/2030				
	NQ	3/22/2019	25	–		$ 1740.00	3/22/2029				
	NQ	3/22/2019	12	–		$ 1740.00	3/22/2029				
	NQ	4/27/2021	43	–		$ 1740.00	4/27/2031				
	NQ	11/18/2021	123	–		$ 1740.00	11/18/2031				
	NQ	2/6/2023	2,224	–		$ 36.00	2/6/2033				
	NQ	6/11/2023	4,950	621		$ 24.00	6/11/2033				
	NQ	3/22/2019	3	–		$ 1740.00	3/22/2029				
	NQ	11/10/2017	31	–		$ 1740.00	11/10/2027				
	NQ	2/19/2020	3	–		$ 1740.00	2/19/2030				
	NQ	11/21/2023	1000	1,000		$ 8.85	11/21/2033				
	NQ	6/12/2015	3	–		$ 1740.00	6/12/2025				
	NQ	3/22/2019	17	–		$ 1740.00	3/22/2029				
	NQ	2/17/2022	79	–		$ 715.65	2/17/2032				
	PRSU	2/6/2023								1,083 [7]	$ 1,787 [7]
Mitchell Jones M.D., Ph.D.	ISO	11/21/2023	736	1,474		$ 8.85	11/21/2033				
	NQ	9/5/2023	2,083	2,917		$ 10.35	9/5/2033				

(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 of continuous service, generally from the date of grant.

(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) The values shown are based on $1.65 per share, which was the closing price of our common stock on December 31, 2024, the last day of our most recent fiscal year.

(7) Performance restricted stock units vest (a) 50% when the volume weighted average price of our common stock over 20 consecutive trading days is $48.00, and (b) 50% when such volume weighted average price of our common stock over 20 consecutive trading days is $6.75, subject to the named executive's continuous service. In accordance with SEC rules, the number of performance restricted stock units in column (k) and the value of those PRSUs in column (l) reflects threshold performance assuming the volume weighted average price of our common stock achieves the $48.00 requirement over 20 consecutive trading days.

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% 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, 2024, 37,586 shares of our common stock were authorized for future grants under the 2021 EIP and there were an aggregate of 43,107 outstanding awards issued 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: (i) a sale of all or substantially all of our assets, (ii) the sale or disposition of more than 50% of our outstanding securities, (ii) a merger or consolidation

where we do not survive the transaction, or (iv) 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 stockholders 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, The 2021 ESPP permits eligible employees (including our named executive officers) while employed by the Company to purchase common stock through payroll deductions, which may not exceed $25,000 in a calendar year or 5,000 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 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% of the total number of shares of our common stock outstanding on December 31 of the preceding year, (2) 28,909 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, 2024, 19,086 shares of our common stock were authorized for future grants under the ESPP. A total of 2,256 shares of our common stock were purchased by employees under participation in the ESPP during the year ended December 31, 2024.

2021 Inducement Plan

Our 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, our Board amended the 2021 Inducement Plan to increase the number of common shares authorized under the plan from 1,000 to 66,666. 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 66,666 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, 2024, there were 52,941 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 10,079 outstanding awards issued under the 2021 Inducement Plan.

DIRECTOR COMPENSATION

Board Compensation Arrangements

Non-employee Director Compensation Policy

We have a compensation policy that is applicable to each member of our Board who is not also serving as an employee or consultant to the Company (the "Director Compensation Policy"). It was most recently amended in June 2024 with respect to the equity compensation payable to our non-employee directors, as further described below. Pursuant to our Director Compensation Policy, our non-employee directors 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 chair of the 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, Governance and Nominating Committee and 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 of the Audit Committee, Compensation Committee, Governance and Nominating Committee and Strategy and Finance Committee, respectively (the Strategy and Finance Committee was removed as a committee of our Board in February 2024).

