

PROSPECTUS

UP TO 8,137,868 Common Shares



Pelthos Therapeutics Inc.

This prospectus relates to the resale, from time to time, of up to 8,137,868 shares of common stock, par value \$0.0001 per share (the "Common Stock") of Pelthos Therapeutics Inc. (the "Company", "we", "us" or "our"), a Nevada corporation, by the certain investors (collectively, the "Selling Stockholders") signatory to that certain Securities Purchase Agreement (as amended, modified or waived from time to time, the "Securities Purchase Agreement") dated April 16, 2025, by and among the Company, LNHC, Inc., a Delaware corporation ("LNHC") and such investors, which include Nomis Bay Ltd ("Nomis Bay") and Ligand Pharmaceuticals Incorporated ("Ligand"), a Delaware corporation.

The Selling Stockholders may sell or otherwise dispose of the shares of Common Stock described in this prospectus in a number of different ways and at varying prices. If any underwriters, dealers, or agents are involved in the sale of any of the shares of Common Stock, their names and any applicable purchase price, fee, commission, or discount arrangement between or among them will be set forth, or will be calculable from the information set forth, in any applicable prospectus supplement. We will pay the expenses incurred in registering under the Securities Act the offer and sale of the shares of Common Stock to which this prospectus relates by the Selling Stockholder, including our legal and accounting fees. See the sections "About this Prospectus" on page 1 and "Plan of Distribution" on page 46 of this prospectus for more information. No shares of Common Stock may be sold without delivery of this prospectus and any applicable prospectus supplement describing the method and terms of the offering of such shares of Common Stock. You should carefully read this prospectus and any applicable prospectus supplement before you invest in our securities.

Our Common Stock is currently listed on the NYSE American LLC (the “NYSE American”) under the symbol “PTHS”. On September 24, 2025, the last reported sale price of our Common Stock on NYSE American was \$33.88.

Investing in our securities involves risks. You should carefully review the risks described under the heading “Risk Factors” beginning on page 7 and in the documents which are incorporated by reference herein and contained in the applicable prospectus supplement before you invest in our securities.

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.

The date of this prospectus is September 24, 2025.

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You should rely only on the information contained in this prospectus and any accompanying prospectus supplement or incorporated by reference in these documents. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained or incorporated by reference in this prospectus or the accompanying prospectus supplement. If anyone provides you with different, inconsistent or unauthorized information or representations, you must not rely on them. This prospectus and any accompanying prospectus supplement are an offer to sell only the securities offered by these documents, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or any prospectus supplement is current only as of the date on the front of those documents.

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the U.S. Securities and Exchange Commission (the “SEC”). By using a shelf registration statement, the Selling Stockholders may, from time to time, sell up to 8,137,868 shares of common stock in one or more offerings as described in this prospectus. In connection with the offer and sale of securities by the selling securityholders, the Selling Stockholders may provide a prospectus supplement to this prospectus that contains specific information about the securities being offered and sold and the specific terms of that offering. The prospectus supplement also may add, update or change information contained in this prospectus. You should read carefully both this prospectus, including the section entitled “Risk Factors,” and any prospectus supplement, together with the additional information described below under the headings “Where You Can Find More Information” and “Incorporation of Documents by Reference”.

In addition, this prospectus does not contain all the information provided in the registration statement that we filed with the SEC. For further information, we refer you to the registration statement, including its exhibits. The registration statement can be read on the SEC’s website or at the SEC’s offices mentioned below under the heading “Where You Can Find More Information”. Statements contained in this prospectus and any prospectus supplement about the provisions or contents of any agreement or other document are not necessarily complete. If the SEC’s rules and regulations require that an agreement or document be filed as an exhibit to the registration statement, please see that agreement or document for a complete description of such matters.

You should rely only on the information contained or incorporated by reference in this prospectus and any prospectus supplement. We, nor the Selling Stockholders, have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. This prospectus is not an offer to sell securities, and it is not soliciting an offer to buy securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus or any prospectus supplement, as well as information we have previously filed with the SEC and incorporated by reference, is accurate as of the date on the front of those documents only. Our business, financial condition, results of operations and prospects may have changed since those dates. This prospectus may not be used to consummate a sale of our securities unless it is accompanied by a prospectus supplement.

In this prospectus, we refer to Pelthos Therapeutics Inc. as “we,” “us,” “our” “PTHS,” “Pelthos,” and the “Company”, unless we specifically state otherwise or the context indicates otherwise.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, the applicable prospectus supplement and the information incorporated by reference in this prospectus contain various forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”) and Section 21E of the Securities and Exchange Act of 1934, as amended (the “Exchange Act”), which represent our expectations or beliefs concerning future events. Forward-looking statements include statements that are predictive in nature, which depend upon or refer to future events or conditions, and/or which include words such as “believes,” “plans,” “intends,” “anticipates,” “estimates,” “expects,” “may,” “will” or similar expressions. In addition, any statements concerning future financial performance, ongoing strategies or prospects, and possible future actions, which may be provided by our management, are also forward-looking statements. Forward-looking statements are based on current expectations and projections about future events and are subject to risks, uncertainties, and assumptions about our company, economic and market factors, and the industry in which we do business, among other things. These statements are not guarantees of future performance, and we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events, or otherwise, except as required by law. Actual events and results may differ materially from those expressed or forecasted in forward-looking statements due to a number of factors. Factors that could cause our actual performance, future results and actions to differ materially from any forward-looking statements include, but are not limited to, those discussed under the heading “Risk Factors” in this prospectus and in any of our filings with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act. The forward-looking statements in this prospectus, any applicable prospectus supplement and the information incorporated by reference herein or therein represent our views as of the date such statements are made. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date such statements are made.

PROSPECTUS SUMMARY

General

We are a biopharmaceutical company committed to commercializing innovative, safe, and efficacious therapeutic products to help patients with unmet treatment burdens. The company's lead product ZELSUVMI™ (berdazimer) topical gel, 10.3%, for the treatment of *molluscum contagiosum*, was approved by the U.S. Food and Drug Administration in 2024.

On July 1, 2025 (the "Merger Closing Date"), we consummated the previously announced merger transaction contemplated by that certain Agreement and Plan of Merger, dated as of April 16, 2025 (the "Merger Agreement"), by and among Channel Therapeutics Corporation ("Channel"), CHRO Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of the Company ("Merger Sub"), LNHC, and solely for the purposes of Article III thereof, Ligand Pharmaceuticals Incorporated, a Delaware corporation ("Ligand"). Pursuant to the Merger Agreement, (i) Merger Sub merged with and into LNHC, with LNHC as the surviving company in the merger and, after giving effect to such merger, continuing as a wholly-owned subsidiary of the Company (the "Merger") and (ii) Channel's name was changed from Channel Therapeutics Corporation to Pelthos Therapeutics Inc.

Risk Factor Summary

Investing in our securities involves significant risks. You should carefully consider all of the information in this prospectus before making an investment in our securities. Below please find a summary of the principal risks we face, organized under relevant headings. These risks are discussed more fully in the section titled "Risk Factors."

Risks Associated with Our Business

Our ability to implement our business strategy is subject to numerous risks that you should be aware of before making an investment decision. These risks are described more fully in the section entitled "Risk Factors," immediately following this prospectus summary. These risks include the following, among others:

Risks Related to Our Financial Position and Capital Needs

- The report of the independent registered public accounting firm on our 2024 and 2023 financial statements contains a going concern qualification.
- We have incurred significant losses since our inception.
- We have a limited operating history and history of commercializing products, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

Risks Related to the Commercialization of Our Product and any Future Product Candidates

- We depend heavily on the commercial success of ZELSUVMI, which was approved by the FDA in January 2024, which we have only recently launched in the United States.
- ZELSUVMI and any of our product candidates that receive regulatory approval, may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.
- If we are unable to establish effective sales, marketing and distribution capabilities for ZELSUVMI or any product candidate that may receive regulatory approval, we may not be successful in commercializing ZELSUVMI or our other product candidates if and when they are approved.
- ZELSUVMI or our product candidates may cause undesirable side effects or have other properties that could limit their commercial profile, expose us to product liability claims, delay or prevent regulatory approval of our product candidates or additional indications, or result in significant negative consequences following any additional marketing approval, any of which may adversely impact our business, financial condition, operating results and prospects.

- We face substantial competition, which may result in a smaller than expected commercial opportunity and/or other firms may discover, develop or commercialize products before or more successfully than we do.
- The commercial success of our products and product candidates will depend upon the degree of market acceptance by physicians, patients, third-party payers and others in the medical community.
- Our products may become subject to unfavorable third-party coverage or reimbursement policies, which would harm our business.
- The market for ZELSUVMI and our future product candidates may not be as large as we expect.
- The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.
- Product liability lawsuits could cause us to incur substantial liabilities and limit commercialization of any products that we may develop.

Risks Related to Our Operations and Manufacturing

- Delays or disruptions in our supply chain and manufacturing of our products, including ZELSUVMI, and potential product candidates could adversely affect our sales and marketing efforts and our development and commercialization timelines and could result in increased costs or in our breaching our obligations to others.
- We have limited experience in producing commercial scale products that utilize the NITRICIL technology, which was assigned to Ligand in March 2024, including the API, berdazimer sodium, used in the ZELSUVMI product.
- Unexpected results in the analysis of raw materials, the API or drug product or problems with the execution of or quality systems supporting the analytical testing work, whether conducted internally or by third-party service providers, could adversely affect our development and commercialization timelines and result in increased costs of potential development programs initiated by us.
- Our business involves the use of hazardous materials and we and our third-party suppliers and manufacturers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.
- We may be adversely affected by the effects of inflation or trade tariffs.

Risks Related to Our Dependence on Third Parties

- We rely on third parties to conduct any preclinical studies, clinical trials, distribution, shipping and logistics, data collection and many other services. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize any of our future product candidates.
- Our employees, independent contractors, principal investigators, CMOs, CROs, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could expose us to liability and hurt our reputation.

Risks Related to Intellectual Property

- We rely on in-licenses from third parties.
- Third party intellectual property may prevent us from developing our potential products; our intellectual property may not prevent competition; and any intellectual property issues may be expensive and time consuming to resolve.
- If we are unable to obtain and maintain sufficient intellectual property protection for our products and technology, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technologies similar to ours, and our ability to successfully sell our products and services may be impaired.
- Issued patents directed to the NITRICIL platform and technology could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.
- Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing Ligand's ability to protect our products, platform and technology on which we rely.

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- We may be subject to claims challenging the inventorship of the patents and other intellectual property on which we rely.
- If we are unable to protect the confidentiality of our information and our trade secrets, the value of our technology could be materially and adversely affected and our business could be harmed.
- If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our competitive position may be harmed.

Risks Related to Legal and Regulatory Compliance Matters

- Current and future healthcare reform legislation or regulation may increase the difficulty and cost for us to commercialize ZELSUVMI and may adversely affect the prices we may obtain and may have a negative impact on our business and results of operations.
- If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in which we participate, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.
- We are subject to federal, state and foreign healthcare laws and regulations, including fraud and abuse laws.
- Changes in and actual or perceived failures to comply with applicable data privacy, security and protection laws, regulations, standards and contractual obligations may adversely affect our business, operations and financial performance.
- If plaintiffs bring product liability lawsuits against us or our partners, we or our partners may incur substantial liabilities and may be required to limit commercialization of our approved products and product candidates.
- We face risks related to handling of hazardous materials and other regulations governing environmental safety.
- We may also be subject to other laws and regulations not specifically targeting the healthcare industry.

Other Risks and Uncertainties Affecting Our Business

- The occurrence of a catastrophic disaster could disrupt our business, damage our facilities beyond insurance limits, increase our costs and expenses, or we could lose key data which could cause us to curtail or cease operations.
- Impairment charges pertaining to goodwill, identifiable intangible assets or other long-lived assets from our mergers and acquisitions could have an adverse impact on our results of operations and our market value.

Corporate Information

We are a biopharmaceutical company committed to commercializing innovative, safe, and efficacious therapeutic products to help patients with significant unmet medical needs.

Our subsidiary LNHC was originally incorporated in the state of Delaware in September 2023 and was initially formed by Ligand to facilitate a transaction between Ligand and Novan, Inc. (“Novan”). On September 27, 2023, Ligand acquired certain assets of Novan, after providing debtor in possession financing and acquiring specific assets from Novan, under Section 363 of the U.S. Bankruptcy Code. Novan was a medical dermatology company focused on developing and commercializing innovative therapeutic products for skin diseases. Through our NITRICIL technology platform, Novan had concentrated on developing ZELSUVMI formerly named SB206 (berdazimer gel, 10.3%) as a topical prescription gel for the treatment of viral skin infections, with a focus on molluscum contagiosum. As of the acquisition, all assets and liabilities acquired by Ligand in the Novan acquisition was held by LNHC, which is a wholly owned subsidiary of Ligand.

In January 2023, Novan submitted a New Drug Application to the U.S. Food and Drug Administration (the “FDA”) for berdazimer gel, 10.3% as a topical treatment for *molluscum contagiosum*. ZELSUVMI (berdazimer) topical gel, 10.3%, was approved by the FDA on January 5, 2024.

ZELSUVMI is a nitric oxide (NO) releasing agent indicated for the topical treatment of *molluscum contagiosum* in adults and pediatric patients 1 year of age and older. ZELSUVMI is the first FDA approved topically applied nitric oxide releasing agent indicated in people ages one year and older and the first and only prescription medication FDA approved for use in non-medical settings that can be safely applied by patients, parents and caregivers. Molluscum contagiosum is a highly contagious viral skin infection that primarily affects children, immunocompromised adults and sexually active persons. The Company estimates that molluscum contagiosum infections afflict an approximately 17 million people of all ages in the United States.

On July 10, 2025, we announced the launch and commercialization of ZELSUVMI and have built our sales, marketing and commercial team to launch ZELSUVMI. The Company expects pediatricians, pediatric dermatologists, dermatologists and infectious disease specialists will be the target prescribers.

On the Merger Closing Date, we consummated the previously announced Merger contemplated by Merger Agreement. Pursuant to the Merger Agreement, (i) Merger Sub merged with and into LNHC, with LNHC as the surviving company in the merger and, after giving effect to such merger, continuing as a wholly-owned subsidiary of the Company and (ii) Channel's name was changed from Channel Therapeutics Corporation to Pelthos Therapeutics Inc.

Channel was incorporated in Delaware on March 19, 2021. On November 18, 2024, Chromocell Therapeutics Corporation, a Delaware corporation, merged with and into its wholly-owned subsidiary, Channel, pursuant to an agreement and plan of merger, dated as of November 18, 2024, for the purposes of reincorporation Channel in Nevada.

Channel was a clinical-stage biotech company focused on developing and commercializing new therapeutics to alleviate pain. Our clinical focus was to selectively target the sodium ion-channel known as "NaV1.7", which has been genetically validated as a pain receptor in human physiology. A NaV1.7 blocker is a chemical entity that modulates the structure of the sodium-channel in a way to prevent the transmission of pain perception to the central nervous system ("CNS"). Channel's goal is to develop a novel and proprietary class of NaV blockers that target the body's peripheral nervous system. Prior to the consummation of the Merger, Channel's stock was traded on The NYSE American under the ticker symbol "CHRO".

All information disclosed in this Registration Statement prior to the Merger Closing Date relates to Channel, and all information disclosed in this registration statement for periods after the Merger Closing Date relates to Pelthos.

Our principal executive offices are located at 4020 Stirrup Creek Drive, Suite 110, Durham, NC, and our telephone number is (919) 908-2400. Our website is <https://pelthos.com>. Information contained on, or that can be accessed through, our website is not incorporated by reference into this information statement, and you should not consider information on our website to be part of this information statement.

Pelthos makes available free of charge under the "Investors" section of our website all of our filings with the SEC including our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements and amendments to such documents, each of which is provided on our website as soon as reasonably practicable after Pelthos electronically files or furnishes, as applicable, the information with the SEC.

Additional information about us is included in documents incorporated by reference in this prospectus. See "Where You Can Find More Information" and "Information Incorporated by Reference."

RISK FACTORS

Investing in our securities involves significant risk. The prospectus supplement applicable to each offering of our securities will contain a discussion of the risks applicable to an investment in our securities. Prior to investing in our securities, you should carefully consider the specific factors discussed under the heading “Risk Factors” in this prospectus and any applicable prospectus supplement, and in the documents incorporated by reference herein, including Channel’s most recent Annual Report on Form 10-K, subsequent Quarterly Reports on Form 10-Q, and any other filings we make with the SEC under the Exchange Act that are incorporated by reference together with all of the other information contained or incorporated by reference herein or therein. The risks and uncertainties we have described are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our operations. The occurrence of any of these risks might cause you to lose all or part of your investment in the offered securities.

Risks Related to Our Financial Position and Capital Needs

The report of the independent registered public accounting firm on our 2024 and 2023 financial statements contains a going concern qualification.

