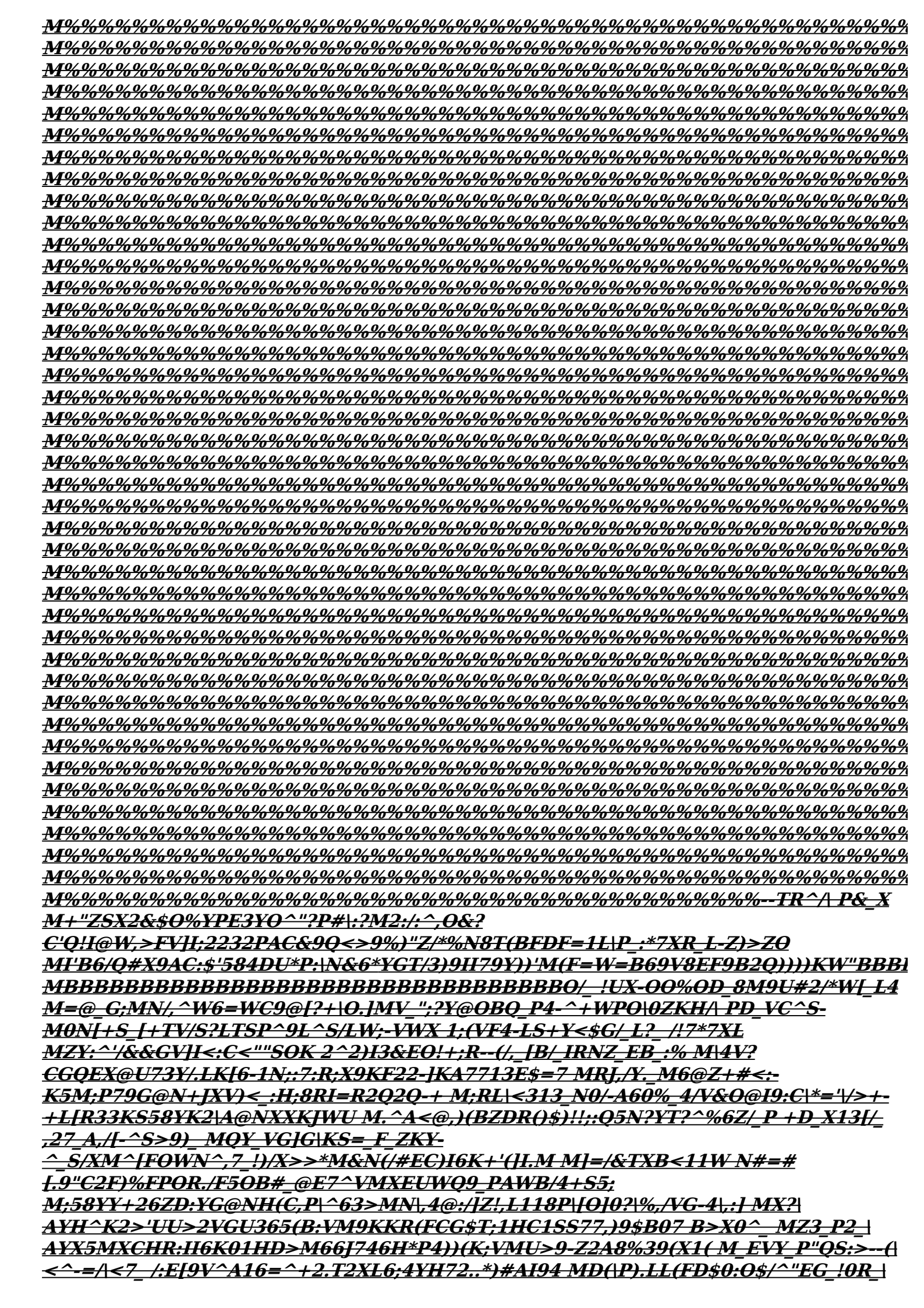

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Employer Identification Number) Â Palisade Bio, Inc. 7750 El Camino Real, Suite 2A Carlsbad, CA 92009 (858) 704-4900 (Address, including zip code, and telephone number, including area code of registrantâ€™s principal executive offices) Â Â Â Paracorp Incorporated 2140 S Dupont highway Camden, DE 19934 (302) 697-4590 (Name, address, including zip code, and telephone number, including area code, of agent for service) Â Â Â Copies to: Â Raul Silvestre, Esq. Michael Nertney, Esq. Dennis Gluck, Esq. Ellenoff Grossman & Schole LLP 2629 Townsgate Road #215 1345 Avenue of the Americas Westlake Village, CA 91361 New York, NY 10105 Â Â Â Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement. Â If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. â˜’ Â If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. â˜ Â If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. â˜ Â If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. â˜ Â 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 â€œlarge accelerated filer,â€ â€œaccelerated filer,â€ â€œsmaller reporting company,â€ and â€œemerging growth companyâ€ in Rule 12b-2 of the Exchange Act. Â Large accelerated filer â˜ Accelerated filer â˜ Â Â Â Â Non-accelerated filer â˜’ Smaller reporting company â˜’ Â Â Â Â Â Â Emerging growth company â˜ Â 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 7(a)(2)(B) of the Securities Act. â˜ Â Â Â The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said section 8(a), may determine. Â Â Â Â Â Â The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted. Â SUBJECT TO COMPLETION, DATED OCTOBER 30, 2024 Â PRELIMINARY PROSPECTUS Â Â [*] Shares of Common Stock or Pre-Funded Warrants to Purchase up to [*] Shares of Common Stock Â Representative Warrants to Purchase up to [*] Shares of Common Stock Â Up to [*] Shares of Common Stock Issuable Upon Exercise of Pre-Funded Warrants and Representative Warrants Â We are offering Â Â Â Â Â Â Â shares of our common stock, par value $0.01 per share (the â€œcommon stockâ€) at a public offering price of $Â Â Â Â Â Â Â Â per share. Â We are also offering to certain purchasers whose purchase of shares of common stock in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the consummation of this offering, the opportunity to purchase, if any such purchaser so chooses, pre-funded warrants to purchase shares of common stock, in lieu of shares of common stock. The purchase price of each pre-funded warrant will be equal to the public offering price for the common stock in this offering, minus $0.0001. Each pre-funded warrant is exercisable for one (1) share of our common stock and has an exercise price of $0.0001 per share. For each pre-funded warrant that we sell, the number of shares of common stock we are offering will be reduced on a one-for-one basis. This prospectus also relates to the offering of common stock issuable upon exercise of the pre-funded warrants. We collectively refer to the shares of common stock and pre-funded warrants offered hereby and the shares of common stock underlying the pre-funded warrants as the â€œsecurities.â€ Â The underwriters have the option to purchase up toÂ Â Â Â Â Â Â Â Â Â additional shares of common stock solely to cover over-allotments, if any, at the price to the public, less the underwriting discounts and commissions. The over-allotment option is exercisable for forty-five days from the date of this prospectus. Â Our common stock is listed on The Nasdaq Capital Market under the symbol â€œPALIâ€. On October 29, 2024, the last reported sale price of our common stock was $3.385 per share. The recent market price used throughout this prospectus may not be indicative of the final public offering price. The final public offering price will be determined through negotiation between us and the underwriters based upon a number of factors, including our history and our prospects, the industry in which we operate, our past and present operating results and the general condition of the securities markets at the time of this offering and may be at a discount to the current market price. Â Investing in our securities involves a high degree of risk. Before making an investment decision, please read the information under â€œRisk Factorsâ€ beginning on page 9 of this prospectus and under similar headings in any amendment or supplement to this prospectus or in any filing with the Securities and Exchange Commission that is incorporated by reference herein. Â Â Â Per ShareÂ Â Per Pre-Funded Warrant Â Â TotalÂ Public offering price (1)Â $Â Â Â Â Â Â Â Â $Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â $Â Â Â Â Â Â Â Â Underwriting discounts and commissions (2)Â $Â Â $Â Â Â $Â Proceeds to us, before expenses (3)Â $Â Â $Â Â $Â Â (1) The public offering price and underwriting discount corresponds to (i) a public offering price per share of common stock of $Â Â Â Â Â Â Â Â Â Â Â Â ($Â Â Â Â Â Â Â Â Â net of the underwriting discount) and (ii) a public offering price per pre-funded warrant of $Â Â Â Â Â Â Â Â ($Â Â Â Â Â Â Â Â Â net of the underwriting discount). Â (2) We have agreed to reimburse the representative of the underwriters for certain expenses and issue the representative, or its designees, warrants to purchase up to 6.0% of the number of shares of common stock and pre-funded warrants sold in this offering, including shares of common stock sold pursuant to the over-allotment option, if any. See â€œUnderwritingâ€ on page 47 for additional information regarding underwriting compensation. Â (3) The above summary of offering proceeds does not give effect to any proceeds from the exercise of any warrants being issued in this offering. Â We have granted a forty-five (45) day option to the underwriters to purchase additional shares of common stock (up to 15% of the aggregate number of shares of common stock and/or pre-funded warrants sold in this offering) solely to cover over-allotments, if any. Â The underwriters expect to deliver the securities to purchasers in the offering on or aboutÂ Â Â Â Â Â Â Â Â Â , 2024. Â NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE. Â Ladenburg Thalmann Â The date of this prospectus is Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â , 2024. Â Â Â Â TABLE OF CONTENTS Â Â Page About this Prospectus 1 Prospectus Summary 2 The Offering 5 Risk Factors Summary 7 Risk Factors 9 Special Note Regarding Forward-Looking Statements 29 Use of Proceeds 30 Dividend Policy 30 Capitalization 31 Dilution 33 Certain Relationships and Related Party Transactions 34 Security Ownership of Certain Beneficial Owners and Management 39 Description of Capital Stock 40 Description of Securities We are Offering 45 Underwriting 47 Legal Matters 50 Experts 50 Where You Can Find More Information 51 Incorporation of Certain Information by Reference 51 Â Â Â Â ABOUT THIS PROSPECTUS Â We incorporate by reference important information into this prospectus. You may obtain the information incorporated by reference without charge by following the instructions under â€œIncorporation of Certain Information by Reference.â€ You should carefully read this prospectus as well as additional information described under â€œIncorporation of Certain Information by Reference,â€ before deciding to invest in our securities. Â Neither we nor the underwriters have authorized anyone to provide you with additional information or information different from that contained or incorporated by reference in this prospectus or in any free writing prospectus that we have authorized for use in connection with this offering. We take no responsibility for, and cannot provide any assurance as to the reliability of, any other information that others may give you. This prospectus does not constitute an offer to sell to any person, or a solicitation of an offer to purchase from any person, the securities offered by this prospectus in any jurisdiction in which it is unlawful to make such offer or solicitation of an offer. Â The underwriters are offering to sell, and seeking offers to buy, our securities only in jurisdictions where offers and sales are permitted. The information contained in this prospectus and any free writing prospectus that we have authorized for use in connection with this offering is accurate only as of the respective dates thereof, and the information in the documents incorporated by reference in this prospectus is accurate only as of the date of those respective documents, regardless of the time of delivery of this prospectus or of any sale of our securities. Our business, financial condition, results of operations, and prospects may have changed since such dates. It is important for you to read and consider all information contained or incorporated by reference in this prospectus in making your investment decision. You should read both this prospectus, as well as the documents incorporated by reference into this prospectus and the additional information described under â€œIncorporation of Certain Information by Referenceâ€ in this prospectus before investing in our securities. Â Unless otherwise indicated, information contained in or incorporated by reference into this prospectus concerning our business and the industry and markets in which we operate, including with respect to our business prospects, our market position and opportunity, and the competitive landscape, is based on information from our managementâ€™s estimates, as well as from industry publications, surveys, and studies conducted by third parties. Our managementâ€™s estimates are derived from publicly available information, their knowledge of our business and industry, and assumptions based on such information and knowledge, which they believe to be reasonable. In addition, while we believe that information contained in the industry publications, surveys, and studies has been obtained from reliable sources, we have not independently verified any of the data contained in these third-party sources, and the accuracy and completeness of the information contained in these sources is not guaranteed. Â Although we are not aware of any misstatements regarding the market and industry data presented in this prospectus and the documents incorporated herein by reference, these estimates involve risks and uncertainties and are subject to change based on various factors, including those discussed under the heading â€œRisk Factorsâ€ in this prospectus and any related free writing prospectus, and under similar headings in the other documents that are incorporated by reference into this prospectus, including in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (the â€œSECâ€) on March 26, 2024 and our Quarterly Reports on Form 10-Q filed with the SEC on May 13, 2024 and August 12, 2024. Accordingly, you should not place undue reliance on this information. Â For investors outside the United States: We and the underwriters have not done anything that would permit this offering or the possession or distribution of this prospectus in any jurisdiction where action for those purposes is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities and the distribution of this prospectus outside of the United States. Â 1 Â Â PROSPECTUS SUMMARY Â This summary highlights certain information about us, this offering and selected information contained elsewhere in or incorporated by reference into this prospectus. This summary is not complete and does not contain all of the information that you should consider before making an investment decision. For a more complete understanding of our company, you should read and consider carefully the more detailed information included or incorporated by reference in this prospectus and any applicable prospectus supplement, including the factors described under the heading â€œRisk Factorsâ€ beginning on page 9 of this prospectus, and in our Annual Report on Form 10-K filed with the SEC on March 26, 2024 and our Quarterly Reports on Form 10-Q filed with the SEC on May 13, 2024 and August 12, 2024, together with any free writing prospectus we have authorized for use in connection with this offering and the financial statements and all other information incorporated by reference in this prospectus. When used in this prospectus, except where the context otherwise requires, the terms the â€œCompany,â€ â€œwe,â€ â€œus,â€ â€œour,â€ â€œPalisade,â€ or similar terms refer to Palisade Bio, Inc. Â Company Overview Â We are a 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 (â€œIBDâ€), including ulcerative colitis (â€œUCâ€) and Crohnâ€™s disease (â€œCDâ€). Â PALI-2108 Â Our lead product candidate, PALI-2108, is a prodrug inhibitor designed to help treat UC by targeting the key enzyme phosphodiesterase-4 (â€œPDE4â€) in colon tissues and preventing it from breaking down cyclic Adenosine Monophosphate (â€œcAMPâ€) 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). Â With a glucuronic-derived sugar moiety, PALI-2108 remains minimally absorbed until activated by the colonic bacterium enzyme Î²-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. Â In UC mouse models, we have demonstrated the dose-dependent efficacy of PALI-2108. Specifically, we utilized Dextran Sodium Sulfate (â€œDSSâ€)-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. This local delivery prevents the systemic toxicity inherent with immunosuppression and avoids the known tolerability issues of PDE4 inhibitors. Â Pipeline Â Program Â Indication Â Status Â Highlights PALI-2108 Â Ulcerative Colitis Â CTA Approved and currently enrolling Phase 1 clinical trial Â Advancing towards first dosing in Phase 1 clinical trial of healthy volunteers and UC patients. Â Â Â Â Â Â Â PALI-1908 Â Fibro Stenotic Crohnâ€™s Disease Â Discovery Â Significant overlap with PALI-2108 CTA for UC approved in 2024. Â POC for fibrosis pathway engagement completed. Â Giiant License Agreement Â On September 1, 2023, we entered into a research collaboration and license agreement (the â€œGiiant License Agreementâ€) with Giiant Pharma Inc. (â€œGiiantâ€). Under the terms of the Giiant License Agreement, we obtained the rights to develop, manufacture, and commercialize all compounds from Giiant, existing now and in the future, and any product containing or delivering any licensed compound, in any formulation or dosage for all human and non-human therapeutic uses for any and all indications worldwide, including those technologies that are the basis of PALI-2108. Pursuant to the terms of the Giiant License Agreement, pre-clinical development 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 â€œGiiant Milestone Paymentsâ€) and (ii) royalty payments upon sales or sublicenses to third parties, with such Giiant Milestone Payments and royalty payments (the â€œGiiant License Paymentsâ€) subject to a payment cap. Â 2 Â Â Our Precision Medicine Approach Â 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 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 planned clinical studies with the aim of developing regulatory approved tests for selecting potential responders to PALI-2108. Â Approval to Commence Phase I Clinical Study in Canada Â On October 9, 2024, Health Canada issued a No Objection Letter (â€œNOLâ€) related to our Phase 1 human clinical study of PALI-2108 for the treatment of UC. Following the NOL, we completed our study site initiation visit on October 10, 2024 and we received Institutional Review Board (â€œIRBâ€) approval for the study on October 11, 2024. Subsequent to the receipt of the IRB approval, we completed the screening of our first cohort of normal healthy volunteers and we are proceeding with our planned Phase 1 clinical study, which will be conducted in Canada. We anticipate that the Phase 1 clinical study will commence during the fourth quarter of 2024. Â Planned Clinical Trial in the United States Â In addition to conducting clinical studies in Canada, we anticipate filing an Investigational New Drug Application (â€œINDâ€) with the United States Food and Drug Administration (â€œFDAâ€) during 2025. If our IND is approved, we anticipate commencing clinical trials of PALI-2108 in the United States during the second half of 2025. Â Phase 1 Clinical Study Â 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 (â€œPKâ€) in both healthy volunteers and UC patients. The clinical study will include an open-label UC patient cohort multiple dosing arms in which we will evaluate the pharmacodynamics of PALI-2108 in healthy volunteers. We plan to enroll approximately 90 subjects across several arms of this Phase 1 clinical study including, (i) more than five subject cohorts receiving a Single Ascending Dose (â€œSADâ€) with a crossover to evaluate Food Effect (â€œFEâ€), (ii) four or more subject cohorts receiving a Multiple Ascending Dose (â€œMADâ€), 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 the plasma, urine, colon tissue, and fecal (MAD healthy subjects and UC patients only) as well as the PK and 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. Assuming the trial meets its primary objectives, we plan to initiate a Phase 1b/2a clinical study in UC patients in the second half of 2025. Â Market Â 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: Â Ulcerative Colitis Â Ulcerative colitis is a chronic inflammatory bowel disease 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 (â€œ8MMâ€), 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 (â€œAGRâ€) of 0.52%. The U.S. is expected to have the highest number of diagnosed incident cases, 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. will again lead in prevalence with 655,317 cases, whereas Canada will 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 at a compound annual growth rate (CAGR) of approximately 2.78% from 2021 to 2031. The market expansion is driven by the increasing prevalence of the disease, advancements in diagnostic techniques, and the development of more effective and targeted therapies. Â 3 Â Â Crohnâ€™s Disease Â Crohnâ€™s disease is a type of inflammatory bowel disease 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 symptoms such as abdominal pain, severe diarrhea, fatigue, weight loss, and malnutrition. The prevalence of CD between 2008 to 2009 is estimated to be approximately 300 cases per 100,000 commercially insured individuals in the United States. 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, with 68,815 cases, while France will report the fewest at 4,560 cases. Additionally, diagnosed prevalent cases 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. will again lead in prevalence, with 755,802 cases, whereas Japan will have the fewest diagnosed prevalent cases at 44,732. These increases in diagnosed cases are attributed to changes in population dynamics across these markets. The global market for Crohnâ€™s disease treatments was valued at $13.3 billion in 2023 and is projected to grow at a CAGR of 4% from 2024 to 2032. This market growth is fueled by the rising prevalence of the disease, improved diagnostic techniques, and increasing research and development activities for new drug therapies. Â We believe that of the addressable patient population for PALI-2108 in the US and the EU will be approximately 205,000 per year consisting of 105,000 in the United States and 90,000 in the European Union. Â Implications of Being a Smaller Reporting Company Â We are a â€œsmaller reporting companyâ€ as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of any fiscal year for so long as either (1) the market value of our shares of common stock held by non-affiliates does not equal or exceed $250.0 million as of the prior June 30th, or (2) our annual revenues did not equal or exceed $100.0 million during such completed fiscal year and the market value of our shares of common stock held by non-affiliates did not equal or exceed $700.0 million as of the prior June 30th. To the extent we take advantage of any reduced disclosure obligations, it may make comparison of our financial statements with other public companies difficult or impossible. Â Corporate Information Â We were incorporated in 2001 in the State of Delaware under the name Neuralstem, Inc. In October 2019, we changed our name from Neuralstem, Inc. to Seneca Biopharma, Inc., or Seneca. In April 2021, we effected a merger transaction with Leading Biosciences, Inc., or â€œLBS,â€ whereby LBS became a wholly owned subsidiary of Seneca. In April 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, CA, 92009, our telephone number is (858) 704-4900 and our website address is www.palisadebio.com. The information contained in or accessible through our website does not constitute part of this prospectus supplement or the accompanying prospectus. As of October 25, 2024, we had eight (8) full-time employees. Â Subsidiaries Â We primarily conduct our operations through LBS, our wholly owned subsidiary. Â 4 Â Â THE OFFERING Â Common stock we are offering Â Â Â Â Â Â Â Â Â Â Â shares of our common stock (or Â Â Â Â Â Â Â Â Â Â Â shares of our common stock if the underwriters exercise the over-allotment option in full). Â Â Â Public offering price Â We have assumed a public offering price of $ Â Â Â Â Â Â Â Â Â Â Â Â per share of common stock, which represents the last reported sale price of our common stock as reported on the Nasdaq Capital Market on Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â , 2024. The final public offering price will be determined through negotiation between us and the underwriters in the offering and may be at a discount to the current market price. Therefore, the assumed public offering price used throughout this prospectus may not be indicative of the final public offering price. Â Â Â Pre-funded warrants we are offering Â We are also offering to certain purchasers whose purchase of shares of common stock in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the closing of this offering, the opportunity to purchase, if such purchasers so choose, pre-funded warrants to purchase shares of common stock, in lieu of shares of common stock that would otherwise result in any such purchaserâ€™s beneficial ownership exceeding 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock. Each pre-funded warrant is exercisable for one share of our common stock. The purchase price of each pre-funded warrant is equal to the price at which a share of common stock is being sold to the public in this offering, minus $0.0001, and the exercise price of each pre-funded warrant is $0.0001 per share. The pre-funded warrants are exercisable immediately and may be exercised at any time until all of the pre-funded warrants are exercised in full. This offering also relates to the shares of common stock issuable upon exercise of any pre-funded warrants sold in this offering. For each pre-funded warrant that we sell, the number of shares of common stock that we are offering will be reduced on a one-for-one basis. Â Â Â Over-allotment option Â The underwriters have the option to purchase an aggregate ofÂ Â Â Â Â Â Â Â Â Â Â Â Â Â additional shares of common stock solely to cover over-allotments, if any, at the price to the public less the underwriting discounts and commissions. The over-allotment option may be used to purchase shares of common stock as determined by the underwriters. The over-allotment option is exercisable for forty-five (45) days from the date of this prospectus. Â Â Â Common stock outstanding immediately before this offering Â Â Â Â Â Â Â Â Â Â Â shares of common stock. Â Â Â Common stock outstanding immediately after this offering Â Â Â Â Â Â Â Â Â Â Â Â Â shares of common stock, or Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â shares if the underwriters exercise the over-allotment option in full, and assuming no sale of any pre-funded warrants and assuming none of the representative warrants issued in this offering are exercised. Â Â Â Use of proceeds Â We estimate that the net proceeds to us from this offering will be approximatelyÂ Â Â Â Â Â Â Â $Â Â Â Â Â Â Â Â Â Â million (or $ Â Â Â Â Â Â Â Â Â Â million if the underwriters exercise the over-allotment option in full), after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering primarily for our recently approved Phase 1 clinical trial of PALI-2108, pre-clinical studies, research and development, and working capital. See â€œUse of Proceedsâ€ for additional information. Â Â Â Lock-Up Agreements Â We, and each of our officers and directors are subject to certain lock-up restrictions as set forth in more detail in the â€œUnderwritingâ€ section. Â 5 Â Â Risk Factors Â An investment in our securities involves a high degree of risk. See â€œRisk Factorsâ€ beginning on page 9 of this prospectus and the other information included and incorporated by reference in this prospectus for a discussion of the risk factors you should carefully consider before deciding to invest in our securities. Â Â Â Nasdaq Symbol Â Our common stock is listed on The Nasdaq Capital Market under the symbol â€œPALI.