Equity Compensation

Prior to June 2024, the equity compensation component of our Director Compensation Policy was not formalized and grants were made on an ad hoc policy. Based upon this policy, each non-employee director was also issued equity grants. In determining the size of such grants, the Compensation Committee would review the Company's market capitalization, equity compensation paid to directors of its peer group companies, and such other factors as the committee deemed appropriate. The goal of such ad hoc policy was to incentivize and retain directors while not causing the excessive dilution that a value-based policy would result in. Ad hoc grants could be made in the form of options, Restricted stock units, or a combination thereof. During the 2024 fiscal year, the Compensation Committee utilized this ad hoc policy to make an option grant to Ms. Fischbein on May 7, 2024 for 1,000 shares of the Company's common stock. This option vests in equal quarterly installments over a three year period from the date of grant, subject to Ms. Fischbein's continued service.

In June 2024, the Compensation Committee approved a formal equity compensation program for our non-employee directors, pursuant to which they receive the following initial and annual equity awards:

•Initial Equity Award — Each non-employee director joining our Board receives an option grant to purchase such number of shares of the Company's common stock equal to 200% of the Black-Scholes

value used to determine the most recent Annual Grant (as defined below) for non-employee directors, or such other amount as determined by the Compensation Committee at its sole discretion (the "Initial Grant"). The Initial Grant will (i) be issued on the date such director joins the Board, vest in equal quarterly installments over a three- year period of continued service, (iii) have a term of 10 years, and (iv) an exercise price equal to the closing price of the Company's common stock on the grant date (or the most recent closing price if not a trading day).

•Annual Equity Award— Following the conclusion of each regular annual meeting of shareholders, each continuing non-employee director receives an option grant to purchase such number of shares of the Company's common stock as determined by: (i) the Black-Scholes value of the 75th percentile of equity compensation granted to the non-employee directors of the Company's peer group most recently approved by the Compensation Committee or (ii) such lesser amount as determined by the Compensation Committee at its sole discretion (the "Annual Grant"). The Annual Grant will (i) be issued three days after the Company's annual meeting of shareholders, (ii) vest fully on the one year anniversary of the grant date, subject to continued service, (iii) have a term of 10 years, and (iv) an exercise price equal to the closing price of the Company's common stock on the grant date (or the most recent closing price if not a trading day).

All of the equity awards granted to our non-employee directors are granted pursuant to our 2021 EIP.

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. Mr. Finley does not participate in any of the foregoing director compensation given his service as an executive officer.

Compensation During 2024

The following table sets forth the total compensation of each person who served as a director during the year ended December 31, 2024, other than a director who also served as a named executive officer.

Name	Fees Earned or Paid in Cash ($)	Option Awards [1][2] ($)	Total ($)
Donald A. Williams [3]	106,875	7,842	114,717
Margery Fischbein [4]	44,918	14,474	59,392
Binxian Wei	53,393	7,842	61,235
James R. Neal [5]	11,466	—	11,466
Stephanie C. Diaz [6]	6,379	—	6,379
Mary Ann Gray, Ph.D. [7]	10,645	—	10,645
Cristina Csimma, PharmD, MHP [6]	5,050	—	5,050
Robert Trenschel, D.O. [6]	5,316	—	5,316

(1)The amounts in this column represent the aggregate grant date fair value of option awards granted to the non-employee director in 2024, computed in accordance with FASB ASC Topic 718. See Note 6 of the notes to our audited consolidated financial statements included in this Annual Report on Form 10-K for the fiscal year ended December 31, 2024.

(2)As of December 31, 2024, our non-employee directors serving on our Board in 2024 held the following options to purchase shares of the Company's common stock: Mr. Williams -3,432 options; Ms. Fischbein - 3,100 options; and Mr. Wei - 3,260 options.

(3)Mr. Williams was appointed chairman of the Board in February 2024.

(4)Ms. Fischbein was appointed to the Board in May of 2024.

(5)Effective February 9, 2024, James R. Neal resigned as a member of our Board.

(6)Effective February 8, 2024, Stephanie C. Diaz, Dr. Cristina Csimma, and Dr. Robert Trenschel resigned as members of our Board.

(7)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, 2024. 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 EIP [1]	43,107	43.95	37,586
2013 Plan [2]	440	14,835.89	-
ESPP [3]	-	-	19,086
Equity compensation plans not approved by security holders			
Palisade 2021 Inducement Plan [4]	10,079	14.26	52,941
Total	53,626	166.48	109,613

(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) Although certain awards under the plan are outstanding, no additional grants will be made pursuant to the 2013 Plan.