The report of the independent registered public accounting firm covering our consolidated financial statements for the years ended December 31, 2024 and 2023 stated that certain factors, including that we have suffered recurring losses from operations and have an accumulated deficit at December 31, 2024, raised substantial doubt as to our ability to continue as a going concern. Because we are not yet producing sufficient revenue to sustain our operating costs, we are dependent upon raising capital to continue our business. If we are unable to raise capital, we may be unable to continue as a going concern.

We have incurred significant losses since our inception. We expect to incur losses until revenue from ZELSUVMI is sufficient to fund our operations, if ever, and may never achieve or maintain profitability. If we do not achieve or maintain profitability, we may need additional funding to continue our business operations.

Since the Merger, we have devoted substantially all of our financial resources and efforts to the development and commercialization of ZELSUVMI, our product for the topical treatment of molluscum contagiosum. ZELSUVMI was approved by the FDA for the treatment of molluscum contagiosum in adults and pediatric patients one year of age and older in January 2024.

We have had net losses since inception, and we had an accumulated deficit of approximately \$26.9 million and \$17.9 million as of June 30, 2025 and June 30, 2024, respectively, which includes a net loss of approximately \$3.2 million for the three months ended June 30, 2025, and approximately \$1.8 million the three months ended June 30, 2024, respectively. Overall, these conditions have raised substantial doubt regarding our ability to continue as a going concern beyond one year of the filing of our consolidated financial statements. Our ability to continue as a going concern is dependent upon the ability to complete clinical studies and implement our business plan, raise capital, generate sufficient revenues and to control operating expenses.

We expect to continue to incur significant expenses and operating losses until revenue from ZELSUVMI is sufficient to fund our operations, if ever. Our net losses may fluctuate significantly from quarter to quarter and year to year. Our expenses may increase substantially, as we:

- commercialize ZELSUVMI;
- operate our manufacturing facility, at which we create the active pharmaceutical ingredient (“API”) for ZELSUVMI;
- work with third-party contract manufacturers to produce the ZELSUVMI finished product;
- maintain or expand a sales, commercial and distribution infrastructure and manufacturing and logistics capabilities to commercialize currently approved products as well as any future products that receive regulatory approval;
- seek to in-license or acquire additional products or programs;
- develop our regulatory compliance efforts to address requirements applicable to marketed products;
- maintain, expand and protect our intellectual property portfolio;
- hire and retain sales, marketing, manufacturing, commercial and scientific personnel;
- incur additional legal, accounting and other expenses in operating as a public company; and
- incur additional legal expenses associated with managing the regulatory environment or any litigations that may arise.

To become and remain profitable, we must succeed in commercializing ZELSUVMI and/or develop and potentially commercialize future product candidates that generate significant revenue. This will require us to be successful in a range of challenging activities, including commercialization of ZELSUVMI, completing preclinical testing and clinical trials of any of our potential future product candidates, acquiring and integrating product candidates, obtaining regulatory approval, and manufacturing, marketing and selling any future product candidates for which we may obtain regulatory approval, as well as discovering and developing additional product candidates. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability.

Our revenue will be dependent, in part, upon the size of the markets in the territories for which we have gained or may gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, if any indication approved by regulatory authorities is narrower than we expect, or any targeted treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products.

Because of the numerous risks and uncertainties associated with commercialization and product development, we may not achieve profitability in the time frame we currently expect, or at all. If we are required by regulatory authorities to perform additional post-approval studies, or if there are any delays in the adoption of ZELSUVMI or the development of any of our future product candidates, our expenses could increase, and we may never reach profitability.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable could depress our value and could impair our ability to raise capital, diversify our offerings or continue our operations.

We have a limited operating history and history of commercializing products, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

Our operations to date have been largely focused on developing and commercializing ZELSUVMI, which was approved by the FDA for the treatment of molluscum contagiosum in adult and pediatric patients one year of age and older in January 2024. We hold a worldwide license to commercialize ZELSUVMI, subject to an out license for Japan, and recently launched the product, but our commercialization efforts are in early stages. We have limited experience in demonstrating the ability to successfully complete clinical trials, obtain regulatory approval for a product, manufacture a product on a commercial scale, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercial launch and commercialization over time. Consequently, any predictions you make 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 commercializing products.

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives.

Risks Related to the Commercialization of Our Product and any Future Product Candidates

We depend heavily on the commercial success of ZELSUVMI, which was approved by the FDA in January 2024, which we have only recently launched in the United States. There is no assurance that our commercialization efforts in the United States with respect to ZELSUVMI will be successful or that we will be able to generate profit at the levels or within the timing we expect.

Our business currently depends heavily on our ability to successfully commercialize ZELSUVMI in the United States. We may never be able to successfully commercialize ZELSUVMI or reach our expectations with respect to revenue or profit. There is no guarantee that the infrastructure, systems, processes, policies, personnel, relationships and materials we built in preparation for the launch and commercialization of ZELSUVMI in the United States will be sufficient for us to achieve success at the levels we expect. Additionally, healthcare providers may not accept a new treatment for the treatment of molluscum contagiosum. We may also encounter challenges related to reimbursement of ZELSUVMI, even if we have positive early indications from payors, including potential limitations in the scope, breadth, availability, or amount of reimbursement covering ZELSUVMI. Similarly, healthcare settings or patients may determine that the financial burdens of treatment are not acceptable. Our results may also be negatively impacted if we encounter deficiencies or inefficiencies in our infrastructure or processes. Any of these issues could impair our ability to successfully commercialize ZELSUVMI or to generate substantial profit or to meet our expectations with respect to the amount or timing of profit. Any issues or hurdles related to our commercialization efforts for ZELSUVMI may materially adversely affect our business, results of operations, financial condition and prospects. There is no guarantee that we will be successful in our commercialization efforts with respect to ZELSUVMI, or that we will generate significant profit from ZELSUVMI or any product candidate or become profitable.

ZELSUVMI and any of our product candidates that receive regulatory approval, may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

ZELSUVMI and any of our product candidates that receive regulatory approval may fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If ZELSUVMI or our potential product candidates, if approved, do not achieve an adequate level of acceptance, we may not generate sufficient revenue, and we may not become profitable. The degree of market acceptance of ZELSUVMI and our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy, safety and potential advantages compared to alternative treatments;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new treatments and of physicians to prescribe these treatments;
- our ability to hire and retain a sales force in the United States;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement for ZELSUVMI and any product candidates that receive regulatory approval;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

The failure of healthcare professionals or patients to perceive the benefits of using ZELSUVMI for the treatment of molluscum contagiosum instead of other alternative therapies, such as curettage, cantharidin application or cryotherapy, would adversely affect the commercial success of ZELSUVMI.

If we are unable to establish effective sales, marketing and distribution capabilities for ZELSUVMI or any product candidate that may receive regulatory approval, we may not be successful in commercializing ZELSUVMI or our other product candidates if and when they are approved.

We have only recently commercially launched ZELSUVMI and to achieve commercial success for it and any other product candidate for which we may obtain regulatory approval, we will need to establish an effective sales and marketing organization. We have built a focused sales and marketing organization to launch ZELSUVMI in the United States, but it may not be large enough to support the market acceptance and revenue growth of ZELSUVMI that we expect and may need to expand if we receive approval of other product candidates. There are inherent risks to establishing and maintaining a standalone commercial organization, which is also time-consuming and requires significant financial resources.

Factors that create risk and may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or educate adequate numbers of physicians on the benefits of prescribing ZELSUVMI or any potential future products;
- inability to obtain favorable insurance coverage of any approved product;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable to maintain our own sales, marketing and distribution capabilities and are forced to enter into arrangements with, and rely on, third parties to perform these services, our revenue and our profitability, if any, is likely to be lower than if we had maintained such capabilities internally. In addition, in the event we proceed with engaging third parties for sales and marketing services, we may not be successful in entering into arrangements with third parties to sell, market and distribute our products or may be unable to do so on terms that are favorable to it. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish and maintain sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our products.

ZELSUVMI or our product candidates may cause undesirable side effects or have other properties that could limit their commercial profile, expose us to product liability claims, delay or prevent regulatory approval of our product candidates or additional indications, or result in significant negative consequences following any additional marketing approval, any of which may adversely impact our business, financial condition, operating results and prospects.

As is the case with biopharmaceuticals generally, it is likely that there may be side effects and adverse events (“AEs”) associated with use of ZELSUVMI or our product candidates. Results of our preclinical testing and clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval of our product candidates by the FDA. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, with respect to ZELSUVMI or any of our product candidates that receive marketing approval, if we or the FDA later identify undesirable side effects caused by ZELSUVMI or such product candidates or other products with the same or related active ingredients, a number of potentially significant negative consequences could result, including, among other things:

- regulatory authorities may withdraw, suspend, or vary approvals of such product, including the FDA, withdrawing approval for the affected medicine;
- regulatory authorities may require additional warnings on the label;
- regulatory authorities may require a recall or we or our potential partners may voluntarily recall such product;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients at significant cost or institute a Risk Evaluation and Mitigation Strategies (“REMS”) or Risk Management Plan (“RMP”);
- regulatory authorities may require the addition of warnings, such as black box or other warnings, or contraindications in the product labeling that could diminish the usage of the product or otherwise limit the commercial success of the affected product;
- our ability to promote our approved medicines may be limited and we could be required to change administration of, or modify, such product in some other way;
- regulatory authorities may require us to modify, suspend or terminate our clinical trials, conduct additional clinical trials or engage in costly post-marketing testing and surveillance to monitor the safety or efficacy of such product;
- undesirable side effects may limit physicians’ or patients’ willingness to initiate or continue therapy with such product;
- sales may decrease significantly;
- we could be sued and held liable for harm caused to patients; and
- our corporate brand and reputation or the reputation of our approved medicines may suffer.

Such events could prevent us from achieving or maintaining market acceptance of ZELSUVMI or our product candidates, and could significantly harm our business, results of operations and prospects.

We face substantial competition, which may result in a smaller than expected commercial opportunity and/or other firms may discover, develop or commercialize products before or more successfully than we do.

The development and commercialization of new products is highly competitive. We face competition with respect to ZELSUVMI and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from many different sources, including major pharmaceutical and specialty pharmaceutical companies, compounding facilities, academic institutions and governmental agencies and public and private research institutions.

ZELSUVMI may compete with other procedure-based treatment regimens currently available for molluscum contagiosum such as curettage, cantharidin application or cryotherapy. In addition, other drugs have been and may continue to be used off label as treatment for molluscum contagiosum.

In addition, our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than ZELSUVMI or any other product that we may develop.

Many of the companies against which we are competing, or against which we may compete in the future, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or that may be necessary for, our programs.

The commercial success of our products and product candidates will depend upon the degree of market acceptance by physicians, patients, third-party payers and others in the medical community.

The commercial success of our products, including ZELSUVMI and any other products for which we may obtain regulatory approval, will depend in part on the medical community, patients and third-party payers accepting our products and product candidates as effective and safe. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of our products will depend on a number of factors, including:

- the safety and efficacy of the products, and advantages over alternative treatments;
- the labeling of any approved product;
- the prevalence and severity of any side effects, including any limitations or warnings contained in a product's approved labeling;
- the prevalence of the disease or condition for which the product is approved;
- the emergence, and timing of market introduction, of competitive products;
- the effectiveness of our and our collaboration partners' marketing strategy;
- obtaining and maintaining adequate pricing and reimbursement; and
- sufficient third-party insurance coverage or governmental reimbursement, which may depend on our ability to provide compelling evidence that a product meaningfully improves health outcomes to support such insurance coverage or reimbursement.

Even if a product candidate displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be known until after it is launched. Any failure to achieve market acceptance of our products will harm our business, results and financial condition.

Furthermore, government agencies, as well as private organizations involved in healthcare, from time to time publish guidelines or recommendations to healthcare providers and patients. Such guidelines or recommendations can be very influential and may adversely affect product usage directly (for example, by recommending a decreased dosage of a product in conjunction with a concomitant therapy) or indirectly (for example, by recommending a competitive product over a product of ours). Consequently, we do not know if physicians or patients will adopt or use our products for their approved indications.

Our products may become subject to unfavorable third-party coverage or reimbursement policies, which would harm our business.

Market acceptance and sales of ZELSUVMI and any product candidates that we may develop will depend in large part on third-party payor coverage and reimbursement policies and may be affected by future healthcare reform measures in the U.S. as well as the EEA countries and other key international markets. The continuing efforts of governmental and other third-party payors to contain, reduce or shift the costs of healthcare through various means, including an increased emphasis on managed care and attempts to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, may result in downward pressure on pricing, reimbursement and utilization, which may adversely affect our product sales and results of operations. Moreover, because private health insurers and other third-party payors in the U.S. often follow the coverage and reimbursement policies of government payors, including the Medicare and Medicaid programs, cost-containment measures under these programs play a particularly significant role in the reimbursement landscape. The government programs relevant to our products include, without limitation, the following:

- the Medicaid Drug Rebate Program, under which manufacturers must report pricing information and pay rebates in order for their drug products to be covered under state Medicaid programs;
- the Public Health Service's 340B Drug Pricing Program, under which manufacturers must offer discounts to certain health care organizations that care for underserved populations; and
- the Tricare Retail Pharmacy Program, under which manufacturers must agree to honor certain discounted prices, specifically Federal Ceiling Prices under the Veterans Health Care Act, as a condition for placement in the Department of Defense uniform formulary.

In addition, in the U.S., third-party payors often develop cost containment measures using policies that specifically target specialty products and high-cost drugs. For example, formulary placements may be less favorable for brand and higher-costing drugs, resulting in, among other things, greater out-of-pocket costs to patients. ZELSUVMI may be subject to such measures and may be impacted by similar future policies addressing such cost-containment measures.

Further, payors also are increasingly considering new metrics as the basis for reimbursement rates, such as average sales price, or ASP, average manufacturer price, or AMP, or actual acquisition cost, or AAC. Although the intent of the changes to reimbursement methodologies generally is to limit payment increases, it is difficult to project the impact of these and other alternative reimbursement methodologies on the willingness of payors to reimburse ZELSUVMI and any product candidates that we may develop. We cannot provide any assurances that ZELSUVMI and any future products, if approved, will be covered and reimbursed in the U.S. and if we do receive coverage and reimbursement, that we will continue over time to receive such coverage and reimbursement. If coverage and reimbursement are not available or available only to limited levels, we may not be able to generate sufficient revenue to meet our operating costs or to achieve our revenue, cash flow breakeven or profitability goals in the timeframe that it expects, or at all.

The market for ZELSUVMI and our future product candidates may not be as large as we expect.

Molluscum contagiosum is a skin disease that is currently undertreated. Even with approval of ZELSUVMI in adult and pediatric patients one year and older, individuals may continue to decline treatment for molluscum contagiosum as, if left untreated, the diseases will eventually be resolved by the body's immune system.

In addition, our estimates of the potential market opportunity for ZELSUVMI include several key assumptions based on our industry knowledge, industry publications, third-party research reports, ICD-10 claims data, and surveys of dermatologists commissioned by us. These assumptions include the current treatment rates and/or prevalence of molluscum contagiosum and other skin diseases as well as the estimated coverage levels for ZELSUVMI. However, there can be no assurance that any of these assumptions are, or will remain, accurate. Furthermore, even if our estimates relating to claims data and/or the prevalence of molluscum contagiosum and other skin diseases as well as the estimated coverage levels for ZELSUVMI or any future product candidate we may develop, as applicable, are accurate, the degree of market acceptance by the medical community and those infected by such skin diseases following regulatory approval could impact our assumptions and reduce the market size for ZELSUVMI and any other product that may be approved. Furthermore, the market research study we commissioned surveying payor organizations has no bearing on the payors, and any assumptions or interpretations based on the results of this study, may ultimately be inaccurate. If the actual markets for ZELSUVMI or any future product candidates are smaller than we expect, our revenues, if any, may be limited and it may be more difficult for us to achieve or maintain profitability.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

The FDA strictly regulates marketing, labeling, advertising and promotion of prescription drugs. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities involving the internet and off-label promotion. Any regulatory approval that the FDA grants, including the approval of ZELSUVMI, is limited to those specific diseases and indications for which a product is deemed to be safe and effective by FDA. While physicians in the United States may choose, and are generally permitted, to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, our ability to promote ZELSUVMI or any future products will be narrowly limited to those indications that are specifically approved by the FDA. ZELSUVMI has been approved by the FDA for the treatment of molluscum contagiosum in adults and pediatric patients one year of age and older, and we are not permitted to promote ZELSUVMI for other uses.