â€ There is no established trading market for the pre-funded warrants and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the pre-funded warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the pre-funded warrants will be limited. Â Unless otherwise indicated, all information in this prospectus assumes no exercise of outstanding options or warrants, no conversion of the Series A 4.5% Convertible Preferred Stock described. Â Unless otherwise indicated, the number of shares of common stock to be outstanding immediately after this offering is based on 966,345 shares of our common stock outstanding as of June 30, 2024, which is then adjusted for the following issuances subsequent to June 30, 2024 for an aggregate of 1,329,516 shares of common stock outstanding as of October 25, 2024: (i) an aggregate of 346,142 shares that were issued pursuant to the exercise of outstanding pre-funded warrants issued in our May 2024 private placement and (ii) 17,029 shares that were issued to consultants, but excludes: Â Â â— Â Â Â Â Â Â Â Â Â Â shares of common stock issuable upon the exercise of pre-funded warrants issued in this offering; Â Â Â Â â— Â Â Â Â Â Â Â Â Â â€¯shares of common stock issuable upon the exercise of the representative warrants issued as compensation to the representative of the underwriters in this offering; Â Â Â Â â— 452 shares of common stock issuable upon exercise of outstanding stock options as of October 25, 2024 granted under the LBS 2013 Amended and Restated Employee, Director, and Consultant Equity Incentive Plan, as amended and restated, or the 2013 Plan, with a weighted-average exercise price of $14,403.57 per share; Â Â Â Â â— 41,091 shares of common stock issuable upon exercise of outstanding stock options as of October 25, 2024, granted under the 2021 Equity Incentive Plan, as amended, or the 2021 Plan, with a weighted-average exercise price of $43.53 per share; Â Â Â Â â— 10,190 shares of common stock issuable upon exercise of outstanding stock options as of October 25, 2024 granted under the 2021 Inducement Plan, with a weighted average exercise price of $17.67 per share; Â Â Â Â â— 776 shares of common stock issuable upon vesting of restricted stock units outstanding as of October 25, 2024, granted under the 2021 Plan; Â Â Â Â â— 2,952 shares of common stock issuable upon vesting of restricted performance stock units outstanding as of October 25, 2024; all of which were issued under the 2021 Plan which vest subject to certain milestones; Â Â Â Â â— 36,653 shares of common stock reserved for future issuances under the 2021 Plan as of October 25, 2024, as well as any future automatic increases in the number of shares of common stock reserved for future issuance under the 2021 Plan; Â Â Â Â â— 20,587 shares of common stock reserved for future issuance under our 2021 Employee Stock Purchase Plan, or the ESPP, as of October 25, 2024, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the ESPP; Â Â Â Â â— 52,831 shares of common stock reserved for issuance under the 2021 Inducement Plan as of October 25, 2024; Â Â Â Â â— 184,000 shares of common stock issuable upon the exercise of outstanding pre-funded warrants issued in our May 2024 offering as of October 25, 2024 with an exercise price of $0.0001 per share; Â Â Â Â â— 1,245,470 shares of common stock issuable upon exercise of outstanding warrants as of October 25, 2024 with a weighted-average exercise price of $27.04 per share; and Â Â Â Â â— 8 shares of common stock issuable upon conversion of the 200,000 outstanding shares of our Series A 4.5% Convertible Preferred Stock as of October 25, 2024, as well as any future shares of common stock issuable upon conversion of additional shares of Series A 4.5% Convertible Preferred Stock that may be issued as payment-in-kind dividends thereon in accordance with their terms. Â 6 Â Â RISK FACTORS SUMMARY Â The Company faces many risks and uncertainties, as more fully described in this prospectus. Some of these risks and uncertainties are summarized below. The summary below does not contain all of 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 the Section entitled â€œRisk Factors.â€ Â Risk Related to This Offering Â Â â— We have broad discretion in how we use the proceeds of this offering and may not use these proceeds effectively, which could affect our results of operations and cause our common stock to decline. Â Â Â Â â— If our stock price fluctuates after the offering, you could lose a significant part of your investment. Â Â Â Â â— You will experience immediate and substantial dilution as a result of this offering and may experience additional dilution in the future. Â Â Â Â â— Future sales of a significant number of our shares of common stock in the public markets, or the perception that such sales could occur, could depress the market price of our shares of common stock. Â Risks Related to Our Development, Commercialization and Regulatory Approval of Our Product Candidates Â â— Our business depends on the successful clinical development, regulatory approval, and commercialization of our therapeutic compounds, including our lead asset PALI-2108. Â Â Â Â â— There are substantial risks in drug development, and, as a result, we may not be able to successfully develop PALI-2108. Â Â Â Â â— We depend on our license agreement with Giiant to permit us to use patents and patent applications relating to PALI-2108. Termination of these rights or the failure to comply with obligations under the license agreement could materially harm our business and prevent us from developing or commercializing PALI-2108, our lead product candidate. Â Â Â Â â— Even if our clinical trials in Canada are successful, our ability to obtain regulatory approval in the United States is uncertain. Â Â Â Â â— 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. Â Â Â Â â— 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. Â Â Â Â â— Our product candidates 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. Â Â Â Â â— There can be no assurance that our product candidates will obtain regulatory approval. Â Â Â Â â— If clinical studies of PALI-2108 do not yield successful results, we may decide not to continue the development of PALI-2108. Â Â Â Â â— We are 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 United States. Â Risks Related to Our Business Â â— We have a limited operating history and have never generated revenue from product sales. Â Â Â Â â— Our business model assumes revenue from, among other activities, marketing or out-licensing the products we develop. PALI-2108 is in the early stages of development, and because we have a short development history with PALI-2108, there is a limited amount of information about us upon which you can evaluate our business and prospects. Â 7 Â Â â— Our common stock could be delisted from the Nasdaq Stock Market if we are unable to maintain compliance with the Nasdaq Stock Marketâ€™s continued listing standards. Â Â Â Â â— Our success depends on the attracting and retaining of senior management and scientists with relevant expertise. Â Â Â Â â— We may choose to discontinue developing or commercializing 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. Â Â Â Â â— Our inability to successfully in-license, acquire, develop and market additional product candidates or approved products could impair our ability to grow our business. Â Risks Related to Our Dependence on Third Parties Â Â â— 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 or obtain regulatory approval for, or commercialize, our product candidates. Â Â Â Â â— We expect to rely on collaborations with third parties for the successful development and commercialization of our product candidates. Â Â Â Â â— We anticipate relying completely on third-party contractors to supply, manufacture and distribute clinical drug supplies for our product candidates. Â Risks Related to Our Financial Operations Â â— We have expressed substantial doubt about our ability to continue as a going concern. Â Â Â Â â— We have a history of net operating losses, and we expect to continue to incur net operating losses and may never achieve profitability. Â Â Â Â â— Failure to remediate a material weakness in internal controls over financial reporting could result in material misstatements in our consolidated financial statements. Â Risks Related to Our Intellectual Property Â Â â— 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. Â Â Â Â â— 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. Â Other Risks Related to Our Securities Â Â â— We will need to raise additional capital in the future to fund our operations, which may not be available to us on favorable terms or at all. Â Â Â Â â— Our common stock price may be highly volatile. Â Â Â Â â— If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired. Â Â Â Â â— Our Board of Directors (â€œBoardâ€) of has broad discretion to issue additional securities, which might dilute the net tangible book value per share of our common stock for existing stockholders. Â 8 Â Â RISK FACTORS Â Investing in our securities involves a high degree of risk. Before investing in our securities, you should carefully consider the risks and uncertainties discussed under â€œRisk Factorsâ€ in our latest annual report on Form 10-K and subsequent quarterly reports on Form 10-Q and current reports on Form 8-K, which are incorporated by reference herein in their entirety. Before making an investment decision, you should carefully consider each of the following risks described below, together with all other information set forth in or incorporated in this prospectus, including the financial statements and the related notes. The risks described in this prospectus or incorporated by reference into this prospectus are not the only ones we face, but those that we consider to be material. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations and could result in a complete loss of your investment. Past financial performance may not be a reliable indicator of future performance, and historical trends should not be used to anticipate results or trends in future periods. If any of the following risks actually occur, our business, financial condition, results of operations or cash flow could be seriously harmed. This could cause the market price of our common stock to decline, and you could lose all or part of your investment. Â Risks Related to This Offering Â We have broad discretion in how we use the proceeds of this offering and may not use these proceeds effectively, which could affect our results of operations and cause our common stock to decline. Â We will have considerable discretion in the application of the net proceeds of this offering. We intend to use the net proceeds from this offering primarily for our recently approved Phase 1 clinical trial of PALI-2108, pre-clinical studies, research and development, and working capital. As a result, investors will be relying upon managementâ€™s judgment with only limited information about our specific intentions for the use of the net proceeds of this offering. We may use the net proceeds for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value. Â If our stock price fluctuates after the offering, you could lose a significant part of your investment. Â The market price of our common stock could be subject to wide fluctuations in response to, among other things, the risk factors described in this prospectus, and other factors beyond our control, such as fluctuations in the valuation of companies perceived by investors to be comparable to us. Furthermore, the stock markets have experienced price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations often have been unrelated or disproportionate to the operating performance of those companies. These broad market and industry fluctuations, as well as general economic, political, and market conditions, such as recessions, interest rate changes or international currency fluctuations, may negatively affect the market price of our common stock. In the past, many companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our managementâ€™s attention from other business concerns, which could seriously harm our business. Â You will experience immediate and substantial dilution as a result of this offering and may experience additional dilution in the future. Â You will incur immediate and substantial dilution as a result of this offering. After giving effect to the sale by us of the shares of common stock and pre-funded warrants offered in this offering and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, investors in this offering can expect an immediate dilution of approximately $Â Â Â Â Â Â Â Â Â Â per share. In addition, our outstanding stock options, warrants and shares of our Series A 4.5% Convertible Preferred Stock are convertible into or exercisable for shares of our common stock. To the extent that such securities are exercised or converted into shares of our common stock, investors purchasing our securities in this offering may experience further dilution. Â 9 Â Â Moreover, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders or result in downward pressure on the price of our common stock. See the section of this prospectus titled â€œDilutionâ€ for a more detailed discussion of the dilution you will incur if you purchase common stock and / or pre-funded warrants in this offering. Â We do not currently intend to pay dividends on our common stock, and any return to investors is expected to come, if at all, only from potential increases in the price of our common stock. Â At the present time, we intend to use available funds to finance our operations. Accordingly, while payment of dividends rests within the discretion of our Board, we have no intention of paying any such dividends in the foreseeable future. Any return to investors is expected to come, if at all, only from potential increases in the price of our common stock. Â Future sales of a significant number of our shares of common stock in the public markets, or the perception that such sales could occur, could depress the market price of our shares of common stock. Â Sales of a substantial number of our shares of common stock in the public markets, or the perception that such sales could occur, including from the exercise of outstanding warrants or sales of common stock issuable thereunder, could depress the market price of our shares of common stock and impair our ability to raise capital through the sale of additional equity securities. A substantial number of shares of common stock are being offered by this prospectus. We cannot predict the number of these shares that might be sold nor the effect that future sales of our shares of common stock, including shares issuable upon the exercise of outstanding warrants, would have on the market price of our shares of common stock. Â There is no public market for the pre-funded warrants being offered in this offering. Â There is no established public trading market for the pre-funded warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the pre-funded warrants on any securities exchange or nationally recognized trading system, including The Nasdaq Stock Market. Without an active market, the liquidity of the pre-funded warrants will be limited. Â Holders of our pre-funded warrants will have no rights as a common stockholder until they acquire our common stock. Â Until holders of our pre-funded warrants sold in this offering acquire shares of our common stock upon exercise of the pre-funded warrants, the holders will have no rights with respect to shares of our common stock issuable upon exercise of pre-funded warrants. Upon exercise of the pre-funded warrants, holders will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date. Â Risks Related to our Development, Commercialization and Regulatory Approval of our Product Candidates Â Our business depends on the successful clinical development, regulatory approval, and commercialization of our therapeutic compounds, including our lead asset PALI-2108. Â On September 1, 2023, we announced that we had entered into the Giiant License Agreement, pursuant to which we exclusively licensed all of Giiantâ€™s current and future technologies, including PALI-2108. PALI-2108 was previously a pre-clinical asset and is our only asset being actively developed. On October 9, 2024, Health Canada approved our Canadian Clinical Trial Application (â€œCTAâ€) to commence a Phase 1 clinical trial for PALI-2108 in Canada. Accordingly, we are preparing to initiate the Phase 1 clinical trial of PALI-2108. Our success depends on the development of PALI-2108, which is subject to a number of risks, including: Â Â â— the continued enforceability of our research collaboration and license agreement with Giiant; Â Â Â Â â— 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); Â Â Â Â â— our ability to develop and implement clinical trial designs and protocols; Â 10 Â Â Â â— the successful initiation and completion of our planned clinical trials and any additionally required pre-clinical studies; Â Â Â Â â— our ability to retain third-party Contract Research Organizations â€œCRO(s)â€ on terms acceptable to us for the conduct and oversight of our anticipated clinical trials, including our Phase 1 clinical trial for PALI-2108; Â Â Â Â â— our ability to bear all future development costs related to PALI-2108 for clinical development; Â Â Â Â â— the approval by the Health Canada or other regulatory authorities to commence the marketing of our product candidates; Â Â Â Â â— the ability for us and third-parties, if applicable, to achieve and maintain compliance with our contractual obligations and applicable regulatory requirements; Â Â Â Â â— the ability of our contract manufacturers to manufacture sufficient supply of our product candidates to meet the required clinical trial supplies and any additionally required pre-clinical studies; Â Â Â Â â— 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 current good manufacturing processes (â€œcGMPâ€); Â Â Â Â â— our ability to obtain favorable labeling for our product candidates through regulators that allows for successful commercialization; Â Â Â Â â— 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; Â Â Â Â â— our ability to price our product candidates to recover our development costs and applicable milestone or royalty payments, and to generate a satisfactory profit margin; and Â Â Â Â â— our ability and our applicable collaboration and licensing partnersâ€™ ability to establish and enforce intellectual property rights related to our product candidates and technologies. Â 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 commencing enrollment 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 study 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. Â There are substantial risks in drug development, and, as a result, we may not be able to successfully develop PALI-2108. Â We are in the process of initiating an early-stage clinical trial of PALI-2108 in our target indication of inflammatory bowel disease are unknown. 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, we will be unable to generate revenue or build a sustainable or profitable business. Â 11 Â Â We depend on our license agreement with Giiant to permit us to use patents and patent applications relating to PALI-2108. Termination of these rights or the failure to comply with obligations under the license agreement could materially harm our business and prevent us from developing or commercializing PALI-2108, our lead product candidate. Â 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. Â Clinical drug development is expensive, time-consuming and uncertain. Â 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. Further, upon receipt of the NOL, we assumed all future development costs related to PALI-2108. 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 IRB at our trial sites, may suspend, delay, require modifications to or terminate our clinical trials, once begun, at any time. Â Even if our clinical trials in Canada are successful, our ability to obtain regulatory approval in the United States is uncertain. Â We are commencing 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 United States, 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 United States, there is no certainty that the FDA will accept the data generated from our Canadian trial. The FDAâ€™s acceptance of foreign clinical data is subject to certain conditions, including whether the trial was conducted in accordance with good clinical practices (â€œGCPâ€) 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 United States. Â In addition, regulatory approval for clinical trials and eventual drug approval in the United States is a complex process, influenced by several factors, including: Â Â â— the adequacy and relevance of the Phase 1 trial data in supporting progression to Phase 2, as evaluated by the FDA; Â Â Â Â â— 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; Â Â Â Â â— 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 Â Â Â Â â— the FDAâ€™s consideration of the risk-benefit ratio for continuing clinical development in the United States, particularly based on data from a non-U.S. population. Â 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 aligns with FDA standards and regulatory expectations. It is also possible that we may be required to conduct additional trials in the United States 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 United States or that if our Canadian trial is successful, a subsequent Phase 2 trial. Â 12 Â Â 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. Â We are currently approved to begin a Phase 1 clinical trial for PALI-2108 in Canada. Identifying and qualifying subjects to participate in our Phase 1 clinical trial and anticipated future clinical trials is critical to its success. Our inability to enroll patients in our clinical trials on a timely basis could result in the trials being delayed or never completed. Â Patient enrollment and trial completion are affected by numerous additional factors, including the: Â Â â— process for identifying patients; Â Â Â Â â— design of the trial protocol; Â Â Â Â â— eligibility and exclusion criteria; Â Â Â Â â— perceived risks and benefits of the product candidate under study; Â Â Â Â â— availability of competing therapies and clinical trials; Â Â Â Â â— severity of the disease under investigation; Â Â Â Â â— proximity and availability of clinical trial sites for prospective patients; Â Â Â Â â— ability to obtain and maintain patientsâ€™ consents; Â Â Â Â â— risk that enrolled patients will drop out before completion of the trial; Â Â Â Â â— patient referral practices of physicians; and Â Â Â Â â— ability to monitor patients adequately during and after treatment. Â 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. Â 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. Â 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. Â Our product candidates 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. Â 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. Â 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. Â 13 Â Â 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. Â There can be no assurance that our product candidates will obtain regulatory approval. Â 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: Â Â â— pre-clinical data required for the submission of an IND or CTA; Â Â Â Â â— controlled research and human clinical testing; Â Â Â Â â— establishment of the safety and efficacy of the proposed product candidate; Â Â Â Â â— government review and approval of a submission containing manufacturing, pre-clinical and clinical data; and Â Â Â Â â— adherence to cGMP regulations during production and storage. Â PALI-2108 will require significant development, clinical testing, possibly additional pre-clinical studies, and the investment of significant funds to gain regulatory approval before it can be commercialized. Although we are approved to commence the 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 United States. 