(3) 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) 28,909 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.

(4) The 2021 Inducement Plan is a non-shareholder approved plan which was adopted by our Board on November 18, 2021 and amended on August 7, 2023. It is intended to satisfy the requirements of Nasdaq Listing Rule 5635(c)(4) or any successor thereto. Nonstatutory stock options, stock appreciation rights, restricted stock, restricted stock units, performance-based awards and other forms of awards valued on common stock may be granted under the 2021 Plan to new employees of the Company. The maximum number of shares of common stock that may be granted under the 2021 Inducement Plan is 66,000 shares of common stock. All option grants made pursuant to the 2021 Inducement Plan must have an exercise price per share of no less than 100% of the fair market value per share of our common stock on the grant date. Our Board may impose vesting conditions on each option or other equity incentive award granted pursuant to the 2021 Inducement Plan. Awards under the 2021 Plan that are forfeited, redeemed or repurchased by the Company generally are returned to the pool of shares of common stock available for issuance under the 2021 Inducement Plan.

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, 2025 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 4,396,646 shares of our common stock outstanding as of March 17, 2025. 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		
Armistice Capital, LLC [2]	285,417	6.49 %
Directors and Named Executive Officers		
Donald Williams [3]	5,078	*
Binxian Wei [4]	2,015	*
Margery Fischbein [5]	333	*
J.D. Finley [6]	27,980	*
Mitchell Jones, M.D., Ph.D. [7]	9,690	*
All directors and executive officers as a group (5 persons) [8]	45,096	**1.02 %**

* 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 Forms 4, 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, restricted stock units, and convertible securities that are currently exercisable or exercisable within 60 days of March 15, 2025 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, restricted stock units, 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 1,514,292 shares of common stock outstanding on March 15, 2025, 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 285,417 shares of common stock as reported by Armistice Capital, LLC on Schedule 13G, filed with the SEC on November 14, 2024. The address of beneficial owner is 510 Madison Avenue, 7th Floor, New York, NY 10022. Excludes common stock purchase warrants and pre-funded warrants held by Armistice Capital, LLC that are subject to beneficial ownership limitations.

(3) Includes (i) 3,728 shares of common stock and (ii) 1,350 shares of common stock underlying stock options.

(4) Includes (i) 855 shares of common stock and (ii) 1,160 shares of common stock underlying stock options.

(5) Margery Fischbein was appointed to the Board on May 7, 2024. Includes 333 shares of common stock underlying options.

(6) Consists of (i)(a) 13,472 shares of common stock held by Mr. Finley, (b) 134 shares of common stock that may be acquired pursuant to the exercise of outstanding warrants held by Mr. Finley, (c) 14,321 shares of common stock underlying options held by Mr. Finley, (ii)(a) 51 shares of common stock held by FCW Investments LLC, and (b) 2 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 2,166 performance stock units (PSUs), which vest based on volume weighted average trading price of the Company's common stock.

(7) Includes (i) 3,852 shares of common stock, and (ii) 5,838 shares of common stock underlying options.

(8) Includes the securities described in footnotes (3)-(7) 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 exceed the lesser of (a) $120,000 or (b) 1% of the average of our total assets for the fiscal years ended December 31, 2024 and 2023. Transactions involving compensation for services provided to the us as an employee, director, consultant or similar capacity by a related person are not covered by this policy. A related person is any of our executive officers, directors, or more than 5% stockholder, 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 us 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 us, (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.

Certain Related Party Transactions

Other than compensation arrangements for our directors and executive officers, which are described above under the heading "Executive Compensation" and "Director Compensation" and except as set forth below, there were no transactions since January 1, 2023 to which we were a party or will be a party, in which:

- 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, 2024 and 2023; and

•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.