If we are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of ZELSUVMI or any future product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Product liability lawsuits could cause us to incur substantial liabilities and limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the commercial sales of ZELSUVMI, as well as the testing of our potential future product candidates in human clinical trials. If we cannot successfully defend ourselves against claims that ZELSUVMI or such product candidates caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for ZELSUVMI and any product candidates that we may develop;
- injury to our reputation and significant negative media attention;
- loss of revenue;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards paid to trial participants or patients;
- reduced resources of management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

We currently hold product liability insurance that covers damages up to a \$15 million annual limit. We may need to secure additional product liability insurance coverage if and when sales of ZELSUVMI grow and may need to further increase our insurance coverage if we initiate clinical trials or expand commercialization activities for our other product candidates that obtain regulatory approval. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to Our Operations and Manufacturing

Delays or disruptions in our supply chain and manufacturing of our products, including ZELSUVMI, and potential product candidates could adversely affect our sales and marketing efforts and our development and commercialization timelines and could result in increased costs or in our breaching our obligations to others.

Our ability to make, move, and sell our products is critical to our success. Damage or disruption to our supply chain, including third-party manufacturing, assembly or transportation and distribution capabilities, due to weather, including any potential effects of climate change, natural disaster, fire or explosion, terrorism, pandemics (such as the COVID-19 pandemic), strikes, tariffs, government action, inflation, war or other reasons beyond our control or the control of our suppliers and business partners, could impair our ability to manufacture or sell our products. Failure to take adequate steps to mitigate the likelihood or potential impact of such events, or to effectively manage such events if they occur, particularly where our product is sourced from a single supplier or location, could adversely affect our business or financial results. Any interruption or failure by our suppliers, distributors and other partners to meet their obligations on schedule or in accordance with our expectations, misappropriation of our proprietary information, including trade secrets and know-how, or any termination by these third parties of their arrangements with us, which, in each case, could be the result of one or many factors outside of our control, could delay or prevent the manufacture or commercialization of our products, disrupt our operations or cause reputational harm to us. In addition, except for the terms and conditions specified in our contractual arrangements with our contract manufacturers, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our API or drug products or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for, market and sell our products and potential product candidates.

We are required to identify the supplier(s) of all the raw materials for our products, including ZELSUVMI, in our applications with the FDA. To the extent practicable, our attempts to identify more than one supplier in each drug application. However, some products and raw materials are available only from a single source and, in some of our drug applications, only one supplier of products and raw materials has been identified, even in instances where multiple sources exist. To the extent any difficulties experienced by our suppliers cannot be resolved within a reasonable time and at reasonable cost, or if raw materials for a particular product become unavailable from an approved supplier and we are required to qualify a new supplier with the FDA, our profit margins and market share for the affected product could decrease and our development and sales and marketing efforts could be delayed or negatively impacted.

We have limited experience in producing commercial scale products that utilize the NITRICIL technology, which was assigned to Ligand in March 2024, including the API, berdazimer sodium, used in the ZELSUVMI product. Any delay or disruptions in the on-going qualification of manufacturing facilities and process or in the manufacture of our (i) API, including berdazimer sodium, or (ii) potential future clinical trial materials or commercial supplies of any other potentially approved product candidates utilizing the NITRICIL technology, could adversely affect our development and commercialization timelines and results or result in increased costs or in our breaching our obligations to others.

We internally manufacture the berdazimer sodium API that is utilized in our ZELSUVMI commercial product. Any delays or disruptions in our manufacturing processes and analytical methods for API testing and commercial manufacturing under cGMP guidelines and regulations, or our inability to execute such activities, could impact the commercialization efforts for ZELSUVMI and/or any future product candidate, as well as increase costs. Further, if we do not appropriately coordinate with, project manage or provide adequate internal expertise, resources and documentation with our third-party drug product manufacturer, we may not be successful, or may be delayed, in the commercialization of ZELSUVMI. We have a limited number of personnel who have experience in drug substance manufacturing and possess the expertise necessary to manufacture berdazimer sodium.

Orion Corporation (“Orion”), with whom we have formed a relationship to manufacture the commercial drug product for ZELSUVMI, including final fill/finish and packaging, must be successful in our execution of our commercial production strategy. For instance, we may not be successful in realizing the intended operating goals from this arrangements based on a number of factors, including, among other things, (i) delays or failures, including delays in our ability to transition applicable technology and processes to our vendors or partners, (ii) reduced quality, (iii) delayed receipt of goods or services, (iv) increased and unexpected costs on the part of the third-party vendors or strategic partners, and (v) certain incremental and discrete costs to effect this strategy. If we are unsuccessful in partnering with third-party manufacturers, we could experience delays in the development and commercialization timelines of our product candidates, as well as increased costs.

We will also have no direct control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any comparable foreign regulatory authority does not approve these facilities for the manufacture of our products, or if such authorities withdraw any such approval in the future, we may be required to find alternative manufacturing facilities, which would significantly impact our ability to obtain approval of and commercialize any product candidates, if approved. our failure, or the failure of any of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our financial position.

Our or a third party's failure to execute on our manufacturing requirements on commercially reasonable terms and in compliance with cGMP or other regulatory requirements could adversely affect our business in a number of ways, including:

- an inability to meet commercial demands;
- an inability to initiate or complete clinical trials in a timely manner;
- delays in submitting regulatory applications, or receiving regulatory approvals;
- subjecting third-party manufacturing facilities to additional inspections by regulatory authorities; and
- requirements to cease development or to recall product batches.

In addition, we may be unable to establish additional long-term supply agreements with third-party manufacturers or to do so on acceptable terms, which increases the risk of failing to timely obtain sufficient quantities of our products or any future product candidates or such quantities at an acceptable cost, which would have a material adverse impact on our financial position. There are risks associated with scaling up manufacturing to commercial volumes including, among others, cost overruns, technical or other problems with process scale-up, process reproducibility, stability issues, lot consistency and timely availability of raw materials. There is no assurance that our manufacturers will be successful in establishing a larger-scale commercial manufacturing process for ZELSUVMI that achieves our objectives for manufacturing capacity and cost of goods, in a timely manner, or at all.

Unexpected results in the analysis of raw materials, the API or drug product or problems with the execution of or quality systems supporting the analytical testing work, whether conducted internally or by third-party service providers, could adversely affect our development and commercialization timelines and result in increased costs of potential development programs initiated by us.

Third parties engaged directly by us or by our API and drug product contract manufacturing organizations ("CMOs"), test all of the raw materials and finished API and drug products. It is a regulatory requirement that raw materials are tested and there are a limited number of suppliers for testing these raw materials. There may be a need to assess alternate suppliers to prevent a possible disruption of the supply of these raw materials for the manufacture of API or drug product. Additionally, the analytical equipment used by these third parties must be maintained and operational. Except for the terms established within our or our CMOs' contracts with the third parties responsible for testing raw materials and finished API and drug products, we have limited ability to control the process or timing of their testing work. Additionally, if the results do not meet specifications, then obtaining additional raw materials may jeopardize our or our CMOs' ability to manufacture API and/or drug product, the start or overall conduct of preclinical studies and clinical trials, the timing of regulatory submissions, or the commercialization of our products and any future product candidates, if approved. We and our CMOs currently engage third parties to perform analytical tests to ensure the API and drug product meets quality specifications. The analytical equipment used by us or our CMOs to perform these tests must be maintained, qualified, calibrated and operational. If there are testing execution delays, equipment problems or if the results of the analytical testing do not meet our quality specifications, then manufacturing additional API or drug product may increase costs and may jeopardize our or our CMOs' ability to manufacture API and/or drug product, which may cause delays in the start or overall conduct of preclinical studies and clinical trials, the submission of regulatory filings, or the commercialization of our products and any future product candidates.

Our business involves the use of hazardous materials and we and our third-party suppliers and manufacturers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our manufacturing activities and the manufacturing activities of our third-party suppliers and manufacturers, involve the controlled storage, use and disposal of hazardous materials. Further, our manufactured drug substances and drug products may be considered hazardous materials under applicable laws and regulations. Our manufacturing activities, whether conducted by us or our third-party suppliers and manufacturers, like all manufacturing processes that utilize hazardous materials, including those under high pressures, must be properly controlled to avoid unintended reactions or other accidents that could cause injury or damage to personnel, equipment or property. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, transportation, handling and disposal of these hazardous materials, and our failure to manage the use, manufacture, storage, transportation, handling or disposal of hazardous materials could subject us to significant costs or future liabilities. In some cases, these hazardous materials and various wastes resulting from their use are transported and stored at our suppliers' or manufacturers' facilities pending use and disposal. We and our suppliers and manufacturers cannot completely eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, injury to our service providers and others and environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the manufacturing controls and safety procedures utilized by us and our third-party suppliers and manufacturers for handling, transporting and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk (i) that the laws and regulations will not restrict our or our third-party suppliers' or manufacturers' ability to use, manufacture, store, transport, handle or dispose of such materials or (ii) of accidental contamination or injury from these hazardous materials and processes. If these risks were to materialize, we could experience an interruption of our business operations, and we may be held liable for any resulting damages, and such liability could exceed our financial resources.

We may be adversely affected by the effects of inflation or trade tariffs.

We have been impacted, and may continue to be impacted, by inflation and/or trade tariffs which have the potential to adversely affect our liquidity, business, financial condition and results of operations by increasing our overall cost structure. The existence of inflation and the recent uncertainty in the levying of certain trade tariffs by the U.S. government, has resulted in, and may continue to result in, higher interest rates and capital costs, supply shortages, increased costs of labor, components, manufacturing and shipping, as well as weakening exchange rates and other similar effects. As a result of inflation and tariffs, we have experienced and may continue to experience cost increases. Although we may take measures to mitigate the effects of inflation and tariffs, if these measures are not effective and if the inflationary and tariff pressure is sustained or increased, our business, financial condition, results of operations and liquidity could be negatively affected. Even if such measures are effective, there could be a difference between the timing of when these beneficial actions impact our results of operations and when the cost of inflation and/or tariffs are incurred.

Risks Related to Our Dependence on Third Parties

We rely on third parties to conduct any preclinical studies, clinical trials, distribution, shipping and logistics, data collection and many other services. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize any of our future product candidates.

We currently do not have the ability to conduct in-house preclinical studies that comply with the regulatory requirements known as good laboratory practice ("GLP"), requirements. We also do not currently have the ability to conduct any clinical trials in-house. The FDA and regulatory authorities in other jurisdictions require us to comply with regulations and standards, commonly referred to as GCPs for conducting, monitoring, recording and reporting the results of clinical trials, in order to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. We will be required to rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct GLP-compliant preclinical studies and GCP-compliant clinical trials on any future product candidates properly and on time. While we will have agreements governing our activities, we will control only certain aspects of our activities and will have limited influence over their actual performance. The third parties with whom we may contract for execution of our GLP preclinical studies and our GCP clinical trials play a significant role in the conduct of these studies and trials and the subsequent collection and analysis of data. These third parties will not be our employees and, except for restrictions imposed by our contracts with such third parties, we will have limited ability to control the amount or timing of resources that they devote to our programs. Although we plan to rely on these third parties to conduct GLP-compliant preclinical studies and GCP-compliant clinical trials, we will remain responsible for ensuring that each of these studies and clinical trials is conducted in accordance with our investigational plan and protocol and applicable laws and regulations, and our reliance on the third parties will not relieve us of our regulatory responsibilities. In addition, if any of our third parties terminate their involvement with us for any reason, we may not be able to enter into similar arrangements with alternative third parties within a short period of time or do so on commercially reasonable terms.

Many of the third parties with whom we may contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. If the third parties conducting our preclinical studies or clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical trial protocols, GLPs or GCPs, or for any other reason, we may need to enter into new arrangements with alternative third parties. This could be difficult, costly or impossible, and our preclinical studies or clinical trials may need to be extended, delayed, terminated or repeated. As a result, we may not be able to obtain regulatory approval in a timely fashion, or at all, for the applicable future product candidate, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA of any NDA we submit. Any such delay or rejection could prevent it from commercializing our future product candidates.

Our employees, independent contractors, principal investigators, CMOs, CROs, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could expose us to liability and hurt our reputation.

We are exposed to the risk that our employees, independent contractors, principal investigators, CMOs, CROs, consultants, commercial partners and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates: (i) FDA laws and regulations, including those laws that require the reporting of true, complete and accurate information to the FDA, (ii) manufacturing standards, (iii) federal, state and foreign data privacy, security, fraud and abuse and other healthcare laws, or (iv) laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending itself or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, reputational harm, diminished profits and future earnings, and curtailment of our operations.

Risks Related to Intellectual Property

We rely on in-licenses from third parties. If we lose these rights, our business may be materially and adversely affected, our ability to develop improvements to our technology platform may be negatively and substantially impacted, and if disputes arise, we may be subjected to future litigation, as well as the potential loss of or limitations on our ability to incorporate the technology covered by these license agreements.

On March 24, 2025, LNHC assigned its IP portfolio related to the Novan acquisition, including the NITRICIL technology, to Ligand Pharmaceuticals Inc. (“Ligand”) and entered into an exclusive license and sublicense agreement with Ligand, pursuant to which Ligand licensed to LNHC the intellectual property rights necessary to make, use, sell or offer to sell ZELSUVMI for the treatment of molluscum contagiosum in humans worldwide, except for Japan. This license agreement imposes various diligence, milestone payment, royalty, insurance, and other obligations on us, while also granting us the rights to certain patents related to our products.

In spite of our efforts to comply with our obligations under our in-license agreements, our licensors might conclude that we have materially breached our obligations under our license agreements and might therefore, including in connection with any aforementioned disputes, terminate the relevant license agreement, thereby removing or limiting our ability to develop and commercialize technology covered by these license agreements. If any such in-license is terminated, or if the licensed patents fail to provide the intended exclusivity, competitors or other third parties might have the freedom to market or develop technologies similar to ours.

In some circumstances, we may not have the right to control the preparation, filing, prosecution, maintenance and defense of patent applications or patents covering technology that we license from third parties. In such circumstances, our licensors generally have rights to file, prosecute, and maintain the licensed patents in their name, generally with our right to comment on such filing, prosecution, and maintenance, with some obligation for the licensor to consider or incorporate our comments. If our licensors having rights to file, prosecute and maintain our patent rights fail to conduct these activities for patents or patent applications covering any of our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using or selling competing products. Additionally, there could also be delays at the USPTO caused by staffing cuts and other U.S. government actions as a result of the Department of Government Efficiency or other executive actions to reduce the size of the U.S. government, which may adversely affect us or our licensors. We cannot be certain that such activities by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights.

In addition, absent the rights granted to us under our license agreements, we may infringe the intellectual property rights that are the subject of those agreements, we may be subject to litigation by the licensor, and if such litigation by the licensor is successful we may be required to pay damages to our licensor, or we may be required to cease our development and commercialization activities that are deemed infringing, and in such event

We may ultimately need to modify our activities or technologies to design around such infringement, which may be time- and resource-consuming, and which ultimately may not be successful. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, our rights to certain components of our technology platform, may be licensed to us on a non-exclusive basis. The owners of these non-exclusively licensed technologies are therefore free to license them to third parties, including our competitors, on terms that may be superior to those offered to us, which could place us at a competitive disadvantage.

Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor’s rights. In addition, certain of our agreements with third parties may provide that intellectual property arising under these agreements, such as data that could be valuable to our business, will be owned by the third party, in which case, we may not have adequate rights to use such data or have exclusivity with respect to the use of such data, which could result in third parties, including our competitors, being able to use such data to compete with us.

Third party intellectual property may prevent us from developing our potential products; our intellectual property may not prevent competition; and any intellectual property issues may be expensive and time consuming to resolve.

The manufacture, use or sale of our potential products may infringe the patent rights of others. If others obtain patents with conflicting claims, we may be required to obtain licenses to those patents or to develop or obtain alternative technology. We may not be able to obtain any such licenses on acceptable terms, or at all. Any failure to obtain such licenses could delay or prevent us from pursuing the development or commercialization of our potential products, platform and technology.

Generally, our success will depend on our and our licensors' ability to obtain and maintain patents and other intellectual property rights for our potential products and technologies. our patent position is uncertain and involves complex legal and technical questions for which legal principles are unresolved. Even if we do obtain patents, such patents may not adequately protect the technology we own or have licensed.

The patents that cover our branded products are listed in the Orange Book. If a third party submits a new drug application ("NDA") or abbreviated new drug application ("ANDA") for a generic drug product that relies in whole or in part on studies contained in the NDA for one of our branded products, the third party will have the option to certify to the FDA that, in the opinion of that third party, the patents listed in the Orange Book for our branded product are invalid, unenforceable, or will not be infringed by the manufacture, use or sale of the third party's generic drug product. A third-party certification that a new product will not infringe Orange Book-listed patents, or that such patents are invalid, is called a paragraph IV patent certification. If the third party submits a paragraph IV patent certification to the FDA, a notice of the paragraph IV patent certification must be sent to the NDA owner and the owner of the patents that are subject to the paragraph IV patent certification notice once the third-party's NDA or ANDA is accepted for filing by the FDA. A lawsuit may then be initiated to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of the receipt of notice of a paragraph IV patent certification automatically prevents the FDA from approving the generic NDA or ANDA until the earlier of the expiration of a 30-month period, the expiration of the patents, the entry of a settlement order stating that the patents are invalid or not infringed, a decision in the infringement case that is favorable to the NDA or ANDA applicant, or such shorter or longer period as the court may order. If a patent infringement lawsuit is not initiated within the required 45-day period, the third-party's NDA or ANDA will not be subject to the 30-month stay. Third parties may challenge the patents covering our branded products. We may from time to time become party to litigation or other proceedings as a result of paragraph IV patent certifications.