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. If we fail to obtain regulatory approvals, we will not be able to market PALI-2108 and our operations will be adversely affected. Â If clinical studies of PALI-2108 do not yield successful results, we may decide not to continue the development of PALI-2108. Â 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: Â Â â— the results of pre-clinical studies that we have completed may not be indicative of results that will be obtained in human clinical trials; Â Â Â Â â— safety and efficacy results attained in pre-clinical studies, may not be indicative of results that are obtained in our clinical trials; Â Â Â Â â— after reviewing early clinical trial results, we may abandon projects that we previously believed to be promising; Â Â Â Â â— 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 Â Â Â Â â— PALI-2108 may not have the desired effects, or may include undesirable side effects or other characteristics, that preclude applicable regulatory approval or limit their commercial use if approved. Â 14 Â Â It may take us longer than we estimate to complete clinical trials, or we may not be able to complete them at all. Â 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. We may not commence or complete clinical trials involving PALI-2108 as currently contemplated or may not be able to conduct them successfully. Â 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. Â 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. Â We are 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 United States. Â We are initiating a Phase 1 clinical trial for PALI-2108 in Canada. Additionally, we may conduct further trials in Canada as well as other countries outside of the U.S. Although the FDA or other applicable foreign regulatory authority may accept data from our clinical trials conducted in Canada, acceptance of such study data by the FDA or applicable foreign regulatory authority may be subject to certain conditions or exclusion. Where data from foreign clinical trials (such as Canada) are intended to serve as the basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless such data are applicable to the U.S. population and U.S. medical practice; the studies were performed by clinical investigators of recognized competence; and the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Many foreign regulatory bodies have similar requirements. In addition, such foreign studies would be subject to the applicable local laws of the foreign jurisdictions where the studies are conducted. There can be no assurance the FDA or applicable foreign regulatory authority will accept data from trials conducted in Canada or elsewhere outside of the United States or the applicable home country. If the FDA or applicable foreign regulatory authority does not accept such data, it would likely result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan. Â 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. Â 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 United States, 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. Â In addition, both the federal and state governments in the United States and foreign governments continue to propose and pass new legislation, regulations, and policies affecting coverage and reimbursement rates, which are designed to contain or reduce the cost of health care. Further federal and state proposals and healthcare reforms are likely, which could limit the prices that can be charged for the product candidates that we develop and may further limit our commercial opportunity. There may be future changes that result in reductions in potential coverage and reimbursement levels for our product candidates, if approved and commercialized, and we cannot predict the scope of any future changes or the impact that those changes would have on our operations. Â 15 Â Â 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. Â 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. Â 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: Â Â â— decreased demand for our product candidates; Â Â Â Â â— impairment of our business reputation; Â Â Â Â â— withdrawal of clinical trial participants; Â Â Â Â â— costs of litigation; Â Â Â Â â— substantial monetary awards to patients or other claimants; and Â Â Â Â â— loss of revenues. Â 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. Â 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. Â 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: Â Â â— patient demand for approved products that treat the indication for which they are approved; Â Â Â Â â— the effectiveness of a product compared to other available therapies or treatment regimens; Â Â Â Â â— the availability of coverage and adequate reimbursement from managed care plans and other healthcare payors; Â Â Â Â â— the cost of treatment in relation to alternative treatments and willingness to pay on the part of patients; Â Â Â Â â— insurersâ€™ willingness to see the applicable indication as a disease worth treating; Â Â Â Â â— proper administration by physicians or patients; Â Â Â Â â— patient satisfaction with the results, administration and overall treatment experience; Â Â Â Â â— limitations or contraindications, warnings, precautions or approved indications for use different than those sought by us that are contained in the final approved labeling; Â Â Â Â â— any requirement of an authoritative regulatory body requirement to undertake a risk evaluation and mitigation strategy; Â Â Â Â â— the effectiveness of our sales, marketing, pricing, reimbursement and access, government affairs, and distribution efforts; Â Â Â Â â— adverse publicity about a product or favorable publicity about competitive products; Â 16 Â Â Â â— 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 Â Â Â Â â— potential product liability claims or other product-related litigation. Â 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. Â Risks Related to our Business Â We have a limited operating history and have never generated revenue from product sales. Â 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. Â Our business model assumes revenue from, among other activities, marketing or out-licensing the products we develop. PALI-2108 is in the early stages of development and because we have a short development history with PALI-2108, there is a limited amount of information about us upon which you can evaluate our business and prospects. Â 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 are currently in the process of preparing to initiate our initial Phase 1 clinical trial of PALI-2108. 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. Â For example, to execute our business plan, we will need to: Â Â â— Execute product development activities using unproven technologies; Â Â Â Â â— Build, maintain, and protect an intellectual property portfolio; Â Â Â Â â— Demonstrate safety and efficacy of our drug candidates in human clinical studies; Â Â Â Â â— Receive approval from Health Canada and / or approval from similar foreign regulatory bodies, such as the FDA; Â Â Â Â â— Retain qualified CROs to oversee and manage our Phase 1 clinical trial for PALI-2108 and future clinical trials; Â Â Â Â â— Gain market acceptance for the development and commercialization of any drugs we develop; Â Â Â Â â— Ensure our products are reimbursed by commercial and/or government payors at a rate that permits commercial viability; Â Â Â Â â— Develop and maintain successful strategic relationships with suppliers, distributors, and commercial licensing partners; Â Â Â Â â— Manage our spending and cash requirements as our expenses will increase in the near term if we add programs and additional pre-clinical and clinical trials; and Â Â Â Â â— Effectively market any products for which we obtain marketing approval. Â If we are unsuccessful in accomplishing these objectives, we may not be able to develop our proposed products, raise sufficient capital to fund our operations, expand our business or continue our operations. Â 17 Â Â Our common stock could be delisted from the Nasdaq Stock Market if we are unable to maintain compliance with the Nasdaq Stock Marketâ€™s continued listing standards. Â 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 its listing on The Nasdaq Stock Market, including the requirement to maintain a minimum bid price of at least $1.00 (the â€œBid Price Ruleâ€). 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. 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, we may again 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. Â Our success depends on attracting and retaining senior management and scientists with relevant expertise. Â 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. Â We may choose to discontinue developing or commercializing 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. Â 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. Â Our inability to successfully in-license, acquire, develop and market additional product candidates or approved products could impair our ability to grow our business. Â 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. Â 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. Â Further, any product candidate that we acquire or license may require additional development efforts prior to commercial sale, including pre-clinical 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. Â 18 Â Â Risks Related to our Dependence on Third Parties Â 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 or obtain regulatory approval for, or commercialize, our product candidates. Â 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 FDAâ€™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 pre-clinical studies and will control only certain aspects of their activities. We and our CROs and other third-party contractors will be required to comply with GCP and good laboratory practice (â€œGLPâ€) requirements, 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 requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP and GLP requirements, or reveal noncompliance from an audit or inspection, any clinical data generated in our clinical trials may be deemed unreliable and the FDA or other regulatory authorities may require us to perform additional clinical trials before approving our or our partnersâ€™ 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 requirements. In addition, our clinical trials generally must be conducted with compounds produced under cGMP regulations. Our failure to comply with these regulations and policies may require it to repeat clinical trials, which would be costly and delay the regulatory approval process. 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. Â We expect to rely on collaborations with third parties for the successful development and commercialization of our product candidates. Â 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: Â Â Â â— our partnersâ€™ ability to execute their responsibilities in a timely, cost-efficient and compliant manner; Â Â Â Â â— reduced control over delivery and manufacturing schedules; Â Â Â Â â— price increases; Â Â Â Â â— manufacturing deviations from internal or regulatory specifications; Â Â Â Â â— quality incidents; Â Â Â Â â— the failure of partners to perform their obligations for technical, market or other reasons; Â Â Â Â â— misappropriation of our product candidates; and Â Â Â Â â— other risks in potentially meeting our product commercialization schedule or satisfying the requirements of our end-users. Â 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. Â 19 Â Â We anticipate relying completely on third-party contractors to supply, manufacture and distribute clinical drug supplies for our product candidates. Â 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 pre-clinical and clinical testing and commercialization. If we fail to develop and maintain supply and other technical relationships with these third parties, we may be unable to continue to develop or commercialize our products and product candidates, which could adversely affect us and our business. Â We are dependent on our contract suppliers and manufacturers for day-to-day compliance with applicable laws and cGMP for production of our proposed products and API. If the safety or quality of any product or product candidate or component is compromised due to a failure to adhere to applicable laws or for other reasons, we may not be able to commercialize or obtain regulatory approval for the affected product or product candidates successfully, and we may be held liable as a result. Â 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 manufacturersâ€™ or suppliersâ€™ facilities or equipment, even by force majeure, may significantly impair our ability to have our products and product candidates manufactured on a timely basis. Our reliance on contract manufacturers and suppliers further exposes us to the possibility that they, or third parties with access to their facilities, may misappropriate our trade secrets or other proprietary information. In addition, the manufacturing facilities of certain of our suppliers may be located outside of the United States. This may give rise to difficulties in importing our products or product candidates or their components into the United States or other countries. Â Risks Related to Our Financial Operations Â We have expressed substantial doubt about our ability to continue as a going concern. Â 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 our most recently filed quarterly report. This determination was based on conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the condensed consolidated financial statements are issued, including the probability that significant changes to our anticipated level of operations, due to factors that are within or outside of our control, would cause our available cash as of the date of this filing to not be sufficient to fund our anticipated level of operations for the next 12 months. Our future consolidated financial statements may include a similar qualification about our ability to continue as a going concern. Our year-end and interim consolidated financial statements were prepared assuming that it will continue as a going concern and do not include any adjustments that may result from the outcome of this uncertainty. Â 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. Â We have a history of net operating losses, and we expect to continue to incur net operating losses and may never achieve profitability. Â We have incurred net operating losses since our inception. We expect that our net operating losses will continue for the foreseeable future as we continue our clinical, 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 were 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 do generate significant revenue, we may never achieve profitability. Â 20 Â Â Failure to remediate a material weakness in internal controls over financial reporting could result in material misstatements in our consolidated financial statements. Â 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. Â If our existing material weakness, which management concluded is still present as of the date of our most recent quarterly report on Form 10-Q, 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. Â Risks Related to Our Intellectual Property Â 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. Â 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. Â The patent application process, also known as patent prosecution, is expensive and time-consuming, and we and our current or future licensors and licensees may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner in all the countries that are desirable. It is also possible that we or our current licensors, or any future licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Moreover, our competitors independently may develop equivalent knowledge, methods and know-how or discover workarounds to our patents that would not constitute infringement. Any of these outcomes could impair our ability to enforce the exclusivity of any issued or pending patents we may have or the ability to obtain future patent protections, which may have an adverse impact on our business, financial condition and operating results. Â 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. Â 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. Â 21 Â Â 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. Â 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. Â We may not be able to protect our intellectual property rights throughout the world. Â 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. Â 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. Â 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. Â 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. Â We have entered into the Giiant License Agreement, with respect to our lead product candidate, PALI-2108, and other assets of Giiant, including PALI-1908. The Giiant License Agreement imposes various diligence, milestone, royalty, insurance, expense reimbursement, and other obligations on us. 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. Â We may be subject to patent infringement claims, which could result in substantial costs and liabilities, and prevent us from commercializing our potential products. Â 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. Â 22 Â Â 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. Â 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. Â 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. Â Other Risks Related to Our Securities Â We will need to raise additional capital in the future to fund our operations, which may not be available to us on favorable terms or at all. Â We have used and we intend to use the proceeds from this offering and any future offerings, to, among other uses, advance PALI-2108 through clinical development, advancing the remainder of the existing portfolio through pre-clinical 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 pre-clinical testing and clinical trials; the ability to manufacture sufficient drug supplies to complete clinical trials or any additional pre-clinical 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 stockholdersâ€™ ownership percentage will be decreased. In addition, any debt financing may subject us to fixed payment obligations and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish certain valuable intellectual property or other rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. Even if we obtain additional funding, there can be no assurance that it will be available on terms acceptable to us or our stockholders. Â 23 Â Â We believe that our existing cash and cash equivalents of approximately $8 million as of September 30, 2024 will be sufficient to fund our planned operations, which include our recently approved Phase 1 clinical program, and preparations for future clinical trials, through the first quarter of 2025, without the issuance of additional securities for cash. Assuming that we receive net proceeds of approximately $Â Â Â Â Â million from this offering (assuming an offering with gross proceeds of approximately $Â Â Â Â Â million), we believe that the net proceeds from this offering will satisfy our capital needs into the Â Â Â Â Â Â Â quarter of 2025 under our current business plan. Assuming that the underwriters exercise the full over-allotment (assuming an offering with gross proceeds of approximately $ Â Â Â Â Â Â Â million), we believe that the net proceeds from this offering will satisfy our capital needs into the Â Â Â Â Â Â quarter of Â Â Â Â Â Â under our current business plan. Â Our common stock price may be highly volatile. Â 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: Â â—failure of our product candidates to show safety and/or efficacy in our clinical trials; Â Â Â â—our ability to obtain timely regulatory approvals for our product candidates, and delays or failures to obtain such approvals; Â Â Â â—the results of our clinical trials, including our decision to pause or terminate any such trials; Â Â Â â—failure of our product candidates, if approved, to achieve commercial success; Â Â Â â—the entry into, or termination of, or breach by parties of key agreements, including the Giiant License Agreement, and employment agreements with our named executive officers; Â Â Â â—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; Â Â Â â—announcements of any financings; Â Â Â â—announcements by commercial partners or competitors of new commercial products, clinical progress or the lack of, significant contracts, commercial relationships or capital commitments; Â Â Â â—failure to elicit meaningful stock analyst coverage and downgrades of our stock by analysts; and Â Â Â â—the loss of key personnel. Â 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 companyâ€™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. Â 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. Â 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. Â 24 Â Â We do not anticipate paying any dividends in the foreseeable future. Â 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 your sole source of gain, if any, for the foreseeable future. Â 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. Â 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. Â 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. Â 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. Â 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. Â Provisions in our certificate of incorporation, as amended (â€œCertificate of Incorporationâ€), and bylaws, as amended (â€œBylawsâ€) 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. Â If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired. Â 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 periodic reports. This reporting will require us to incur substantial professional fees and internal costs to expand our accounting and finance functions and to expend significant management efforts. Â 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. Â 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. Â 25 Â Our Board of Directors has broad discretion to issue additional securities, which might dilute the net tangible book value per share of our common stock for existing stockholders. Â We are entitled under our Certificate of Incorporation to issue up to 280,000,000 shares of common stock and 7,000,000 â€œblank checkâ€ 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 October 25, 2024, we had outstanding, common stock or securities convertible into common stock, totaling 2,814,455 shares. As a result, we are authorized to issue up to an additional 277,185,545 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. Â General Risk Factors Â 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. Â 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 CMOsâ€™ 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 pre-clinical 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. Â 26 Â Â Unstable economic and market conditions may have serious adverse consequences on our business, financial condition, and stock price. Â 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 customersâ€™ 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. Â 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. Â 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. Â In the ordinary course of our business, it may process, as defined above, proprietary, confidential, and sensitive data, including personal data (such as health-related patient data), intellectual property, and trade secrets (collectively, sensitive information). We may rely upon third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, third-party providers of cloud-based infrastructure, employee email, CROs, and other functions. Our ability to monitor these third partiesâ€™ 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. Â 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. Â 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. Â 27 Â Â 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. Â 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. Â 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. Â 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. Â 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. Â Our business and operations would suffer in the event of system failures, cyber-attacks or a deficiency in our cybersecurity. Â 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. Â 28 Â Â NOTE REGARDING FORWARD-LOOKING STATEMENTS Â This prospectus and any applicable prospectus supplement or free writing prospectus, including the documents that we incorporate by reference herein and therein, contain â€œforward-looking statementsâ€ within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements relate to future events or to our future operating or financial performance and involve known and unknown risks, uncertainties and other factors 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. Forward-looking statements may include, but are not limited to, statements about: Â Â â— the results of our pre-clinical studies and clinical trials; Â Â Â Â â— 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 generated; Â Â Â Â â— future regulatory, judicial, and legislative changes or developments in the U.S. and foreign countries and the impact of these changes; Â Â Â Â â— our ability to successfully develop our licensed technologies; Â Â Â Â Â â— our ability to build a commercial infrastructure in the U.S. and other markets; Â Â Â Â â— our ability to compete effectively in a competitive industry; Â Â Â Â â— our ability to identify and qualify additional manufacturers to provide API and manufacture drug product; Â Â Â Â â— our ability to enter into commercial supply agreements; Â Â Â Â â— the success of competing technologies that are or may become available; Â Â Â Â â— our ability to attract and retain key scientific or management personnel; Â Â Â Â â— the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing; Â Â Â Â â— our ability to obtain funding for our operations; and Â Â Â Â â— our ability to attract collaborators and strategic partnerships. Â In some cases, you can identify forward-looking statements by terms such as â€œmay,â€ â€œwill,â€ â€œintend,â€ â€œshould,â€ â€œcould,â€ â€œwould,â€ â€œexpects,â€ â€œplans,â€ â€œanticipates,â€ â€œbelieves,â€ â€œestimates,â€ â€œprojects,â€ â€œpredicts,â€ â€œpotentialâ€ and similar expressions intended to identify forward-looking statements. 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. Â These forward-looking statements are based on the current beliefs and expectations of our management and are subject to significant risks and uncertainties. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results may differ materially from current expectations and projections. Factors that might cause such a difference include the risk factors identified under the caption â€œRisk Factorsâ€ in this prospectus, as well as those identified under the caption â€œRisk Factorsâ€ in our Annual Report on Form 10-K, filed with the SEC on March 26, 2024 and our Quarterly Reports on Form 10-Q, filed with the SEC on May 13, 2024 and August 12, 2024. Â 29 Â Â You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this prospectus or, in the case of documents referred to or incorporated by reference, the date of those documents. Â All subsequent written or oral forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. We do not undertake any obligation to release publicly any revisions to these forward-looking statements to reflect events or circumstances after the date of this prospectus or to reflect the occurrence of unanticipated events, except as may be required under applicable U.S. securities law. If we do update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements. Â All subsequent written or oral forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. We do not undertake any obligation to release publicly any revisions to these forward-looking statements to reflect events or circumstances after the date of this prospectus or to reflect the occurrence of unanticipated events, except as may be required under applicable U.S. securities law. If we do update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements. Â USE OF PROCEEDS Â We estimate that the net proceeds from the sale of securities in this offering will be approximately $ Â Â Â Â Â Â Â million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise the over-allotment option in full, we estimate that our net proceeds will be approximately $ Â Â Â Â Â million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. Â Our expected use of the net proceeds from this offering represents our current intentions based upon our present plans and business condition. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon completion of this offering, or the amounts that we will actually spend on the uses set forth above. However, we currently plan to use the net proceeds to us from this offering primarily for our recently approved Phase 1 clinical trial of PALI-2108, pre-clinical studies, research and development, and working capital. Â The amounts and timing of our actual use of net proceeds will vary depending on numerous factors, including the relative success and cost of our research and development programs and our ability to gain access to additional financing. As a result, our management will have broad discretion in the application of the net proceeds, and investors will be relying on our managementâ€™s judgment regarding the application of the net proceeds of this offering. In addition, we might decide to postpone or not pursue certain development activities if the net proceeds from the offering and any other sources of cash are less than expected. Â Pending the uses described above, we plan to invest these net proceeds in short-term, interest-bearing investments, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the United States. We also may use a portion of the net proceeds from the offering to fund acquisitions or other business development opportunities. However, we have no current commitments or obligations with respect to any such acquisitions or business development opportunities at this time. Â MARKET INFORMATION Â Our common stock is listed on The Nasdaq Capital Market under the symbol â€œPALI.â€ On October 29, 2024, the last reported sale price for our common stock on The Nasdaq Capital Market was $3.385 per share. As of October 29, 2024, we had approximately 139 stockholders of record. Â DIVIDEND POLICY Â We do not anticipate declaring or paying, in the foreseeable future, any cash dividends on our capital stock. We intend to retain all available funds and future earnings, if any, to fund the development and expansion of our business. Any future determination regarding the declaration and payment of dividends, if any, will be at the discretion of our Board and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our Board may deem relevant. Â 30 Â Â CAPITALIZATION Â The following table sets forth our cash and cash equivalents and capitalization as of June 30, 2024 on: Â Â â— an actual basis; Â Â Â Â â— a proforma basis after adjusting for the following issuances subsequent to June 30, 2024: (i) an aggregate of 346,142 shares that were issued pursuant to the exercise of outstanding pre-funded warrants issued in our May 2024 private placement and (ii) 17,029 shares that were issued to consultants; and Â Â Â Â â— a pro forma as adjusted basis, giving effect to the sale of Â Â Â Â Â Â shares of common stock, at the assumed public offering price of $ Â Â Â Â Â Â Â per share of common stock, which was the last reported sale price of our common stock on the Nasdaq Capital Market on Â Â Â Â Â Â Â ,2024, and no exercise by the underwriters of the over-allotment option after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Â The pro forma as adjusted information below is illustrative only, and our capitalization following the closing of this offering will be adjusted based on the actual public offering price and other terms of this offering determined at pricing. You should read the following table in conjunction with our consolidated financial statements, including the related notes, and â€œManagementâ€™s Discussion and Analysis of Financial Condition and Results of Operationsâ€ from our Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, which are incorporated by reference into this prospectus. Â Â Â As of June 30, 2024Â Â Â (unaudited) (in thousands)Â Â Â ActualÂ Â Pro FormaÂ Â Pro Forma as AdjustedÂ Cash and cash equivalentsÂ $11,353Â Â $11,353Â Â $Â Â Â Â Â Â Â Â Â Â Â Stockholdersâ€™ equity:Â Â Â Â Â Â Â Â Â Â Â Â Series A Convertible Preferred Stock, $0.01 par value per share, 7,000,000 shares authorized as of June 30, 2024, actual, pro forma and pro forma as adjusted; 200,000 shares issued and outstanding as of June 30, 2024, actual, pro forma and pro forma as adjustedÂ Â 2Â Â Â 2Â Â Â Â Â Common stock, $0.01 par value; 280,000,000 shares authorized as of June 30, 2024 actual, pro forma, and adjusted pro forma, 966,345 shares issued and outstanding as of June 30, 2024, actual, 1,329,516 shares issued and outstanding as of June 30, 2024, proforma, and shares issued and outstanding as of June 30, 2024, pro forma as adjustedÂ Â 9Â Â Â 12Â Â Â Â Â Additional paid-in capitalÂ Â 139,051Â Â Â 139,109Â Â Â Â Â Accumulated deficitÂ Â (129,113)Â Â (129,174)Â Â () Total stockholdersâ€™ equityÂ Â 9,949Â Â Â 9,949Â Â Â Â Â Total capitalizationÂ $12,871Â Â $12,871Â Â $Â Â 31 Â Â The foregoing table is based on 966,345 shares of our common stock outstanding as of June 30, 2024, which is then adjusted for the following issuances subsequent to June 30, 2024 for an aggregate of 1,329,516 shares outstanding: (i) an aggregate of 346,142 shares that were issued pursuant to the exercise of outstanding pre-funded warrants issued in our May 2024 private placement and, and (ii) 17,029 shares that were issued to consultants, but excludes: Â â—Â Â Â Â Â Â Â shares of common stock issuable upon the exercise of pre-funded warrants issued in this offering; Â Â Â â—Â Â Â Â Â Â Â shares of common stock issuable upon the exercise of the representative warrants issued as compensation to the representative of the underwriters in this offering; Â Â Â â—452 shares of common stock issuable upon exercise of outstanding stock options as of October 25, 2024 granted under the LBS 2013 Amended and Restated Employee, Director, and Consultant Equity Incentive Plan, as amended and restated, or the 2013 Plan, with a weighted-average exercise price of $14,403.57 per share; Â Â Â â—41,091 shares of common stock issuable upon exercise of outstanding stock options as of October 25, 2024, granted under the 2021 Equity Incentive Plan, as amended, or the 2021 Plan, with a weighted-average exercise price of $43.53 per share; Â Â Â â—10,190 shares of common stock issuable upon exercise of outstanding stock options as of October 25, 2024 granted under the 2021 Inducement Plan, with a weighted average exercise price of $17.67 per share; Â Â Â â—776 shares of common stock issuable upon vesting of restricted stock units outstanding as of October 25, 2024, granted under the 2021 Plan; Â Â Â â—2,952 shares of common stock issuable upon vesting of restricted performance stock units outstanding as of October 25, 2024; all of which were issued under the 2021 Plan which vest subject to certain milestones; Â Â Â â—36,653 shares of common stock reserved for future issuances under the 2021 Plan as of October 25, 2024, as well as any future automatic increases in the number of shares of common stock reserved for future issuance under the 2021 Plan; Â Â Â â—20,587 shares of common stock reserved for future issuance under our 2021 Employee Stock Purchase Plan, or the ESPP, as of October 25, 2024, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the ESPP; Â Â Â â—52,831 shares of common stock reserved for issuance under the 2021 Inducement Plan as of October 25, 2024; Â Â Â â—184,000 shares of common stock issuable upon the exercise of outstanding pre-funded warrants issued in our May 2024 offering as of October 25, 2024 with an exercise price of $0.0001 per share; Â Â Â â—1,245,470 shares of common stock issuable upon exercise of outstanding warrants as of October 25, 2024 with a weighted-average exercise price of $27.04 per share; and Â Â Â â—8 shares of common stock issuable upon conversion of the 200,000 outstanding shares of our Series A 4.5% Convertible Preferred Stock as of October 25, 2024, as well as any future shares of common stock issuable upon conversion of additional shares of Series A 4.5% Convertible Preferred Stock that may be issued as payment-in-kind dividends thereon in accordance with their terms. Â 32 Â Â DILUTION Â If you invest in our securities, your ownership interest will be diluted to the extent of the difference between the public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after the closing of this offering. Â Our historical net tangible book value as of June 30, 2024 was $9.9 million, or $10.30 per share. Our historical net tangible book value is the amount of our total tangible assets less our liabilities. Our historical net tangible book value per share is our historical net tangible book value divided by the number of shares of common stock outstanding on June 30, 2024. As of June 30, 2024, we had 966,345 shares outstanding and subsequent to June 30, 2024, we issued the following: (i) an aggregate of 346,142 shares that were issued pursuant to the exercise of outstanding pre-funded warrants issued in our May 2024 private placement and, and (ii) 17,029 shares that were issued to consultants for an aggregate of 1,329,516 shares outstanding as of October 25, 2024. Accordingly, our pro forma net tangible book value was $9.9 million, or $7.48 per share as of June 30, 2024. The dilution information set forth in the table below is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing. Â Pro forma as adjusted net tangible book value dilution per share to new investors represents the difference between the amount per share paid by purchasers of shares of common stock in this offering and the pro forma as adjusted net tangible book value per share of common stock immediately after completion of this offering. After giving effect to the sale by us in this offering of Â Â Â Â Â Â shares of common stock at a public offering price of $ Â Â Â Â Â Â Â Â Â per share of common stock, which was the last reported sale price of our common stock on the Nasdaq Capital Market on Â Â Â Â Â Â Â Â Â , 2024, and no exercise by the underwriters of the over-allotment option and no sale of any pre-funded warrants, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses that we will pay, our pro forma as adjusted net tangible book value as of June 30, 2024 would have been approximately $ Â Â Â Â Â Â Â million or $ Â Â Â Â Â Â Â per share of common stock. This amount represents an immediate increase in net tangible book value of $ Â Â Â Â Â Â Â per share to existing shareholders and an immediate dilution of $ Â Â Â Â Â Â per share to investors in this offering. Â The following table illustrates this dilution on a per share basis to new investors: Â Assumed public offering price per share of common stockÂ Â Â Â Â $Â Pro Forma net tangible book value per share as of June 30, 2024Â $7.48Â Â Â Â Increase in pro forma net tangible book value per share attributable to new investors in this offeringÂ $Â Â Â Â Pro forma as adjusted net tangible book value per share after giving effect to this offeringÂ Â Â Â $Â Dilution per share to new investors participating in this offeringÂ Â Â Â $Â Â The discussion and table above are based 966,345 shares of our common stock outstanding as of June 30, 2024, which is then adjusted for the following issuances subsequent to June 30, 2024 for an aggregate of 1,329,516 shares outstanding as of October 25, 2024: (i) an aggregate of 346,142 shares that were issued pursuant to the exercise of outstanding pre-funded warrants issued in our May 2024 private placement and, and (ii) 17,029 shares that were issued to consultants, but excludes: Â â—

Â Â Â Â Â Â Â Â shares of common stock issuable upon the exercise of pre-funded warrants issued in this offering; Â Â Â â—Â Â Â Â Â Â Â Â Â shares of common stock issuable upon the exercise of the representative warrants issued as compensation to the representative of the underwriters in this offering; Â Â Â â—452 shares of common stock issuable upon exercise of outstanding stock options as of October 25, 2024 granted under the LBS 2013 Amended and Restated Employee, Director, and Consultant Equity Incentive Plan, as amended and restated, or the 2013 Plan, with a weighted-average exercise price of $14,403.57 per share; Â Â Â â—41,091 shares of common stock issuable upon exercise of outstanding stock options as of October 25, 2024, granted under the 2021 Equity Incentive Plan, as amended, or the 2021 Plan, with a weighted-average exercise price of $43.53 per share; Â Â Â â—10,190 shares of common stock issuable upon exercise of outstanding stock options as of October 25, 2024 granted under the 2021 Inducement Plan, with a weighted average exercise price of $17.67 per share; Â 33 Â Â â—776 shares of common stock issuable upon vesting of restricted stock units outstanding as of October 25, 2024, granted under the 2021 Plan; Â Â Â â—2,952 shares of common stock issuable upon vesting of restricted performance stock units outstanding as of October 25, 2024; all of which were issued under the 2021 Plan which vest subject to certain milestones; Â Â Â â—36,653 shares of common stock reserved for future issuances under the 2021 Plan as of October 25, 2024, as well as any future automatic increases in the number of shares of common stock reserved for future issuance under the 2021 Plan; Â Â Â â—20,587 shares of common stock reserved for future issuance under our 2021 Employee Stock Purchase Plan, or the ESPP, as of October 25, 2024, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the ESPP; Â Â Â â—52,831 shares of common stock reserved for issuance under the 2021 Inducement Plan as of October 25, 2024; Â Â Â â—184,000 shares of common stock issuable upon the exercise of outstanding pre-funded warrants issued in our May 2024 offering as of October 25, 2024 with an exercise price of $0.0001 per share; Â Â Â â—1,245,470 shares of common stock issuable upon exercise of outstanding warrants as of October 25, 2024 with a weighted-average exercise price of $27.04 per share; and Â Â Â â—8 shares of common stock issuable upon conversion of the 200,000 outstanding shares of our Series A 4.5% Convertible Preferred Stock as of October 25, 2024, as well as any future shares of common stock issuable upon conversion of additional shares of Series A 4.5% Convertible Preferred Stock that may be issued as payment-in-kind dividends thereon in accordance with their terms. Â CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS Â Other than compensation arrangements, including employment, termination of employment and change in control arrangements, with our directors and executive officers, and the other transactions discussed in the sections titled â€œExecutive Compensation,â€ â€œDirector Compensation,â€ and â€œCertain Relationships and Related Party Transactionsâ€ in our Definitive Proxy Statement on Schedule 14A filed with the SEC on May 22, 2024 and incorporated by reference herein, the following is a description of each transaction since January 1, 2021 and each currently proposed transaction in which: Â Â (i) the amounts involved exceeded or will exceed the lesser of (a) $120,000 or (b) 1% of the average of our total assets for the fiscal years ended December 31, 2023 or 2022; and Â (ii) any of our directors, executive officers or holders of more than 5% of our capital stock, or any member of the immediate family of, or person sharing the household with, the foregoing persons, had or will have a direct or indirect material interest. Â Â â— In April 2021, Dr. Kenneth Carter, Dr. Matthew Kalnik, and Mr. Dane Saglio, and Senecaâ€™s senior vice president of research and development agreed to the cancellation of their respective outstanding options to purchase common stock in Seneca immediately prior to the closing of our merger with Seneca in exchange for aggregate consideration of $1,423,012. Dr. Carter, Dr. Kalnik, and Mr. Saglio served as (i) Executive Chairman, (ii) President and Chief Operating Officer, and (iii) Chief Financial Officer of Seneca, respectively, until the closing of our merger with Seneca in April 2021. Â 34 Â Â â— In July 2021, Altium Growth Fund, LP (â€œAltiumâ€), a then holder of more than five percent of our common stock, entered into a Waiver and Amendment Agreement with the Company (the â€œWaiver Agreementâ€). Pursuant to the Waiver Agreement, we and Altium agreed to waive certain rights, waive the reset provisions with respect to the exercise price and number of shares subject to the outstanding warrants held by Altium, eliminate certain financing restrictions, and accelerate registration rights for the shares underlying the warrants. As consideration for the foregoing, pursuant to the Waiver Agreement, we issued Altium an additional warrant to purchase up to 1,466 shares of our common stock. The Waiver Agreement also provides that we will file a resale registration statement for the shares underlying Altiumâ€™s warrants, including the additional warrant to purchase up to 1,466 shares of our common stock, before July 31, 2021, which was completed. Â Effective January 31, 2022 (the â€œ2022 Effective Timeâ€), Altium entered into a Waiver and Amendment Agreement with us (the â€œ2022 Waiver Agreementâ€). Pursuant to the 2022 Waiver Agreement, we agreed with Altium to irrevocably waive any adjustment to the exercise price of the existing warrants held by Altium from and after 2022 Effective Time for our issuances of equity or equity-linked securities at a price below the exercise price of the warrants. The 2022 Waiver Agreement also includes agreement by the parties to, among other things, (i) restrict Altiumâ€™s ability to sell our securities through a â€œleak outâ€ provision whereby sales are restricted by applying a volume limitation, (ii) shorten the notice period for Altiumâ€™s participation rights related to certain future securities offerings, (iii) restrict our ability to conduct a primary offering of its securities for a specified period of time, and (iv) provide registration rights for the shares underlying the January 2022 Warrant (defined below). As consideration for the foregoing, pursuant to the 2022 Waiver Agreement, we issued Altium an additional warrant to purchase up to 3,000 shares of our common stock (the â€œJanuary 2022 Warrantâ€). The January 2022 Warrant was exercisable beginning six months following the 2022 Effective Time. Â Â Â Â â— In August 2021, we and Yuma Regional Medical Center (â€œYumaâ€), a then holder of more than five percent of our common stock, entered into a Securities Purchase Agreement pursuant to which Yuma purchased 2,013 shares of our common stock and a warrant to purchase up to 503 shares of our common stock for a total purchase price of $5.2 million. The warrant is exercisable for five years. Dr. Trenschel, our former director, did not have any pecuniary interest in these securities and disclaimed beneficial ownership of them. Dr. Trenschel is the president and chief executive officer of Yuma. Â Pursuant to the securities purchase agreement, we agreed to file one or more registration statements with the SEC registering the resale of the shares and the shares of our common stock issuable upon exercise of the warrant by Yuma, to have all such registration statements declared effective within the timeframes set forth in the purchase agreement, and to keep such registration statements effective for up to five years. Â Â Â Â â— In October 2020, we issued and sold to Yuma (i) an unsecured promissory note in the principal amount of $0.5 million with an interest rate of 10% per annum (the â€œYuma Notesâ€) and (ii) warrants to purchase 2 shares of our common stock at an exercise price of $20,137.50 per share (the â€œOld Yuma Warrantsâ€). The Old Yuma Warrants were immediately exercisable and expire ten years from the date of issuance. In May 2021, we entered into an agreement with Yuma to amend the Yuma Notes to extend the maturity date of the Yuma Notes to November 15, 2021 (the â€œNotes Amendmentâ€). In connection with the Notes Amendment, the Old Yuma Warrants were cancelled and we issued new warrants to purchase 7 shares of our common stock at $4,500.00 per share to Yuma. Â Â Â Â â— We determined that the outstanding stock options under the 2013 Plan had an exercise price per share that was significantly higher than the current fair market value of our common stock (the â€œUnderwater Optionsâ€). On November 18, 2021, the Compensation Committee resolved that it was in the best interests of the Company and its stockholders to amend the Underwater Options for Dr. Hallam, Mr. Finley and Dr. Dawson, our former Chief Executive Officer, current Chief Executive Officer, and former Chief Medical Officer, respectively, to reduce the exercise price per share to $1,740.00, the closing per share price of the Companyâ€™s common stock on November 18, 2021 (the â€œRepricingâ€). In accordance with the 2013 Plan requirements, the holders of the Underwater Options identified under the Repricing consented to the modification of their affected awards. All the other terms of the Underwater Options other than the exercise price remained the same, including the number of shares granted, vesting schedule and expiration date. We determined that the Repricing represented a modification of share-based awards under ASC 718. Accordingly, we recognized an incremental compensation expense of $0.4 million for the year ended December 31, 2021. Of the incremental compensation expense recognized, $200,939, $147,197 and $37,574 was attributable to shares held by Dr. Hallam, Mr. Finley and Dr. Dawson, respectively Â 35 Â Â â— During the fiscal year ended December 31, 2021, the Company paid the following compensation to its non-executive directors that served as directors at any time during such year: Â Â â—‹ An aggregate of $492,102 in cash; Â â—‹ An aggregate of $36,960 in stock awards consisting of 1,600 restricted stock units awarded to directors by Seneca Biopharma, Inc., prior to the merger with LBS; and Â â—‹ An aggregate of $489,489 in value of stock option grants consisting of 64 options granted to 7 directors during 2021, each having an exercise price of $1,740.00 per share and a term of 10 years. Â Â â— Pursuant to a registered offering in May 2022, we sold an aggregate of 4,862 shares of our common stock, par value $0.01 per share, at a purchase price per share of $412.50 to certain investors. In a concurrent private placement, we also sold purchase warrants to such purchasers to purchase up to 4,862 shares of our common stock at an exercise price of $532.875 per share, the closing bid price of our common stock on May 5, 2022. Altium Growth Fund LP, a holder of greater than 5% of our common stock at the time of purchase, purchased 1,200 shares and 1,200 common stock warrants. The warrants were not exercisable until six months following the date of issuance and expire five and a half years from the date of issuance Â Â Â Â â— On August 16, 2022, J.D. Finley, our current Chief Executive Officer and Chief Financial Officer, participated in the Companyâ€™s underwritten offering. Pursuant to the offering, Mr. Finley invested $25,000 in exchange for 133 units at $187.50 per unit consisting of an aggregate of (i) 133 shares of Common Stock, (ii) 133 Series 1 Common Stock purchase warrants and (iii) 133 Series 2 Common Stock purchase warrants. The Series 1 warrants had a term of one year from issuance and expired on August 16, 2023. The Series 2 warrants have a term of five years from issuance. Both Series 1 and Series 2 warrants initially had exercises prices of $187.50 but have been subsequently reduced as a result of adjustments to the exercise prices for future offerings contained in the warrants. As of October 25, 2024, the Series 2 warrants have an exercise price of $6.31 per share. Â Â Â Â â— On August 16, 2022, Thomas Hallam, PhD, our former Chief Executive Officer and former member of our Board, participated in the Companyâ€™s underwritten offering. Pursuant to the offering, Dr. Hallam invested $10,000 in exchange for 53 units at $187.50 per unit consisting of an aggregate of (i) 53 shares of Common Stock, (ii) 53 Series 1 Common Stock purchase warrants and (iii) 53 Series 2 Common Stock purchase warrants. The Series 1 warrants had a term of one year from issuance and expired on August 16, 2023. The Series 2 warrants have a term of five years from issuance. Both Series 1 and Series 2 warrants initially had exercises prices of $187.50 but have been subsequently reduced as a result of adjustments to the exercise prices for future offerings contained in the warrants. As of October 25, 2024, the Series 2 warrants have an exercise price of $6.31 per share. Â Â Â Â â— On October 11, 2022, we entered into a separation agreement with Thomas Hallam, Ph.D., our former chief executive officer and member of its Board whereby the Company and Dr. Hallam agreed to a mutual release of claims in exchange for (i) the payment of an aggregate of $530,000 payable in twelve equal monthly installments, (ii) up to twelve (12) months of continued COBRA coverage, (iii) twelve (12) months of immediate vesting of his outstanding equity grants subject to time based vesting, and (iv) up to six (6) months of virtual job replacement services valued at $3,100. Subsequent to entering into the separation agreement, certain facts and conduct by Dr. Hallam were discovered that excused the Companyâ€™s performance under the settlement agreement. As a result, subsequent to paying Dr. Hallam an aggregate of $22,000, we determined that it is not probable that any additional compensation would be due to Dr. Hallam. Â Â Â Â â— During the fiscal year ended December 31, 2022, we paid our non-employee directors an aggregate of $475,000 in cash for services on the Board and associated committees. No individual director received more than $115,000 in such fiscal year. Â Â Â Â Â â— 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 vested in 4 equal quarterly installments over the grant year. The restricted stock units were issued from the 2021 Plan. Â 36 Â Â Â Â â— 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. Â Â Â Â â— On February 6, 2023, we granted Robert McRae, our former Chief Operating Officer: (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. Â Â Â Â â— On February 22, 2023, the Compensation Committee amended our non-employee director compensation policy. The Compensation Committee again amended the non-employee director compensation policy June 24, 2024. For a full discussion of this policy, see the section of this S-1 entitled â€œDirector Compensationâ€. Â Â Â Â â— 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 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. Â Â Â Â â— Effective May 15, 2023, Robert McRae, our then Chief Operating Officer (â€œCOOâ€) 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 us and his outstanding equity awards ceased vesting. Â Â Â Â â— Effective June 1, 2023, we increased J.D. Finleyâ€™s base salary from $490,000 to $542,000 contemporaneous with his appointment from interim CEO to CEO. Additionally, Mr. Finleyâ€™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 ten (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 twelve (12) equal installments on a quarterly basis over three (3) years. The equity grants were issued from our 2021 Plan. Â Â Â Â â— On June 11, 2023, the Company granted to the 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 ten (10) years and an exercise price of $24.00 per share and (ii) 2,416 restricted stock units. Each of the grants vests fully on the one (1) year anniversary of the grant date. The aggregate options were valued at $78,136 and the aggregate restricted stock units were valued at $57,984. The equity grants were issued from the 2021 Plan. Â 37 Â Â Â Â â— 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 ten (10) years and an exercise price of $10.35 per share and (ii) 3,646 restricted stock units. The options vest quarterly over three (3) 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 eleven (11) equal quarterly periods after the initial vesting date. The options were valued at $33,267 and the restricted stock units were valued at $37,727, respectively from the grant date. The equity grants were issued from the Palisade 2021 Inducement Plan. Â Â Â Â â— 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 Plan, 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 ten (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 twelve (12) equal installments on a quarterly basis over three (3) years. Â Â Â Â â— 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 Plan, 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 ten (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 twelve (12) equal installments on a quarterly basis over three (3) years. Â Â Â Â â— On November 21, 2023, the Company 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 ten (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 (1) year anniversary of the grant date. The aggregate of all options were valued at $23,494 and the aggregate of all restricted stock units were valued at $24,037. The equity grants were issued from the 2021 Plan. Â Â Â Â Â â— 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) 2,898 options issued on June 11, 2023 having an exercise price of $24.00 per share and a term of 10 years and (ii) 1,834 options issued on November 21, 2023, having an exercise price of $8.85 per share and a term of 10 years. Â Â Â Â â— 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 (10) years and an exercise price of $7.90 per share. The options vest in twelve (12) 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 Plan. Â Â Â Â â— On July 11, 2024, we granted each of our three (3) 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 (10) years and an exercise price of $4.49 per share. The options vest fully on the one (1) 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 Plan. Â Â Â Â â— 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. Â Â Â Â â— 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. Â 38 Â Â SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT Â The following table sets forth information regarding beneficial ownership of our capital stock as of October 25, 2024 by: Â Â â— each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock; Â Â Â Â Â â— each of our directors; Â Â Â Â Â â— each of our named executive officers; and Â Â Â Â Â â— all of our current executive officers and directors as a group. Â The information in the following table is calculated based on 1,329,516 shares of our common stock outstanding as of October 25, 2024. Beneficial ownership is determined according to the rules of the SEC. Beneficial ownership means that a person has or shares voting or investment power of a security and includes any securities that person or group has the right to acquire within 60 days after the measurement date, including upon the exercise of common stock purchase options or warrants or the conversion of preferred stock. Â Name of Beneficial Owner (1)Â Number of Shares Beneficially OwnedÂ Â Percentage of Shares Beneficially OwnedÂ Greater than 5% StockholdersÂ Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Directors and Named Executive OfficersÂ Â Â Â Â Â Â Â Thomas Hallam, Ph.D. (2)Â Â 54Â Â Â *Â Donald Williams (3)Â Â 5,078Â Â Â *Â Binxian Wei (4)Â Â 2,015Â Â Â *Â J.D. Finley (5)Â Â 22,358Â Â Â 1.67% Michael Dawson, M.D. (6)Â Â -Â Â Â *Â Herbert Slade, MD FAAAAI (7)Â Â -Â Â Â *Â Robert McRae (8)Â Â 304Â Â Â *Â Mitchell Jones, M.D., Ph.D. (9)Â Â 6,671Â Â Â *Â Margery Fischbein (10)Â Â 167Â Â Â *Â All directors and executive officers as a group (9 persons) (11)Â Â 36,647Â Â Â 2.73% Â Â * Represents less than one percent Â (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 October 25, 2024 are deemed to be outstanding for the purpose of computing the number of shares held and the percent of total ownership of the person holding those options, warrants, 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 1,329,516 shares of common stock outstanding on October 25, 2024, adjusted as required by rules promulgated by the SEC. Unless otherwise indicated, the address of the beneficial owner is c/o Palisade Bio, Inc. 7750 El Camino Real, Suite 2A, Carlsbad, CA 92009. Â 39 Â Â (2) Includes 54 shares of common stock underlying common stock purchase warrants. Dr. Hallam ceased to be an officer and director of the Company effective October 11, 2022. Â Â (3) Includes (i) 3,340 shares of common stock, (ii) 388 shares of common stock underlying restricted stock units (RSUs), and (iii) 1,350 shares of common stock underlying stock options. Â Â (4) Includes (i) 467 shares of common stock, (ii) 388 shares of common stock underlying RSUs, and (iii) 1,160 shares of common stock underlying stock options. Â Â (5) 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) 8,699 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 Companyâ€™s common stock. Â Â (6) Dr. Dawson ceased to be an officer of the Company effective October 11, 2022. Â Â (7) Dr. Slade was appointed to serve as our Chief Medical Officer on November 17, 2022 and ceased to be our Chief Medical Officer on September 5, 2023. Â Â (8) Includes (i) 289 shares of common stock and (ii) 15 shares of common stock that may be acquired pursuant to the exercise of outstanding warrants. Mr. McRae was appointed to serve as our Chief Operating Officer on February 2, 2023. Effective May 15, 2023, Mr. McRae transitioned to a consultant until January 15, 2024. Â Â (9) Includes (i) 3,852 shares of common stock, and (ii) 2,819 shares of common stock underlying options. Â Â (10) Margery Fischbein was appointed to the Board on May 7, 2024. Includes 167 shares of common stock underlying options. Â Â (11) Includes the securities described in footnotes (2)-(10) above. Â Â * Represents less than one percent. Â DESCRIPTION OF CAPITAL STOCK Â The following summary is a description of the material terms of our capital stock. This summary is not complete and is qualified by reference to our Certificate of Incorporation and our Bylaws, which are filed as exhibits to this prospectus and are incorporated by reference herein. We encourage you to read our Certificate of Incorporation, our Bylaws and the applicable provisions of the Delaware General Corporation Law for additional information. Â As of the date of this prospectus, our authorized capital stock consists of 280,000,000 shares of common stock, par value $0.01 per share, and 7,000,000 shares of preferred stock, par value $0.01 per share. Â Common Stock Â Shares of our common stock have the following rights, preferences and privileges: Â 40 Â Â Fully Paid and Non-Assessable. All outstanding shares of common stock are duly authorized, validly issued, fully paid, and nonassessable. All authorized but unissued shares of our common stock are available for issuance by our Board without any further stockholder action, except as required by the listing standards of the Nasdaq Stock Market. Â Voting Rights. Our common stock is entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders. Any action at a meeting at which a quorum is present will be decided by a majority of the voting power present in person or represented by proxy, except in the case of any election of directors, which will be decided by a plurality of votes cast. There is no cumulative voting. Â Dividends and Distributions. Subject to preferences that may be applicable to any then outstanding preferred stock, holders of our common stock are entitled to receive dividends when, as and if declared by our Board out of funds legally available for payment, subject to the rights of holders, if any, of any class of stock having preference over the common stock. Any decision to pay dividends on our common stock will be at the discretion of our board of directors. Our Board may or may not determine to declare dividends in the future. The Boardâ€™s determination to issue dividends will depend upon our profitability and financial condition any contractual restrictions, restrictions imposed by applicable law and the SEC, and other factors that our Board deems relevant. Â Liquidation Rights. In the event of a voluntary or involuntary liquidation, dissolution or winding up of the company, the holders of our common stock will be entitled to share ratably on the basis of the number of shares held in any of the assets available for distribution after we have paid in full, or provided for payment of, all of our debts and after the holders of all outstanding series of any class of stock have preference over the common stock, if any, have received their liquidation preferences in full. Â Other. Holders of shares of our common stock are not entitled to preemptive rights. Shares of our common stock are not convertible into shares of any other class of capital stock, nor are they subject to any redemption or sinking fund provisions. Â Preferred Stock Â Under the terms of our Certificate of Incorporation, our Board has the authority, without further action by our stockholders, to issue up to 7,000,000 shares of preferred stock in one or more series pursuant to a resolution or resolutions providing for such issue duly adopted by our Board. Our Board is further authorized, subject to limitations prescribed by law, to fix by resolution or resolutions the designations, powers, preferences and rights, and the qualifications, limitations or restrictions thereof, of any wholly unissued series of preferred stock, including without limitation authority to fix by resolution or resolutions the dividend rights, dividend rate, conversion rights, voting rights, rights and terms of redemption (including sinking fund provisions), redemption price or prices, and liquidation preferences of any such series, and the number of shares constituting any such series and the designation thereof, or any of the foregoing. Â Our Board may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control and may adversely affect the market price of the common stock and the voting and other rights of the holders of our common stock. Â Series A 4.5% Convertible Preferred Stock Â In December 2016, we designated a series of our preferred stock as Series A 4.5% Convertible Preferred Stock consisting of 1,000,000 designated shares (which is subject to increase without the consent of all of the holders of the Series A 4.5% Convertible Preferred Stock in the event such additional shares of Series A 4.5% Convertible Preferred Stock are issued solely to the holders as payment of accrued dividends). Â 41 Â Â As of October 25, 2024, we had outstanding 200,000 shares of Series A 4.5% Convertible Preferred Stock with a stated value of $12.79 per share held by one holder and which are immediately convertible into an aggregate of 8 shares of common stock. The Series A 4.5% Convertible Preferred Stock have no provisions regarding subsequent securities issuances or so called â€œprice protection provisions.â€ The holders of Series A 4.5% Convertible Preferred Stock shall be entitled to receive dividends in cash or additional shares of Series A 4.5% Convertible Preferred Stock if and when declared by our Board in preference to the payment of any dividends on our common stock. The holders of Series A 4.5% Convertible Preferred Stock shall have no voting rights but shall be entitled to appoint one member to our Board. This right to appoint a member of the Board will terminate when there are less than 200,000 shares of Series A 4.5% Convertible Preferred Stock outstanding. As long as any shares of Series A 4.5% Convertible Preferred Stock are outstanding, we shall not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series A 4.5% Convertible Preferred Stock, alter or change adversely the powers, preferences or rights given to the Series A 4.5% Convertible Preferred Stock or alter or amend the Certificate of Designation, other than to authorize and issue additional shares of Series A 4.5% Convertible Preferred Stock. In addition, holders of Series A 4.5% Convertible Preferred Stock are subject to certain beneficial ownership limitations. Â Pre-Funded Warrants (Issued May 2024) Â The following summary of certain terms and provisions of pre-funded warrants that we issued during our private offering in May of 2024 to one investor and is not complete and is subject to, and qualified in its entirety by, the provisions of the pre-funded warrant, the form of which is filed as an exhibit 4.01 to our Current Report on Form 8-K that was filed with the SEC on May 3, 2024, is incorporated herein by reference. Â Form. The pre-funded warrants were issued as an individual warrant agreement to one investor. You should review the form of pre-funded warrant for a complete description of the terms and conditions applicable to such pre-funded warrant. Â Exercisability. The pre-funded warrant is exercisable, at the holderâ€™s option, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full in immediately available funds for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as described below). The holder (together with its affiliates) may not exercise any portion of the pre-funded warrant to the extent that it will own more than 9.99% of our outstanding common stock immediately after exercise, after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the pre-funded warrant. No fractional shares of common stock will be issued in connection with the exercise of such pre-funded warrant. In lieu of fractional shares, we will pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price. Â Duration and Exercise Price. The exercise price per whole share of our common stock purchasable upon the exercise of the pre-funded warrant is $0.0001 per share of common stock. The pre-funded warrant is immediately exercisable and may be exercised at any time until the pre-funded warrant is exercised in full. The exercise price of the pre-funded warrant is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and upon any distributions of assets, including cash, stock or other property to our stockholders. Â Cashless Exercise. If, at any time a registration statement registering the issuance of the shares of common stock underlying the pre-funded warrant under the Securities Act is not then effective or available (or a prospectus is not available for the resale of shares of common stock underlying the pre-funded warrant), then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder shall instead receive upon such exercise (either in whole or in part) only the net number of shares of common stock determined according to a formula set forth in the pre-funded warrant. Notwithstanding anything to the contrary, in the event we do not have or maintain an effective registration statement, there are no circumstances that would require us to make any cash payments or net cash settle the pre-funded warrant to the holder. Â Transferability. Subject to applicable laws, the pre-funded warrant may be offered for sale, sold, transferred or assigned at the option of the holder upon surrender of the pre-funded warrant to us together with the appropriate instruments of transfer. Â Exchange Listing. We do not plan on applying to list the pre-funded warrant on the Nasdaq Capital Market, any other national securities exchange or any other nationally recognized trading system. Â 42 Â Â Fundamental Transactions. In the event of a fundamental transaction, as described in the pre-funded warrant and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holder of the pre-funded warrant will be entitled to receive upon exercise of the pre-funded warrant, the kind and amount of securities, cash or other property that the holder would have received had they exercised the pre-funded warrant immediately prior to such fundamental transaction. Â Rights as a Stockholder. Except by virtue of such holderâ€™s ownership of shares of our common stock, the holder of a pre-funded warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the pre-funded warrant. Â Options Â As of October 25, 2024, we had outstanding stock options to purchase an aggregate of 51,733 shares of common stock issued pursuant to (i) Leading BioSciences 2013 Amended and Restated, Employee, Director and Consultant Equity Incentive Plan, (ii) the 2021 Plan, and (iii) the 2021 Inducement Plan, as amended. The options have a remaining weighted average term of approximately 8.8 years and an average weighted exercise price of $163.90 per share. Â Restricted Stock Units Â As of October 25, 2024, we had an aggregate of 776 shares of common stock underlying restricted stock units. The restricted stock units outstanding vest fully on the one (1) year anniversary of the grant date and currently have a remaining average vesting term of approximately 0.12 years. Â Performance Restricted Stock Units Â As of October 25, 2024, we had an aggregate of 2,952 restricted performance stock units that 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. Â Warrants Â As of October 25, 2024, we had outstanding common stock purchase warrants to purchase an aggregate of 1,245,470 shares of common stock, with a remaining average term of 5.98 years and a weighted average exercise price of $27.04 per share. Â Additionally, as of October 25, 2024, we had outstanding pre-funded common stock purchase warrants to purchase an aggregate of 184,000 shares of common stock, with a perpetual term and an exercise price of $0.0001 per share that were all issued to a single investor in our May 2024 private placement. Â Limitations on Liability and Indemnification of Officers and Directors Â Our Certificate of Incorporation and our Bylaws limit the liability of our officers and directors and provide that we will indemnify our officers and directors, in each case, to the fullest extent permitted by the Delaware General Corporation Law. Â We have entered into separate indemnification agreements with each of our directors and executive officers. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors or executive officers, we have been informed that in the opinion of the SEC such indemnification is against public policy and is therefore unenforceable. Â 43 Â Â Certificate of Incorporation and Bylaw Provisions Â Our Certificate of Incorporation and our Bylaws include a number of anti-takeover provisions that may have the effect of encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include: Â Board Composition and Filling Vacancies. Because our stockholders do not have cumulative voting rights, the holders of a plurality of the voting power of the shares present in person or represented by proxy at the meeting and entitled to vote on the election of directors, can elect all of the directors standing for election, if they so choose, other than any directors that holders of any preferred stock we have or may issue may be entitled to elect. Our Bylaws also provide that subject to the rights of the holders of any series of preferred stock then outstanding, any director or the entire Board may be removed from office at any time, with or without cause, by the affirmative vote of the holders of at least a majority of the voting power of the issued and outstanding shares of capital stock of the Company then entitled to vote in the election of directors. Â Special Meeting of Stockholders. Our Bylaws also provides that a special meeting of stockholders may be called only by our chairperson of the Board, chief executive officer or president, the secretary or any two directors. Â Advance Notice Requirements. Our Bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of stockholders. These procedures provide that notice of stockholder proposals must be timely and given in writing to our corporate Secretary. Generally, to be timely, notice must be received at our principal executive offices not fewer than 120 calendar days prior to the first anniversary date on which our notice of meeting and related proxy statement were mailed to stockholders in connection with the previous yearâ€™s annual meeting of stockholders. The notice must contain the information required by the Bylaws, including information regarding the proposal and the proponent. Â Amendment to Bylaws. The Board is expressly empowered to adopt, amend or repeal the Bylaws. The stockholders shall also have power to adopt, amend or repeal the Bylaws; provided, however, that, in addition to any vote of the holders of any class or series of stock of the Company required by law or by the Certificate of Incorporation, the affirmative vote of the holders of at least a majority of the voting power of all of the then outstanding shares of capital stock of the Company entitled to vote generally in the election of directors, voting together as a single class, shall be required to adopt, amend or repeal any provision of the Bylaws. Â Exclusive Forum Provision. Our Bylaws provide that unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the Company, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Company to the Company or the Companyâ€™s stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL or the Certificate of Incorporation or Bylaws (as either may be amended from time to time), or (iv) any action asserting a claim governed by the internal affairs doctrine shall be the Court of Chancery in the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware). If any action the subject matter of which is within the scope of the preceding sentence is filed in a court other than a court located within the State of Delaware (a â€œForeign Actionâ€) in the name of any stockholder, such stockholder shall be deemed to have consented to (i) the personal jurisdiction of the state and federal courts located within the State of Delaware in connection with any action brought in any such court to enforce the preceding sentence and (ii) having service of process made upon such stockholder in any such action by service upon such stockholderâ€™s counsel in the Foreign Action as agent for such stockholder. Â Delaware Takeover Statute Â We are subject to Section 203 of the DGCL which, subject to certain exceptions, prohibits a Delaware corporation from engaging in any â€œbusiness combinationâ€ (as defined below) with any interested stockholder for a period of three years following the date that such stockholder became an interested stockholder, unless: (1) prior to such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder; (2) on consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding those shares owned (x) by persons who are directors and also officers and (y) by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to this plan will be tendered in a tender or exchange offer; or (3) on or subsequent to such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2â„3% of the outstanding voting stock that is not owned by the interested stockholder. Â 44 Â Â Section 203 of the DGCL defines generally â€œbusiness combinationâ€ to include: (1) any merger or consolidation involving the corporation and the interested stockholder; (2) any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder; (3) subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder; (4) any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or (5) the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation. In general, Section 203 defines an â€œinterested stockholderâ€ as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by such entity or person. Â Transfer Agent and Registrar Â The transfer agent and registrar for our common stock is Equiniti Trust Company, LLC. We act as the transfer agent and registrar for our Series A 4.5% Convertible Preferred Stock and Series B Convertible Preferred Stock to the extent any shares are outstanding. Â Listing on the Nasdaq Capital Market Â Our common stock is listed on The Nasdaq Capital Market under the symbol â€œPALI.