The proposed or undertaken transactions are:

- On January 3, 2023, we granted J.D. Finley, our Chief Executive Officer and Chief Financial Officer, 349 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 3,813 shares of our common stock valued at approximately $87,853, having an exercise price of $36.00 per share, a term of 10 years, and which vests quarterly over a three year period (ii) 2,780 restricted stock units valued at approximately $100,080 which vests in 12 equal installments quarterly over a three year period, and (iii) 2,166 performance restricted 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 $48.00, and (b) 50% when such volume weighted average price of our common stock over 20 consecutive trading days is $63.75. All of the grants issued to Mr. Finley were issued on a conditional basis, and were 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 ("COO"): (i) an option to purchase 800 shares of common stock valued at approximately $18,431, having an exercise price of $36.00 per share, a term of 10 years, and which vests quarterly over three years (ii) 533 restricted stock units valued at approximately $21,120 which vests in 12 equal installments quarterly over a three year period, and (iii) 1,193 performance restricted 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 $48.00 and (b) 50% when such volume weighted average price of our common stock over 20 consecutive trading days is $63.75. All of the grants issued to Mr. McRae were issued on a conditional basis, and were 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 50,421 shares of our common stock at a purchase price per share of $39.60 to certain institutional and accredited investors. In a concurrent private placement, we also sold (i) 30,349 unregistered shares of common stock, (ii) 70,744 prefunded warrants to purchase common stock with a perpetual term and exercise price of $0.0015 per share, and (iii) 151,514 unregistered shares of common stock purchase warrants with a term of five (5) years and an exercise price of $39.60 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) 25,210 shares in the registered offering and (ii) in the concurrent private placement: (a) 5,076 unregistered shares of our common stock, (b) 45,470 prefunded warrants, and (c) 75,757 warrants to purchase common stock in exchange for an aggregate of $2,999,930.11.

- Effective May 15, 2023, Robert McRae, our then 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 and 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 9,900 shares of our common stock with a term of 10 years and an exercise price of $24.00 per share,

valued at $151,978 on the grant date and (ii) 4,446 restricted stock units valued at $106,720. Each of the options and restricted stock units granted to Mr. Finley vest in 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 our non-employee members of the Board of Directors, as supplemental grants, an aggregate of: (i) options to purchase 5,158 shares of common stock with a term of 10 years and an exercise price of $24.00 per share and (ii) 2,756 restricted stock units. Each of the grants vests fully on the one year anniversary of the grant date. The aggregate options were valued at $78,136 and the aggregate restricted stock units were valued at $66,120. 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 5,000 shares of common stock with a term of 10 years and an exercise price of $10.35 per share and (ii) 3,646 restricted stock units. The options vest quarterly over three years from the grant date and the restricted stock units vest as follows: (a) 303 shares on November 6, 2023, and (b) the remaining 3,343 shares vest over 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 the 2021 Inducement Plan.

- On November 21, 2023, we granted J.D. Finley, our CEO and CFO, 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 3,000 shares of common stock with a term of 10 years and an exercise price of $8.85 per share, valued at $22,114 on the grant date and (ii) 2,533 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 EIP, which occurred upon the annual evergreen share increase on January 1, 2024: (i) options to purchase 2,210 shares of common stock with a term of 10 years and an exercise price of $8.85 per share, valued at $16,296 on the grant date and (ii) 1,866 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.

- On November 21, 2023, we granted to each of the non-employee members of the Board of Directors, as supplemental grants: (i) options to purchase 458 shares of common stock with a term of 10 years and an exercise price of $8.85 per share and (ii) 388 restricted stock units. Each of the grants vests fully on the one 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, 2024 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 3,162 of our common stock shares upon vesting of outstanding restricted stock units and extended the exercise period for an aggregate of (i) 2,896 options issued on June 11, 2023 having an exercise price of $24.00 per share and a term of 10 years and (ii) 1,832 options issued on November 21, 2023, having an exercise price of $8.85 per share and a term of 10 years.

- On May 7, 2024, we granted Margery Fischbein, upon her appointment to serve on the Board, options to purchase 1,000 shares of common stock with a term of ten years and an exercise price of $7.90 per share. The options vest in twelve quarterly installments over a three (3) year period. The options were valued at $6,632 on the date of issuance and were issued from our 2021 EIP.

- On July 11, 2024, we granted each of our three non-employee Board members, pursuant to our non-employee director compensation plan, options to purchase 2,100 shares of common stock with a term of ten years and an exercise price of $4.49 per share. The options vest fully on the one year anniversary of the grant date. The options were valued at $23,527.23 in the aggregate on the date of issuance and were issued from our 2021 EIP.