In addition, we cannot assure you that all of the potentially relevant prior art information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention-relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent from issuing from a pending patent application (whether owned by us or in-licensed from Ligand or another third party), and we may be subject to a third-party pre-issuance submission of prior art to the United States Patent and Trademark Office ("USPTO"). Even if our patent applications (whether owned by us or in-licensed from Ligand or another third party) do successfully issue and even if such patents cover our products or potential products, third parties may initiate litigation or opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices, or similar proceedings challenging the validity, enforceability or scope of such patents, which may result in the patent claims being narrowed or invalidated, may allow third parties to commercialize our products and compete directly with us, without payment to us, or limit the duration of the patent protection of our technology and products.

In addition, similar to what other companies in our industry have experienced, we expect our competitors and others may have patents or may in the future obtain patents and claim that making, having made, using, selling, offering to sell or importing our technologies infringes these patents. Defense of infringement and other claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and employee resources from our business. Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources, or may be able to obtain injunctive or other relief, which could block our ability to develop, commercialize, and sell products or services and could result in the award of substantial damages against us, including treble damages, attorney's fees, costs and expenses if we are found to have willfully infringed. In the event of a successful claim of infringement against us, we may be required to pay damages and ongoing royalties and obtain one or more licenses from third parties or be prohibited from selling certain products or services. As discussed above, we may not be able to obtain these licenses on acceptable or commercially reasonable terms, if at all, or these licenses may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we could encounter delays in product or service introductions while we attempt to develop alternative products or services to avoid infringing third-party patents or proprietary rights. Defense of any lawsuit or failure to obtain any of these licenses could prevent us from commercializing products or services, and the prohibition of sale of any of our technologies could materially affect our business and our ability to gain market acceptance for our technology.

Litigation or other proceedings to enforce or defend intellectual property rights are often very complex in nature, may be very expensive and time-consuming, may divert our management's attention from our core business, and may result in unfavorable results that could adversely impact our ability to prevent third parties from competing with our products or technologies. Any adverse outcome of such litigation or other proceedings could result in one or more of our patents (whether owned by us or in-licensed from Ligand or another third party) being held invalid or unenforceable, which could adversely affect our ability to successfully execute our business strategy and negatively impact our financial condition and results of operations. However, given the unpredictability inherent in litigation, we cannot predict or guarantee the outcome of these matters or any other litigation. Regardless of how these matters are ultimately resolved, these matters may be costly, time-consuming and distracting to our management, which could have a material adverse effect on our business. It may be necessary for us or our licensors to pursue litigation or adversarial proceedings before the patent office in order to enforce their patent and proprietary rights or to determine the scope, coverage and validity of the proprietary rights of others. The outcome of any such litigation might not be favorable, and even if we or our licensors were to prevail, such litigation could result in substantial costs and diversion of resources and could have a material adverse effect on our business, operating results or financial condition.

In addition, periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the U.S. and various foreign patent offices at various points over the lifetime of our and our licensors' patents and/or applications. We will rely on Ligand to pay these fees with respect to the patents covering ZELSUVMI and cannot ensure Ligand will pay these fees in a timely manner. Additionally, the U.S. and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We will rely on Ligand to comply with these requirements. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, 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. If such an event were to occur, it could have a material adverse effect on our business.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Any conflicts with the patent rights of others could significantly reduce the coverage of our patents (whether owned by us or in-licensed from Ligand or another third party) or limit our ability to obtain meaningful patent protection. In addition, any determination that our patent rights are invalid may result in early termination of our agreements with our license partners and could adversely affect our ability to enter into new license agreements. We also rely on unpatented trade secrets and know-how to protect and maintain our competitive position. We require our employees, consultants, licensees, and others to sign confidentiality agreements when they begin their relationship with us. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our competitors may independently discover our trade secrets.

We may also need to initiate litigation, which could be time-consuming and expensive, to enforce our proprietary rights or to determine the scope and validity of others' rights. If this occurs, a court may find our patents or those of our licensors invalid or may find that we have infringed on a competitor's rights. In addition, if any of our competitors have filed patent applications in the United States prior to March 2013 which claim technology we also have invented, the USPTO may require us or our licensors to participate in expensive interference proceedings to determine who has the right to a patent for the technology.

In addition, our agreements with some of our suppliers or other entities with whom we do business require us to defend or indemnify these parties to the extent they become involved in infringement claims, including the types of claims described above. We could also voluntarily agree to defend or indemnify third parties in instances where we are not obligated to do so if we determine it would be important to our business relationships. If we are required or agrees to defend or indemnify third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, financial condition, results of operations, and prospects. The occurrence of any of the foregoing problems could be time-consuming and expensive and could adversely affect our financial position, liquidity and results of operations.

If we are unable to obtain and maintain sufficient intellectual property protection for our products and technology, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technologies similar to ours, and our ability to successfully sell our products and services may be impaired.

Our success depends in part on our and our licensor's ability to obtain and maintain adequate protection of the intellectual property we may own solely and jointly with others or otherwise have rights to, particularly patents, in the United States and in other countries with respect to our platform, our software and our technologies, without infringing the intellectual property rights of others.

We strive to protect and enhance the proprietary technologies that we believe are important to our business, including seeking patents intended to cover our platform and related technologies and uses thereof, as we deem appropriate. However, obtaining and enforcing patents in our industry is costly, time-consuming and complex, and we may fail to apply for patents on important products and technologies in a timely fashion or at all, or we may fail to apply for patents in potentially relevant jurisdictions. There can be no assurance that the claims of our patents or any patent application that issues as a patent (whether owned by us or in-licensed from Ligand or another third party) will exclude others from making, using, importing, offering for sale, or selling products or services that are substantially similar to ours. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. In countries where we have not sought and do not seek patent protection, third parties may be able to manufacture and sell our technology without our permission, and we may not be able to stop them from doing so. We may not be able to file and prosecute all necessary or desirable patent applications, or maintain, enforce and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents licensed to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

It is possible that none of our pending patent applications (whether owned by us or in-licensed from Ligand or another third party) will result in issued patents in a timely fashion or at all, and even if patents are granted, they may not provide a basis for intellectual property protection of commercially viable products or services, may not provide us with any competitive advantages, or may be challenged and invalidated by third parties or deemed unenforceable by a court. It is possible that others will design around our current or future patented technologies. As a result, our owned and licensed patents and patent applications comprising our patent portfolio may not provide us with sufficient rights to exclude others from commercializing technology and products similar to any of our products, platform and technology.

In addition, we may identify third party intellectual property and technology we may need to acquire or license in order to engage in our business, including to develop or commercialize new technologies. However, such licenses may not be available to us on acceptable terms or at all. Furthermore, geopolitical actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future license partners and the maintenance, enforcement or defense of our issued patents or those of any current or future license partners. For example, the United States and foreign government actions related to Russia's conflict in Ukraine may limit or prevent filing, prosecution, and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our or our license partners' patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees from the United States without consent or compensation. Consequently, we or our license partners would not be able to prevent third parties from practicing our or our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Issued patents directed to the NITRICIL platform and technology could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

The issuance of a patent is not conclusive as to our inventorship, scope, validity or enforceability. Some of our patents or patent applications (whether owned by us or in-licensed from Ligand or another third party) may be challenged at a future point in time in opposition, derivation, reexamination, inter partes review, post-grant review or interference. Any successful third-party challenge to our patents in this or any other proceeding could result in the unenforceability or invalidity of such patents or amendment to our patents in such a way that any resulting protection may lead to increased competition to our business, which could harm our business. In addition, in patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on certain aspects of our platform technologies. In addition, if the breadth or strength of protection provided by our patents and patent applications (whether owned by us or in-licensed from Ligand or another third party) is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future products, platform and technology.

We may not be aware of all third-party intellectual property rights potentially relating to our products, platform and technology. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until approximately 18 months after filing or, in some cases, not until such patent applications issue as patents. We or our licensors might not have been the first to make the inventions included in each of our pending patent applications and we or our licensors might not have been the first to file patent applications for these inventions. There is also no assurance that all of the potentially relevant prior art relating to our patents and patent applications or licensed patents and patent applications have been found, which could be used by a third party to challenge their validity or prevent a patent from issuing from a pending patent application.

To determine the priority of these inventions, we may have to participate in interference proceedings (with respect to patent applications filed prior to March 2013), derivation proceedings or other post-grant proceedings declared by the USPTO that could result in substantial cost to us. The outcome of such proceedings is uncertain. No assurance can be given that other patent applications will not have priority over our patent applications (whether owned by us or in-licensed from Ligand or another third party). In addition, changes to the patent laws of the United States allow for various post-grant opposition proceedings that have not been extensively tested, and their outcome is therefore uncertain. Furthermore, if third parties bring these proceedings against our patents (whether owned by us or in-licensed from Ligand or another third party), we could experience significant costs and management distraction.

Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing Ligand's ability to protect our products, platform and technology on which we rely.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, and may diminish our ability to protect our inventions, obtain, maintain, enforce and protect our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our future owned and licensed patents. Depending on future actions by the United States Congress, the United States courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our or our license partners' ability to obtain new patents and patents that we or our license partners might obtain in the future. For example, on June 1, 2023, the European Union Patent Package ("EU Patent Package") regulations were implemented with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court ("UPC") for litigation involving European patents. As a result, all European patents, including those issued prior to ratification of the EU Patent Package, now by default automatically fall under the jurisdiction of the UPC. It is uncertain how the UPC will impact granted European patents in the biotechnology and pharmaceutical industries. Our or our license partners' European patent applications, if issued, could be challenged in the UPC. During the first seven years of the UPC's existence, the UPC legislation allows a patent owner to opt out European patents out of the jurisdiction of the UPC. We or our license partners may decide to opt out future European patents from the UPC, but doing so may preclude we or our license partners from realizing the benefits of the UPC. Moreover, if we or our license partners do not meet all of the formalities and requirements for opt-out under the UPC, our or our license partners' future European patents could remain under the jurisdiction of the UPC. The UPC will provide our and our license partners' competitors with a new forum to centrally revoke our European patents and allow for the possibility of a competitor to obtain pan-European injunction. Such a loss of patent protection could have a material adverse impact on our or our license partners' business and ability to commercialize our technology and product candidates and, resultantly, on our business, financial condition, prospects and results of operations.

In addition, the U.S. federal government retains certain rights in inventions produced with our financial assistance under the Patent and Trademark Law Amendments Act (Bayh-Dole Act). For example, certain patents and patent applications licensed from the University of North Carolina at Chapel Hill (through Ligand) were made with financial assistance from the federal government. The federal government retains a “nonexclusive, nontransferable, irrevocable, paid-up license” for our own benefit. The Bayh-Dole Act also provides federal agencies with “march-in rights.” March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a “nonexclusive, partially exclusive, or exclusive license” to a “responsible applicant or applicants.” If the patent owner refuses to do so, the government may grant the license itself. If we choose to collaborate with academic institutions for our research or development, we cannot be sure that any co-developed intellectual property will be free from government rights pursuant to the Bayh-Dole Act. If, in the future, we co-own or license in technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

We may be subject to claims challenging the inventorship of the patents and other intellectual property on which we rely.

We or our licensors may be subject to claims that former employees or other third parties have an interest in our or our in-licensed patents, trade secrets or other intellectual property as an inventor or co-inventor. Litigation may be necessary to defend against these and other claims challenging inventorship of our or our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our systems, including our software, workflows, consumables and reagents. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees, and certain partners may defer engaging with us until the particular dispute is resolved. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our information and our trade secrets, the value of our technology could be materially and adversely affected and our business could be harmed.

We rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology and other proprietary information, including parts of our technology platform, and to maintain our competitive position. However, trade secrets and know-how can be difficult to protect. In addition to pursuing patents on our technology, we take steps to protect our intellectual property and proprietary technology by entering into agreements, including confidentiality agreements, non-disclosure agreements and intellectual property assignment agreements, with our employees, consultants, academic institutions, corporate partners and, when needed, our advisers. However, we cannot be certain that such agreements have been entered into with all relevant parties, and we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. For example, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements, and we may not be able to prevent such unauthorized disclosure, which could adversely impact our ability to establish or maintain a competitive advantage in the market. If we are required to assert our rights against such party, it could result in significant cost and distraction.

Monitoring unauthorized disclosure and detection of unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time-consuming, and the outcome would be unpredictable. In addition, some courts both within and outside the United States may be less willing, or unwilling, to protect trade secrets. Further, we may need to share our trade secrets and confidential know-how with current or future partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors.

We also seek to preserve the integrity and confidentiality of our confidential proprietary information by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. If any of our confidential proprietary information were to be lawfully obtained or independently developed by a competitor or other third party, absent patent protection, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. If any of our trade secrets were to be disclosed to or independently discovered by a competitor or other third party, it could harm our business, financial condition, results of operations and prospects.

If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our competitive position may be harmed.

We rely on our trademarks, trade names and brand names to distinguish our products from the products of our competitors and have registered or applied to register many of these trademarks. We cannot guarantee that our trademark applications will be approved. Third parties may also oppose our trademark applications or otherwise challenge our use of the trademarks. Our registered and unregistered trademarks, trade names, and brand names may be challenged, infringed, circumvented, declared generic or determined to be violating or infringing on other marks. We may not be able to protect our rights to these trademarks, trade names, and brand names which we rely upon to build name recognition among potential partners and customers in our markets of interest. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Further, there can be no assurance that competitors will not infringe our trademarks or that we will have adequate resources to enforce our trademarks.

Risks Related to Legal and Regulatory Compliance Matters

Current and future healthcare reform legislation or regulation may increase the difficulty and cost for us to commercialize ZELSUVMI and may adversely affect the prices we may obtain and may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions there have been, and continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, restrict or regulate post-approval activities with respect to ZELSUVMI and affect our ability to profitably sell our products. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States and elsewhere, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative and regulatory initiatives. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for ZELSUVMI or any product candidates approved for sale. New and changing laws and regulations may also create uncertainty about how such laws and regulations will be interpreted and applied. If we are found to have violated laws and regulations, it could materially adversely affect our business, results of operations and financial condition.

The ACA was signed into law in 2010. The ACA substantially changed the way healthcare is financed by both governmental and private insurers and significantly affects the U.S. pharmaceutical industry. Among the provisions of the ACA of importance to our business, including, without limitation, our ability to commercialize and the prices we may obtain for any product candidates that are approved for sale, are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, although this fee does not apply to sales of certain products approved exclusively for orphan indications;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs, revising the "average manufacturer price" definition, and extending rebate liability from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well;
- expansion of the list of entity types eligible for participation in the Public Health Service 340B drug pricing program, or the 340B program, to include certain free-standing cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals, but exempting "orphan drugs" from the 340B ceiling price requirements for these covered entities;
- a Patient Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, including prescription drug spending.

Since its enactment, certain provisions of the ACA have been subject to judicial, executive, and legislative challenges and may be subject to additional challenges in the future. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap, beginning January 1, 2024. Previously, the Medicaid rebate was capped at 100% of a drug's average manufacturer price.

The cost of prescription pharmaceuticals in the United States has also been the subject of considerable discussion in the United States. There have been several Congressional inquiries, as well as legislative and regulatory initiatives and executive orders designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products.

Most significantly, in August 2022, the Inflation Reduction Act of 2022 ("IRA") was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); redesigns the Medicare Part D benefit (which began in 2024); and replaces the Part D coverage gap discount program with a new manufacturer discount program (which began in 2025). CMS has published the negotiated prices for the initial ten drugs, which will first be effective in 2026, and the list of the subsequent 15 drugs that will be subject to negotiation. The IRA permits the Secretary of the Department of Health and Human Services ("HHS") to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented, although the Medicare drug price negotiation program is currently subject to legal challenges. The impact of the IRA on us and the pharmaceutical industry cannot yet be fully determined but is likely to be significant.

Congress and the Trump administration are considering significant reductions in the funding of the Medicaid program. If such reductions are adopted and decrease the number of persons enrolled in Medicaid or reduce the services covered by Medicaid, our sales of ZELSUVMI could be adversely affected.

Moreover, the federal government and the individual states in the United States have become increasingly active in developing proposals, passing legislation and implementing regulations designed to control drug pricing, including price or patient reimbursement constraints, discounts, formulary flexibility, marketing cost disclosure, drug price reporting, and other transparency measures. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states. These types of initiatives may result in additional reductions in Medicare, Medicaid, and other healthcare funding, and may otherwise affect the prices we may obtain for ZELSUVMI or the frequency with which ZELSUVMI is prescribed or used.