â€ Â DESCRIPTION OF SECURITIES WE ARE OFFERING Â The following summary of certain terms and provisions of the securities that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the underlying securities, the forms of which are filed as exhibits to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the forms of securities for a complete description of the terms and conditions. Â Common Stock Â The material terms and provisions of our common stock and each other class of our securities which qualifies or limits our common stock are described under the caption â€œDescription of Capital Stockâ€ in this prospectus. Â Description of Pre-Funded Warrants Â The following summary of certain terms and provisions of pre-funded warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the pre-funded warrant, the form of which will be filed as an exhibit to the registration statement of which this prospectus forms a part. You should review the form of pre-funded warrant for a complete description of the terms and conditions applicable to the pre-funded warrants. Â Form. Pursuant to a warrant agency agreement between us and Equiniti Trust Company, LLC, as warrant agent, the pre-funded warrants will be issued in book-entry form and shall initially be represented only by one or more global warrants deposited with the warrant agent, as custodian on behalf of The Depository Trust Company, or DTC, and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC. Â 45 Â Â Exercisability. The pre-funded warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full in immediately available funds for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as described below). A holder (together with its affiliates) may not exercise any portion of the pre-funded warrant to the extent that the holder would own more than 4.99% (or, at the election of the holder, 9.99%) of the outstanding common stock immediately after exercise, except that upon at least 61 daysâ€™ prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holderâ€™s pre-funded warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the pre-funded warrants. Purchasers of pre-funded warrants in this offering may also elect prior to the issuance of the pre-funded warrants to have the initial exercise limitation set at 9.99% of our outstanding common stock. No fractional shares of common stock will be issued in connection with the exercise of a pre-funded warrant. In lieu of fractional shares, we will either pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price or round up to the nearest whole share. Â Duration and Exercise Price. The exercise price per whole share of our common stock purchasable upon the exercise of the pre-funded warrants is $0.0001 per share of common stock. The pre-funded warrants will be immediately exercisable and may be exercised at any time until the pre-funded warrants are exercised in full. The exercise price of the pre-funded warrants is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and upon any distributions of assets, including cash, stock or other property to our stockholders. Â Cashless Exercise. If, at any time after the holderâ€™s purchase of pre-funded warrants, such holder exercises its pre-funded warrants and a registration statement registering the issuance of the shares of common stock underlying the pre-funded warrants under the Securities Act is not then effective or available (or a prospectus is not available for the resale of shares of common stock underlying the pre-funded warrants), then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder shall instead receive upon such exercise (either in whole or in part) only the net number of shares of common stock determined according to a formula set forth in the pre-funded warrants. Notwithstanding anything to the contrary, in the event we do not have or maintain an effective registration statement, there are no circumstances that would require us to make any cash payments or net cash settle the pre-funded warrants to the holders. Â Transferability. Subject to applicable laws, the pre-funded warrants may be offered for sale, sold, transferred or assigned at the option of the holder upon surrender of the pre-funded warrant to us together with the appropriate instruments of transfer. Â Exchange Listing. We do not plan on applying to list the pre-funded warrants on the Nasdaq Capital Market, any other national securities exchange or any other nationally recognized trading system. Without an active trading market, the liquidity of the pre-funded warrants will be limited. Â Fundamental Transactions. In the event of a fundamental transaction, as described in the pre-funded warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the pre-funded warrants will be entitled to receive upon exercise of the pre-funded warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the pre-funded warrants immediately prior to such fundamental transaction. Â Rights as a Stockholder. Except by virtue of such holderâ€™s ownership of shares of our common stock, the holder of a pre-funded warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the pre-funded warrant. Â 46 Â Â UNDERWRITING Â We are offering the securities described in this prospectus through the underwriters named below. We have entered into an underwriting agreement dated Â , 2024 with Ladenburg Thalmann & Co. Inc., as the representative of the underwriters in this offering. Subject to the terms and conditions of the underwriting agreement, the underwriters have agreed to purchase the number of our securities set forth opposite its name below. Â UnderwritersÂ Number of SharesÂ Â Number of Pre-funded WarrantsÂ Ladenburg Thalmann & Co. Inc.Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â TotalsÂ Â Â Â Â Â Â Â Â A copy of the underwriting agreement will be filed as an exhibit to the registration statement of which this prospectus is part. Â We have been advised by the underwriters that they propose to offer the shares of common stock and pre-funded warrants, if any, directly to the public at the public offering price set forth on the cover page of this prospectus. Any securities sold by the underwriters to securities dealers will be sold at the public offering price less a selling concession not in excess of $ Â Â Â Â Â Â Â per share of common stock (or per pre-funded warrant). Â The underwriting agreement provides that the underwritersâ€™ obligation to purchase the securities we are offering is subject to conditions contained in the underwriting agreement. Â No action has been taken by us or the underwriters that would permit a public offering of the securities in any jurisdiction outside the United States where action for that purpose is required. None of our securities included in this offering may be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sales of any of the securities offering hereby be distributed or published in any jurisdiction except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons who receive this prospectus are advised to inform themselves about and to observe any restrictions relating to this offering of securities and the distribution of this prospectus. This prospectus is neither an offer to sell nor a solicitation of any offer to buy the securities in any jurisdiction where that would not be permitted or legal. Â The underwriters have advised us that they do not intend to confirm sales to any account over which they exercise discretionary authority. Â Underwriting Discount and Expenses Â The following table summarizes the underwriting discount and commission to be paid to the underwriters by us. Â Â Â Per ShareÂ Â Per Pre-Funded WarrantÂ Â Total Without Over- AllotmentÂ Â Total With Full Over-AllotmentÂ Public offering price (1)Â $Â Â Â Â Â Â Â Â Â $Â Â Â Â Â Â Â Â Â $Â Â Â Â Â Â Â Â Â Â $Â Â Â Â Â Â Â Â Â Â Underwriting discounts and commissions (2)(3)Â $Â Â Â $Â Â Â $Â Â Â $Â Â Proceeds to us, before expensesÂ $Â Â Â $Â Â Â $Â Â Â $Â Â Â (1)The public offering price and underwriting discount corresponds, in respect of the securities of a public offering price per share of common stock (or pre-funded warrant) of $ Â Â Â Â Â Â Â Â Â ($Â Â Â Â Â Â Â Â net of the underwriting discount). (2)We have also agreed to reimburse the accountable expenses of the representative, including a pre-closing expense allowance of up to a maximum of $20,000 and an additional closing expense allowance up to a maximum of $95,000. (3)We have granted a forty-five day over-allotment option to the underwriters to purchase up to an aggregate of additional shares of common stock at the assumed public offering price per share of common stock set forth above less the underwriting discounts and commissions solely to cover over-allotments, if any. Â 47 Â Â Assuming gross proceeds of $ Â Â Â Â Â , we estimate the total expenses payable by us for this offering to be approximately $ Â Â Â Â Â , which amount includes (i) the underwriting discount of approximately $Â Â Â Â Â Â , (ii) reimbursement of the accountable expenses of the underwriters, including the legal fees of the representative of the underwriters, in an amount not to exceed $115,000 and (iii) other estimated company expenses of approximately $ Â Â Â Â Â Â , which includes legal, accounting, printing costs and various fees associated with the registration and listing of our securities. Â The securities we are offering are being offered by the underwriters subject to certain conditions specified in the underwriting agreement. Â Over-allotment Option Â We have granted to the underwriters an option exercisable not later than forty-five days after the date of this prospectus to purchase up to an aggregate of an additional Â Â Â Â Â shares of common stock at the assumed public offering price per share of common stock set forth on the cover page hereto less the underwriting discounts and commissions. The underwriters may exercise the option solely to cover overallotments, if any, made in connection with this offering. If any additional shares of common stock are sold, the underwriters will offer such securities on the same terms as those on which the other securities are being offered. Â Representative Warrants Â We have agreed to issue certain common stock purchase warrants (â€œrepresentative warrantsâ€) to the representative, or its designees, of the underwriters, upon the closing of this offering, which entitle it to purchase up to Â Â Â Â shares of common stock, or Â Â Â Â shares of common stock assuming the exercise of the over-allotment option in full. The representative warrants will have an exercise price equal to $ Â Â Â Â Â per share of common stock, will be exercisable immediately upon issuance, at any time and from time to time, in whole or in part, during the five-year period commencing from the commencement of sales of this offering. The representative warrants and the shares of common stock underlying the representative warrants are being registered on the registration statement of which this prospectus is a part. See the form of representative warrant for a more complete description of the terms of such representative warrants which will be filed as an exhibit to the registration statement of which this prospectus is part. Â Listing Â Our shares of common stock are listed on The Nasdaq Capital Market under the symbol â€œPALI.â€ Â The last reported sale price of our shares of common stock on October 29, 2024, was $3.385 per share. The final public offering price will be determined between us, the underwriters and the investors in the offering, and may be at a discount to the current market price of our common stock. Therefore, the assumed public offering price used throughout this prospectus may not be indicative of the final public offering price. There is no established public trading market for the pre-funded warrants, and we do not expect such a market to develop. In addition, we do not intend to apply for a listing of the pre-funded warrants on any national securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the pre-funded warrants will be limited. Â Lock-up Agreements Â Each of our officers, directors and each of their respective affiliates and associated partners, and certain affiliated stockholders have agreed with the underwriters to be subject to a lock-up period of ninety (90) days following the closing of this offering, subject to certain exceptions. This means that, during the applicable lock-up period, such persons may not offer for sale, contract to sell, sell, distribute, grant any option, right or warrant to purchase, pledge, hypothecate or otherwise dispose of, directly or indirectly, any shares of our common stock or any securities convertible into, or exercisable or exchangeable for, shares of our common stock. Certain limited transfers are permitted during the lock-up period if the transferee agrees to these lock-up restrictions. We have also agreed, in the underwriting agreement, to similar lock-up restrictions on the issuance and sale of our securities from the date of this prospectus for a period of ninety (90) days following the closing of this offering, subject to certain exceptions. The representative may, in its sole discretion and without notice, waive the terms of any of these lock-up agreements. Â 48 Â Â Right of First Refusal Â Pursuant to our investment banking agreement with the representative dated April 10, 2024, provided that the Company consummates transactions during the term of our agreement (â€œTermâ€) resulting in at least $4 million of gross proceeds, from the nine (9) months following the date of such closing and expiration of the Term, should we propose to effect an additional financing, we have agreed to offer the representative the opportunity to participate as a joint bookrunner, co-lead placement agent or co-lead sales agent or financial advisor in respect of such financing, provided the right of first refusal period may be extended depending on certain conditions being met during the Term. Â Transfer Agent and Registrar Â The transfer agent and registrar for our common stock is Equiniti Trust Company, LLC. Â Determination of Offering Price Â Our common stock is currently traded on The Nasdaq Capital Market under the symbol â€œPALI.â€ On October 29, 2024, the closing price of our common stock was $3.385 per share. We do not intend to apply for listing of the pre-funded warrants on any securities exchange or other trading system. Â The public offering price of the securities offered by this prospectus will be determined by negotiation between us and the underwriters. Among the factors that will be considered in determining the public offering price: Â â—our history and our prospects; â—the industry in which we operate; â—our past and present operating results; â—the previous experience of our executive officers;

and â—the general condition of the securities markets at the time of this offering. Â The public offering price stated on the cover page of this prospectus should not be considered an indication of the actual value of the shares of common stock or pre-funded warrants sold in this offering. That price is subject to change as a result of market conditions and other factors, and we cannot assure you that the shares of common stock and warrants sold in this offering can be resold at or above the public offering price. Â Stabilization, Short Positions and Penalty Bids Â The underwriters may engage in syndicate covering transactions stabilizing transactions and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of our common stock: Â â—Syndicate covering transactions involve purchases of securities in the open market after the distribution has been completed in order to cover syndicate short positions. Such a naked short position would be closed out by buying securities in the open market. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the securities in the open market after pricing that could adversely affect investors who purchase in the offering. â—Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specific maximum. â—Penalty bids permit the underwriters to reclaim a selling concession from a syndicate member when the securities originally sold by the syndicate member are purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions. Â 49 Â Â These syndicate covering transactions, stabilizing transactions, and penalty bids may have the effect of raising or maintaining the market prices of our securities or preventing or retarding a decline in the market prices of our securities. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may be effected on The Nasdaq Capital Market, in the over-the-counter market or on any other trading market and, if commenced, may be discontinued at any time. Â In connection with this offering, the underwriters also may engage in passive market making transactions in our common stock in accordance with Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of the distribution. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for that security. However, if all independent bids are lowered below the passive market makerâ€™s bid that bid must then be lowered when specific purchase limits are exceeded. Passive market making may stabilize the market price of the securities at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time. Â Neither we nor the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the prices of our securities. In addition, neither we nor the underwriters make any representation that the underwriters will engage in these transactions or that any transactions, once commenced will not be discontinued without notice. Â Other Relationships Â From time to time, certain of the underwriters and their affiliates may provide in the future, various advisory, investment and commercial banking and other services to us in the ordinary course of business, for which they will receive customary fees and commissions. The representative has acted as underwriter and placement agent in connection with our past offerings consummated in May 2022, August 2022, January 2023, April 2023, September 2023, February 2024, and May 2024, and may receive additional compensation in connection with advisory services. Â Indemnification Â We have agreed to indemnify the underwriters against certain liabilities, including certain liabilities arising under the Securities Act, or to contribute to payments that the underwriters may be required to make for these liabilities. Â Electronic Distribution Â A prospectus in electronic format may be made available on the websites maintained by the underwriters, if any, participating in this offering and the underwriters may distribute prospectuses electronically. Other than the prospectus in electronic format, the information on these websites is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or the underwriters, and should not be relied upon by investors. Â LEGAL MATTERS Â The validity of the shares of common stock being offered hereby will be passed upon for us by Silvestre Law Group, P.C., Westlake Village, California. The underwriters are being represented by Ellenoff, Grossman & Schole LLP. Â EXPERTS Â The consolidated financial statements of Palisade Bio, Inc. for the year ended December 31, 2023, incorporated by reference in this Prospectus, have been audited by Baker Tilly US, LLP, an independent registered public accounting firm, as stated in their report, which is incorporated herein by reference. Such consolidated financial statements have been so incorporated by reference in reliance upon the report of such firm given their authority as experts in accounting and auditing. The report on the consolidated financial statements contains an explanatory paragraph regarding the Companyâ€™s ability to continue as a going concern. Â 50 Â Â WHERE YOU CAN FIND MORE INFORMATION Â We have filed with the SEC a registration statement on Form S-1 under the Securities Act, with respect to the securities being offered by this prospectus. This prospectus does not contain all of the information in the registration statement and its exhibits. For further information with respect to us and the securities offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference. Â We are subject to the information and periodic reporting requirements of the Exchange Act, and we file periodic reports, proxy statements and other information with the SEC. You can read our SEC filings, including the registration statement, over the Internet at the SECâ€™s website at www.sec.gov. You may also request a copy of these filings, at no cost, by writing us at Palisade Bio, Inc., 7750 El Camino Real, Suite 2A, Carlsbad, CA 92009 or telephoning us at (858) 704-4900. We also maintain a website at www.palisadebio.com, at which you may access these materials free of charge after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not incorporated by reference in, and is not part of, this prospectus and any references to this web site or any other web site are inactive textual references only. Â INCORPORATION OF CERTAIN INFORMATION BY REFERENCE Â The SEC allows us to â€œincorporate by referenceâ€ the information we file with it, which means that we can disclose important information to you by referring to those documents. The information incorporated by reference is an important part of this prospectus, and information that we file later with the SEC will automatically update and supersede this information. This prospectus omits certain information contained in the registration statement, as permitted by the SEC. You should refer to the registration statement, including the exhibits, for further information about us and the securities we may offer pursuant to this prospectus. Statements in this prospectus regarding the provisions of certain documents filed with, or incorporated by reference in, the registration statement are not necessarily complete and each statement is qualified in all respects by that reference Â We incorporate by reference the following documents we filed with the SEC pursuant to Section 13 of the Exchange Act and any future filings we will make with the SEC under Sections 13(a), 13(c), 14, or 15(d) of the Exchange Act after the date of this prospectus until the termination of the offering of the securities covered by this prospectus (other than information furnished under Item 2.02 or Item 7.01 of Form 8-K): Â â—Our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on March 26, 2024, including the Part III information contained therein; Â â—Our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2024 and June 30, 2024, filed with the SEC on May 13, 2024 and August 12, 2024, respectively. Â â—our Current Reports on Form 8-K filed on January 29, 2024, February 1, 2024, February 13, 2024, March 6, 2024, March 27, 2024, April 5, 2024, April 10, 2024, May 3, 2024, May 10, 2024, July 8, 2024, and September 27, 2024; Â â—our Definitive Proxy Statement on Schedule 14A, filed with the SEC on May 22, 2024 (other than the portions thereof which are furnished and not filed); and Â â—the description of our common stock which is registered under Section 12 of the Exchange Act, in our registration statement on Form 8-A filed with the SEC on July 1, 2015, including any amendments or reports filed for the purpose of updating such description, including Exhibit 4.2 to our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on March 17, 2022. Â You may access the Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, Proxy Statements, and amendments, if any, to those documents filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act with the SEC free of charge at the SECâ€™s website (www.sec.gov) or our website (www.palisadebio.com) as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The reference to our website does not constitute incorporation by reference of the information contained in our website. We do not consider information contained on, or that can be accessed through, our website to be part of this prospectus or the related registration statement. Â We will provide to each person, including any beneficial owner, to whom a prospectus is delivered, without charge upon written or oral request, a copy of any or all of the information that is incorporated by reference into this prospectus but not delivered with the prospectus, including exhibits which are specifically incorporated by reference into such documents. You should direct any requests for documents to 7750 El Camino Real, Suite 2A, Carlsbad, CA 92009, Attn: Secretary or may be made telephonically at (858) 704-4900. Â 51 Â Â Â [*] Shares of Common Stock or Pre-Funded Warrants to Purchase up to [*] Shares of Common Stock Â Representative Warrants to Purchase up to [*] Shares of Common Stock Â Up to [*] Shares of Common Stock Issuable Upon Exercise of Pre-Funded Warrants and Representative Warrants Â PRELIMINARY PROSPECTUS Â Ladenburg Thalmann Â The date of this prospectus isÂ Â Â Â Â Â , 2024 Â Â Â Â PART II Â INFORMATION NOT REQUIRED IN PROSPECTUS Â Item 13. Other Expenses of Issuance and Distribution Â The following table sets forth the expenses to be incurred in connection with the offering described in this registration statement, all of which will be paid by the registrant. All amounts are estimates except the SEC registration fee. Â Â Â AmountÂ SEC registration feeÂ $ 841.28Â FINRA filing feeÂ $ [*]Â Printing expensesÂ $ [*]Â Legal fees and expensesÂ $ [*]Â Accounting fees and expensesÂ $ [*]Â Transfer agent fees and expensesÂ $ [*]Â Miscellaneous fees and expensesÂ $ [*]Â Â Â Â Â Â TotalÂ $ [*]Â Â Item 14. Indemnification of Directors and Officers Â We are incorporated under the laws of the State of Delaware. Sections 145 and 102(b)(7) of the General Corporation Law of the State of Delaware provide that a corporation may indemnify any person made a party to an action by reason of the fact that he or she was a director, executive officer, employee or agent of the corporation or is or was serving at the request of the corporation against expenses (including attorneysâ€™ fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by him or her in connection with such action if he or she acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful, except that, in the case of an action by or in right of the corporation, no indemnification may generally be made in respect of any claim as to which such person is adjudged to be liable to the corporation. Â Our Certificate of Incorporation contains provisions that eliminate, to the maximum extent permitted by the General Corporation Law of the State of Delaware, the personal liability of directors and executive officers for monetary damages for breach of their fiduciary duties as a director or officer. Our amended and restated Certificate of Incorporation and Bylaws provide that we shall indemnify our directors and executive officers and may indemnify our employees and other agents to the fullest extent permitted by the General Corporation Law of the State of Delaware. Â We have purchased and intend to maintain insurance on behalf of any person who is or was a director or officer of our company against any loss arising from any claim asserted against him or her and incurred by him or her in any such capacity, subject to certain exclusions. Â We have entered, and intend to continue to enter, into separate indemnification agreements with our directors and executive officers to provide these directors and executive officers additional contractual assurances regarding the scope of the indemnification set forth in the registrantâ€™s Certificate of Incorporation and amended and restated Bylaws and to provide additional procedural protections. At present, there is no pending litigation or proceeding involving a director or executive officer of the Company regarding which indemnification is sought. The indemnification provisions in our Certificate of Incorporation, amended and restated Bylaws and the indemnification agreements entered into or to be entered into between us and each of our directors and executive officers may be sufficiently broad to permit indemnification of our directors and executive officers for liabilities arising under the Securities Act. Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers or persons controlling the registrant pursuant to the foregoing provisions, the registrant has been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is therefore unenforceable. We carry liability insurance for our directors and officers. Â II-1 Â Â Item 15. Recent Sales of Unregistered Securities Â Set forth below is information regarding securities sold by us since January 1, 2021 that were not registered under the Securities Act. Also included is the consideration, if any, received by us for such shares and options and information relating to the section of the Securities Act, or rule of the Securities and Exchange Commission, under which exemption from registration was claimed. Â (a) Issuances of Securities Â Â 1. Immediately prior to the Merger with Seneca, we and LBS completed a private placement transaction (the â€œPre-Merger Financingâ€) with Altium Growth Fund, LP (â€œAltiumâ€) pursuant to that certain Securities Purchase Agreement, by and among us, LBS and the Investor, dated December 16, 2020, as amended, for an aggregate purchase price of $20.0 million. In connection with the closing of the Merger in April 2021 and the Pre-Merger Financing, we issued to Ecoban Securities, LLC (i) a warrant to purchase 24 shares of the Companyâ€™s common stock at a price of $13,290.00 per share and (ii) 158 shares of common stock, as payment for a success fee for closing the Merger and Pre-Merger Financing. Â Â 2. On May 20, 2021, we issued Altium a warrant to purchase 6,661 shares of common stock at a price of $4,147.50 per share. The warrant was immediately exercisable and has a term of five years from the date all of the shares underlying the warrant have been registered for resale. Â Â Â Â 3. On May 25, 2021, we amended outstanding notes originally issued by LBS in 2020 in order to extend the maturity date. In connection with such amendments, certain outstanding warrants to purchase 4,666 shares were canceled, and we issued warrants to the noteholders to purchase an aggregate of 10 shares of Company common stock at a purchase price of $4,500.00 per share. Â Â 4. Effective July 21, 2021, we entered into a Waiver and Amendment Agreement with Altium pursuant to which Altium agreed to waive certain rights, waive reset provisions with respect to the exercise price and number of shares subject to outstanding warrants held by Altium, eliminate certain financing restrictions, and accelerate registration rights for the shares underlying the warrants. As consideration for the foregoing, pursuant to the Waiver Agreement, we issued Altium an additional warrant to purchase up to 1,466 shares of our common stock with an exercise price of $2,723.25 per share. The warrant is exercisable beginning six months following the date on which the underlying shares are registered for resale and for five years thereafter. Â Â Â Â 5. On August 19, 2021, we issued 2,013 shares of common stock and a warrant to purchase up to 503 shares of common stock to Yuma Regional Medical Center for a total purchase price of $5,209,141.20. The shares were sold at a purchase price of $2,587.50 per share. The warrant has an exercise price of $2,587.50 per share, subject to certain adjustments, and is exercisable for five years. Â Â Â Â 6. Effective January 31, 2022, we and Altium entered into a Waiver and Amendment Agreement, pursuant to which Altium agreed to waive any adjustment to the exercise price of the existing warrants held by it from and after such date for issuances of equity or equity-linked securities at a price below the exercise price of the warrants. The Waiver Agreement also includes agreement to, among other things, (i) restrict Altiumâ€™s ability to sell our securities through a â€œleak outâ€ provision whereby sales are restricted by applying a volume limitation, (ii) shorten the notice period for Altiumâ€™s participation rights related to certain future securities offerings, (iii) restrict our ability to conduct a primary offering of our securities for a specified period of time, and (iv) provide registration rights for the shares underlying the warrant issued to Altium in consideration of the foregoing. As consideration for the foregoing, pursuant to the Waiver Agreement, we issued Altium an additional warrant to purchase up to 3,000 shares of our common stock. The warrant is exercisable beginning six months following January 31, 2022 and the exercise price is $825.00 (the closing price of our common stock on January 28, 2022), subject to customary adjustments for stock splits, stock dividends, stock combinations, reclassifications and similar transactions. Â II-2 Â Â Â 7. On May 6, 2022, we entered into a securities purchase agreement with certain institutional and accredited investors, pursuant to which we agreed to sell and issue, in a registered direct offering, an aggregate of 4,862 shares of our common stock at a purchase price per share of $412.50, for aggregate gross proceeds to us of approximately $2.0 million, before deducting fees payable to the placement agent and other estimated offering expenses payable by us. The shares were offered pursuant to an effective shelf registration statement on Form S-3. In connection with such offering, in a concurrent private placement, we also agreed to sell and issue to such purchasers warrants to purchase up to 4,862 shares of common stock at an exercise price of $532.875 per share, the closing bid price of our common stock on May 5, 2022. Such warrants are not exercisable until six months following the date of issuance and expire five and a half years from the date of issuance. In addition, pursuant to a placement agency agreement dated as of May 6, 2022, we engaged Ladenburg Thalmann & Co. Inc. (â€œLadenburgâ€) to act as our exclusive placement agent in connection with the aforementioned registered offering and private placement offering. We agreed to pay Ladenburg a cash fee equal to 7.75% of the aggregate gross proceeds raised in the aforementioned registered offering and private placement offering and to reimburse its expenses up to an aggregate of $85,000. In addition, we issued Ladenburg warrants on substantially the same terms as the warrants issued to the purchasers in an amount equal to 6.0% of the aggregate number of shares sold in the offering, or 292 shares of common stock, at an exercise price of $532.95 per share and a five-and-a-half year term. The placement agent warrants are not exercisable until six months following the date of issuance. Â Â Â Â 8. On December 30, 2022, we entered into securities purchase agreements with certain institutional and accredited investors, pursuant to which we agreed to sell and issue, in a registered direct offering, an aggregate of (i) 31,789 shares of our common stock at a purchase price per share of $35.63 and (ii) registered prefunded warrants to purchase 2,466 shares of common stock at an exercise price of $0.0015 per share. The transaction closed on January 4, 2023. The shares were offered pursuant to an effective shelf registration statement on Form S-3. In connection with such offering, in a concurrent private placement, we also agreed to sell and issue to such purchasers (i) prefunded warrants to purchase 35,919 shares of common stock at an exercise price of $0.0015 per share and (ii) warrants to purchase 70,175 shares of common stock at an exercise price of $35.63 per share. Such prefunded warrants and warrants are immediately exercisable and the prefunded warrants have a perpetual term and the other warrants expire five years from the date of issuance. Gross proceeds for the registered offering and concurrent private placement were approximately $2.5 million, before deducting fees payable to the placement agent and other estimated offering expenses payable by us. In addition, pursuant to a placement agency agreement dated as of December 30, 2022, we engaged Ladenburg to act as our exclusive placement agent in connection with the aforementioned registered offering and private placement offering. We agreed to pay Ladenburg a cash fee equal to 7.75% of the aggregate gross proceeds raised in the aforementioned registered offering and private placement offering and to reimburse its expenses up to an aggregate of $105,000. In addition, we issued Ladenburg warrants on substantially the same terms as the warrants issued to the purchasers in an amount equal to 6.0% of the aggregate number of shares sold in the offering, or 4,210 shares of common stock, at an exercise price of $44.53 per share and a five-year term. Â Â Â Â 9. On April 3, 2023, we entered into securities purchase agreements with certain institutional and accredited investors, pursuant to which we agreed to sell and issue, in a registered offering, an aggregate of 50,421 shares of our common stock. The transaction closed on April 5, 2023. Concurrently, in a private offering we offered and sold an aggregate of: (i) 30,349 unregistered shares of common stock, (ii) prefunded warrants to purchase 70,744 shares of common stock at an exercise price of $0.015 per share and (iii) warrants to purchase 151,514 shares of common stock at an exercise price of $40.35 per share. Such prefunded warrants and warrants were immediately exercisable and expire five years from the date of issuance. In addition, pursuant to a placement agency agreement dated as of April 3, 2023, we engaged Ladenburg to act as our exclusive placement agent in connection with the April 2023 Offering. We agreed to pay Ladenburg a cash fee equal to 7.75% of the aggregate gross proceeds received from the April 2023 Offering or $465,000 and we reimbursed its expenses of $85,000. In addition, we issued Ladenburg 9,090 placement agent warrants with terms substantially similar to the warrants issued in the offering. Â II-3 Â Â Â 10. On September 7, 2023, we entered into securities purchase agreements with certain institutional and accredited investors, pursuant to which we agreed to sell and issue, in a Registered Offering, an aggregate of 155,959 shares of our common stock. The transaction closed on September 11, 2023. In addition, pursuant to a placement agency agreement dated as of September 7, 2023, we engaged Ladenburg to act as our exclusive placement agent in connection with the September 2023 Offering. We agreed to pay Ladenburg a cash fee equal to 7.75% of the aggregate gross proceeds received from the September 2023 Offering or $152,294 and we reimbursed its expenses of $75,000. In addition, we issued Ladenburg 9,357 placement agent warrants. The placement agent warrants have a term of five (5) years and an exercise price of $15.75 per share. Â Â Â Â 11. On December 15, 2023, we entered into an engagement letter with MDM Worldwide Solutions, Inc. for the purpose of providing us with business advisory services. Pursuant to the agreement, in the event that we chose to renew the six (6) month term, we would be obligated to issue the consultant $50,000 of common stock based on the closing price of the Companyâ€™s common stock on the date of the agreement, or an aggregate of 5,603 shares of common stock, which occurred on June 17, 2024. The shares issued were fully vested on the grant date and valued at $26,222.04. Â Â Â Â 12. On May 6, 2024, we completed a private placement with an institutional investor whereby we sold (i) 85,100 shares of common stock, (ii) 530,142 prefunded warrants at a price per share or prefunded warrant of $6.5015. Each prefunded warrants has a perpetual term and an exercise price of $0.0001 per share. Additionally, we issued the purchaser warrants to purchase 922,863 shares of common stock, with an exercise price of $6.314 per share, and a term of seven (7) years from issuance. We received gross proceeds of approximately $4 million pursuant to the offering. We agreed to pay Ladenburg, our exclusive placement agent, a cash fee equal to 7.75% of the aggregate gross proceeds received from the offering or $310,000 and we reimbursed its expenses of $75,000. In addition, we issued Ladenburg 136,363 placement agent warrants. The placement agent warrants have a term of five (5) years and an exercise price of $10.727 per share. Â Â Â Â 13. On May 28, 2024, we issued 10,000 restricted shares of common stock to consultants as partial payment for rebranding and website services. The common stock shares were fully vested on the grant date and valued at $47,600 on the date of issuance. Â Â Â Â 14. On September 4, 2024, we issued 14,029 restricted shares of common stock to a consultant as partial payment for financial advisory services. The common stock shares were fully vested on the grant date and valued at $50,644.69 in aggregate on the date of issuance. Â Â Â Â 15. On October 1, 2024, we issued 3,000 restricted shares of common stock to a consultant as partial payment for services. The common stock shares were fully vested on the grant date and valued at $10,650 in aggregate on the date of issuance. Â The offers, sales and issuances of the securities described in this section (a) of Item 15 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 Regulation D promulgated under the Securities Act as transactions by an issuer not involving a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited investor within the meaning of Rule 501 of Regulation D under the Securities Act and had adequate access, through employment, business or other relationships, to information about the Company. Â (b) Issuances of Equity Awards Â Â 1. On April 1, 2021, we issued an aggregate of 4 restricted stock units (1 to each of our then current four current directors) as partial compensation for their service on the Board. Â Â Â 2. On September 8, 2021, we issued 16 shares of common stock to a consultant in exchange for services to the Company. Â II-4 Â Â Â 3. On February 6, 2023, the Company granted J.D. Finley, our interim Chief Executive Officer and Chief Financial Officer: (i) an option to purchase 3,813 shares of 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 restricted performance stock units valued at approximately $78,000, which vest (a) 50% when the volume weighted average price of the Companyâ€™s common stock over 20 consecutive trading days is $48.00, and (b) 50% when such volume weighted average price of the Companyâ€™s common stock over 20 consecutive trading days is $63.75. All of the grants issued to Mr. Finley as described in this paragraph were issued on a conditional basis and were subject to the receipt of shareholder approval of the grants, which was subsequently received on June 8, 2023. Â Â Â Â 4. On February 6, 2023, the Company granted Robert McRae, our Chief Operating Officer: (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) 586 restricted stock units valued at approximately $21,120 which vests in 12 equal installments quarterly over a three year period, and (iii) 1,193 restricted performance stock units valued at approximately $42,960, which vest (a) 50% when the volume weighted average price of the Companyâ€™s common stock over 20 consecutive trading days is $48.00, and (b) 50% when such volume weighted average price of the Companyâ€™s common stock over 20 consecutive trading days is $63.75. All of the grants issued to Mr. McRae as described in this paragraph were issued on a conditional basis and are subject to the receipt of shareholder approval of the grants, which were subsequently received on June 8, 2023. Â Â Â Â 5. On February 6, 2023, the Company granted certain non-executive employees, an aggregate of (i) options to purchase 820 shares of common stock valued at approximately $18,891, having an exercise price of $36.00 per share, a term of 10 years, and which vest quarterly over three years, (ii) 600 restricted stock units valued at approximately $21,600 which vest in 12 equal installments quarterly over a three year period, and (iii) 1,220 restricted performance stock units valued at approximately $43,920, which vest (a) 50% when the volume weighted average price of the Companyâ€™s common stock over 20 consecutive trading days is $48.00, and (b) 50% when such volume weighted average price of the Companyâ€™s common stock over 20 consecutive trading days is $63.75. All of the grants issued to such employees as described in this paragraph were issued on a conditional basis and are subject to the receipt of shareholder approval of the grants, which was subsequently received on June 8, 2023. Â Â Â Â 6. On June 11, 2023, the Company granted Mr. Finley: (i) options to purchase 9,900 shares of common stock with a term of ten (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 twelve (12) equal installments on a quarterly basis over three (3) years. The equity grants were issued from the Companyâ€™s 2021 Plan, which such shares were registered under the 2021 Plan on September 14, 2023. Â Â 7. On June 11, 2023, the Company granted to its non-executive employees an aggregate of: (i) options to purchase 6,477 shares of common stock with a term of ten (10) years and an exercise price of $24.00 per share, valued in aggregate at $99,436 at the grant date and (ii) 3,022 restricted stock units valued at $72,528. Each of the options and restricted stock units granted to the employees vest in twelve (12) equal installments on a quarterly basis over three (3) years. The equity grants were issued from the Companyâ€™s 2021 Plan, which such shares were registered under the 2021 Plan on September 14, 2023. Â Â Â Â 8. On June 11, 2023, the Company granted to the 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 ten (10) years and an exercise price of $24.00 per share and (ii) 2,416 restricted stock units. Each of the grants vests fully on the one (1) year anniversary of the grant date. The aggregate options were valued at $78,136 and the aggregate restricted stock units were valued at $57,984. The equity grants were issued from the 2021 Plan, which such shares were registered under the 2021 Plan on September 14, 2023. Â Â Â Â 9. 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 ten (10) years and an exercise price of $10.35 per share and (ii) 3,646 restricted stock units. The options vest quarterly over three (3) years from the grant date and the restricted stock units vests as follows: (a) 303 shares on November 6, 2023, and (b) the remaining 3,343 shares vest over eleven (11) equal quarterly periods after the initial vesting date. The options were valued at $33,267 and the restricted stock units were valued at $37,727, respectively from the grant date. The equity grants were issued from the 2021 Inducement Plan. Â II-5 Â Â The offers, sales and issuances of the securities described in this section (b) of Item 15 were deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act or Rule 506 of D promulgated under the Securities Act as transactions by an issuer not involving a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited investor within the meaning of Rule 501 of Regulation D under the Securities Act and had adequate access, through employment, business or other relationships, to information about the Company. Â Item 16. Exhibits and Financial Statement Schedules Â (a) Exhibits Â Exhibit Number Â Description of document 1.1& Â Form of Underwriting Agreement. 2.2â€ Â 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 Registrantâ€™s Current Report on Form 8-K, filed with the SEC on December 21, 2020). 3.1 Â Amended and Restated Certificate of Incorporation of the Registrant (Incorporated by reference to Exhibit 3.1 to the Registrantâ€™s Current Report on Form 8-K, filed with the SEC on April 27, 2021). 3.2 Â Certificate of Designation of Series A 4.5% Convertible Preferred Stock (Incorporated by reference to Exhibit 3.01 to the Registrantâ€™s Current Report on Form 8-K, filed with the SEC on September 12, 2016). 3.3 Â Amended and Restated Bylaws of the Registrant (Incorporated by reference to Exhibit 3.1 to the Registrantâ€™s Current Report on Form 8-K, filed with the SEC on March 6, 2024). 3.4 Â Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (Incorporated by reference to Exhibit 3.1 to the Registrantâ€™s Current Report on Form 8-K, filed with the SEC on August 16, 2022). 3.5 Â 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 Registrantâ€™s Current Report on Form 8-K, filed with the SEC on November 16, 2022). 3.6 Â 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 Registrantâ€™s Current Report on Form 8-K, filed with the SEC on April 5, 2024). 4.1 Â Reference is made to Exhibits 3.1, 3.2, 3.3, and 3.4 of this Exhibit Table. 4.2 Â Description of Securities (incorporated by reference to Exhibit 4.2 to the Registrantâ€™s Form 10-K, filed with the SEC on March 17, 2022). 4.3 Â Specimen Common Stock Certificate. (Incorporated by reference to Exhibit 4.3 to the Registrantâ€™s Annual Report on Form 10-K, filed with the SEC on March 17, 2022). 4.4 Â Form of Series A Preferred Stock Certificate (Incorporated by reference to Exhibit 4.01 to the Registrantâ€™s Current Report on Form 8-K, filed with the SEC on September 12, 2016). Â II-6 Â Â 4.5 Â Form of Consulting Warrant issued January 2011 and March 2012 (Incorporated by reference to Exhibit 4.01 to the Registrantâ€™s Registration Statement on Form S-3 (File No. 333-188859) original filed with the SEC on May 24, 2013 4.6 Â Form of Common Stock Purchase Warrant from August 2017 Public Offering Dated August 1, 2017 (Incorporated by reference to Exhibit 4.01 to the Registrantâ€™s Current Report on Form 8-K, filed with the SEC on July 28, 2017). 