- On May 28, 2024, we fully accelerated the vesting of an aggregate of (i) 7,068 restricted stock units held by J.D. Finley, our Chief Executive Officer and Chief Financial Officer and (ii) 4,290 restricted stock units held by Dr. Mitchell Jones, our Chief Medical Officer.

- On September 25, 2024, we entered into a revised employment agreement with J.D. Finley, our chief executive and chief financial officer. Pursuant to the terms of the employment agreement, Mr. Finley (i) receives a base salary of $542,000 per year, (ii) is eligible to receive an annual cash bonus based on the achievement of certain performance goals with a target of up to 50% of his base salary and (iii) is eligible to receive an annual market-based stock option grant as determined by the Board

- On February 11, 2025, we granted J.D. Finley, our Chief Executive Officer and Chief Financial Officer, (i) options to purchase 47,000 shares of our common stock with a term of 10 years and an exercise price of $1.13 per share, valued at approximately $47,400 on the grant date and (ii) 40,000 restricted stock units valued at approximately $45,200. The options to purchase our common stock granted to Mr. Finley vest in 12 equal installments on a quarterly basis over three years. The restricted stock units granted to Mr. Finley vest in 3 equal installments on a yearly basis over three years. The equity grants were issued from our 2021 EIP.

- On February 11, 2025, we granted Mitchell Jones, our Chief Medical Officer, (i) options to purchase 29,000 shares of our common stock with a term of 10 years and an exercise price of $1.13 per share, valued at approximately $29,200 on the grant date and (ii) 24,000 restricted stock units valued at approximately $27,120. The options to purchase our common stock granted to Dr. Jones vest in 12 equal installments on a quarterly basis over three years. The restricted stock units granted to Dr. Jones vest in 3 equal installments on a yearly basis over three years. The equity grants were issued from our 2021 EIP.

Item 14. Principal Accounting Fees and Services.

Principal Accountant Fees and Services

The following table represents aggregate fees billed to us for services performed by our independent registered public accounting firm, Baker Tilly US, LLP, New York, NY, PCAOB ID #23 (“Baker Tilly”).

	Year Ended December 31,	
	2024	2023
Audit Fees [1]	$ 454,213	$ 422,500
Audit-related Fees	—	—
Tax Fees	—	—
All Other Fees	—	—
Total Fees	$ 454,213	$ 422,500

(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 and annual report on Form 10-K, reviews of our current reports on Form 8-K, services rendered in connection with SEC registration statements, and related services that are normally provided in connection with regulatory filings or engagements.

All fees described above were pre-approved by our Audit Committee.

Pre-Approval Policies and Procedures

Our Audit Committee has adopted a policy and procedures for the pre-approval of audit and non-audit services rendered by the Company’s independent registered public accounting firm, Baker Tilly. The policy generally pre-approves specified services in the defined categories of audit services, audit-related services and tax services up to specified amounts. Pre-approval may also be given as part of our Audit Committee’s approval of the scope of the

engagement of the independent auditor or on an individual, explicit, case-by-case basis before the independent auditor is engaged to provide each service. The pre-approval of services may be delegated to one or more of our Audit Committee's members, but the decision must be reported to the full Audit Committee at its next scheduled meeting.

Our Audit Committee has determined that the rendering of services other than audit services by Baker Tilly is compatible with maintaining the principal accountant's independence.

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 Preferences, Rights and Limitations 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).
3.6	Amendment to the Amended and Restated Certificate of Incorporation of Palisade Bio, Inc. effective April 5, 2024 (Incorporated by reference to Exhibit 3.01(i) to the Registrant's Current Report on Form 8-K, filed with the SEC on April 5, 2024).
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 Common Stock Purchase Warrant from August 2017 Public Offering (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).
4.6	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)
4.7	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)
4.8	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)
4.9	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)
4.10	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)
4.11	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)

4.12	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)
4.13	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)
4.14	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)
4.15	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)
4.16	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)
4.17	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).
4.18	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).
4.19	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).
4.20†	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).
4.21	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).
4.22	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).
4.23	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).
4.24	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).
4.25	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).
4.26	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).
4.27	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).
4.28	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).
4.29	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).
4.30	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).