We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage and payment criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicaid or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. We cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, any of which could adversely affect our business, results of operations and financial condition.

The pricing of prescription pharmaceuticals is also subject to governmental control outside the United States. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of ZELSUVMI to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenues and become profitable could be impaired.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in which we participate, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Medicaid is a joint federal and state program administered by the states for low income and disabled beneficiaries. We intend to participate in and will have certain price reporting obligations under the Medicaid Drug Rebate Program (“MDRP”) as a condition of having covered outpatient drugs payable under Medicaid. The MDRP requires us to pay a rebate to state Medicaid programs every quarter for each unit of our covered outpatient drugs dispensed to Medicaid beneficiaries and paid for by a state Medicaid program. The rebate is based on pricing data that we must report on a monthly and quarterly basis to CMS, the federal agency that administers the MDRP and other governmental healthcare programs. These data include the average manufacturer price (“AMP”) for each drug and, in the case of innovator products, the best price, which in general represents the lowest price available from the manufacturer to certain entities in the United States in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions. The Medicaid rebate consists of two components, the basic rebate and the additional rebate, which is triggered if the AMP for a drug increases faster than inflation. If we become aware that our MDRP government price reporting submission for a prior quarter was incorrect or has changed as a result of recalculation of the pricing data, we must resubmit the corrected data for up to three years after those data originally were due. If we fail to provide information timely or are found to have knowingly submitted false information to the government, we may be subject to civil monetary penalties and other sanctions, including termination from the MDRP. In the event that CMS terminates our rebate agreement pursuant to which we participate in the MDRP, no federal payments would be available under Medicaid for our covered outpatient drugs. Our failure to comply with our MDRP price reporting and rebate payment obligations could negatively impact our financial results.

Federal law requires that any company that participates in the MDRP also participate in the Public Health Service’s 340B drug pricing program in order for federal funds to be available for the manufacturer’s drugs under Medicaid. We intend to participate in the 340B program, which is administered by the Health Resources and Services Administration (“HRSA”) and requires us to charge statutorily defined covered entities no more than the 340B “ceiling price” for our covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The ACA expanded the list of covered entities to include certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, but exempts “orphan drugs” from the ceiling price requirements for these covered entities. The 340B ceiling price is calculated using a statutory formula based on the AMP and rebate amount for the covered outpatient drug as calculated under the MDRP, and in general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price calculation and discount requirement. We will be required to report 340B ceiling prices to HRSA on a quarterly basis, and HRSA publishes those prices to 340B covered entities. In addition, HRSA has finalized regulations regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities for 340B-eligible drugs. HRSA has also finalized a revised regulation implementing an administrative dispute resolution process through which 340B covered entities may pursue claims against participating manufacturers for overcharges, and through which manufacturers may pursue claims against 340B covered entities for engaging in unlawful diversion or duplicate discounting of 340B drugs. Our failure to comply with 340B program requirements could negatively impact our financial results. Any additional future changes to the definition of average manufacturer price and the Medicaid rebate amount under legislation or regulation could affect our 340B ceiling price calculations and also negatively impact our financial results.

In order for ZELSUVMI or any product candidates, if approved, to be paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, we also participate in the U.S. Department of Veterans Affairs (“VA”) Federal Supply Schedule (“FSS”) pricing program. As part of this program, we are required to make our products available for procurement on an FSS contract under which we must comply with standard government terms and conditions and charge a price that is no higher than the statutory Federal Ceiling Price (“FCP”) to four federal agencies (VA, U.S. Department of Defense (“DOD”), Public Health Service, and U.S. Coast Guard). The FCP is based on the Non-Federal Average Manufacturer Price, or Non-FAMP, which we must calculate and report to the VA on a quarterly and annual basis. Pursuant to applicable law, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to significant civil monetary penalties for each item of false information. The FSS pricing and contracting obligations also contain extensive disclosure and certification requirements.

We also intend to participate in the Tricare Retail Pharmacy program, under which we will be required to pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare Retail Pharmacy network to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non-FAMP and FCP. We are required to list our innovator products on a Tricare Agreement in order for them to be eligible for DOD formulary inclusion. If we overcharge the government in connection with our FSS contract or Tricare Agreement, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges could result in allegations against us under the False Claims Act (“FCA”) and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Individual states continue to consider and have enacted legislation to limit the growth of healthcare costs, including the cost of prescription drugs and combination products. A number of states have either implemented or are considering implementation of drug price transparency legislation. Requirements of pharmaceutical manufacturers under such laws include advance notice of planned price increases, reporting price increase amounts and factors considered in taking such increases, wholesale acquisition cost information disclosure to prescribers, purchasers, and state agencies, and new product notice and reporting. Such legislation could limit the price or payment for certain drugs, and a number of states are authorized to impose civil monetary penalties or pursue other enforcement mechanisms against manufacturers who fail to comply with drug price transparency requirements, including the untimely, inaccurate, or incomplete reporting of drug pricing information.

Pricing and rebate calculations vary among products and programs. The calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies, and the courts. CMS, the Department of Health & Human Services Office of Inspector General, and other governmental agencies have pursued manufacturers that were alleged to have failed to report these data to the government in a timely or accurate manner. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. We cannot assure you that any submissions we are required to make under the MDRP, the 340B program, the VA/FSS program, the Tricare Retail Pharmacy Program, and other governmental drug pricing programs will not be found to be incomplete or incorrect.

We are subject to federal, state and foreign healthcare laws and regulations, including fraud and abuse laws. If we are unable to comply or have not fully complied with such laws and regulations, we could face criminal sanctions, damages, substantial civil penalties, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others will play a primary role in the recommendation and prescription of ZELSUVMI, and other product candidates, if approved. Our arrangements and interactions with healthcare professionals, third-party payors, patients and others will expose us to broadly applicable fraud and abuse, antikickback, false claims and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell, and distribute ZELSUVMI and other product candidates, if we obtain regulatory approval. The U.S. federal healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- the federal healthcare Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, or receiving remuneration, (anything of value), directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease order or arranging for or recommending the purchase, lease or order of any good or service for which payment may be made, in whole or in part, by federal healthcare programs such as Medicare and Medicaid. This statute has been interpreted to apply to arrangements between pharmaceutical companies on one hand and prescribers, purchasers, formulary managers, and patients on the other. Liability under the Anti-Kickback Statute may be established without proving actual knowledge of the statute or specific intent to violate it;
- the federal civil FCA, which prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented a false or fraudulent claim for payment of government funds, or knowingly making, using or causing to be made or used a false record or statement material to an obligation to pay money to the government or knowingly concealing or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the federal government. Actions under the FCA may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Such private individuals may share in amounts paid by the entity to the government in recovery or settlement. The government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil FCA;
- the federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer or remuneration to a Medicare or state healthcare program beneficiary, if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state health care program, unless an exception applies;
- the federal HIPAA imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, including private third-party payors, or for knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal healthcare Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the federal Physician Payments Sunshine Act, implemented as the Open Payments Program, requires certain manufacturers of drugs, devices, biologics and medical supplies to report payments and other transfers of value to physicians for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants and certified nurse-midwives) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Manufacturers must submit reports on or before the 90th day of each calendar year disclosing reportable payments made in the previous calendar year;

- analogous state laws and regulations, such as state anti-kickback and false claims laws, which may apply to items or services reimbursed under Medicaid and other state programs or, in several states, regardless of the payer, including private insurers. Some state laws require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual health care providers in those states. Some of these states also prohibit certain marketing- related activities including the provision of gifts, meals, or other items to certain health care providers. Some states restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs. Some states require the posting of information relating to clinical studies and their outcomes. Other states and cities require identification or licensing of sales representatives. In addition, several states require pharmaceutical companies to implement compliance programs or marketing codes of conduct; and
- analogous foreign laws and regulations, including restrictions imposed on the promotion and marketing of medicinal products in the EU member states and other countries, restrictions on interactions with healthcare professionals and requirements for public disclosure of payments made to physicians. Laws (including those governing promotion, marketing and anti-kickback provisions), industry regulations and professional codes of conduct often are strictly enforced. Even in those countries where we may decide not to directly promote or market our products, inappropriate activity by our international distribution partners could have implications for us.

Ensuring that our business arrangements and interactions with healthcare professionals, third-party payors, patients and others comply with applicable healthcare laws and regulations will require substantial resources. Various state, federal and foreign regulatory and enforcement agencies continue actively to investigate violations of healthcare laws and regulations, and the United States Congress continues to strengthen the arsenal of enforcement tools.

It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to costly investigations, significant civil, criminal and administrative monetary penalties, imprisonment, damages, fines, disgorgement, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could substantially disrupt our operations or financial results. Any action against us for violation of these laws or regulations, even if we successfully defend against us, could cause us to incur significant legal expenses and generate negative publicity, which could harm our financial condition and divert our management's attention from the operation of our business.

Changes in and actual or perceived failures to comply with applicable data privacy, security and protection laws, regulations, standards and contractual obligations may adversely affect our business, operations and financial performance.

We and our partners are or may become subject to federal, state, and foreign laws, requirements and regulations that govern data privacy and security. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact of future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer, use, and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability, or impose additional costs on us. The cost of compliance with these laws, regulations, and standards is high and likely to increase in the future.

In the United States, numerous federal and state laws and regulations govern the collection, use, disclosure, and protection of personal information, including state data breach notification laws, federal and state health information privacy laws, and federal and state consumer protection laws. Each of these laws is subject to varying interpretations by courts and government agencies, creating complex compliance issues. If we fail to comply with applicable laws and regulations, we could be subject to penalties or sanctions, including criminal penalties if we knowingly obtain or disclose individually identifiable health information from a covered entity in a manner that is not authorized or permitted by HIPAA or applicable state laws. HIPAA imposes, among other things, certain standards relating to the privacy, security, transmission, and breach reporting of individually identifiable health information. We may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPAA.

Certain states have also adopted comparable privacy and security laws and regulations, which govern the privacy, processing and protection of health-related and other personal information. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, the California Consumer Privacy Act of as amended by the California Privacy Rights Act (collectively, the “CCPA”) requires covered businesses that process the personal information of California residents to, among other things: (i) provide certain disclosures to California residents regarding the business’s collection, use, and disclosure of their personal information; (ii) receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt out of certain disclosures of their personal information; and (iii) enter into specific contractual provisions with service providers that process California resident personal information on the business’s behalf. Additional compliance investment and potential business process changes may be required. Similar laws have passed in other states and are continuing to be proposed at the state and federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

We also may become subject to rapidly evolving data protection laws, rules and regulations in foreign jurisdictions. For example, the European Union General Data Protection Regulation (“GDPR”) went into effect in May 2018 and imposes strict requirements for processing the personal data of individuals within the European Economic Area (“EEA”) or in the context of our activities within the EEA. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. In addition to fines, a breach of the GDPR may result in regulatory investigations, reputational damage, orders to cease/change our data processing activities, enforcement notices, assessment notices (for a compulsory audit) and/or civil claims (including class actions). Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EEA and the United States remains uncertain. Case law from the Court of Justice of the European Union (“CJEU”) states that reliance on the standard contractual clauses - a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism - alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. On July 10, 2023, the European Commission adopted our Adequacy Decision in relation to the new EU-US Data Privacy Framework (“DPF”), rendering the DPF effective as a GDPR transfer mechanism to U.S. entities self-certified under the DPF. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue. In particular, we expect the DPF Adequacy Decision to be challenged and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As a result, we may have to make certain operational changes, and we will have to implement revised standard contractual clauses and other relevant documentation for existing data transfers within required time frames. Further, the U.S. Department of Justice recently issued a final rule that went into effect in April 2025, known as the “Data Security Program,” (the “DSP Rule”), which regulates data transactions that could grant access to US sensitive personal data to certain foreign actors with connections to “countries of concern,” such as China, which the DSP refers to as “covered persons.” As supervisory authorities issue further guidance on personal data export mechanisms, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Since the beginning of 2021, after the end of the transition period following the United Kingdom's departure from the European Union, we are also subject to the United Kingdom General Data Protection Regulation and Data Protection Act 2018 (collectively, the "UK GDPR"), which imposes separate but similar obligations to those under the GDPR and comparable penalties, including fines of up to £17.5 million or 4% of a noncompliant company's global annual revenue for the preceding financial year, whichever is greater. On October 12, 2023, the UK Extension to the DPF came into effect (as approved by the UK Government), as a data transfer mechanism to U.S. entities self-certified under the DPF. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business. Failure or perceived failure to comply with the GDPR, the UK GDPR, and other countries' privacy or data security-related laws, rules, or regulations could result in significant regulatory penalties and fines, affect our compliance with contracts entered into with our partners, collaborators and other third-party payors, and could have an adverse effect on our reputation, business, and financial condition.

Furthermore, the Federal Trade Commission ("FTC") also has authority to initiate enforcement actions against entities that make deceptive statements about privacy and data sharing in privacy policies, fail to limit third-party use of personal health information, fail to implement policies to protect personal health information or engage in other unfair practices that harm customers or that may violate Section 5 of the Federal Trade Commission Act. Failing to take appropriate steps to keep consumers' personal information secure can constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information we hold, the size and complexity of our business, and the cost of available tools to improve security and reduce vulnerabilities. Additionally, federal and state consumer protection laws are increasingly being applied by FTC and states' attorneys general to regulate the collection, use, storage, and disclosure of personal or personally identifiable information, through websites or otherwise, and to regulate the presentation of website content.

Compliance with applicable data privacy and security laws, rules and regulations could require us to take on more onerous obligations in our contracts, require us to engage in costly compliance exercises, restrict our ability to collect, use and disclose data, or in some cases, impact our or our partners' ability to operate in certain jurisdictions. Each of these constantly evolving laws can be subject to varying interpretations and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, collaborators, or other third parties comply with any such laws, rules, or regulations, or adequately address privacy and security concerns, even if unfounded, could result in government investigations and/or enforcement actions, fines, civil or criminal penalties, private litigation or adverse publicity that could adversely affect our business, financial condition and results of operations.

If plaintiffs bring product liability lawsuits against us or our partners, we or our partners may incur substantial liabilities and may be required to limit commercialization of our approved products and product candidates.

As is common in our industry, we and our partners face an inherent risk of product liability as a result of the clinical testing of our product candidates in clinical trials and face an even greater risk for commercialized products. Although we are not currently a party to product liability litigation, if we are sued, we may be held liable if any product or product candidate we develop causes injury or is found otherwise unsuitable during product testing, manufacturing, marketing or sale. Regardless of merit or eventual outcome, liability claims may result in decreased demand for any product candidates, partnered products or products that we may develop, injury to our reputation, discontinuation of clinical trials, costs to defend litigation, substantial monetary awards to clinical trial participants or patients, loss of revenue and product recall or withdrawal from the market and the inability to commercialize any products that we develop. We have product liability insurance that covers up to a \$15 million annual limit. Our insurance coverage may not be sufficient to cover all of our product liability-related expenses or losses and may not cover us for any expenses or losses we may suffer. If we are sued for any injury caused by our product candidates, partnered products or any future products, our liability could exceed our total assets.

We face risks related to handling of hazardous materials and other regulations governing environmental safety.

Our operations are subject to complex and stringent environmental, health, safety and other governmental laws and regulations that both public officials and private individuals may seek to enforce. Our activities that are subject to these regulations include, among other things, our use of hazardous materials and the generation, transportation and storage of waste. Although we have secured clearance from the EPA historically, and while we are currently operating in material compliance with applicable EPA rules and regulations, our business could be adversely affected if the EPA discovers that we or an acquired business is not in material compliance with these rules and regulations.

In the future, we may pursue the use of other surfactant substances that will require clearance from the EPA, and we may fail to obtain such clearance. Existing laws and regulations may also be revised or reinterpreted, or new laws and regulations may become applicable to us, whether retroactively or prospectively, that may have a negative effect on our business and results of operations. It is also impossible to eliminate completely the risk of accidental environmental contamination or injury to individuals. In such an event, we could be liable for any damages that result, which could adversely affect our business.

We may also be subject to other laws and regulations not specifically targeting the healthcare industry.

Certain regulations not specifically targeting the healthcare industry also could have material effects on our operations. For example, the California Financing Law (“CFL”), Division 9, Sections 22000-22780.1 of the California Financial Code, could be applied to us as a result of loans or similar arrangements we enter into with partners. If a regulator were to take the position that such loans were covered by the California Financing Law, we could be subject to regulatory action that could impair our ability to continue to operate and may have a material adverse effect on our profitability and business as we currently do not hold a CFL finance lenders license. Pursuant to an exemption under the CFL, a person may make five or fewer commercial loans with a California nexus in a 12-month period without a CFL finance lenders license if such loans are “incidental” to the business of the person making the loan. This exemption, however, creates some uncertainty as to which loans could be deemed as incidental to our business. In addition, there is another exemption that would allow a person without a CFL finance lenders license to make a single commercial loan with a California nexus in a 12-month period.