4.7 Â Form of Common Stock Purchase Warrant from October 2018 Offering (Incorporated by reference to Exhibit 4.01 to the Registrantâ€™s Current Report on Form 8-K, originally filed with the SEC on October 29, 2018) 4.8 Â Form of Placement Agent Common Stock Purchase Warrant from October 2018 Offering (Incorporated by reference to Exhibit 4.02 to the Registrantâ€™s Current Report on Form 8-K, originally filed with the SEC on October 29, 2018) 4.9 Â Consultant Warrant for Hibiscus BioVentures, LLC issued January 2019 (Incorporated by reference to Exhibit 4.40 to the Registrantâ€™s Form 10-Q, originally filed with the SEC on May 14, 2019) 4.10 Â Form of Series M and Series N warrant from July 2019 Offering (Incorporated by reference to Exhibit 4.45 to the Registrantâ€™s Registration Statement on Form S-1/A (File No. 333-232273), filed with the SEC on July 24, 2019) Â 4.11 Â Letter Agreement from January 2020 Offering (Incorporated by reference to Exhibit 10.01 to the Registrantâ€™s Current Report on Form 8-K, originally filed with the SEC on January 22, 2020) 4.12 Â Form of Series O Pre-Funded Warrant from July 2019 Offering (Incorporated by reference to Exhibit 4.45 to the Registrantâ€™s Registration Statement on Form S-1/A (File No. 333-232273), filed with the SEC on July 24, 2019) 4.13 Â Form of Series Q Replacement Warrant issued in January 2020 Offering (Incorporated by reference to Exhibit 4.02 to the Registrantâ€™s Current Report on Form 8-K, originally filed with the SEC on January 22, 2020) 4.14 Â Form of Placement Agent Agreement from January 2020 Offering (Incorporated by reference to Exhibit 10.02 to the Registrantâ€™s Current Report on Form 8-K, originally filed with the SEC on January 22, 2020) 4.15 Â Form of Placement Agent Warrant issued in January 2020 Offering (Incorporated by reference to Exhibit 4.03 to the Registrantâ€™s Current Report on Form 8-K, originally filed with the SEC on January 22, 2020) 4.16 Â Form of Placement Agent Warrant issued in May 2020 Offering (Incorporated by reference to Exhibit 4.01 to the Registrantâ€™s Current Report on Form 8-K, originally filed with the SEC on May 27, 2020) 4.17 Â Form of Securities Purchase Agreement with Investors from May 2020 Offering (Incorporated by reference to Exhibit 10.01 to the Registrantâ€™s Current Report on Form 8-K, originally filed with the SEC on May 27, 2020) 4.18 Â Form of Warrant to Purchase Shares of Common Stock of Leading BioSciences, Inc. (Incorporated by reference to Exhibit 4.30 to the Registrantâ€™s Registration Statement on Form S-4 (File No. 333-251659), originally filed with the SEC on December 23, 2020, as amended). 4.19 Â Form of Bridge Warrant of Leading BioSciences, Inc. (Incorporated by reference to Exhibit 4.1 to the Registrantâ€™s Current Report on Form 8-K, filed with the SEC on December 21, 2020). 4.20 Â Form of Equity Warrant of Leading BioSciences, Inc. (Incorporated by reference to Exhibit 4.2 to the Registrantâ€™s Current Report on Form 8-K, filed with the SEC on December 21, 2020). 4.21â€ Â 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 Registrantâ€™s Current Report on Form 8-K, filed with the SEC on December 21, 2020). 4.22 Â 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 Registrantâ€™s Current Report on Form 8-K, filed with the SEC on July 22, 2021). Â II-7 Â Â 4.23 Â Warrant, dated as of July 21, 2021, issued to Altium Growth Fund, LP (Incorporated by reference to Exhibit 4.2 to the Registrantâ€™s Current Report on Form 8-K, filed with the SEC on July 22, 2021). 4.24 Â 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 Registrantâ€™s Current Report on Form 8-K, filed with the SEC on February 21, 2022). 4.25 Â Warrant, dated as of January 31, 2022, issued to Altium Growth Fund, LP (Incorporated by reference to Exhibit 4.2 to the Registrantâ€™s Current Report on Form 8-K, filed with the SEC on February 21, 2022). 4.26 Â 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 Registrantâ€™s Current Report on Form 8-K, filed with the SEC on August 24, 2021). 4.27 Â Warrant, dated as of August 19, 2021, issued to Yuma Regional Medical Center (Incorporated by reference to Exhibit 4.2 to the Registrantâ€™s Current Report on Form 8-K, filed with the SEC on August 24, 2021). 4.28 Â Form of Common Stock Purchase Warrant (Incorporated by reference to Exhibit 4.1 to the Registrantâ€™s Current Report on Form 8-K, filed with the SEC on May 6, 2022). 4.29 Â Form of Placement Agent Warrant (Incorporated by reference to Exhibit 4.1 to the Registrantâ€™s Current Report on Form 8-K, filed with the SEC on May 6, 2022). 4.30 Â Form of Series 1 Common Stock Warrant (Incorporated by reference to Exhibit 4.1 to the Registrantâ€™s Current Report on Form 8-K, filed with the SEC on August 16, 2022). 4.31 Â Form of Series 2 Common Stock Warrant (Incorporated by reference to Exhibit 4.2 to the Registrantâ€™s Current Report on Form 8-K, filed with the SEC on August 16, 2022). 4.32 Â 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 Registrantâ€™s Current Report on Form 8-K, filed with the SEC on August 16, 2022). 4.33 Â Form of Series B Preferred Stock Certificate of Registrant (Incorporated by reference to Exhibit 4.33 to the Registrantâ€™s Registration Statement on Form S-1/A, filed with the SEC on August 9, 2022) 4.34 Â Form of Underwriter Warrant issued August 16, 2022 (Incorporated by reference to Exhibit 4.33 to the Registrantâ€™s Quarterly

Report on Form 10-Q, filed with the SEC on November 14, 2022). 4.35 Â Form of Registered Prefunded Warrant issued in January 2023 Registered Offering (Incorporated by reference to Exhibit 4.01 to the Registrantâ€™s Current Report on Form 8-K, filed with the SEC on January 4, 2023). 4.36 Â Form of Prefunded Warrant issued in January 2023 Private Placement (Incorporated by reference to Exhibit 4.02 to the Registrantâ€™s Current Report on Form 8-K, filed with the SEC on January 4, 2023). 4.37 Â Form of Warrant issued in January 2023 Private Placement (Incorporated by reference to Exhibit 4.03 to the Registrantâ€™s Current Report on Form 8-K, filed with the SEC on January 4, 2023). 4.38 Â Form of Placement Agent Warrant issued in January 2023 Private Placement (Incorporated by reference to Exhibit 4.04 to the Registrantâ€™s Current Report on Form 8-K, filed with the SEC on January 4, 2023). 4.39 Â Form of Prefunded Warrant issued in April 2023 Private Placement (Incorporated by Reference to Exhibit 4.01 to the Registrantâ€™s Current Report on Form 8-K, filed with the SEC on April 5, 2023). 4.40 Â Form of Warrant issued in April 2023 Private Placement (Incorporated by Reference to Exhibit 4.02 to the Registrantâ€™s Current Report on Form 8-K, filed with the SEC on April 5, 2023). 4.41 Â Form of Placement Agent Warrant issued in April 2023 Private Placement (Incorporated by reference to Exhibit 4.03 to the Registrantâ€™s Current Report on Form 8-K filed with the SEC on April 5, 2023). 4.42 Â Form of Placement Agent Warrant issued in September 2023 Private Placement (Incorporated by reference to Exhibit 4.01 to the Registrantâ€™s Current Report on Form 8-K filed with the SEC on September 11, 2023). Â II-8 Â Â 4.43 Â Form of Replacement Warrant issued in February 2024 Warrant Inducement Transaction (Incorporated by reference to Exhibit 4.01 to the Registrantâ€™s Current Report on Form 8-K filed with the SEC on February 1, 2024). 4.44 Â Form of Placement Agent Warrant issued in February 2024 Warrant Inducement Transaction (Incorporated by reference to Exhibit 4.02 to the Registrantâ€™s Current Report on Form 8-K filed with the SEC on February 1, 2024). 4.45 Â Form of Prefunded Common Stock Warrant issued in May 2024 Private Placement (Incorporated by reference to Exhibit 4.01 to the Registrantâ€™s Current Report on Form 8-K filed with the SEC on May 3, 2024). 4.46 Â Form of Common Stock Warrant issued in May 2024 Private Placement (Incorporated by reference to Exhibit 4.02 to the Registrantâ€™s Current Report on Form 8-K filed with the SEC on May 3, 2024). 4.47 Â Form of Placement Agent Warrant issued in May 2024 Private Placement (Incorporated by reference to Exhibit 4.03 to the Registrantâ€™s Current Report on Form 8-K filed with the SEC on May 3, 2024). 4.48& Â Form of Prefunded Common Stock Warrant 4.49& Â Form of Representative Warrant 4.50& Â Form of Warrant Agency Agreement 5.01& Â Opinion of Silvestre Law Group, P.C. 10.1+ Â Seneca Biopharma 2019 Equity Incentive Plan (Incorporated by reference to Appendix A to the Registrantâ€™s Definitive Proxy Statement, originally filed with the SEC on April 29, 2019). 10.2+ Â Form of Restricted Option Grant from 2019 Equity Incentive Plan (Incorporated by reference to Exhibit 4.43 to the Registrantâ€™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# Â 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 Registrantâ€™s Registration Statement on Form S-4 (File No. 333-251659), originally filed with the SEC on December 23, 2020, as amended). 10.4# Â 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 Registrantâ€™s Registration Statement on Form S-4 (File No. 333-251659), originally filed with the SEC on December 23, 2020, as amended). 10.5# Â License Agreement, by and between Palisade Bio, Inc. and The Regents of the University of California, dated July 6, 2021 (incorporated by reference to Exhibit 10.5 to the Registrantâ€™s Form 10-K, filed with the SEC on March 17, 2022). 10.6# Â 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 Registrantâ€™s Registration Statement on Form S-4 (File No. 333-251659), originally filed with the SEC on December 23, 2020, as amended). 10.7 Â 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 Registrantâ€™s Current Report on Form 8-K, filed with the SEC on December 21, 2020). 10.8 Â 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 Registrantâ€™s Current Report on Form 8-K, filed with the SEC on December 21, 2020). Â II-9 Â Â 10.9â€ Â 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 Registrantâ€™s Current Report on Form 8-K, filed with the SEC on December 21, 2020). 10.10â€ Â 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 Registrantâ€™s Current Report on Form 8-K, filed with the SEC on December 21, 2020). 10.11 Â 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 Registrantâ€™s Quarterly Report on Form 10-Q, filed with the SEC on May 14, 2021). 10.12 Â Form of Separation Agreement with Seneca Biopharma, Inc. Executives (Incorporated by reference to Exhibit 10.01 to the Registrantâ€™s Current Report on Form 8-K, filed with the SEC on March 18, 2021). 10.13â€ Â 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 Registrantâ€™s Current Report on Form 8-K, filed with the SEC on April 27, 2021). 10.14+ Â Form of Indemnification Agreement (incorporated by reference from Exhibit 10.03 to the Registrantâ€™s Current Report on Form 8-K filed with the SEC on December 18, 2018). 10.15+ Â 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 Registrantâ€™s Registration Statement on Form S-4 (File No. 333-251659), originally filed with the SEC on December 23, 2020, as amended). 10.16+ Â Palisade Bio, Inc. 2021 Equity Incentive Plan, as amended (Incorporated by reference to Exhibit 10.01 to the Registrantâ€™s Current Report on Form 8-K, filed with the SEC on June 9, 2023). 10.17+ Â 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 Registrantâ€™s Current Report on Form 8-K, filed with the SEC on November 23, 2021). 10.18+ Â 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 Registrantâ€™s Current Report on Form 8-K, filed with the SEC on November 23, 2021). 10.19+ Â Palisade Bio, Inc. Employee Stock Purchase Plan (Incorporated by reference to Exhibit 10.02 to the Registrantâ€™s Current Report on Form 8-K, filed with the SEC on June 9, 2023). 10.20+ Â Palisade Bio, Inc. 2021 Inducement Incentive Plan, as Amended August 7, 2023 (Incorporated by reference to Exhibit 10.20 to the Registrantâ€™s Quarterly Report on Form 10-Q, filed with the SEC on August 10, 2023). 10.21+ Â 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 Registrantâ€™s Registration Statement on Form S-8 (File No. 333-261196), filed with the SEC on November 19, 2021). 10.22+ Â 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 Registrantâ€™s Registration Statement on Form S-8 (File No. 333-261196), filed with the SEC on November 19, 2021). 10.23+ Â Non-Employee Director Compensation Policy (Incorporated by reference to Exhibit 10.35 to the Registrantâ€™s Annual Report on Form 10-K filed with the SEC on March 22, 2023). 10.24+ Â Amended and Restated Executive Employment Agreement, by and between Leading BioSciences, Inc. and JD Finley, dated January 24, 2021(Incorporated by reference to Exhibit 10.23 to the Registrantâ€™s Registration Statement on Form S-4 (File No. 333-251659), originally filed with the SEC on December 23, 2020, as amended). 10.25+ Â 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 Registrantâ€™s Registration Statement on Form S-4 (File No. 333-251659), originally filed with the SEC on December 23, 2020, as amended). Â II-10 Â Â 10.26+ Â 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 Registrantâ€™s Registration Statement on Form S-4 (File No. 333-251659), originally filed with the SEC on December 23, 2020, as amended). 10.27â€ Â 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 Registrantâ€™s Form 10-K, filed with the SEC on March 17, 2022). 10.28 Â Office Lease Between AP Beacon Carlsbad, LP, and Palisade Bio, Inc., dated May 12, 2022 (Incorporate by reference to Exhibit 10.1 to the Registrantâ€™s Form 10-Q filed with the SEC on May 13, 2022). 10.29 Â 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 Â 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 Registrantâ€™s Current Report on Form 8-K, filed with the SEC on May 6, 2022). 10.31+ Â Separation Agreement and Release with former Chief Executive Officer (Incorporated by reference to Exhibit 10.01 to the Registrantâ€™s Current Report on Form 8-K filed with the SEC on October 14, 2022). 10.32 Â 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 Registrantâ€™s Current report on Form 8-K, filed with the SEC on January 4, 2023). 10.33 Â Form of Registration Rights Agreement, dated December 30, 2022, by and among the Company and signatories named therein (Incorporated by reference to Exhibit 10.02 to the Registrantâ€™s Current Report on Form 8-K, filed with the SEC on January 4, 2023). 10.34 Â 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 Registrantâ€™s Current Report on Form 8-K, filed with the SEC on January 4, 2023). 10.35+ Â 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 Registrantâ€™s Annual Report on Form 10-K filed with the SEC on March 22, 2023). 10.36+ Â 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 Registrantâ€™s Annual Report on Form 10-K filed with the SEC on March 22, 2023). 10.37 Â 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 Registrantâ€™s Current Report on Form 8-K, filed with the SEC on April 5, 2023). 10.38 Â Form of Registration Rights Agreement dated April 3, 2023, by and among the Company and the signatories named therein (Incorporated by Reference to Exhibit 10.02 to the Registrantâ€™s Current Report on Form 8-K, filed with the SEC on April 5, 2023). 10.39 Â Form of Placement Agency Agreement dated April 3, 2023, by and among the Company and Ladenburg Thalmann & Co Inc. (Incorporated by Reference to Exhibit 10.01 to the Registrantâ€™s Current Report on Form 8-K, filed with the SEC on April 5, 2023). 10.40# Â Form of Research, Collaboration, and License Agreement with Giiant Pharma (Incorporated by reference to Exhibit 10.01 to the Registrantâ€™s Current Report on Form 8-K, filed with the SEC on September 8, 2023. 10.41 Â 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 Registrantâ€™s Current report on Form 8-K, filed with the SEC on September 11, 2023). Â II-11 Â Â 10.42 Â 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 Registrantâ€™s Current Report on Form 8-K, filed with the SEC on September 11, 2023). 10.43 Â Form of Employment Agreement with Mitchell Jones, dated September 5, 2023 (Incorporated by reference to Exhibit 10.01 to the Registrantâ€™s Current Report on Form 8-K, filed with the SEC on September 11, 2023). 10.44 Â Form of Warrant Inducement Agreement entered into pursuant to February 2024 Warrant Inducement Transaction (Incorporated by reference to Exhibit 10.01 to the Registrantâ€™s Current Report on Form 8-K, filed with the SEC on February 1, 2024). 10.45 Â Form of Securities Purchase Agreement entered into pursuant to the May 2024 Private Placement (Incorporated by reference to Exhibit 10.01 to the Registrantâ€™s Current Report on Form 8-K, filed with the SEC on May 3, 2024). 10.46 Â Form of Registration Right Agreement entered into Pursuant to the May 2024 Private Placement (Incorporated by reference to Exhibit 10.02 to the Registrantâ€™s Current Report on Form 8-K, filed with the SEC on May 3, 2024). 10.47 Â Form of Placement Agency Agreement entered into Pursuant to the May 2024 Private Placement (Incorporated by reference to Exhibit 10.03 to the Registrantâ€™s Current Report on Form 8-K, filed with the SEC on May 3, 2024. 10.48 Â Amendment to Research Collaboration and License Agreement with Giiant Pharma, Inc. dated August 2, 2024 (Incorporated by reference to Exhibit 10.48 to the Registrantâ€™s Quarterly Report on Form 10-Q filed with the SEC on August 12, 2024). 10.49+ Â Form of Employment Agreement with J.D. Finley, dated September 25, 2024 (Incorporated by reference to Exhibit 10.01 to the Registrantâ€™s Current Report on Form 8-K, filed with the SEC on September 27, 2024). 16.1 Â Letter dated July 8, 2021 from â€ŽDixon Hughes Goodman LLP to the Securities and Exchange Commission (incorporated by reference to Exhibit 16.1 to the Registrantâ€™s Current Report on Form 8-K, filed with the SEC on July 9, 2021). 16.2 Â Letter dated September 26, 2022 from BDO USA, LLP to the Securities and Exchange Commission (Incorporated by reference to Exhibit 16.1 to the Registrantâ€™s Current Report on Form 8-K, filed with the SEC on September 26, 2022). 19.01 Â Registrantâ€™s Insider Trading Policy. 21.01 Â Subsidiaries of Registrant (Incorporated by reference to Exhibit 21.1 to the Registrantâ€™s Annual Report on Form 10-K, filed with the SEC on March 22, 2023). 23.1* Â Consent of Baker Tilly US, LLP, Independent Registered Public Accounting Firm 23.2& Â Consent of Silvestre Law Group, P.c. (included in Exhibit 5.1) 107* Â Filing Fee Table Â * Filed herewith ** Furnished herewith. & To be Filed by Amendment. + Indicates management contract or compensatory plan. # Certain portions of this exhibit (indicated by â€œ[***]â€) have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K. â€ Certain schedules and exhibits 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. Â II-12 Â Â (b) Financial Statement Schedules Â No financial statement schedules are provided because the information called for is not required or is shown either in the financial statements or related notes, which are incorporated herein by reference. Â Item 17. Undertakings Â The undersigned Registrant hereby undertakes: Â (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement: Â (i) To include any prospectus required by section 10(a)(3) of the Securities Act of 1933; Â (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the â€œCalculation of Registration Feeâ€ table in the effective registration statement; and Â (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement. Â (2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Â (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering. Â (4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser: each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness; provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use. Â (5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities: The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser: Â (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424; Â (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant; Â (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and Â II-13 Â Â (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser. Â (6) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrantâ€™s annual report pursuant to section 13(a) or section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit planâ€™s annual report pursuant to section 15(d) of the

Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Â (7) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective. Â (8) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Â Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue. Â II-14 Â Â SIGNATURES Â Pursuant to the requirements of the Securities Act of 1933, the Registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Carlsbad, State of California on October 30, 2024. Â Â Palisade Bio, Inc. Â Â Â Â By: /s/ J.D. Finley Â Â J.D. Finley Â Â Chief Executive Officer Â POWER OF ATTORNEY Â Each person whose signature appears below constitutes and appoints J.D. Finley, as his or her true and lawful attorneys-in-fact and agent, each acting alone, 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 (i) act on, sign and file with the Securities and Exchange Commission any and all amendments (including post-effective amendments) to this registration statement together with all schedules and exhibits thereto and any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, together with all schedules and exhibits thereto, (ii) act on, sign and file such certificates, instruments, agreements and other documents as may be necessary or appropriate in connection therewith, (iii) act on and file any supplement to any prospectus included in this registration statement or any such amendment or any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and (iv) take any and all actions which may be necessary or appropriate to be done, as fully for all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof. Â Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities indicated on the dates indicated. Â Signature Â Title Â Date Â Â Â Â Â /s/ J.D. Finley Â Chief Executive Officer and Director Â October 30, 2024 J.D. Finley Â (Principal Executive Officer) Â Â Â Â Â Â Â /s/ J.D. Finley Â Chief Financial Officer Â October 30, 2024 J.D. Finley Â (Principal Financial and Accounting Officer) Â Â Â Â Â Â Â /s/ Donald Williams Â Chairman of the Board and Director Â October 30, 2024 Donald A. Williams Â Â Â Â Â Â Â Â Â /s/ Binxian Wei Â Director Â October 30, 2024 Binxian Wei Â Â Â Â Â Â Â Â Â /s/ Margery Fischbein Â Director Â October 30, 2024 Margery Fischbein Â Â Â Â Â II-15 Â EX-19.01 2 ex19-01.htm Â Exhibit 19.01 Â EX-23.1 3 ex23-1.htm Â Exhibit 23.1 Â CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM Â We hereby consent to the incorporation by reference in the Registration Statement on Form S-1 of Palisade Bio, Inc. of our report dated March 26, 2024, relating to the consolidated financial statements of Palisade Bio, Inc. in the Annual Report on Form 10-K for the year ended December 31, 2023, which includes an explanatory paragraph relating to the Companyâ€™s ability to continue as a going concern as described in Note 1 to the consolidated financial statements. Â We also consent to the reference to us under the heading â€œExpertsâ€ in such Registration Statement. Â /s/ BAKER TILLY US, LLP Â New York, New York October 30, 2024 Â Â Â EX-FILING FEES 4 ex107.htm Â Exhibit 107 Â Calculation of Filing Fee Tables Form S-1 (Form Type) Â Palisade Bio, Inc. (Exact Name of Registrant as Specified in its Charter) Â Table 1: Newly Registered and Carry Forward Securities Â Â Â Security TypeÂ Security Class TitleÂ Fee Calculation or Carry Forward RuleÂ Amount RegisteredÂ Â Proposed Maximum Offering Price Per UnitÂ Â Maximum Aggregate Offering Price(1)(2)(3)Â Â Fee RateÂ Â Amount of Registration FeeÂ Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Fees to Be PaidÂ EquityÂ Shares of Common Stock, par value $0.01 per share (4)Â 457(o)Â Â -Â Â Â -Â Â $5,000,000Â Â Â 0.00015310Â Â $765.50Â Fees to Be PaidÂ EquityÂ Pre-funded warrants (4)(5)Â 457(g)Â Â -Â Â Â -Â Â Â Included aboveÂ Â Â -Â Â Â -Â Fees to Be PaidÂ EquityÂ Shares of Common Stock issuable upon exercise of pre-funded warrants (4)Â 457(o)Â Â -Â Â Â -Â Â Â Included aboveÂ Â Â -Â Â Â -Â Fees to Be PaidÂ EquityÂ Representative Warrants (5)Â 457(g)Â Â -Â Â Â -Â Â Â -Â Â Â -Â Â Â -Â Fees to Be PaidÂ EquityÂ Shares of Common Stock issuable upon exercise of Representative Warrants (6)Â 457(o)Â Â -Â Â Â -Â Â Â 495,000Â Â Â 0.00015310Â Â $75.79Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Total Offering Amounts Â Â Â Â $5,495,000Â Â Â Â Â Â $841.29Â Â Â Total Fees Previously Paid Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Total Fee Offsets Â Â Â Â Â Â Â Â Â Â Â Â Â â€”Â Â Â Net Fee Due Â Â Â Â Â Â Â Â Â Â Â Â $841.29Â Â (1) Estimated solely for purposes of calculating the registration fee in accordance with Rule 457(o) under the Securities Act of 1933, as amended (the â€œSecurities Actâ€). (2) Pursuant to Rule 416 under the Securities Act, the securities registered hereby also include an indeterminate number of additional securities as may from time to time become issuable by reason of stock splits, stock dividends, recapitalizations, or other similar transactions. (3) Includes the price of additional shares of common stock that may be issued upon exercise of the over-allotment option granted to the underwriters to cover over-allotments, if any. (4) The proposed maximum aggregate offering price of the common stock will be reduced on a dollar-for-dollar basis based on the offering price of any pre-funded warrants issued in the offering, and the proposed maximum aggregate offering price of the pre-funded warrants to be issued in the offering will be reduced on a dollar-for-dollar basis based on the offering price of any common stock issued in the offering. Accordingly, the proposed maximum aggregate offering price of the common stock, and pre-funded warrants (including the common stock issuable upon exercise of the pre-funded warrants), if any, is $5,000,000. (5) No fee pursuant to Rule 457(g) of the Securities Act. (6) The registrant has agreed to issue upon the closing of this offering, warrants (the â€œRepresentative Warrantsâ€) to the representative of the underwriters entitling it to purchase up to 6% of the number of shares of common stock and pre-funded warrants sold in this offering. The exercise price of the Representative Warrants is equal to 165% of the public offering price of the securities offered hereby. As estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act, the proposed maximum aggregate offering price of the Representative Warrants is $495,000, which is equal to 165% of $300,000 (6% of $5,00,000). Â Â GRAPHIC 5 ex19-01_001.jpg

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