4.31	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).
4.32	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).
4.33	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).
4.34	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).
4.35	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).
4.36	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).
4.37	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).
4.38	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).
4.39	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).
4.40	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).
4.41	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).
4.42	Form of Prefunded Common Stock Warrant issued in May 2024 Private Placement (Incorporated by reference to Exhibit 4.01 to the Registrant's Current Report on Form 8-K filed with the SEC on May 3, 2024).
4.43	Form of Common Stock Warrant issued in May 2024 Private Placement (Incorporated by reference to Exhibit 4.02 to the Registrant's Current Report on Form 8-K filed with the SEC on May 3, 2024).
4.44	Form of Placement Agent Warrant issued in May 2024 Private Placement (Incorporated by reference to Exhibit 4.03 to the Registrant's Current Report on Form 8-K filed with the SEC on May 3, 2024).
4.45	Form of Prefunded Common Stock Warrant issued in December 2024 Underwritten Public Offering (Incorporated by reference to Exhibit 1.01 to the Registrant's Current Report on Form 8-K filed with the SEC on December 16, 2024).
4.46	Form of Five-Year Common Stock Purchase Warrant issued in December 2024 Underwritten Public Offering (Incorporated by reference to Exhibit 1.01 to the Registrant's Current Report on Form 8-K filed with the SEC on December 16, 2024).
4.47	Form of Warrant Agency Agreement by and between Palisade Bio, Inc. and Equiniti Trust Company LLC (Incorporated by reference to Exhibit 1.01 to the Registrant's Current Report on Form 8-K filed with the SEC on December 16, 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 30, 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 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 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 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).
10.45	Form of Securities Purchase Agreement entered into pursuant to the May 2024 Private Placement (Incorporated by reference to Exhibit 10.01 to the Registrant's Current Report on Form 8-K, filed with the SEC on May 3, 2024).
10.46	Form of Registration Right Agreement entered into Pursuant to the May 2024 Private Placement (Incorporated by reference to Exhibit 10.02 to the Registrant's Current Report on Form 8-K, filed with the SEC on May 3, 2024).
10.47	Form of Placement Agency Agreement entered into Pursuant to the May 2024 Private Placement (Incorporated by reference to Exhibit 10.03 to the Registrant's Current Report on Form 8-K, filed with the SEC on May 3, 2024.
10.48#	Amendment to Research Collaboration and License Agreement with Giiant Pharma, Inc. dated August 2, 2024 (Incorporated by reference to Exhibit 10.48 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 12, 2024).
10.49+	Form of Employment Agreement with J.D. Finley, dated September 25, 2024 (Incorporated by reference to Exhibit 10.01 to the Registrant's Current Report on Form 8-K, filed with the SEC on September 27, 2024).
10.50	Form of Underwriting Agreement by and between Palisade Bio, Inc. and Ladenburg Thalmann & Co. Inc. (Incorporated by reference to Exhibit 1.01 to the Registrant's Current Report on Form 8-K filed with the SEC on December 16, 2024).

10.51	Form of Warrant Amendment Agreement entered into Pursuant to the December 2024 Underwritten Public Offering (Incorporated by reference to Exhibit 1.01 to the Registrant's Current Report on Form 8-K filed with the SEC on December 16, 2024).
19.1	Registrant's Insider Trading Policy (Incorporated by reference to Exhibit 19.1 to the Registrant's Registration Statement on Form S-1, filed with the SEC on October 30, 2024).
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 (Incorporated by reference to Exhibit 97.1 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 26, 2024).
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.
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 24, 2025

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 or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place, and stead, in any and all capacities, to sign any and all amendments 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 attorney-in-fact and agent 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 or she might or could do in person, hereby ratifying and confirming that said attorney-in-fact and agent, or his 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 24, 2025
/s/ Mitchell Jones, M.D., Ph.D. **Mitchell Jones, M.D., Ph.D.**	Chief Medical Officer	March 24, 2025
/s/ Donald A. Williams **Donald A. Williams**	Chairman of the Board of Directors	March 24, 2025
/s/ Binxian Wei **Binxian Wei**	Director	March 24, 2025
/s/ Margery Fischbein **Margery Fischbein**	Director	March 24, 2025