Other Risks and Uncertainties Affecting Our Business

The occurrence of a catastrophic disaster could disrupt our business, damage our facilities beyond insurance limits, increase our costs and expenses, or we could lose key data which could cause us to curtail or cease operations.

We are vulnerable to damage, business disruptions and/or loss of vital data from natural or man-made disasters, such as earthquakes, tornadoes, severe weather conditions, power loss, fire, floods and similar events, as well as from accidental loss or destruction. If any disaster were to occur, our ability to operate our business could be seriously impaired. We maintain property, liability, and business interruption insurance which may not be adequate to cover our losses resulting from disasters or other similar significant business interruptions, and we do not plan to purchase additional insurance to cover such losses due to the cost of obtaining such coverage. Any significant losses that are not recoverable under our insurance policies could seriously impair our business, financial condition and prospects.

Impairment charges pertaining to goodwill, identifiable intangible assets or other long-lived assets from our mergers and acquisitions could have an adverse impact on our results of operations and our market value.

The total purchase price pertaining to transactions that result in the fair valuing of assets and liabilities, may be allocated to net tangible assets, identifiable intangible assets, in-process research and development and goodwill. To the extent the value of goodwill or identifiable intangible assets or other long-lived assets become impaired, we will be required to incur material charges relating to the impairment. Any impairment charges could have a material adverse impact on our results of operations and our market value.

Our results of operations and liquidity needs could be materially negatively affected by market fluctuations and economic downturn.

Our results of operations could be materially negatively affected by economic conditions generally, both in the United States and elsewhere around the world. Concerns over inflation, energy costs, geopolitical issues, military conflicts, including the wars between Russia and Ukraine and Israel and Hamas, terrorism, public health emergencies or pandemics, the availability and cost of credit, and the U.S. financial markets have in the past contributed to, and may continue in the future to contribute to, increased volatility and diminished expectations for the economy and the markets. Sanctions imposed by the United States and other countries in response to military conflicts, including the wars between Russia and Ukraine and Israel and Hamas, may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. Domestic and international equity markets periodically experience heightened volatility and turmoil. These events may have an adverse effect on us. In the event of a market downturn, our results of operations could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds if necessary, and our value may decline. We cannot provide assurance that our investments are not subject to adverse changes in market value. If our investments experience adverse changes in market value, we may have less capital to fund our operations.

Our business is subject to risks arising from pandemic and epidemic diseases.

Future pandemics, including the residual effects of the COVID-19 pandemic, or other public health epidemics, pose the risk that we or our employees, contractors, including our CROs, suppliers, and other partners may be prevented from conducting business activities for an indefinite period of time, including due to spread of the disease within these groups or due to shutdowns that may be requested or mandated by governmental authorities. Although we currently do not believe the COVID-19 pandemic is having a material impact on our business, we cannot guarantee that pandemics, such as COVID-19 or the emergence of variants thereof, or a similar event, will not impact our operations in the future.

Although we believe that we and our partners have adjusted their business practices to the impacts of the COVID-19 pandemic, in the future, we may experience similar pandemics or epidemic diseases that could severely impact our business, drug manufacturing and supply chain, nonclinical activities and clinical trials, including due to delays or difficulties in enrolling patients in clinical trials, diversion of healthcare resources away from the conduct of clinical trials, interruption of, or delays in receiving, supplies of product or product candidates from contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems, interruption or delays to discovery and development pipelines and difficulties launching or commercializing products, including due to reduced access to doctors as a result of social distancing protocols.

The extent to which the emergence of new variants of COVID-19, or any other outbreak of a pandemic or epidemic disease, impacts our results will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of the virus and the actions to contain our impact. Further, to the extent any pandemic or epidemic disease adversely affects our business and financial results, we may also have the effect of heightening many of the other risks described in this section.

The biopharmaceutical industry may be negatively affected by federal government deficit reduction policies, which could reduce the value of ZELSUVMI.

In an effort to contain the U.S. federal deficit, the biopharmaceutical industry could be considered a potential source of savings and could be the target of legislative proposals aimed at reducing federal expenditures. Government action to reduce U.S. federal spending on entitlement programs, including Medicare, Medicaid or other publicly funded or subsidized health programs, or to lower drug spending, may affect payment for ZELSUVMI. These and any other cost controls or any significant additional taxes or fees that may be imposed on the biopharmaceutical industry as part of deficit reduction efforts could reduce cash flows and adversely affect our business, financial condition or results of operations.

THE OFFERING

Company Common Stock offered by the Selling Stockholders:	This prospectus relates to 8,137,868 shares of Company Common Stock that may be sold from time to time by the Selling Stockholders named in this prospectus.
Company Common Stock outstanding at commencement of the offering ⁽¹⁾ :	3,067,974 shares of Company Common Stock.
Use of proceeds:	We will not receive any proceeds from the sales of outstanding shares of Common Stock by the Selling Stockholders.
Risk factors:	Investing in our Company Common Stock involves a high degree of risk. See “Risk factors” beginning on page 7 of this prospectus for a discussion of some of the factors you should carefully consider before deciding to invest in our Company Common Stock.
Trading market and symbol:	Our Common Stock is currently listed on the NYSE American LLC under the symbol “PTHS”.

(1) The number of shares of Common Stock outstanding at the commencement of the offering is based on 3,067,974 shares of Company Common Stock outstanding as of the date of this prospectus, and excludes:

- 2,628,900 shares of Common Stock issuable upon conversion of 26,289 shares of Series A Preferred Stock which have not yet been converted into shares of our Common Stock;
- 1,557,074 shares of Common Stock issuable upon the exercise of outstanding options granted under our amended and equity incentive plan, with a weighted average exercise price of \$16.01;
- 515,520 shares of Common Stock underlying restricted stock units granted under our amended and restated equity incentive plan;
- 5,500 shares of Common Stock issuable upon the exercise of outstanding warrants to purchase shares of our Common Stock granted under our equity incentive plan, with a weighted average exercise price of \$75.00; and
- 327,406 shares of Common Stock that are reserved for future grants or sale under our amended and restated equity incentive plan.

USE OF PROCEEDS

We will not receive any of the proceeds from the sale of our Common Stock by the Selling Stockholders. The Selling Stockholders will receive all of the net proceeds from the sales of the shares of our Common Stock offered by them pursuant to this prospectus. We have agreed to bear the expenses relating to the registration of the Common Stock for the Selling Stockholders.

PRIVATE PLACEMENT OF SERIES A PREFERRED STOCK

On April 16, 2025, the Company entered into the Merger Agreement with Merger Sub, LNHC and, solely for purposes of Article III thereof, Ligand, pursuant to which (i) Merger Sub merged with and into LNHC, with LNHC as the surviving company in the merger and, after giving effect to such merger, continuing as a wholly-owned subsidiary of the Company (the “Merger”) and (ii) the Company’s name was changed from Channel Therapeutics Corporation to Pelthos Therapeutics Inc. In connection with the Merger, the Company issued 31,278 shares of the Company’s Series A Preferred Stock as consideration for the LNHC shares (the “Merger Consideration Shares”).

On April 16, 2025, the Company entered into the Securities Purchase Agreement, pursuant to which, among other things, on July 1, 2025, the date of the consummation of the transaction contemplated by the Securities Purchase Agreement (the “PIPE Closing Date”) and immediately prior to the consummation of the Merger, the Selling Stockholders purchased (either for cash or in exchange for the conversion of principal and interest payable under an outstanding convertible note issued by the Company), and the Company issued and sold to the Selling Stockholders (the “PIPE Investors”), an aggregate of 50,100 shares of the Company’s Series A Preferred Stock at a price per share equal to \$1,000 (such transaction, the “PIPE Financing”). The gross proceeds from the PIPE Financing were approximately \$50.1 million, consisting of approximately \$50.0 million in cash and the conversion of approximately \$0.1 million of principal and interest payable under an outstanding convertible note issued by the Company, before paying estimated expenses. The Securities Purchase Agreement contained customary representations and warranties of the Company and LNHC, on the one hand, and the Selling Stockholders, on the other hand, and customary conditions to closing.

On July 1, 2025, in connection with the closing of the Merger, the Company, LNHC and the Selling Stockholders entered into Amendment No. 1 to Securities Purchase Agreement, pursuant to which, the Company, LNHC and the Selling Stockholders consented to the inclusion of two additional Selling Stockholders in the PIPE Financing and a corresponding decrease in the amount of certain Selling Stockholders’ investments in the PIPE Financing such that the aggregate amount of the PIPE Financing would remain unchanged (the “Securities Purchase Agreement Amendment”).

Each share of Series A Preferred Stock is convertible at any time at the holder’s option into a number of shares of Common Stock equal to (i) \$1,000, subject to adjustment, plus any all declared and unpaid dividends thereon as of such date of determination, plus any other amounts owed to such holder pursuant to the Certificate of Designations of Rights and Preferences of Series A Convertible Preferred Stock (the “Certificate of Designations”), divided by (ii) \$1 (adjusted to \$10 as a result of the ten-for-one Reverse Stock Split), subject to adjustments.

In general, a holder of shares of Series A Preferred Stock may not convert any portion of Series A Preferred Stock if the holder, together with its affiliates, would beneficially own more than 49.9% in the case of Ligand or 4.99%, in the case of the other Selling Stockholders (the “Maximum Percentage”), of the number of shares of the Company’s Common Stock outstanding immediately after giving effect to such exercise, provided, however, that a holder may increase or decrease the Maximum Percentage by giving 61 days’ notice to the Company, but not to any percentage in excess of 9.99%.

The shares of Series A Preferred Stock to be issued and sold to the Selling Stockholders were not registered under the Securities Act, and were issued and sold in reliance on the exemption from registration requirements thereof provided by Section 4(a)(2) of the Securities Act as a transaction by an issuer not involving a public offering.

The closing of the PIPE Financing occurred on July 1, 2025, immediately prior to the consummation of the Merger.

On July 1, 2025, certain Selling Stockholders entered into Series A Convertible Preferred Stockholder Side Letters (each, a “Side Letter”) with the Company, pursuant to which, immediately after the closing of the PIPE Financing on July 1, 2025, the Selling Stockholders converted 23,810 shares of Series A Preferred Stock not exceeding such Selling Stockholders’ Maximum Percentage into an aggregate of 2,381,000 shares of the Company’s Common Stock (after giving effect to the Reverse Stock Split), by providing the Company with a completed and signed Conversion Notice under the Certificate of Designation.

JULY 2025 MERGER TRANSACTION

The Merger

On the Merger Closing date, we consummated the previously announced merger transaction contemplated by the Merger Agreement, by and among Channel, Merger Sub, LNHC, and solely for the purposes of Article III thereof, Ligand. Pursuant to the Merger Agreement, (i) Merger Sub merged with and into LNHC, with LNHC as the surviving company in the merger and, after giving effect to such merger, continuing as a wholly-owned subsidiary of the Company and (ii) Channel's name was changed from Channel Therapeutics Corporation to Pelthos Therapeutics Inc.

Following the completion of the Merger, the business conducted by the Company became primarily the business conducted by LNHC, which is a biopharmaceutical company committed to commercializing innovative, safe, and efficacious therapeutic products to help patients with unmet treatment burdens.

At the effective time of the Merger (the "Effective Time"), the Company issued an aggregate of approximately 31,279 shares of Series A Preferred Stock to Ligand, based on the exchange ratio set forth in the Merger Agreement, resulting in approximately 57,569 shares of the Company's Series A Preferred Stock being issued and outstanding immediately following the Effective Time. There are 3,127,868 shares of Common Stock (the "Merger Shares") issuable to Ligand upon conversion of the shares of Series A Preferred Stock that Ligand owns. Immediately following the Merger, the Company's securityholders as of immediately prior to the Merger owned approximately 7.9% of the outstanding shares of the Company and LNHC securityholders owned approximately 55.8% of the outstanding shares of the Company, in each case on a fully diluted basis, calculated using the treasury stock method.

Each share of Series A Preferred Stock is convertible at any time at the holder's option into a number of shares of Common Stock equal to (i) \$1,000, subject to adjustment, plus any all declared and unpaid dividends thereon as of such date of determination, plus any other amounts owed to such holder pursuant to the Certificate of Designations, divided by (ii) \$1 (adjusted to \$10 as a result of the ten-for-one Reverse Stock Split), subject to adjustments.

The shares of Series A Preferred Stock to be issued and sold to the Selling Stockholders were not registered under the Securities Act, and were issued and sold in reliance on the exemption from registration requirements thereof provided by Section 4(a)(2) of the Securities Act as a transaction by an issuer not involving a public offering.

The Registration Rights Agreement

On the Merger Closing Date and in connection with the Merger, the Company and the PIPE Investors entered into a registration rights agreement (the "Registration Rights Agreement") pursuant to which the PIPE Investors are entitled to certain resale registration rights with respect to shares of the Company's Common Stock issuable upon conversion of the Series A Preferred Stock issued to the PIPE Investors. Pursuant to the Registration Rights Agreement, the Company is required to prepare and file a resale registration statement with the SEC on or prior to the later of (i) 30 calendar days following the closing of the PIPE Financing and (ii) fifteen (15) calendar days after the Company's next periodic report required pursuant to Section 13 of the Exchange Act. The Company is obligated to use reasonable best efforts to cause this registration statement to be declared effective by the SEC within 120 calendar days following the closing of the PIPE Financing (or within 150 calendar days following the closing of the PIPE Financing if the SEC reviews the registration statement).

DESCRIPTION OF CAPITAL STOCK

General

The following description of Pelthos' securities is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to our articles of incorporation, and our bylaws, each of which are filed as an exhibit to Pelthos' Current Report on Form 8-K for the year filed on July 2, 2025. Copies of these documents can be accessed through hyperlinks to those documents in the list of exhibits in our Current Report on Form 8-K filed on July 2, 2025.

Authorized Capital Stock

Pelthos' authorized capital shares consist of (a) 200,000,000 shares of Common Stock and (b) 20,000,000 shares of "blank check" preferred stock, par value \$0.0001 per share (our "Preferred Stock"). The outstanding shares of our Common Stock are fully paid and nonassessable.

Voting Rights

The holders of shares of Common Stock vote together as one class on all matters as to which holders of Common Stock are entitled to vote. Except as otherwise required by applicable law, all voting rights are vested in and exercised by the holders of Common Stock with each share of Common Stock being entitled to one vote, including in all elections of directors. The vote of the holders of a majority of the issued and outstanding shares of Common Stock entitled to vote thereon is sufficient to authorize, affirm, ratify or consent to such act or action, except as otherwise provided by law.

Dividend Rights

Subject to the rights of holders of outstanding shares of Preferred Stock, if any, holders of Common Stock are entitled to receive such dividends and distributions and other distributions in cash, stock or property of Pelthos when, as and if declared thereon by the Pelthos board of directors from time to time out of assets or funds of Pelthos legally available therefor.

Liquidation Rights

Subject to the rights of holders of outstanding shares of Preferred Stock, if any, upon our liquidation, dissolution or winding up, the holders of Common Stock will be entitled to share ratably in the net assets and funds legally available for distribution to stockholders after the payment of all of Pelthos' debts and other liabilities.

Other Rights and Preferences

Holders of Common Stock have no preemptive rights or other subscription rights, conversion rights, registration rights, redemption or sinking fund provisions by virtue of only holding such shares.

Preferred Stock

Pelthos' board of directors has the authority, without further action by Pelthos stockholders, to issue up to 20,000,000 shares of Preferred Stock in one or more classes or series and to fix the designations, rights, preferences, privileges and restrictions thereof, without further vote or action by the stockholder. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such class or series, any or all of which may be greater than the rights of Common Stock. The issuance of Preferred Stock could adversely affect the voting power of holders of Common Stock and the likelihood that such holders will receive dividend payments and payments upon Pelthos' liquidation. In addition, the issuance of Preferred Stock could have the effect of delaying, deferring or preventing a change in control of the Company or other corporate action.

Series A Convertible Preferred Stock

Pelthos has filed a Series A Certificate of Designations of Series A Convertible Preferred Stock with the Secretary of State of the State of Nevada designating 150,000 shares of Preferred Stock as Pelthos Series A Preferred Stock.

Dividend Rights

Holders of Pelthos Series A Preferred Stock are entitled to receive dividends as and when declared by Pelthos' board of directors, in its sole discretion. Any such dividends are payable in cash out of legally available funds and are calculated based on the stated value of each share of Pelthos Series A Preferred Stock. Dividends are not guaranteed and will only be paid if and when declared by Pelthos' board of directors.

Voting Rights

Holders of Pelthos Series A Preferred Stock are entitled to receive notice of and vote at all shareholder meetings alongside holders of Common Stock, voting together as a single class provided, that each Holder will be deemed to have waived any voting rights such that the aggregate voting rights of any Common Stock beneficially owned by such holder and/or any of its Attribution Parties (as defined in the Series A Certificate of Designations), collectively, on any record date shall not exceed the Maximum Percentage (as defined below). Each share of Pelthos Series A Preferred Stock has the right to vote together with the shares of Common Stock in an amount equal to the voting power of the aggregate number of shares of Common Stock that would be issuable to such holder upon conversion of such share of Pelthos Series A Preferred Stock as if the conversion price of such share of Pelthos Series A Preferred Stock was \$1.255 (the "Voting Conversion Price"), such that each share of Pelthos Series A Preferred Stock shall be entitled to vote, with the aggregate voting power of a holder's Pelthos Series A Preferred Stock limited by the Maximum Percentage, subject to adjustment in the event of stock splits, combinations, or stock dividends affecting the Common Stock. Except as otherwise required by the Charter, Bylaws, or applicable law, Pelthos Series A Preferred Stockholders have no special voting rights. However, where Nevada law requires a separate class or series vote for certain corporate actions, approval by the holders of a majority of the outstanding Pelthos Series A Preferred Stock, voting together as a class, will be sufficient.

Conversion

Each share of Pelthos Series A Preferred Stock will be convertible at any time at the holder's option into a number of shares of Common Stock equal to (i) \$1,000, subject to adjustment, plus any all declared and unpaid dividends thereon as of such date of determination, plus any other amounts owed to such holder pursuant to the Series A Certificate of Designations, divided by (ii) \$1, subject to adjustments.

In general, a holder will not have the right to convert any portion of Pelthos Series A Preferred Stock if the holder (together with its Attribution Parties) would beneficially own in excess of 49.9%, in the case of Ligand, and 4.99%, in the case of the other PIPE Investors (in each case, the "Maximum Percentage"), of the number of shares of Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Series A Certificate of Designations. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99% upon notice to us, provided, that any increase in this limitation will not be effective until 61 days after such notice from the holder to us and such increase or decrease will apply only to the holder providing such notice.

The Series A Certificate of Designations requires liquidated damages and "buy-in" payments to be made by us for failure to deliver shares of Common Stock issuable upon conversion.

Liquidation Rights

In the event of a liquidation event, the holders of the Pelthos Series A Preferred Stock shall be entitled to receive in cash out of the assets of Pelthos, whether from capital or from earnings available for distribution to our shareholders, the amount per share such holder would receive if such holder converted such shares of Pelthos Series A Preferred Stock into Pelthos Common Stock immediately prior to the date of such payment (without regard to any limitation on conversion set forth herein). Upon payment of such amount in full on the outstanding Pelthos Series A Preferred Stock, holders of the Pelthos Series A Preferred Stock will have no rights to Pelthos' remaining assets or funds, if any.

Series C Convertible Redeemable Preferred Stock

Pelthos has filed a Certificate of Designation of Series C Redeemable Convertible Redeemable Preferred Stock with the Secretary of State of the State of Nevada designating 5,000 shares of Preferred Stock as Series C Convertible Redeemable Preferred Stock (the “Series C Preferred Stock”).

Dividend Rights

The Series C Preferred Stock has no dividend rights.

Voting Rights

Holders of Pelthos Series C Preferred Stock are not entitled to vote, unless otherwise permitted by the NRS.

Redemption Rights

The Company, at its option shall have the right to redeem a portion or all of the outstanding shares of Series C Preferred Stock at any time; provided, however, that Pelthos may not redeem any share of Pelthos Series C Preferred Stock prior to the expiration of the lock-up period associated with this IPO without first obtaining consent of the holder of shares being redeemed. The Pelthos shall pay in cash an amount equal to the Stated Value (as defined in the Certificate of Designation of Series C Convertible Redeemable Preferred Stock) per share of Series C Convertible Redeemable Preferred Stock redeemed.

Conversion

Each share of Series C Convertible Redeemable Preferred Stock will be convertible at any time at the holder’s option into a number of shares of Common Stock determined by (i) multiplying the number of Series C Convertible Redeemable Preferred Shares by the Stated Value of the Pelthos Series C Preferred Stock, and then (ii) dividing the value obtained from the preceding clause (i) by 125% of the IPO Price (as defined in the Certificate of Designation of Series C Convertible Redeemable Preferred Stock). If the Pelthos common trades for twenty (20) consecutive trading days above 175% of the IPO Price, each share of Series C Convertible Redeemable Preferred Stock shall mandatorily convert into a number of shares of Common Stock equal to the result by multiplying 120% with the quotient obtained by dividing the Stated Value by the price per IPO Share issued to the public in connection with the IPO.

Liquidation Rights

The shares of Series C Convertible Redeemable Preferred Stock will be entitled to a liquidation preference of \$1,000 per share of Series C Convertible Redeemable Preferred Stock (the “Pelthos Series C Liquidation Preference”). In the event that Pelthos voluntarily or involuntarily liquidates, dissolves, or winds up its affairs, holders of the shares of Series C Convertible Redeemable Preferred Stock are entitled to receive out of Pelthos’ assets available for distribution to stockholders, after satisfaction of liabilities and obligations to creditors, if any, and subject to the rights of holders of any shares of capital stock then outstanding ranking senior to or on parity with the Series C Convertible Redeemable Preferred Stock with respect to distributions upon the voluntary or involuntary liquidation, dissolution, or winding-up of Pelthos’ business and affairs, and before Pelthos makes any distribution or payment out of Pelthos’ assets to the holders of Common Stock or any other class or series of Pelthos’ capital stock ranking junior to the Series C Convertible Redeemable Preferred Stock with respect to distributions upon Pelthos’ liquidation, dissolution, or winding-up, an amount per share equal to the Pelthos Series C Liquidation Preference.

Anti-Takeover Provisions

Some features of the NRS, which are further described below, may have the effect of deterring third parties from making takeover bids for control of us or may be used to hinder or delay a takeover bid. This would decrease the chance that our stockholders would realize a premium over market price for their shares of Common Stock as a result of a takeover bid. These provisions may also adversely affect the prevailing market price for shares of our Common Stock.

Acquisition of Controlling Interest

The NRS contain provisions governing acquisition of a controlling interest of a Nevada corporation. These provisions provide generally that any person or entity that acquires a certain percentage of the outstanding voting shares of a Nevada corporation may be denied voting rights with respect to the acquired shares, unless certain criteria are satisfied.

Combination with Interested Stockholder

The NRS contains provisions governing combinations of a Nevada corporation that has 200 or more stockholders of record with an “interested stockholder.” These provisions only apply to a Nevada corporation that, at the time the potential acquirer became an interested stockholder, has a class or series of voting shares listed on a national securities exchange, or has a class or series of voting shares traded in an “organized market” and satisfies certain specified public float and stockholder levels. As we do not now meet those requirements, we do not believe that these provisions are currently applicable to us. However, to the extent they become applicable to us in the future, they may have the effect of delaying or making it more difficult to affect a change in control of Pelthos in the future.

A corporation affected by these provisions may not engage in a combination within two years after the interested stockholder acquires his, her or its shares unless the combination or purchase is approved by the board of directors before the interested stockholder acquired such shares. Generally, if approval is not obtained, then after the expiration of the two-year period, the business combination may be consummated with the approval of the board of directors before the person became an interested stockholder or a majority of the voting power held by disinterested stockholders, or if the consideration to be received per share by disinterested stockholders is at least equal to the highest of:

- the highest price per share paid by the interested stockholder within the three years immediately preceding the date of the announcement of the combination or within three years immediately before, or in, the transaction in which he, she or it became an interested stockholder, whichever is higher;
- the market value per share on the date of announcement of the combination or the date the person became an interested stockholder, whichever is higher; or
- if higher for the holders of preferred stock, the highest liquidation value of the preferred stock, if any.

Generally, these provisions define an interested stockholder as a person who is the beneficial owner, directly or indirectly of 10% or more of the voting power of the outstanding voting shares of a corporation, and define combination to include any merger or consolidation with an interested stockholder, or any sale, lease, exchange, mortgage, pledge, transfer or other disposition, in one transaction or a series of transactions with an interested stockholder of assets of the corporation:

- having an aggregate market value equal to 5% or more of the aggregate market value of the assets of the corporation;
- having an aggregate market value equal to 5% or more of the aggregate market value of all outstanding shares of the corporation; or
- representing 10% or more of the earning power or net income of the corporation.

Pelthos’ articles of incorporation expressly include a provision by which the combined company elects to opt out of these provisions if and when Pelthos becomes a “resident domestic corporation” (as defined in NRS Section 78.427).

Anti-Takeover Effects of Certain Provisions of our Charter and Bylaws

Pelthos' articles of incorporation provide that directors may be removed by the stockholders with or without cause upon the vote of a majority of the holders of Common Stock then entitled to vote. Except as otherwise provided in Pelthos' bylaws and articles of incorporation, any vacancies or newly created directorships on Pelthos' board of directors resulting from any increase in the authorized number of directors elected by all of the stockholders having the right to vote as a single class may be filled by a majority of the directors then in office, although less than a quorum, or by a sole remaining director.

Pelthos' bylaws also provide that only our chairman of the board of directors, chief executive officer, president or one or more stockholders holding shares in the aggregate entitled to cast not less than ten percent of the votes at that meeting may call a special meeting of stockholders.

The combination of these provisions makes it more difficult for Pelthos' existing stockholders to replace Pelthos' board of directors as well as for another party to obtain control of us by replacing Pelthos' board of directors. Since Pelthos' board of directors has the power to retain and discharge Pelthos' officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated Pelthos preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change Pelthos' control.

These provisions are intended to enhance the likelihood of continued stability in the composition of Pelthos' board of directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce Pelthos' vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for Pelthos' shares and may have the effect of delaying changes in Pelthos' control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of Common Stock that could result from actual or rumored takeover attempts. Pelthos believes that the benefits of these provisions, including increased protection of Pelthos' potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure Pelthos, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover proposals could result in an improvement of their terms.

Limitations of Director Liability and Indemnification of Directors, Officers and Employees

NRS 78.138 provides that a director of a corporation is not individually liable to the corporation or its stockholders or creditors for any damages as a result of any act or failure to act in his or her capacity as a director or officer unless: (a) the presumption that directors and officers acted in good faith on an informed basis with a view toward the best interest of the corporation has been rebutted and (b) it is proven that:

- The director's or officer's act or failure to act constituted a breach of his or her fiduciary duties as a director or officer; and
- such breach involved intentional misconduct, fraud or a knowing violation of law.

Our articles of incorporation provide that we will indemnify our directors, officers, employees, and agents to the fullest extent permitted by law. Indemnification applies to legal proceedings arising from service to the company or to another entity at the company's request. However, indemnification for proceedings initiated by the individual requires prior Board authorization.

We have obtained a policy of directors' and officers' liability insurance.

We have entered into indemnification agreements with our directors and certain of our executive officers that provide, to the fullest extent permitted by applicable law, for indemnification, advancement of expenses, and other rights. These agreements generally require us to indemnify and hold harmless each director or officer against expenses (including reasonable attorneys' fees and other costs), judgments, fines, penalties, and settlement amounts actually and reasonably incurred in proceedings arising out of their service to the company or at our request, provided they meet the applicable standards of conduct and comply with the procedures for requesting indemnification and advancement set forth in the agreements.

These agreements also provide for advancement of expenses prior to final disposition of a proceeding, subject to an undertaking to repay amounts advanced if it is ultimately determined that the individual is not entitled to indemnification. In certain circumstances, if indemnification is unavailable, the company may be obligated to contribute to losses or settle claims under terms favorable to the indemnitee, and it may not settle any matter involving the indemnitee without their written consent.

We believe these indemnification protections are necessary to attract and retain qualified individuals as directors and officers.

The limitation of liability and indemnification provisions in our articles of incorporation, bylaws and these agreements could discourage stockholders from bringing derivative or direct actions, even if such actions might be in the company's or stockholders' interests. Our financial condition could be adversely impacted to the extent we are required to pay for indemnification, advancement, or settlement costs.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers, or controlling persons, the SEC has stated that such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

At present, no litigation or proceeding is pending or threatened involving any of our directors or officers for which indemnification is required or expected to be sought.

Listing

Shares of Pelthos Common Stock are listed on the NYSE American LLC under the symbol "PTHS".

Transfer Agent and Registrar

The transfer agent and registrar for Pelthos Common Stock is Nevada Agency and Transfer Company. The transfer agent's address is 50 West Liberty Street, Suite 880, Reno NV 89501 and its telephone number is (775) 322-0626.

SELLING STOCKHOLDERS

The shares of Common Stock being offered by the Selling Stockholders are those issuable to the Selling Stockholders upon conversion of the Series A Preferred Stock. For additional information regarding the issuance of the Series A Preferred Stock, see “Private Placement of Series A Preferred Stock” above. We are registering the shares of Common Stock in order to permit the Selling Stockholders to offer the shares for resale from time to time.

The table below lists the Selling Stockholders and other information regarding the beneficial ownership (as determined under Section 13(d) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and the rules and regulations thereunder) of the shares of Common Stock held by each of the Selling Stockholders. The second column lists the number of shares of Common Stock beneficially owned by the Selling Stockholders, based on their respective ownership of shares of Common Stock and Series A Preferred Stock, as of September 24, 2025, assuming conversion of the Series A Preferred Stock held by each such Selling Stockholder on that date but taking account of any limitations on conversion set forth therein.

The third column lists the shares of Common Stock being offered by this prospectus by the Selling Stockholders and does not take in account any limitations on conversion of the Series A Preferred Stock set forth therein.

In accordance with the terms of a registration rights agreement with the holders of the Series A Preferred Stock, this prospectus generally covers the resale of 100% of the maximum number of shares of Common Stock issued or issuable pursuant to the Certificate of Designations (with the maximum number of shares of Common Stock issued determined as if the outstanding Series A Preferred Stock were converted in full (without regard to any limitations on conversion contained therein solely for the purpose of such calculation) at a conversion price calculated as of the trading day immediately preceding the date this registration statement was initially filed with the SEC). Because the conversion price of the Series A Preferred Stock may be adjusted, the number of shares of Common Stock that will actually be issued may be more or less than the number of shares of Common Stock being offered by this prospectus. The fourth column assumes the sale of all of the shares of Common Stock offered by the Selling Stockholders pursuant to this prospectus.

Under the terms of the Series A Preferred Stock, a Selling Stockholder may not convert the Series A Preferred Stock to the extent (but only to the extent) such Selling Stockholder or any of its affiliates would beneficially own a number of shares of our Common Stock which would exceed 4.99% or 49.99% of the outstanding shares of the Company, as applicable. The number of shares of Common Stock in the second column reflects these limitations. The Selling Stockholders may sell all, some or none of their shares of Common Stock in this offering. See “Plan of Distribution.”

Name of Selling Stockholder	Number of Shares of Common Stock Owned Prior to Offering ⁽¹⁾		Maximum Number of Shares of Common Stock to be Sold Pursuant to this Prospectus ⁽²⁾	Number of Shares of Common Stock Owned After Offering ⁽³⁾	
	Number	Percent		Number	Percent
Nomis Bay LTD ⁽⁴⁾	161,132 ⁽¹⁷⁾ ₍₁₈₎	4.99%	1,152,600	—	—%
BPY Limited ⁽⁵⁾	161,132 ⁽¹⁷⁾ ₍₁₈₎	4.99%	706,400	—	—%
Boothbay Absolute Return Strategies, LP ⁽⁶⁾	161,132 ⁽¹⁷⁾ ₍₁₈₎	4.99%	300,000	—	—%
3i, LP ⁽⁷⁾	340,507	9.99%	500,000	—	—%
Ligand Pharmaceuticals Incorporated ⁽⁸⁾	3,066,747	49.99%	4,927,868	—	—%
Key Recovery Group LLC ⁽⁹⁾	40,000	1.30%	40,000	—	—%
Balmoral Financial Group LLC ⁽¹⁰⁾	92,072	3.00%	40,000	—	—%
2632809 Ontario Inc. ⁽¹¹⁾	50,000	1.63%	50,000	—	—%
Camden Capital LLC ⁽¹²⁾	10,000	*%	10,000	—	—%
David Danovitch ⁽¹³⁾	10,000	*%	10,000	—	—%
Jacqueline Esposito ⁽¹⁴⁾	1,220	*%	1,000	—	—%
Nomis Bay Opportunity Ltd ⁽¹⁵⁾	161,132 ⁽¹⁷⁾ ₍₁₈₎	4.99%	250,000	—	—%
Oramed Pharmaceuticals Inc. ⁽¹⁶⁾	150,000	4.89%	150,000	—	—%

* Less than 1%

- (1) Unless otherwise indicated herein, represents shares of Common Stock issued by the Company to such Selling Stockholder in the PIPE Financing.
- (2) Assumes the sale of all shares of our Common Stock being offered by the Selling Stockholder pursuant to this prospectus. For purposes of the calculation of shares of Common Stock to be sold pursuant to this Prospectus we are assuming 100% of the maximum number of shares of Common Stock have been issued pursuant to Certificate of Designations (with the maximum number of shares of Common Stock issued determined as if the outstanding shares of Series A Preferred Stock were converted in full (without regard to any limitations on conversion contained therein solely for the purpose of such calculation) at a conversion price of \$10.00.
- (3) Represents the number of shares of Common stock that will be held by the Selling Stockholder after completion of this offering based on the assumptions that (a) no other shares of Common Stock are acquired or sold by the Selling Stockholder prior to completion of this offering and (b) all shares of Common Stock underlying registered for sale by the registration statement of which this Prospectus is part of will be sold. However, the Selling Stockholder is not obligated to sell all or any portion of the shares of Common Stock offered pursuant to this prospectus. Applicable percentage ownership is based on 8,824,774 shares of our Common Stock outstanding after this offering.
- (4) In his capacity as director of Nomis Bay Ltd, James Keyes has voting control and investment discretion over securities beneficially owned directly or indirectly by Nomis Bay Ltd. Mr. Keyes disclaims any beneficial ownership of the securities beneficially owned directly or indirectly by Nomis Bay Ltd. The business address of Nomis Bay Ltd. is 5 Reid Street, Hamilton, Bermuda HM 11.
- (5) In his capacity as director of BPY Limited, James Keyes has voting control and investment discretion over securities beneficially owned directly or indirectly by BPY Limited. Mr. Keyes disclaims any beneficial ownership of the securities beneficially owned directly or indirectly by BPY Limited. The business address of BPY Limited is 5 Reid Street, Hamilton, Bermuda HM 11.
- (6) Boothbay Absolute Return Strategies LP, a Delaware limited partnership (this “Selling Stockholder”), is managed by Murchinson Ltd. (“Manager”). The Manager, in its capacity as an investment manager of this Selling Stockholder, has the power to vote and the power to direct the disposition of these securities held by this Selling Stockholder. Paul Zogala in his capacity as a Portfolio Manager of the Manager may also be deemed to have investment discretion and voting power over the shares held by the Selling Stockholder. Each of the Manager and Portfolio Manager disclaim beneficial ownership of these securities. The address of this Selling Stockholder is 145 Adelaide St West, 4th Floor, Toronto, ON, M5H 4E5, Canada.
- (7) 3i Management LLC is the general partner of 3i, LP, and Maier Joshua Tarlow is the manager of 3i Management LLC. As such, Mr. Tarlow exercises sole voting and investment discretion over securities beneficially owned directly or indirectly by 3i, LP and 3i Management LLC. Mr. Tarlow disclaims beneficial ownership of the securities beneficially owned directly by 3i, LP and indirectly by 3i Management LLC. The business address of each of the aforementioned parties is 2 Wooster Street, 2nd Floor, New York, NY 10013. We have been advised that none of Mr. Tarlow, 3i Management LLC, or 3i, LP is a member of the Financial Industry Regulatory Authority, or FINRA, or an independent broker-dealer, or an affiliate or associated person of a FINRA member or independent broker-dealer.
- (8) Includes 3,127,868 Merger Shares. Todd Davis is the Chief Executive Officer of Ligand Pharmaceuticals, Inc. and is a member of our Board. The address for above referenced entity is 555 Heritage Drive, Suite 200, Jupiter, FL 33458.
- (9) Ezra Friedberg has sole voting and dispositive power over the shares held by Key Recovery Group LLC. The principal executive office of Key Recovery Group LLC is 106 Old Court Road, Suite 202, Baltimore, MD 21208.
- (10) Ezra Friedberg has sole voting and dispositive power over the shares held by Balmoral Financial Group LLC. The principal executive office of Balmoral Financial Group LLC is 106 Old Court Road, Suite 202, Baltimore, MD 21208.
- (11) Aimee Wachsman has sole voting and dispositive power over the shares held by 2632803 Ontario Ltd. The principal executive office of 2632803 Ontario Ltd. is 970 Lawrence Ave West Suite 904, Toronto ON M6A3B6 Canada.

- (12) Francis Knuettel II serves as Managing Member of Camden and, accordingly, may be deemed to beneficially own the shares of Common Stock owned directly by Camden. Mr. Knuettel has sole voting and dispositive power over such shares of Common Stock issuable to Camden.
- (13) David Danovitch is the sole and beneficial owner of the shares listed opposite his name, and has sole voting and dispositive power with respect to such shares.
- (14) Jacqueline Esposito is the sole and beneficial owner of the shares listed opposite her name, and has sole voting and dispositive power with respect to such shares.
- (15) In his capacity as director of Nomis Bay Opportunity Ltd James Keyes has voting control and investment discretion over securities beneficially owned directly or indirectly by Nomis Bay Opportunity Ltd. Mr. Keyes disclaims any beneficial ownership of the securities beneficially owned directly or indirectly by Nomis Bay Opportunity Ltd. The business address of Nomis Bay Opportunity Ltd is 31 Victoria Street, 1st Floor, Hamilton, Pembroke, HM10, Bermuda.
- (16) In his capacity as Chief Executive Officer of Oramed Pharmaceuticals Inc., Nadav Kidron does not possess sole voting or dispositive power over the securities of Oramed Pharmaceuticals Inc., as the company is publicly held and ownership is widely distributed among its shareholders. Mr. Kidron disclaims any beneficial ownership of the securities beneficially owned directly or indirectly by Oramed Pharmaceuticals Inc. The business address of Oramed Pharmaceuticals Inc. is 1185 Avenue of the Americas, 3rd Floor, New York, NY 10036.
- (17) This column lists the number of shares of our common stock beneficially owned by each of Nomis Bay Ltd., Nomis Bay Opportunity Ltd., BPY Limited, and Boothbay Absolute Return Strategies, LP (collectively, the "Funds") which entities are under common control, as of September 24, 2025 after giving effect to the Maximum Percentage. Without regard to the Maximum Percentage, as of September 24, 2025, the Funds would beneficially own an aggregate number of 2,409,000 shares of our common stock, consisting of (A) 1,152,600 shares of our Common Stock beneficially owned by Nomis Bay Ltd., consisting of (i) 140,000 shares of Common Stock held by this selling stockholder, all of which shares are being registered under this Prospectus and (ii) 1,012,600 shares of Common Stock underlying the 10,126 shares of Series A Preferred Stock held by this selling stockholder, with a stated value of \$1,000 per share, convertible at a price of \$10.00 per share, all of which shares are being registered for resale under this Prospectus; and (B) 250,000 shares of our Common Stock beneficially owned by Nomis Bay Opportunity Ltd., consisting of 250,000 shares of Common Stock underlying the 2,500 shares of Series A Preferred Stock held by this selling stockholder, with a stated value of \$1,000 per share, convertible at a price of \$10.00 per share, all of which shares are being registered for resale under this Prospectus, all of which shares are being registered under this Prospectus; (C) 706,400 shares of our Common Stock beneficially owned by BPY Limited, consisting of (i) 140,000 shares of Common Stock held by this selling stockholder, all of which shares are being registered under this Prospectus and (ii) 566,400 shares of Common Stock underlying the 5,664 shares of Series A Preferred Stock held by this selling stockholder, with a stated value of \$1,000 per share, convertible at a price of \$10.00 per share, all of which shares are being registered for resale under this Prospectus; and (D) 300,000 shares of our Common Stock beneficially owned by Boothbay Absolute Return Strategies, LP, consisting of 300,000 shares of Common Stock underlying the 3,000 shares of Series A Preferred Stock held by this selling stockholder, with a stated value of \$1,000 per share, convertible at a price of \$10.00 per share, all of which shares are being registered for resale under this Prospectus
- (18) Applicable percentage ownership is based on 3,067,974 shares of our Common Stock outstanding as of September 24, 2025.

PLAN OF DISTRIBUTION

We are registering the shares of Common Stock issuable upon conversion of the Series A Preferred Stock to permit the resale of these shares of Common Stock by the holders of the Series A Preferred Stock from time to time after the date of this prospectus. We will not receive any of the proceeds from the sale by the Selling Stockholders of the shares of Common Stock. We will bear all fees and expenses incident to our obligation to register the shares of Common Stock.

The Selling Stockholders may sell all or a portion of the shares of Common Stock held by them and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. If the shares of Common Stock are sold through underwriters or broker-dealers, the Selling Stockholders will be responsible for underwriting discounts or commissions or agent's commissions. The shares of Common Stock may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale or at negotiated prices. These sales may be effected in transactions, which may involve crosses or block transactions, pursuant to one or more of the following methods:

- on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale;
- in the over-the-counter market;
- in transactions otherwise than on these exchanges or systems or in the over-the-counter market;
- through the writing or settlement of options, whether such options are listed on an options exchange or otherwise;
- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales made after the date the registration statement is declared effective by the SEC;
- broker-dealers may agree with a selling security holder to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The Selling Stockholders may also sell shares of Common Stock under Rule 144 promulgated under the Securities Act, if available, rather than under this prospectus. In addition, the Selling Stockholders may transfer the shares of Common Stock by other means not described in this prospectus. If the Selling Stockholders effect such transactions by selling shares of Common Stock to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from the Selling Stockholders or commissions from purchasers of the shares of Common Stock for whom they may act as agent or to whom they may sell as principal (which discounts, concessions or commissions as to particular underwriters, broker-dealers or agents may be in excess of those customary in the types of transactions involved). In connection with sales of the shares of Common Stock or otherwise, the Selling Stockholders may enter into hedging transactions with broker-dealers, which may in turn engage in short sales of the shares of Common Stock in the course of hedging in positions they assume. The Selling Stockholders may also sell shares of Common Stock short and deliver shares of Common Stock covered by this prospectus to close out short positions and to return borrowed shares in connection with such short sales. The Selling Stockholders may also loan or pledge shares of Common Stock to broker-dealers that in turn may sell such shares.

The Selling Stockholders may pledge or grant a security interest in some or all of the Series A Preferred Stock or shares of Common Stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of Common Stock from time to time pursuant to this prospectus or any amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending, if necessary, the list of Selling Stockholders to include the pledgee, transferee or other successors in interest as Selling Stockholders under this prospectus. The Selling Stockholders also may transfer and donate the shares of Common Stock in other circumstances in which case the transferees, donees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

To the extent required by the Securities Act and the rules and regulations thereunder, the Selling Stockholders and any broker-dealer participating in the distribution of the shares of Common Stock may be deemed to be “underwriters” within the meaning of the Securities Act, and any commission paid, or any discounts or concessions allowed to, any such broker-dealer may be deemed to be underwriting commissions or discounts under the Securities Act. At the time a particular offering of the shares of Common Stock is made, a prospectus supplement, if required, will be distributed, which will set forth the aggregate amount of shares of Common Stock being offered and the terms of the offering, including the name or names of any broker-dealers or agents, any discounts, commissions and other terms constituting compensation from the Selling Stockholders and any discounts, commissions or concessions allowed or re-allowed or paid to broker-dealers.

Under the securities laws of some states, the shares of Common Stock may be sold in such states only through registered or licensed brokers or dealers. In addition, in some states the shares of Common Stock may not be sold unless such shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with.

There can be no assurance that any Selling Stockholder will sell any or all of the shares of Common Stock registered pursuant to the registration statement, of which this prospectus forms a part.

The Selling Stockholders and any other person participating in such distribution will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including, without limitation, to the extent applicable, Regulation M of the Exchange Act, which may limit the timing of purchases and sales of any of the shares of Common Stock by the Selling Stockholders and any other participating person. To the extent applicable, Regulation M may also restrict the ability of any person engaged in the distribution of the shares of Common Stock to engage in market-making activities with respect to the shares of Common Stock. All of the foregoing may affect the marketability of the shares of Common Stock and the ability of any person or entity to engage in market-making activities with respect to the shares of Common Stock.

We will pay all expenses of the registration of the shares of Common Stock pursuant to the registration rights agreement, estimated to be \$150,000 in total, including, without limitation, Securities and Exchange Commission filing fees and expenses of compliance with state securities or “blue sky” laws; provided, however, a Selling Stockholder will pay all underwriting discounts and selling commissions, if any. We will indemnify the Selling Stockholders against liabilities, including some liabilities under the Securities Act in accordance with the registration rights agreements or the Selling Stockholders will be entitled to contribution. We may be indemnified by the Selling Stockholders against civil liabilities, including liabilities under the Securities Act that may arise from any written information furnished to us by the Selling Stockholder specifically for use in this prospectus, in accordance with the related registration rights agreements or we may be entitled to contribution.

Once sold under the registration statement, of which this prospectus forms a part, the shares of Common Stock will be freely tradable in the hands of persons other than our affiliates.

LEGAL MATTERS

The validity of the issuance of the securities offered hereby will be passed upon for us by Sullivan & Worcester LLP of New York, New York. Additional legal matters may be passed upon for us or any underwriters, dealers or agents, by counsel that we will name in the applicable prospectus supplement.

EXPERTS

The consolidated financial statements of Channel Therapeutics Corporation (n/k/a Pelthos Therapeutics Inc.) as of December 31, 2024 and 2023 and for each of the two years in the period ended December 31, 2024, incorporated in this prospectus by reference to the Annual Report on Form 10-K for the year ended December 31, 2024, have been so incorporated in reliance on the report (which contains an explanatory paragraph relating to the Company's ability to continue as a going concern as described in Note 2 to the consolidated financial statements) of Marcum LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

This prospectus constitutes a part of a registration statement on Form S-3 filed under the Securities Act. As permitted by the SEC's rules, this prospectus and any prospectus supplement, which form a part of the registration statement, do not contain all the information that is included in the registration statement. You will find additional information about us in the registration statement and its exhibits. Any statements made in this prospectus or any prospectus supplement concerning legal documents are not necessarily complete and you should read the documents that are filed as exhibits to the registration statement or otherwise filed with the SEC for a more complete understanding of the document or matter.

You can read our SEC filings, including the registration statement, over the internet at the SEC's website at www.sec.gov.

We are subject to the information reporting requirements of the Exchange Act, and we file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection and copying at the public reference room and website of the SEC referred to above. We also maintain a website at <https://pelthos.com>, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. However, the information contained in or accessible through our website is not part of this prospectus or the registration statement of which this prospectus forms a part, and investors should not rely on such information in making a decision to purchase our securities in this offering.

INCORPORATION OF DOCUMENTS BY REFERENCE

The SEC permits us to “incorporate by reference” into this prospectus the information contained in documents we file with the SEC, which means that we can disclose important information to you by referring you to those documents. Information that is incorporated by reference is considered to be part of this prospectus and you should read it with the same care that you read this prospectus. Information that we file later with the SEC will automatically update and supersede the information that is either contained, or incorporated by reference, in this prospectus, and will be considered to be a part of this prospectus from the date those documents are filed. We have filed with the SEC and incorporate by reference in this prospectus, except as superseded, supplemented or modified by this prospectus, the documents listed below:

- our Annual Report on [Form 10-K](#) for the fiscal year ended December 31, 2024, filed with the SEC on March 27, 2025;
- our Quarterly Reports on Form 10-Q for the fiscal quarter ended March 31, 2025, filed with the SEC on [May 13, 2025](#), and for the fiscal quarter ended June 30, 2025, filed with the SEC on [August 13, 2025](#);
- our Current Reports on Form 8-K filed with the SEC on [March 3, 2025](#), [April 17, 2025](#), [July 2, 2025](#) and September 16, 2025; and
- the description of our Common Stock contained in (i) our registration statement on [Form 8-A](#), filed with the SEC on February 15, 2024 under Section 12(b) of the Exchange Act, including any amendments or reports filed for the purpose of updating such description and (ii) [Exhibit 4.2](#)—Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934, to our Annual Report on Form 10-K for the fiscal year ended December 31, 2024, filed with the SEC on March 27, 2025.

We also incorporate by reference into this prospectus additional documents that we may file with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date hereof but before the completion or termination of this offering (excluding any information not deemed “filed” with the SEC). Any statement contained in a previously filed document is deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or in a subsequently filed document incorporated by reference herein modifies or supersedes the statement, and any statement contained in this prospectus is deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in a subsequently filed document incorporated by reference herein modifies or supersedes the statement.

We will provide, without charge, to each person to whom a copy of this prospectus is delivered, including any beneficial owner, upon the written or oral request of such person, a copy of any or all of the documents incorporated by reference herein, including exhibits. Requests should be directed to:

Pelthos Therapeutics Inc.
4020 Stirrup Creek Drive
Suite 110
Durham, NC 27703
(919) 908-2400

Copies of these filings are also available on our website at <https://pelthos.com>. For other ways to obtain a copy of these filings, please refer to “Where You Can Find More Information” above.



Up to 8,137,868 Common Shares

PROSPECTUS

The date of this prospectus is September 24, 2025.

We have not authorized any dealer, salesperson or other person to give any information or represent anything not contained in this prospectus. You must not rely on any unauthorized information. If anyone provides you with different or inconsistent information, you should not rely on it. This prospectus does not offer to sell any securities in any jurisdiction where it is unlawful. Neither the delivery of this prospectus, nor any sale made hereunder, shall create any implication that the information in this prospectus is correct after the date hereof.
